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Health Literacy Interventions and Outcomes: An Updated Systematic Review

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Health Literacy Interventions and Outcomes: An Updated Systematic Review

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This report is based on research conducted by the RTI International–University of North Carolina at Chapel Hill, North Carolina (RTI-UNC) Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10056-I). The findings and conclusions in this document are those of the author(s), who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care decision-makers, patients and clinicians, health system leaders, and policymakers make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.gov.

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We extend our appreciation to our Technical Expert Panel (TEP). All provided thoughtful advice and input during our research process. The TEP was both a substantive resource and a "sounding board" throughout the study. It was also the body from which expertise was formally sought at several junctions. The investigators would like to particularly thank Cindy Brach for her assistance in querying intervention study researchers. TEP members are listed below:

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Health Literacy Interventions and Outcomes: An Updated Systematic Review

Structured Abstract

Objectives. To update a 2004 systematic review of health care service use and health outcomes related to differences in health literacy level and interventions designed to improve these outcomes for individuals with low health literacy. Disparities in health outcomes and effectiveness of interventions among different sociodemographic groups were also examined.

Data sources. We searched MEDLINE,® the Cumulative Index to Nursing and Allied Health Literature, the Cochrane Library, PsychINFO, and the Educational Resources Information Center. For health literacy, we searched using a variety of terms, limited to English and studies published from 2003 to May 25, 2010. For numeracy, we searched from 1966 to May 25, 2010.

Review methods. We used standard Evidence-based Practice Center methods of dual review of abstracts, full-text articles, abstractions, quality ratings, and strength of evidence grading. We resolved disagreements by consensus.

We evaluated whether newer literature was available for answering key questions, so we broadened our definition of health literacy to include numeracy and oral (spoken) health literacy. We excluded intervention studies that did not measure health literacy directly and updated our approach to evaluate individual study risk of bias and to grade strength of evidence.

Results. We included good- and fair-quality studies: 81 studies addressing health outcomes (reported in 95 articles including 86 measuring health literacy and 16 measuring numeracy, of which 7 measure both) and 42 studies (reported in 45 articles) addressing interventions.

Differences in health literacy level were consistently associated with increased hospitalizations, greater emergency care use, lower use of mammography, lower receipt of influenza vaccine, poorer ability to demonstrate taking medications appropriately, poorer ability to interpret labels and health messages, and, among seniors, poorer overall health status and higher mortality. Health literacy level potentially mediates disparities between blacks and whites.

The strength of evidence of numeracy studies was insufficient to low, limiting conclusions about the influence of numeracy on health care service use or health outcomes. Two studies suggested numeracy may mediate the effect of disparities on health outcomes. We found no evidence concerning oral health literacy and outcomes.

Among intervention studies (27 randomized controlled trials [RCTs], 2 cluster RCTs, and 13 quasi-experimental designs), the strength of evidence for specific design features was low or insufficient. However, several specific features seemed to improve comprehension in one or a few studies. The strength of evidence was moderate for the effect of mixed interventions on health care service use; the effect of intensive self-management inventions on behavior; and the effect of disease-management interventions on disease prevalence/severity. The effects of other mixed interventions on other health outcomes, including knowledge, self-efficacy, adherence, and quality of life, and costs were mixed; thus, the strength of evidence was insufficient.

Conclusions. The field of health literacy has advanced since the 2004 report. Future research priorities include justifying appropriate cutoffs for health literacy levels prior to conducting studies; developing tools that measure additional related skills, particularly oral (spoken) health

literacy; and examining mediators and moderators of the effect of health literacy. Priorities in advancing the design features of interventions include testing novel approaches to increase motivation, techniques for delivering information orally or numerically, “work around” interventions such as patient advocates; determining the effective components of already-tested interventions; determining the cost-effectiveness of programs; and determining the effect of policy and practice interventions.

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Executive Summary

Introduction

Health literacy is “the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions.” It represents a constellation of skills necessary for people to function effectively in the health care environment and act appropriately on health care information. These skills include the ability to interpret documents, read and write prose (print literacy), use quantitative information (numeracy), and speak and listen effectively (oral literacy).

Low health literacy is a significant problem in the United States. In 2003, approximately 80 million adults in the United States (36 percent) had limited health literacy. Rates of limited health literacy in certain population subgroups were higher. For instance, rates were higher among the elderly, minorities, individuals who have not completed high school, adults who spoke a language other than English before starting school, and people living in poverty. Highlighting the health impact of low health literacy, a 2004 systematic evidence review found a relationship between low health literacy and poor health outcomes. Specifically, health literacy (measured by reading skills) was associated with health-related knowledge and comprehension, hospitalization rates, global health measures, and some chronic diseases.

Given the burden of low health literacy and the potential to reduce poor outcomes using novel interventions to address it, several national organizations have called for action. In 2010, the U.S. Department of Health and Human Services (HHS) released a National Action Plan to Improve Health Literacy. Additionally, in recent years, several national organizations and agencies, including the Institute of Medicine, American Medical Association, National Institutes of Health, and HHS (in Healthy People 2010), have promoted health literacy as a research priority.

Researchers responded to these calls with new and more sophisticated work. Thus, to synthesize the increasing volume of literature on health literacy, the Agency for Healthcare Research and Quality (AHRQ) commissioned the RTI International−University of North Carolina Evidence-based Practice Center (EPC) to update its 2004 systematic review examining the effects of literacy on health outcomes and interventions to improve those outcomes. In this updated report, we focus on the same Key Questions as the original report:

Key Question 1. Outcomes: Are health literacy skills related to (a) use of health care services, (b) health outcomes, (c) costs of health care, and (d) disparities in health outcomes or health care service use?

Key Question 2. Interventions: For individuals with low health literacy skills, what are effective interventions to (a) improve use of health care services, (b) improve health outcomes, (c) affect the costs of care, and (d) improve health care service use and/or health outcomes among different racial, ethnic, cultural, or age groups?

In contrast to our earlier report, we concentrate on “health literacy” rather than “literacy” for several reasons. First, we aimed to be consistent with recent conceptualizations of health literacy skills that separately examine print literacy, numeracy, and oral literacy. Second, an increasing number of newer measures are framed in specific health contexts and assess condition-related skills. Finally, measures of health literacy, print literacy (including prose and document literacy), and numeracy are highly correlated in national samples.

Although we believe our focus on health literacy appropriately represents the directions of research and policy in this field, we acknowledge that the literature contributing to this field does not organize itself neatly within our health literacy framework. For instance, several measures of health literacy assess a combination of print literacy and numeracy skills, making distinctions between print literacy and numeracy difficult. Furthermore, the quantitative skills components of some measures have been extracted and used independently as measures of numeracy. To simplify this report, we separate health literacy (including any studies that presume to measure literacy or health literacy) from those that solely measure numeracy or oral literacy.

Methods

Changes From Our Prior Review

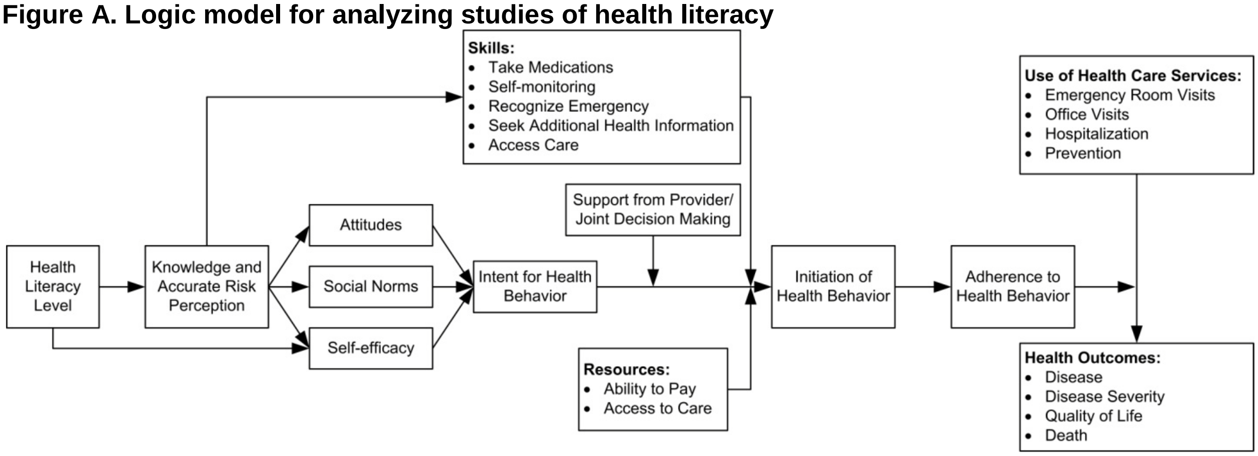
Our overall goals in this update were to evaluate whether newer literature was appropriate for answering our Key Questions and to determine whether earlier conclusions changed. Following discussions with our Technical Expert Panel, we modified the original methods as follows:

- We broadened our definition of health literacy to be consistent with the Ratzan and Parker (2000) definition used by Healthy People 2010 and the Institute of Medicine. Thus, our inclusion criteria included studies that measured numeracy and oral skills of participants.
- We required that studies directly measured the health literacy of the study population and did not assign health literacy level via self-report or similarity to other populations.
- To evaluate individual study quality, we incorporated advances in the methods of conducting systematic reviews.
- We included studies conducted in developing countries as long as they used an objective measure of literacy or health literacy in their participants.
- We reviewed knowledge as an outcome only for numeracy and intervention studies because evidence in the earlier review clearly concluded that greater literacy skills and higher health-related knowledge levels are positively related.
- If articles about intervention studies were missing information about intervention content, we queried the investigators to allow richer interpretation about what interventions may be effective in mitigating the effects of low health literacy.

Outcomes of Interest

The logic model in Figure A details outcomes that we included in our review as well as other conceptually important variables. It draws on several models of health literacy proposed by researchers in the field and on an integrated model of behavioral theory called the Integrative Theory. We applied this model to determine whether studies considered for inclusion had relevant health outcomes and to guide our presentation of included articles. It is not, however, a definitive guide to the relationship among variables because researchers have not explicitly tested many of these relationships yet. Furthermore, it does not specify the directionality of a good outcome; for some outcomes, increases represent the good outcome (e.g., adherence, most screening tests) and for others, decreases represent the good outcome (e.g., hospitalizations, mortality). We did not examine outcomes related to attitudes because of the belief that attitudes result from knowledge, which, as mentioned above, is not examined in the current report. Further, we did not examine outcomes related to social norms or patient-provider relationships (e.g., shared decisionmaking) because we thought that these variables likely affected the direction or strength of the relationship between behavioral intent and health outcomes, rather than laying on the causal pathway. Clearly, however, empiric work is needed to test these assertions prior to future reviews.

Figure A. Logic model for analyzing studies of health literacy



Literature Search and Retrieval Process

We searched MEDLINE,® the Cumulative Index to Nursing and Allied Health Literature, the Cochrane Library, PsycINFO, and the Educational Resources Information Center. For health literacy, we searched from 2003 to May 25, 2010. For numeracy, we searched from 1966 to May 25, 2010. We conducted keyword searches because no Medical Subject Headings terms specifically identify health-literacy-related articles. The terms health literacy, numeracy, and literacy, and terms or phrases related to instruments known to measure health literacy and numeracy, were the focus of the search. We excluded editorials, letters to the editor, case reports, and non-English language studies. We also manually searched reference lists of pertinent review articles and editorials for additional studies.

Article Review and Data Abstraction

We used standard EPC methods for dual review of abstracts and full text of articles to determine article inclusion. After determining article inclusion, one reviewer entered data about studies into evidence tables and a second, senior reviewer checked information for accuracy and completeness.

Quality Review

Two reviewers independently rated the quality of studies (good, fair, or poor) using criteria designed to detect selection bias, measurement bias, confounding, and inadequate power. Reviewers resolved all disagreements about quality ratings by consensus. We did not consider further any studies that we rated poor quality.

Data Synthesis and Grading Strength of Evidence

We synthesized the data in our review qualitatively. We did not have a sufficient number of studies with similar outcomes or similar interventions to consider quantitative analysis (meta-analysis or statistical pooling) of data. Furthermore, we primarily discussed information from the current searches, providing only aggregate summaries of data from our 2004 review. As part of data synthesis, we paid particular attention to a few issues. First, we closely examined whether studies accounted for relevant confounding variables in their analyses. Because the goal of etiologic research focuses on understanding the relationship between exposures and outcomes of interest, it is important that confounders are controlled for to determine accurate estimates of effect. Second, we looked closely at studies that reported the relationship between both health literacy and numeracy and the same outcome. This allowed inferences about the relative strengths of the measures on outcomes. Third, for intervention studies, we looked at common features of successful interventions and at the impact of interventions on multiple related outcomes. This allowed inference about the effective components and mechanisms of health literacy interventions.

The investigative team jointly discussed and graded the overall body of literature and generated recommendations for future research. For grading strength of evidence, we used the AHRQ EPC program's approach: assigning grades of high, moderate, low, or insufficient to the evidence after considering the domains of risk of bias, consistency, directness, and precision. We resolved disagreements by consensus discussion.

Results

Search Results and Included Studies

Our searches of electronic databases and review articles produced 3,496 unduplicated records. Ultimately, for the two main questions, we included studies rated either good or fair quality: 81 studies (95 articles) addressed Key Question 1 and 42 studies (45 articles) addressed Key Question 2. Key Question 1 results are presented separately in relation to health literacy (86 articles) and numeracy (16 articles). Of these, we identify the 7 articles that address both health literacy and numeracy.

Key Question 1. Relationship of health literacy to various outcomes and disparities

Sixty-four articles pertaining to this part of Key Question 1 had cross-sectional designs; 22 were cohort studies. We categorized studies examining outcomes associated with differences in health literacy level into two main domains: use of health care services and health outcomes. Strength of evidence evaluations focused on the relationship between the lowest health literacy group and the highest. The evidence was sparse for evaluating differences between those with marginal health literacy (a middle category) and adequate health literacy (the highest category).

Use of Health Care Services—Health Literacy

Moderate evidence about health care service use showed that lower health literacy was associated with increased hospitalization (five studies), greater emergency care use (nine studies), lower use of mammography (four studies), and lower receipt of influenza vaccine (four studies). Evidence for all other analyses of health care service use was low or insufficient because of inconsistent findings or outcomes; this includes studies about colon screening, Papanicolau (Pap) tests, testing for sexually transmitted infections, pneumococcal immunization, and access to care.

Health Outcomes—Health Literacy

Lower health literacy was associated with poorer outcomes in some of the health outcomes examined. A higher risk of mortality for seniors (two studies) was clearly associated with lower health literacy (high strength of evidence). Lower health literacy was associated with poorer ability to demonstrate taking medications appropriately (five studies), poorer ability to interpret labels and health messages (three studies), and poorer overall health status among seniors (five studies) (all of moderate strength of evidence). In these studies, the evidence consisted of all observational studies, generally with a medium risk of bias and results in a consistent direction.

The strength of evidence for the many other outcomes we examined—adherence, self-efficacy, smoking, alcohol use, healthy lifestyle, review of prescription information, HIV risks and sexual behaviors, chronic disease prevalence, HIV severity and symptoms, asthma severity and control, diabetes control and related symptoms, hypertension control, prostate cancer control, quality of life, and costs—was either low or insufficient. The literature consisted of only a small number of studies, poorly designed studies, and/or inconsistent results.

Potential moderators and mediators of the relationship between health literacy and health outcomes were also identified during our review. Two studies concluded that social support and health care system characteristics modify the magnitude and/or direction of the relationship between health literacy and adherence and health literacy and blood pressure control. Four studies concluded that knowledge, patient self-efficacy, and stigma might act as mediators or intermediaries in the causal pathway between health literacy and health outcomes and explain at least some of the negative impact of low health literacy on these health outcomes. In addition, one study suggested that health literacy may mediate the effect of education, income, and urbanicity on health outcomes.

Costs—Health Literacy

Evidence was insufficient to evaluate the relationship between differences in health literacy levels and costs. The two relevant studies examined different payment sources (Medicaid and Medicare) and different populations, and found inconsistent results.

Disparities in Outcomes—Health Literacy

In relation to disparities, health literacy appeared to mediate the effect of race on several health outcomes. These included conditions that keep a person from working, long-term illness, self-reported health status, receipt of an influenza vaccine, physical and mental health-related quality of life, self-reported health, prostate-specific antigen levels, nonadherence to HIV medications, and enrollment in health insurance. Health literacy also mediated differences by both race and gender in the misinterpretation of medication label instructions.

Key Question 1. Relationship of numeracy to various outcomes and disparities

In this update, we identified 16 studies examining the relationship between numeracy and health outcomes. Eleven were cross-sectional in design. Four studies were randomized controlled trials (RCTs) that analyzed their data in a cross-sectional manner for this analysis; one study used a prospective cohort design.

In general, the evidence pertaining to this Key Question was either low or insufficient given the small number of studies; these studies often had high risk of bias or, collectively, gave us mixed results.

Use of Health Care Services—Numeracy

Only one study addressed the relationship between numeracy and use of health care services (low strength of evidence). It reported no effect of numeracy on up-to-date screening for breast and colon cancer, but it appeared to be limited by inadequate power to detect a meaningful effect.

Health Outcomes—Numeracy

Relationships between numeracy level and accuracy of risk perception (five studies), knowledge (four studies), skills taking medication (six studies), and disease prevalence and severity (three studies) were mixed. The evidence for the relationship between numeracy and other health outcomes, such as self-efficacy or behavior, was insufficient to draw conclusions. No study addressed the costs associated with differences in numeracy level.

Disparities in Outcomes—Numeracy

Two studies examined whether numeracy level mediates health disparities. Numeracy appeared to mediate the relationship between race and levels of hemoglobin A1c and between gender and HIV medication management capacity.

Key Question 1. Comparison of the relationship of health literacy and numeracy to the same outcomes

Seven studies addressed the effects of both health literacy and numeracy on various outcomes. Of the seven, only four performed adjusted analyses on the same outcomes, thereby allowing assessment of whether these exposures affect health outcomes differently. All suggest that numeracy is more highly correlated with outcomes than health literacy. However, all must be interpreted with caution, because the proportion of individuals with low health literacy was small, raising the possibility of ceiling effects that could obscure effects in the literacy analyses.

Key Question 2. Interventions to improve low health literacy

In this update, we included 42 studies of good or fair quality addressing the effect of interventions designed to mitigate the effects of low health literacy; of these, 27 were RCTs, 2 were cluster randomized trials, and 13 were quasi-experimental studies. We focused our analyses on 2 separate sets of studies: 21 that used one specific strategy (single design features) to lessen the effects of low health literacy and 21 that used a mixture of strategies combined into a single intervention.

Interventions With Single Design Features

Of intervention studies testing single design features, two focused on alternative document design, three on alternative numerical presentation, eight on additive or alternative pictorial representations, four on alternative media, and seven on a combination of alternative readability and document design. Additionally, one intervention focused on the effects of physician notification about patients' literacy status on health outcomes. Effects were measured primarily in terms of comprehension.

Overall, the strength of evidence for specific design features in these interventions was low or insufficient. This is attributable, in large part, to differences in the types of interventions and, subsequently, in the mix of results. Looking closely within categories of design features, however, the following specific design features seemed to improve comprehension for low-health-literacy populations in one or a few studies: (1) presenting essential information by itself (i.e., information on hospital death rates without other distracting information, such as information on consumer satisfaction); (2) presenting essential information first (i.e., information on hospital death rates before information about consumer satisfaction); (3) presenting health plan quality information such that the higher number (rather than the lower number) indicates better quality; (4) using the same denominators to present baseline risk and treatment benefit; (5) adding icon arrays to numerical presentations of treatment benefit; and (6) adding video to verbal narratives. Additionally, in reexamining data from our 2004 review within these categories, we identified further evidence of potential benefit from using reduced reading level and/or illustrated narratives. In contrast, one study raised questions about whether certain design features, such as colored traffic symbols to denote death rates in hospitals of varying quality or symbols accompanying nonessential quality information, may actually worsen health choices among those with low health literacy.

Interventions With a Combination of Features

The strength of evidence for studies combining multiple strategies to mitigate the effects of low health literacy on either health care use or outcomes was more variable than it was for single-feature interventions.

Use of Health Care Services

Across all studies in this category, we found moderate strength of evidence that interventions included in the review changed health care service use. Specifically, intensive self-management and adherence interventions appeared to be effective in reducing emergency room visits and hospitalizations. Additionally, educational interventions and/or cues for screening increased colorectal cancer and prostate cancer screening (although we note that the health benefits of additional prostate cancer screening are not clear).

Health Outcomes

We found evidence of moderate strength that some interventions changed health outcomes. For instance, intensive disease-management programs appeared to be effective at reducing disease prevalence/severity. Furthermore, self-management interventions increased self-management behavior; however, in the only study that stratified a subgroup analysis by health literacy level, improvements were sometimes greater for those who had adequate health literacy and at other times greater for those with inadequate health literacy in adjusted analyses. The effects of other interventions on other health outcomes, including knowledge, self-efficacy, health-related skills, adherence, quality of life, and costs were mixed; thus, the strength of evidence was insufficient.

Components of effective interventions were their high intensity, theory basis, pilot testing before full implementation, emphasis on skill building, and delivery of the intervention by a health professional. Interventions that changed distal outcomes (e.g., health care service use or health outcomes) appeared to work by affecting intermediate factors, such as increasing knowledge or self-efficacy, or by changing behavior.

Too few studies addressed the effects of health literacy interventions on the outcomes of behavioral intent, and disparities to draw any meaningful conclusions; the strength of evidence is insufficient.

Discussion

What This Update Adds to the 2004 Review

The results of this review expand our understanding of the relationship between health literacy and health outcomes in several ways. First, a majority of studies included in this review performed multivariate analysis, allowing us to make better estimates of the true effect of health literacy on health outcomes. Second, new studies have addressed the relationship between numeracy level and health outcomes. This allows a better understanding of what it means to be health literate. Third, we identified a limited body of research that begins to identify variables that may be on a causal pathway between health literacy and health outcomes. These variables include knowledge, self-efficacy, and social stigma. Finally, new studies suggest that health literacy can be a mediator of racial disparities in health outcomes.

We also learned many new things about interventions to mitigate the effect of low health literacy. First, we identified several design features of interventions that were effective in one or a few studies (enumerated above); they all warrant further study in broader populations. Second, interventions focused on a broader range of outcomes, allowing us to make inferences about effect across outcomes. Preliminary examination of these studies suggests that effective interventions to mitigate the effects of low health literacy may work by increasing knowledge and self-efficacy or by changing behavior. Additionally, certain factors appear to be key in making the interventions effective with respect to distal outcomes (e.g., self-management, hospitalizations, mortality); these include high intensity, theory basis, pilot testing before full implementation, emphasis on skill building, and delivery of the intervention by a health professional (e.g., pharmacist, diabetes educator).

Limitations of the Literature

As with all systematic reviews, our results and conclusions depend on the quality of the published literature. Heterogeneity in outcomes, populations, study designs (or interventions), and measured outcomes was a problem for both Key Questions. This level of diversity in the knowledge base precluded us from pooling results statistically.

The limitations of the literature for Key Question 1 studies included:

- Lack of a priori specification and inconsistent approaches to creating health literacy and numeracy levels or thresholds in analyses, hampering comparisons between studies;
- Inconsistent choices of potential confounding variables in multivariate analyses;
- Small sample sizes, making it impossible for us to determine whether null findings represented a true lack of effect or simply limitations in statistical power;
- Studies in just one clinic or in other narrowly defined patient populations, rendering the applicability of findings to other settings or populations unknowable;
- Use of health literacy tools that continue to focus primarily on reading ability;

- The limited number of studies examining potential mediators of health literacy, such as self-efficacy, knowledge, or beliefs;
- Few studies examining the role of health literacy on health disparities; and
- No studies examining differences in outcomes related to oral literacy skills.

The limitations of the literature for Key Question 2 studies included:

- Lack of an adequate control or comparator group in many studies, limiting the ability to determine the true effect(s) of the intervention;
- Measurement of multiple outcomes with insufficient attention to ensure that each had been adequately powered to detect a difference;
- Testing interventions that combined various design features to mitigate the effect of low health literacy but offering no way to determine the effectiveness of individual components;
- Failure to perform adequately controlled subgroup analyses that would elucidate differential effects of interventions in low- and high-health-literacy populations; and
- Failure to report adequately the intervention design features that would allow future content analyses of effective interventions.

Future Research

The field of health literacy has clearly advanced since our 2004 review appeared. The progress has been both conceptual and empirical. Nonetheless, many opportunities remain for important future research. Such investigations will improve our understanding of the impact of health literacy on the use and outcomes of health care and will expand the knowledge base about the impact of interventions intended to improve health literacy. Our recommendations for future research involve both better methods and specific clinical or operational topics.

In examining the relationship between literacy and health outcomes, investigators should consider:

- Specifying a priori their cutpoints for distinguishing levels of health literacy and noting the relevance of those levels to (a) the outcomes and population being studied and (b) the body of similar work in the field;
- Using health literacy measurement tools that go beyond health-related literacy and numeracy to capture additional and potentially critical skills, particularly oral health literacy;
- Ensuring sufficient statistical power to detect differences among relevant health literacy levels;
- Controlling for an adequate set of potential confounders;
- Improving the applicability of results to broader populations and settings; and
- Further examining potential mediators and moderators of the relationship between health literacy and health outcomes.

In examining the impact of interventions to mitigate the effects of low health literacy, investigators should consider:

- Testing novel approaches to increase motivation; improved techniques for delivering written, oral, or numerical information; and “work-around” interventions such as patient advocates;

- Determining the effective components of already-tested interventions that employ a combination of features intended to lessen the effects of low health literacy. Although a combination of intervention features has repeatedly been shown to ensure the success of interventions, paring away ineffective features could save delivery time and result in more cost-effective delivery;
- Determining the cost-effectiveness of effective programs; and
- Determining the effect of practice and policy interventions. We found almost no studies that addressed such interventions.

Implications of This Report for Clinicians and Policymakers

We anticipate that this update will continue to raise awareness among clinicians and policymakers alike that low health literacy has a substantial impact on the use of health care services and health outcomes; it also hints at the role of health literacy in disparities in utilization or outcomes among groups defined by various sociodemographic characteristics. However, little remains known about the direct effect of lower health literacy on the costs of health care. Addressing the burden of low health literacy that we have identified warrants the attention of many stakeholders.

We highlight effective interventions that could be implemented in clinical practice now. Intensive interventions related to medication adherence, self-management, and disease management delivered by clinical practitioners are of special interest.

Additionally, for policymakers, we underscore the critical need for research funding to test practice and policy interventions, particularly those that, to date, have gone largely untested. The recent HHS National Action Plan to Improve Health Literacy helps enumerate these and other critical actions for health care professionals and policymakers to take in addressing the multifaceted issues involving health literacy in this country.

Introduction

In 2004, the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) published a systematic review examining the relationship between literacy and health outcomes.[1] This work, supported by the Agency for Healthcare Research and Quality (AHRQ), concluded:

- Low literacy is associated with several adverse health outcomes, including low health knowledge, increased incidence of chronic illness, poorer intermediate disease markers, and less than optimal use of preventive health services. Interventions to mitigate the effects of low literacy have been studied, and some have shown promise for improving patient health and receipt of health care services. Future research, using more rigorous methods, is required to better define these relationships and to guide development of new interventions.
- Given a rapidly growing body of literature on literacy and health outcomes, AHRQ commissioned an update to the 2004 review. The current report describes that update and focuses on health literacy as contrasted with literacy per se. Although the first report was limited to the print literacy component of health literacy, we now consider numeracy (ability to use numbers) and oral literacy (speaking and listening skills) as crucial components of health literacy.

Health Literacy

Definition

Health literacy, as defined by Ratzan and Parker[2] and adopted by *Healthy People 2010*[2,3] and the Institute of Medicine (IOM) in their 2004 report *Health Literacy: A Prescription to End Confusion*[4] is "the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions." The concept of health literacy represents a constellation of skills necessary to function effectively in the health care environment and act appropriately on health care information. These skills include print literacy (the ability to read and understand text and locate and interpret information in documents), numeracy (the ability to use quantitative information), and oral literacy (the ability to speak and listen effectively).[5,6] Some authors include in this definition a working knowledge of disease processes, an ability to use technology, an ability to network and interact with others socially, motivation for political action regarding health issues, and self-efficacy.[7,8]

Numeracy is an important component of health literacy and represents "the ability to understand and use numbers in daily life."[9] Numeracy has been independently associated with health outcomes.[10] Additionally, some individuals may have adequate print literacy but lack the numeracy skills needed to interact successfully with the health care system.[11] These individuals cannot reliably carry out health-related tasks that rely on numeric information, such as interpreting food labels, measuring blood sugar, comparing risk information, or following dosing instructions for medications.[9]

Burden of Low Literacy and Low Health Literacy

In 2003, the US Department of Education conducted a survey entitled "National Assessment of Adult Literacy" (NAAL). The most comprehensive examination of adult literacy to date, the

NAAL surveyed more than 19,000 adults age 16 and older and included items intended to measure health literacy directly. More than one-third of respondents (36 percent) taking the NAAL scored in the lowest two ("basic" and "below basic") out of four categories on health literacy items, suggesting that approximately 80 million adults in the United States have limited health literacy, including related prose, document, and quantitative skills.[12] These adults may have difficulty with even simple tasks such as reading and understanding the instructions on a prescription bottle or filling out an insurance form. Although the NAAL did not independently report on prose, document, or quantitative health literacy, its predecessor, the National Adult Literacy Survey (NALS), reported similar proportions of individuals scoring in the lowest proficiency levels across these domains.[11,13] More recent (although not nationally representative) data suggest that many adults may have higher print literacy than quantitative literacy.[14]

Although a significant proportion of the general population has low health literacy, certain groups have an even higher prevalence of the problem. Such groups include the elderly, minorities, individuals who have not completed high school, adults who spoke a language other than English before starting school, and people living in poverty.[12] For instance, the NAAL demonstrated a higher prevalence of poor health literacy among the elderly. Compared with the 36 percent of all adults who scored in the bottom two categories on the NAAL survey, 59 percent of adults age 65 and older scored in the "below basic" and "basic" range.[12] This association between age and health literacy has proven consistent in other studies of literacy in health care settings. However, the majority of these studies are cross-sectional, making it difficult to determine whether the higher prevalence of poor health literacy in the elderly population results from a cohort effect (e.g., fewer educational opportunities; higher prevalence of a native language other than English) or whether literacy declines with age or cognitive function.[15] Both factors likely play a contributing role.

The NAAL also reported a strong relationship between health literacy and race or ethnicity. White respondents scored better on the survey than any of the other racial or ethnic groups evaluated. Only 9 percent of white respondents scored in the lowest ("below basic") category on the NAAL survey, but 24 percent of black, 41 percent of Hispanic, 13 percent of Asian, and 25 percent of American Indian and Native Alaskan respondents scored in the "below basic" range.[12] Differences in the quality of education received by disadvantaged members of nonwhite populations may, at least partially, explain this finding. Further, issues of language and acculturation likely play a significant role. The association between health literacy and race and ethnicity raises the question of whether health literacy serves as a mediator of racial and ethnic disparities in health. If literacy is related to health outcomes, disparate health literacy levels among different groups could contribute to differential health outcomes.

In addition to age, race, and ethnicity, educational attainment plays a predictably strong role in health literacy. In the NAAL study, more than three-quarters (76 percent) of respondents who had not completed high school scored in the "below basic" or "basic" range of health literacy, compared with only 13 percent of individuals with 4-year college degrees.[12] Although one's literacy level is related to one's educational status, the correlation between years of education and literacy is imperfect. People often score reading grade levels that are several grades lower than the last year of school they completed.[16] In addition to the ability to read, the ability to complete 12 years of education may draw on several factors, including social support, community resources, motivation, and family expectations.

Using statistical modeling and demographics, such as those above, the National Center for Education Statistics and others[17-20] have provided estimates of local and regional literacy and health literacy prevalence. As might be expected, these estimates suggest variation across states and counties,[18,20] which might affect health outcomes in important ways. To assist clinicians and policymakers in estimating the health literacy prevalence in their own environments, calculators based on such work are now available online.[19]

Measuring Health Literacy

To date, instruments for measuring health literacy skill levels have focused primarily on the ability to read and, in some cases, to use numbers. A variety of measures focusing on these skills are available and have been applied in the health setting (see Tables 1 and 2). Currently, no instruments are widely available to measure oral health literacy or a comprehensive set of skills that have been conceptualized as the components of health literacy.

Commonly used measures of health literacy. The instruments most commonly used in the health literature to measure health literacy are the Rapid Estimate of Adult Literacy in Medicine (REALM)[21] and the Test of Functional Health Literacy in Adults (TOFHLA).[22] The REALM is a word recognition test that assesses whether a person can correctly pronounce a series of health-related words listed in order of increasing difficulty. The REALM has been validated as an instrument of reading ability and is highly correlated with traditional reading assessments in the educational literature (correlation with the Wide Range Achievement Test [WRAT]: $r = 0.88$).[21]

The TOFHLA employs a different approach and assesses both reading skills and numeracy. It assesses reading skills using a modified cloze procedure. In this procedure, subjects read health-related passages in which every fifth to seventh word has been deleted; they then fill in the blanks by selecting the correct word from four choices.[22] The TOFHLA assesses numeracy by asking a subject to respond to health-related prompts, such as pill bottle instructions and appointment slips. While developing and validating the TOFHLA, the authors found that the reading comprehension subtest and quantitative or “numeracy” subtest were highly correlated ($r = 0.79$). The TOFHLA has also been noted to be highly correlated with the REALM ($r = 0.84$) and the WRAT ($r = 0.74$).[22] A short version (S-TOFHLA)[23] is available and has also been widely applied in the literature.

The most common instruments used to measure numeracy in the health literature are the Schwartz and Woloshin Numeracy Test and the WRAT math subtest. Neither of these focuses specifically on the health context. The Schwartz and Woloshin Numeracy Test consists of three items that assess individuals’ understanding of probability and their ability to convert between percentages and proportions.[24] The WRAT math subtest assesses individuals’ ability to count, read numerical symbols, and perform simple arithmetic operations.[25] A growing number of newer tools (e.g., Diabetes Numeracy Test) measure numerical skills in the health context, but have not been widely employed to assess the relationship between numeracy and health outcomes.

No gold-standard instrument is currently available to assess adequately the more global concept of health literacy, including the interactions of reading ability, numeracy, and oral literacy. However, as recommended by policymakers, work to define and measure a wider set of skills that might more adequately reflect health literacy has begun.[26]

Table 1. Measures of health literacy

Instrument	Description of Test	Method of Assessment	Type of Score	Health Focus	Validation
Chew Subjective Literacy Screener[27]	1-item self-reported assessment of confidence in filling out hospital forms; 2 additional items were tested, but didn't increase performance of measure	Self-report	Categorical score: inadequate literacy/literacy	Yes	Partial validation
Demographic Assessment of Health Literacy (DAHL)[28]	A demographic assessment of the likelihood of low health literacy; S-TOFHLA scores predicted from 4 demographic variables: age, gender, race, education	Demographics used to predict reading ability	1. Continuous score (14-91) 2. Categorical score: 0-53: inadequate 53-100: marginal/	Yes	Yes
Hebrew Health Literacy Test[29]	12-item instrument, assessing reading comprehension and quantitative skills (based on s-TOFHLA)	Reading comprehension (Cloze method) plus quantitative skills test	1. Continuous score (0-12) 2. Categorical score: 0-2: low 3-10: marginal 11-12: high	Yes	Partial validation
Literacy Assessment for Diabetes (LAD)[30]	60-item word recognition test for diabetes Length ≤ 3 minutes	Word recognition	1. Continuous score 2. Grade level (4th-16th)	Yes	Yes
Medical Terminology Achievement Reading Test (MART)[31]	42-item measure of health literacy; designed with small print size and glossy cover to allow patients an excuse for difficulties in completing the task	Word recognition and pronunciation test	1.Continuous score (range NR) 2. Categorical score (grade level range NR)	Yes	Partial validation
National Adult Literacy Survey (NALS)[11]	~200 questions measuring literacy (prose, quantitative, and document literacy); delivered by item-response theory; includes questions on health literacy	Reading passages, documents, word problems	1. Continuous score (0-500) 2. Grouped into 5 levels (1-5, 5 best): Level 1: <224 Level 2: 225-274 Level 3: 275-324 Level 4: 325-374 Level 5: ≥375	No; however, health questions embedded in survey	Yes

Table 1. Measures of health literacy (continued)

Instrument	Description of Test	Method of Assessment	Type of Score	Health Focus	Validation
National Assessment of Adult Literacy (NAAL)[12]	~200 questions measuring functional health literacy (prose, quantitative, and document literacy), delivered by item-response theory; includes separate 28-item subtest on health literacy	Reading passages, documents, word problems	1. Continuous score (0-500) 2. Grouped into four categories: below basic, basic, intermediate and proficient literacy level	Yes, separate health literacy assessment	Yes
Newest Vital Sign[32]	6 questions about an ice cream nutrition label Length: 3 minutes	Document and quantitative literacy skill test	1. Continuous score (0-6) 2. Categorical score: < 2: low literacy 2-4: possible low literacy > 4: adequate literacy	Yes	Partial validation
Nutritional Literacy Scale (NLS)[33]	28-item assessment of reading comprehension in the context of food content areas such as foods, fiber, calcium, and sugar	Reading comprehension (modified-cloze method)	Continuous score (0-28)	Yes	Yes
Rapid Estimate of Adult Literacy in Medicine (REALM)[21]	66-item measure of health literacy Length about 1 to 2 minutes Also available in short form as REALM-R and REALM-SF and for special populations as REALD-30 and REALM-Teen[34-37]	Word recognition and pronunciation	1. Continuous score (0-66) 2. Grade level: 0-18: $\leq$3rd grade 19-44: 4-6th grade 45-60: 7th-8th grade 61-66: $\geq$9th grade	Yes	Yes
Short Assessment of Health Literacy for Spanish Adults (SAHLSA)[38]	50-item instrument that includes word recognition and comprehension test to examine health literacy for the Spanish-speaking population	Word recognition and reading comprehension	1. Continuous score (0-50) 2. Categorical score: 0-37: inadequate 38-50: adequate	Yes	Yes
Single Item Literacy Screener (SILS)[39]	1-item assessment of whether an individual needs help reading health-related materials	Self-report	Continuous score (0-5) Categorical/cut-off score: SILS 2-5: positive SILS < 2: negative	Yes	Partial validation

Table 1. Measures of health literacy (continued)

Instrument	Description of Test	Method of Assessment	Type of Score	Health Focus	Validation
Test of Functional Health Literacy in Adults (TOFHLA)[22]	67-item measure of health literacy, including reading comprehension and quantitative skills Length about 20 to 25 minutes. Available in Spanish and English Also available in short form (S-TOFHLA) and for special populations as British version (UK-TOFHLA) and dental version (TOFHLiD);[40] length about 5 to 10 minutes	Reading comprehension (Cloze method) and quantitative skills test	1. Continuous weighted score (0-100) 2. Categorical score: 0-59: inadequate 60-74: marginal 75-100: adequate	Yes	Yes
Wide Range Achievement Test, Reading subtest (WRAT)[41]	57-item measure of literacy from educational literature Length about 10 minutes	Word recognition and pronunciation	Continuous score (0-57)	No	Yes
Woodcock Johnson, Passage Comprehension SubTest[42]	Test of literacy from educational literature Length 60 to 70 minutes	Reading comprehension (cloze method)	Continuous score (0-43)	No	Yes

Table 2. Measures of numeracy

Instrument	Description of Test	Method of Assessment	Type of Score	Health Focus	Validation
Diabetes Numeracy Test (DNT)[43]	43-item scale assessing essential numeracy skills for diabetes self-management. Topic areas include: nutrition, exercise, blood glucose monitoring, oral medications, insulin 30 minutes to administer	Addition, subtraction, multiplication, division, fractions and decimals, multistep mathematics, time, numeration, counting Includes word problems; interpretation of tables, graphs, or figures; and selection of necessary math functions to solve diabetes-specific problems	Percentage of correct responses	Yes	Yes Performance on the DNT correlates with diabetes knowledge, self-efficacy, behaviors, and glycemic control
Lipkus Numeracy Test[44]	8 or 11 questions assessing numeracy	Converting percentages to proportions, proportions to percentages, and using probability	Percentage of correct responses	No	Yes
Schwartz and Woloshin Numeracy Test[24]	3 word problems assessing numeracy	1. Probability 2. Converting a percentage to a proportion 3. Converting a proportion to a percentage	Percentage of correct responses	No	Yes
Subjective Numeracy Scale (SNS)[45,46]	8-item measure of perceived ability to perform various mathematical tasks and preference for the use of numerical vs. prose information	Self-report	Not reported	No	Yes
Test of Functional Health Literacy in Adults (TOFHLA), numeracy[22]	17-item scale assessing ability to apply numbers in health context	Assessed the ability to employ numbers in health setting through interpretation of pill bottles, appointment slips, etc.	Continuous score (weighted 0-50)	Yes	Yes
Wide Range Achievement Test WRAT-3, arithmetic subtest[25]	55-item scale assessing numeracy skills Length about 15 minutes	Counting, reading number symbols, solving simple arithmetic problems Standard scores and percentiles compare individual performance with that of others of the same age	Continuous score (0-55)	No	Yes
Woodcock Johnson, applied problems subtest[47]	63-item numeracy test from educational literature	Identify relevant information to solve problems, simple arithmetic	Continuous score (0-63); converted to demographically corrected z-scores with mean of 0 and standard deviation of 1	No	Yes

Measuring Health Literacy vs. Literacy

As we note in our original report (and reiterate above), several of the primary instruments used to measure health literacy are highly correlated with general measures of literacy applied in the health care setting.[21] This suggests that health literacy and literacy measures are strongly related. It has additionally raised questions about what terminology to apply to measures in the field.[48]

In this review, in distinction to our earlier report, we focus on "health literacy" rather than "literacy." We made this decision for several reasons. First, we were interested in expanding our review to be consistent with the recent conceptions of health literacy skills[17-20] that separately focus on print literacy, numeracy, and oral literacy. To acknowledge this spectrum of skills, we felt it important to focus on health literacy. The traditional conception of literacy has focused more narrowly on print literacy and numeracy skills.[18] Second, an increasing number of newer measures (e.g., Newest Vital Sign, Diabetes Numeracy Test) are framed in specific health contexts and assess condition-related skills. Finally, measures of health literacy, print literacy (including prose and document literacy), and numeracy are highly correlated in national samples.[18]

Although we believe our focus on "health literacy" appropriately represents the directions of research and policy in the field, we acknowledge that the literature contributing to this field does not organize itself neatly within our health literacy framework. For instance, several measures of health literacy assess a combination of print literacy and numeracy skills (e.g., Newest Vital Sign, TOFHLA), making distinctions between print literacy and numeracy difficult. Furthermore, the quantitative skills components of some measures (e.g., TOFHLA) have been extracted and used independently as measures of numeracy. To simplify this report, we separate "health literacy" (including any studies that presume to measure literacy or health literacy) from "numeracy" and "oral literacy."

Relationship Between Health Literacy and Outcomes

In the past 15 years, researchers have demonstrated that low literacy can have far-reaching consequences for an individual's health. In our 2004 systematic review and related articles,[49,50] we identified 44 articles describing results that addressed the relationship between literacy and use of health care services, health outcomes, costs of health care, and disparities. The report found that low or inadequate literacy (compared to adequate literacy) was strongly associated with poorer knowledge or comprehension of health care services and health outcomes.[49,50] Limited literacy was also associated with higher probability of hospitalization, higher prevalence and severity for some chronic diseases, poorer global measures of health, and lower utilization of screening and preventive services.[49,50] In many cases, however, the evidence was mixed; both outcomes assessed and analytic methods differed across studies.[49,50] Although literacy was often related to health outcomes in bivariate associations, the relationship sometimes weakened and became statistically nonsignificant after the investigators adjusted results for covariates such as age, education, socioeconomic status, health care access, or experience in the health care setting, calling into question whether low literacy was truly an independent problem or merely a marker of other social problems. Outcome differences were rare between a middle literacy group (marginal) and the adequate group. Only one study that was reviewed examined differences in costs and one study examined differences between race or ethnicity groups, resulting in insufficient data to reach conclusions concerning these issues.

Based on these findings, the 2004 review recommended that future research: (1) examine more closely and include in analytic models factors that may be confounding the relationship between literacy and health outcomes (e.g., age, income, or health insurance status); (2) consider other factors, referred to as mediators, that may be in the causal pathway between health literacy and health outcomes (e.g., self-efficacy, self-care, trust, and satisfaction); (3) consider prospective cohort studies to examine the relationship between literacy, age, and changes in health outcomes such as health status; (4) stratify outcomes by numeracy level to gain a greater understanding of how these skills may uniquely affect health outcomes and under what conditions numeracy would be a useful indicator for targeting individuals for interventions; and (5) examine the effect of literacy on costs and on racial, ethnic, and age-related disparities.

Effects of Interventions To Reduce Burden of Low Health Literacy

In our prior review,[49,51] we identified 29 articles describing interventions to mitigate the effects of low literacy on health outcomes. Of the 29 articles, 20 measured literacy in individual participants and were performed in developed countries. These 20 studies tested a wide range of interventions for improving health outcomes in patients with poor literacy. Most of the interventions occurred in a single session and attempted to make health information more readily available to patients with limited literacy. Some studies compared standard handouts with materials that were written in simpler, easier-to-read prose. Others compared standard materials with pictographs, booklets, videotapes, or CD-ROMs specially designed for low-literacy audiences. A few interventions used multiple methods.

In aggregate, these studies suggested that interventions may reduce the adverse health effects associated with low literacy.[49,51] However, few studies examined each type of intervention; few examined the interventions' effects in literacy subgroups; a minority examined outcomes other than knowledge; and many had methodological flaws limiting conclusions.

Based on observations from our 2004 review, we recommended that (1) additional studies of interventions be pursued, (2) any new investigations measure the interventions' effects by literacy subgroup, and (3) investigations examine a broader range of outcomes.

Need for Update of the Earlier Review

Given the ongoing concern about an association between health literacy level and poor health outcomes and the potential to reduce these outcomes with novel interventions, the US Department of Health and Human Services (HHS) has released a National Action Plan to Improve Health Literacy.[52] Additionally, several national organizations, including the IOM,[53] the American Medical Association (AMA),[5] the National Institutes of Health (NIH), and HHS (*Healthy People 2010*),[3] have promoted health literacy as a research priority. With such attention, the research community in this field has responded with considerable new work since 2004. Additionally, AHRQ has released a Health Literacy Universal Precautions Toolkit based on evidence and best practices.[54]

To synthesize the increasing volume of literature on health literacy and further the larger goal of improvements in health literacy, AHRQ commissioned the RTI–UNC EPC to update its 2004 systematic review to examine the effects of health literacy on health outcomes and interventions to improve those outcomes. In this updated report, we focus on the same key questions as the original report, but we expand our conception of literacy to health literacy and consider—

separately and in combination—print literacy, numeracy, and oral health literacy skills. In the results chapters of this report (Chapters 3 and 4), we include only studies that have been published since our last review; we did not systematically reabstract studies from our earlier review or reassess their quality. We did, however, reorganize data about intervention studies from our first review to highlight features of the interventions reviewed earlier and allow interpretation of these features in light of current evidence. Additionally, we compared all findings from the current review to findings from our 2004 review to allow for comprehensive conclusions.

Further, following our review of information available through publications and our review of the quality of the studies based on that information, we queried intervention authors from both the first review and this updated review about key features of the interventions that they had not reported in published articles. This additional information is included in Appendix A.

Production of This Report

Organization

Health literacy is of particular concern to the AMA, which had originally nominated the topic in 2004, and whose continued interest in the topic is expressed through their representation on the Technical Expert Panel (TEP) for the update review. The earlier report was updated to incorporate an expanding literature and an ongoing interest in the topic area. Our new systematic review consolidates and analyzes the body of literature that has been produced to date regarding the relationship between health literacy and health outcomes and the evidence about interventions intended to improve the health of people with low health literacy.

Chapter 2 describes our methodological approach, including the development of key questions (KQ s) and their analytic framework, our search strategies, and inclusion/exclusion criteria. In Chapter 3, we present the results of our literature search and synthesis of KQ 1 concerning the relationship between health literacy and numeracy levels and health outcomes and we evaluate the strength of the evidence concerning these outcomes. In Chapter 4, we present the results of our literature search and synthesis of KQ 2 concerning interventions to assist populations with low health literacy and evaluate the strength of the evidence concerning these interventions. Chapter 5 further discusses the findings and offers our recommendations for future research as well as for clinicians and policymakers. Chapter 5 is followed by the list of references. Appendixes are provided electronically at Appendixes and Evidence Tables for this report are provided electronically at http://www.ahrq.gov/clinic/tp/lituptp.htm and provide a detailed description of our search strings (Appendix B), our Full-Text Inclusion/Exclusion Form and our quality review form used for evaluating the internal validity (including risk of bias) of included studies (Appendix C), detailed evidence tables (Appendix D), poor quality studies (Appendix E), Strength of Evidence (SOE) tables (Appendix F), peer reviewers (Appendix G), excluded studies (Appendix H), full bibliography (Appendix I), and summary tables of KQ 1 findings from our original literacy and health outcomes report (Appendix J).

Technical Expert Panel

We identified technical experts in the field of health literacy to provide assistance throughout the project. The TEP was expected to contribute to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included eight members: five technical/clinical experts; one member whose expertise and mission concerns the interests and perspectives of patients and consumers; one potential user of the final evidence report; and an AHRQ health literacy expert (see Acknowledgments, page iv).

To ensure robust, scientifically relevant work, the TEP was called on to provide advice on substantive issues or possibly overlooked areas of research. TEP members participated in conference calls and discussions through e-mail to refine the scope of this update (including inclusion/exclusion criteria) and discuss our preliminary assessment of the literature. Because of their extensive knowledge of the literature on health literacy, including numerous articles authored by TEP members themselves, and their active involvement in professional societies and as practitioners in the field, we also asked some TEP members to participate in the external peer review of the draft report.

Use of This Updated Systematic Review

This updated report addresses the key questions outlined in Chapter 2 through a systematic review of published literature. We anticipate that the report will be of value to the AMA for its various efforts to inform and educate physicians. This report can also inform practitioners about the current state of evidence and provide an assessment of the quality of studies that aim to improve health for people with low health literacy. Researchers can obtain a concise analysis of the current state of knowledge in this field and will be poised to pursue further investigations that are needed to improve health for low-health-literacy populations. Health educators can also use this report to guide future interventions to improve health communication. Finally, policymakers can use this report to inform new strategies and the allocation of resources toward future research and initiatives that are likely to be successful.

Methods

In this chapter, we document the procedures used by the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) to develop this comprehensive evidence report *Health Literacy Interventions and Outcomes*, an update to our 2004 systematic review *Literacy and Health Outcomes*. The key questions (KQ s) for this update review are the same as those in the original review, with the exception that *literacy* has been replaced by the broader term *health literacy*. This decision, which is discussed in detail in Chapter 1, was primarily made to acknowledge numeracy (the ability to use quantitative information) and oral literacy (the ability to listen and speak effectively) in addition to print literacy. Thus, in this review as in our original report, we include studies that purport to measure either participants' health literacy or their general literacy in a health setting; we, however, refer to these measures in aggregate as measures of health literacy. We additionally separately review studies of numeracy and health outcomes to highlight the findings from this relatively new body of research. Although we attempted to review the relationship between oral health literacy skills and health outcomes, we found no studies that measured oral health literacy skills that met our other inclusion criteria.

Our specific methodology in conducting an updated review is discussed below. To provide a framework for the review, we first present changes from our prior review. We then describe the KQ s and their underlying analytic framework, our inclusion and exclusion criteria, search and retrieval process, and methods of abstracting relevant information from the eligible articles to generate evidence tables. We also discuss our criteria for rating the quality of individual studies and for grading the strength of evidence as a whole.

Our overall goals were to evaluate whether newer literature was appropriate for answering our key questions and to determine whether earlier conclusions changed. We modified the original methods as follows:

- We broadened our definition of health literacy to be consistent with the Ratzan and Parker (2000) definition used by Healthy People 2010 and the Institute of Medicine. Thus, we now include studies that evaluated the numeracy skills of participants. Our inclusion criteria also encompassed studies that used measures of oral (spoken) health literacy or other skills-based approaches to health literacy measurement, but we did not find any such published studies.
- We examined the outcome of knowledge only in relation to outcomes related to numeracy level and intervention studies because evidence in the earlier review clearly concluded that greater literacy skills and higher health-related knowledge levels are positively related.
- We required that studies directly measured the health literacy of the study population and did not conclude health literacy level via self-report or similarity to other populations.
- We modified criteria for evaluating individual study quality to incorporate advances in the methodology of conducting systematic reviews, including not using a numeric summary of individual criteria in determining the overall quality rating.
- We included studies conducted in developing countries as long as an objective assessment of literacy or health literacy was measured directly in participants.

- If information was missing from articles about intervention studies, we queried the investigators to allow richer interpretation about what interventions may be effective in mitigating the effects of low health literacy.

Key Questions and Analytic Framework

Based on the growing appreciation of the complexity of the relationship between health literacy and obtaining medical care and achieving good health outcomes, we pose two key questions in this report. Both have four parts.

KQ 1. Are health literacy skills related to
(a) Use of health care services?
(b) Health outcomes?
(c) Costs of health care?
(d) Disparities in health outcomes or health care service use according to race, ethnicity, culture, or age?

KQ 2. For individuals with low health literacy skills, what are effective interventions to
(a) Improve use of health care services?
(b) Improve health outcomes?
(c) Affect the costs of health care?
(d) Improve health outcomes and/or health care service use among different racial, ethnic, cultural, or age groups?

Figure 1. Analytic framework for the health literacy systematic review

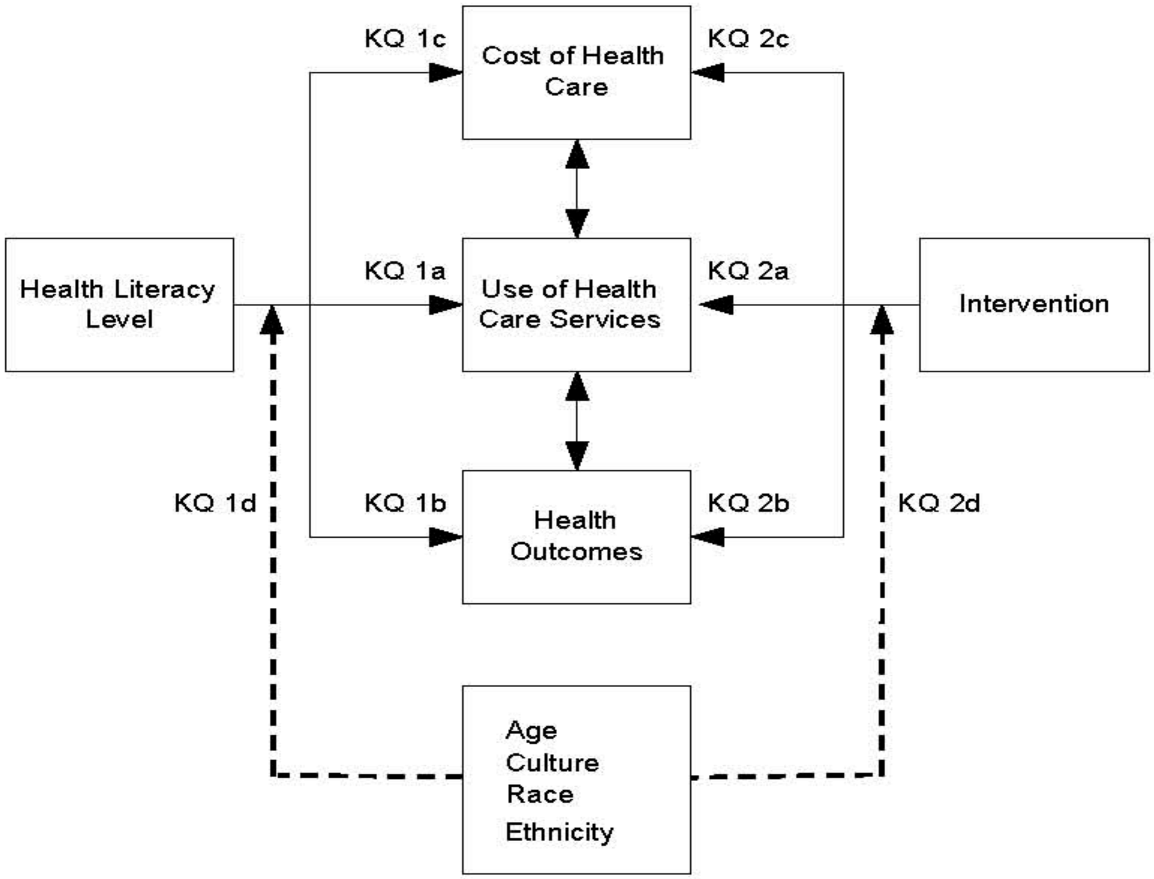
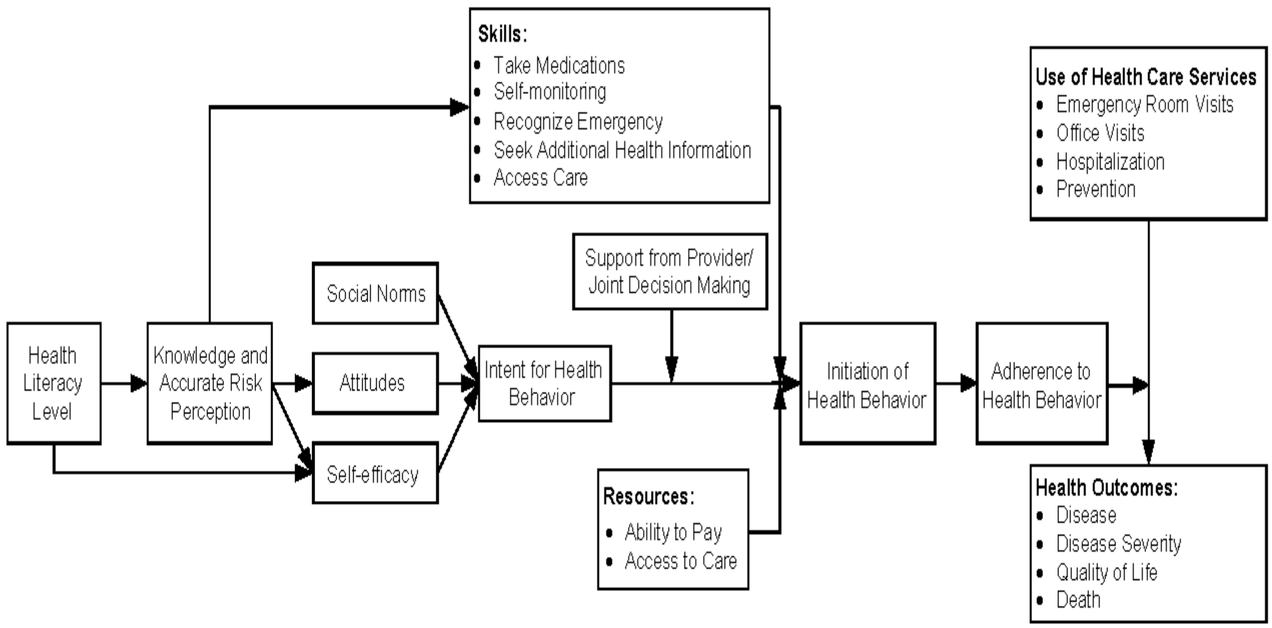


Figure 1 depicts the analytic framework for our KQ s. Solid lines show the relationship between health literacy skills and outcomes (KQ 1) and between interventions and outcomes (KQ 2); dotted lines show factors that might influence or be intermediaries in these relationships.

Figure 2 outlines a more detailed logic model explicating outcomes that were included in our review. This model draws both on several models of health literacy proposed by researchers in the field and on an integrated model of behavioral theory.[55,56] The Integrative Theory, proposed by Fishbein in 2000, reflects a growing consensus that (1) a core set of variables (e.g., attitudes, social norms, and self-efficacy) derived from the major predictive theories of behavior change (e.g., Health Belief Model, Theory of Reasoned Action, Social Cognitive Theory) are responsible for most of behavioral intention, and that (2) these variables, in combination with an adequate skill set and removal of environmental constraints, predict actual behavior change.[55]

Figure 2. Logic model for the health literacy systematic review



Our logic model was used to determine whether studies considered for inclusion have relevant health outcomes. It also guided our presentation of included articles. It was not meant to be a definitive guide to the relationship between variables because many of these relationships have not been explicitly tested in the field of health literacy. Furthermore, it was not meant to provide a definitive statement about what constitutes a "good outcome." For some outcomes in the logic model, increases represent the good outcome (e.g., adherence, most screening tests).

For other outcomes, decreases represent the good outcome (e.g., hospitalizations, mortality). For KQ 1a and 2a, we consider any process of care as a health service; this includes clinic and hospital visits, hospitalizations, and use of preventive and screening services. For KQ 1b and 2b, we use the term "health outcomes" broadly to encompass both intermediate and distal outcomes, even though in many cases the intermediate outcomes will be only surrogates or proxies for health-related end results of care. Outcome categories include the following:

Knowledge: As described above, we consider knowledge as a final outcome only in relation to numeracy (KQ 1) and intervention studies (KQ 2). We do not include it in our consideration of the relationship between health literacy and health outcomes (KQ 1) because evidence in the earlier review clearly concluded that greater literacy skills and higher health-related knowledge levels are positively related.

Self-efficacy: Self-efficacy, a person's confidence in his or her ability to carry out a health behavior, is an important intermediate outcome in many behavioral theoretical models. It is a predictor of behavioral intent.

Behavioral intent: Behavioral intent is a person's stated likelihood of starting a behavior. It is an important hypothesized intermediate step in the causal pathway between health literacy level and health outcomes.

Skills and behaviors: The relationship between health literacy and intermediate and ultimate outcomes depends on a person's health skills and behaviors. Skills include a person's ability to recognize emergency situations, seek additional health information, or access needed health care. Behaviors include actions such as taking medication, changing one's lifestyle, or monitoring one's health.

Adherence to health behavior: Adherence is the ability to carry out a health behavior over a meaningful period of time, such as regularly taking a medication "as prescribed" over the period of time for which it is prescribed. Adherence is an important predictor of health outcomes.

Measures of disease incidence, prevalence, morbidity, and mortality: This category includes such outcomes as rates of physical and mental health conditions, stages of cancer presentation, severity of diseases, measures of disease control and complications, and death rates. These outcomes may be measured by biomarkers, validated survey instruments and questionnaires, patient self-report, or, in the case of mortality, vital records or proxy reports.

Health status: This outcome includes generic (and condition-specific) measures of health status or health-related quality of life; the domains of interest are physical health and mental health functioning (e.g., cognitive abilities), pain or fatigue, and perhaps social functioning and social networks. They are usually assessed by self-report questionnaires that have been shown to predict health outcomes.

Of particular note for KQ 1b is that we did not examine outcomes related to attitudes. This decision was based on the belief that attitudes result from knowledge, which, as described above, is not examined in the current report. Further, we did not examine outcomes related to social norms or patient-provider relationships (e.g., shared decisionmaking) because we thought that these variables likely affected the direction or strength of the relationship between behavioral intent and health outcomes rather than lying on the causal pathway. Clearly, however, empiric work is needed to test these assertions prior to future reviews.

For KQ 1c on measuring the cost of health care, we included any study that measured the monetary cost of health care services, including both direct and indirect costs. For KQ 2c, we also included studies measuring the cost of the intervention.

Finally, to address KQ s 1d and 2d concerning disparities in health outcomes and use of health care services, we looked for studies that reported on health literacy level as a *mediator* of the relationship between age, race, ethnicity, or cultural background and health outcomes (or the effectiveness of interventions) and also included studies that reported *moderators* of the strength of the relationship between health literacy and health outcomes. This distinction between mediating and moderating is important. A moderator affects the direction or strength of a relationship between an independent and dependent variable and is generally examined by looking for differential effects in subgroup analysis. A moderator effect is commonly observed in an analytic model through a statistically significant interaction of the exposure and the moderator. A mediator, on the other hand, *accounts* for that relationship, answering the question as to how or why things occur. There are multiple approaches to mediation analysis, including path analysis, structural equation modeling, and methods such as those proposed by Baron and Kenny.[57] All test the relationships between the exposure and mediator, mediator and outcome, and exposure and outcome before and after adjusting for the mediator. To determine mediation, they require a reduction in the magnitude of the relationship between the exposure and outcome when the mediator is added to the model.

Literature Search and Retrieval Process

Database Search Terms

To identify the relevant literature for our review, we searched five electronic databases: MEDLINE,® the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Library, PsychINFO, and the Educational Resources Information Center (ERIC). For health literacy, we searched using a variety of terms limited to English and studies conducted with human participants (no laboratory or animal studies) published from 2003 to May 25, 2010. For numeracy, we searched the same databases from 1966 to May 25, 2010. We conducted key word searches because no MeSH headings specifically identify health-literacy-related articles. The terms "health literacy," "numeracy," and "literacy," and terms or phrases related to instruments known to measure health literacy and numeracy were the focus of the search. We limited the "health literacy" and "literacy [tw = 'text word']" searches to 2003 forward (including up to 1 year overlap with our earlier review) to be confident that we did not miss studies between the first review and this update, and we compared new and earlier reference lists to ensure that we did not unnecessarily overlap with the literature reviewed earlier. Editorials, letters to the editor, and case reports were excluded.

Across all databases searched, our initial searches yielded 2,855 citations (Appendix A). We reviewed our search strategy with the TEP and further supplemented our electronic searches by hand searching pertinent excluded articles, including other reviews.

We imported all citations into an electronic database (EndNote X.3) for a final unduplicated yield of 3,496 articles.

Study Selection Process

Inclusion and Exclusion Criteria

For each KQ , we developed detailed eligibility criteria with respect to population, intervention, comparison, outcomes, time frames, and settings (the PICOTS framework).[58] The final criteria include the following:

KQ 1. Relationship of health literacy levels to utilization, outcomes, costs, and disparities

Population: Individuals and caregivers of all races and ethnicities.

Intervention: Not applicable.

Comparison: Different levels of health literacy or numeracy skills.

Outcomes: For studies of outcomes by levels of health literacy, relevant health or cost outcomes with the exception of knowledge; the relationship between literacy and health-related knowledge was considered well-established through the earlier review. For studies of outcomes by numeracy levels, relevant health or cost outcomes *and* knowledge.

Time: Cross-sectional or longitudinal studies, with varying lengths of time for followup, and with no restrictions for when the studies or data collection activities were done.

Setting: No exclusions by setting, so includes inpatient or outpatient settings in health care systems and institutions, various community-based settings, or homes.

KQ 2. Effective interventions to improve utilization or health outcomes or to affect costs or disparities among low literacy individuals

Population: Populations including individuals and caregivers of all races and ethnicities with low health literacy. Although the ideal populations to answer our question would include only individuals with low health literacy, much of the research about interventions designed to mitigate the effects of low health literacy has been done in populations that include a combination of low and high health literacy individuals and failed to perform separate analyses in these subgroups. Instead of excluding a large portion of the intervention literature, we decided to permit inclusion of populations with a combination of low and high literacy individuals (but no subgroup analysis), knowing that they may provide only indirect information about the effect of interventions on an exclusively low literacy population.

Intervention: All interventions specifically designed to mitigate the effects of low health literacy by improving the use of health care services or health outcomes in low-health-literacy or low-numeracy individuals; this includes, but is not limited to, interventions designed to simplify information presentation, circumvent poor reading skills (e.g. video), facilitate patient/provider communication, circumvent barriers to health care, improve self-efficacy or health-related skills.

Comparison: Any comparator designated by the investigators. A comparator is not necessary for studies with pre/post-intervention measures.

Outcomes: Any health-related health care utilization, outcome, or cost.

Time: Studies (controlled and uncontrolled trials and observational studies) with varying lengths of time for followup and with no restrictions for when the studies or data collection activities were done.

Setting: No exclusions by settings.

Based on the final KQ s specified above, we generated a list of inclusion and exclusion criteria (Table 3). We included prospective and cross-sectional observational studies of health outcomes, trials of materials developed for low-health-literacy populations, and trials of interventions that compared materials designed to be “easier to read or understand” with standard materials. We limited studies to those with outcomes related to health and use and costs of health services. Because this is an update to our original report, we limited our searches to studies that would not have been considered during the earlier review (e.g., those more recently published or those for which numeracy was the exposure).

As described in Table 3, we excluded studies for several reasons, including lack of any outcome of interest or results limited to the readability of materials. We also excluded studies that focused on literacy or health literacy as an outcome rather than an exposure, as is seen, for instance, in studies of physician office-based programs designed to improve children’s literacy or studies of sociodemographic characteristics more likely to be associated with differences in health literacy level. We also excluded studies that used cognitive impairment or dementia as an outcome of interest because we would not be able to determine whether health literacy levels were causing or being affected by the condition.

Table 3. Inclusion/exclusion criteria for studies considered in this update

Category	Criteria
Study population	All races, ethnicities, and cultural groups. Patients of all ages and caregivers whose primary language is the same as that of the health care provider or intervention material. Health literacy, numeracy, or oral health literacy levels of the population must be reported.
Time period	Published from 2003 to May 25, 2010: Print literacy or health literacy studies meeting other inclusion criteria and newly published since our earlier review. Published from 1980 to May 25, 2010: Numeracy and oral health literacy studies excluded from the earlier review and meeting other inclusion criteria.
Publication criteria	English only. Articles in print. Excluded were articles accepted for publication but not in print in the journal, articles in the so-called “gray literature,” and articles we could not obtain during the review period.
Admissible evidence (study design and other criteria)	Original research studies that provided sufficient detail regarding methods and results to enable use and adjustment of the data and results. Eligible study designs included before-and-after studies; controlled trials; and observational studies: prospective and retrospective cohort studies, case control studies and cross-sectional studies. Relevant outcomes must be able to be abstracted from data presented in the papers. Sample sizes must be appropriate for the study question addressed in the paper; single case reports or small case series (fewer than 10 subjects) were excluded. Other study exclusion criteria included studies of dyslexia and dementia. of normal reading development in children. with no health outcomes or no use of health care services. with an outcome limited to satisfaction or likeability of one intervention material compared to another, or attitudes, perceived social norms, or patient-physician interaction measures. solely about the readability of materials, but not about the relationship between health literacy and outcomes when readability is the focus of the intervention. in which health literacy, numeracy, or oral health literacy are not directly measured in the population by an objective measure or linked to outcomes at an individual level. in which the outcome is limited to dementia or cognitive impairment. in which health literacy is the exposure (KQ 1) and the only study outcome is knowledge. of the basic experimental science of reading ability (e.g., studies of brain function, including results from magnetic resonance imaging or electroencephalogram) or basic educational achievement. solely or chiefly for validation of an instrument. in which the intervention was not designed to address low health literacy or numeracy.

Process for Considering Abstracts and Full Articles for Inclusion

Once we had identified articles through the electronic database searches, review articles, and reference lists, we examined abstracts of articles to determine whether the studies met our criteria for inclusion. Each abstract was independently, dually reviewed for inclusion or exclusion. If one reviewer concluded that the article should be included in the review, we obtained the full text. If two reviewers independently determined that the abstract did not meet eligibility criteria, we excluded it.

In the full article review, two team members again read each article and decided whether it met our inclusion criteria, using a Full-Text Inclusion/Exclusion Form (Appendix C). Reviewers discussed any disagreements, and, if they could not resolve them, the disposition of the article was decided by discussion among the larger team. Excluded articles are listed in Appendix H.

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

The senior staff members for the systematic review jointly developed the design of the evidence tables. Evidence tables were designed to provide sufficient information to enable readers to understand the study and to determine study quality. In our design, we gave particular emphasis to essential information to answer our KQ s and to determine study quality. The format of the tables, which was based on successful designs used for many prior systematic reviews from this EPC (not just the review of health literacy and outcomes), varied slightly by KQ; the tables for KQ 2 have additional columns that describe the control group, the intervention group, and specifics of the intervention.

We trained abstractors by having them abstract several articles into evidence tables and then reconvened as a group to discuss the results, including the utility of the table design. The abstractors repeated this process several times until everybody was capable of working with the tables, instructions, and other elements of the process.

Abstractors entered data directly into evidence tables. The first abstractors entered all relevant information into the evidence table. Second reviewers subsequently checked each abstraction for accuracy and completeness against the original articles. Abstractors reconciled all disagreements concerning the information reported in the evidence tables.

Abstractors, at the time of initial data abstraction, also performed a quality review (internal validity including risk of bias relevant to the study design) and rating of each study, using a separate quality review form for this process (Appendix C). As with data abstraction, second reviewers independently conducted a quality review and rating of each article. When ratings conflicted, each pair of reviewers discussed the problem; issues they could not resolve were brought to a third party for resolution.

The final evidence tables for KQ 1 (health literacy and numeracy separately) and KQ 2 are presented in their entirety in Appendix D. Entries for all evidence tables are listed alphabetically by the last name of the first author; multiple articles by the same team of authors are entered alphabetically by second or later authors. A list of abbreviations used in the evidence tables appears at the beginning of the appendix.

Quality Rating of Individual Studies

To assess the quality (internal validity including risk of bias) of studies, we used predefined criteria based on those developed for the earlier review. We adapted criteria from the US Preventive Services Task Force, the National Health Service Centre for Reviews and Dissemination, the AHRQ's *Evidence-based Practice Center Systematic Review Manual*, and a report on the quality of observational studies developed by the RTI-UNC EPC.[59] We specifically addressed methodological issues including selection bias, measurement bias, confounding, and power.

Unlike our previous review, we rated the overall quality of studies qualitatively. In general terms, a "good" study has the least bias and results are considered to be valid. A "fair" study is susceptible to some bias but probably not enough to invalidate its results. A "poor" rating indicates significant bias (stemming, e.g., from serious errors in design or analysis) that may invalidate the study's results. Studies rated as "poor" were excluded from the analysis. A copy of the form used for quality rating a study is included in Appendix C.

As described above, two independent reviewers with no conflict of interest assigned quality ratings to each study. Disagreements were resolved by discussion and consensus or by discussion with the larger study team. Studies that met all criteria were rated good quality. Studies received a quality rating of fair when they presumably fulfilled all quality criteria but did not report their methods to an extent that answered all our questions or did not adequately fulfill all quality criteria. Thus, the fair-quality category includes studies with quite different strengths and weaknesses. Studies that had a fatal flaw (defined as a methodological shortcoming that leads to a very high probability of bias) in one or more categories were rated poor quality and excluded from our analyses. Poor-quality studies and reasons for that rating are presented in Appendix E. In situations where we concluded different quality ratings for different outcomes within the same study, we provide the quality rating for each.

Data Synthesis

We synthesized the data in our review qualitatively. We did not have a sufficient number of studies with similar outcomes or similar interventions to consider quantitative analysis (meta-analysis or statistical pooling) of data. Furthermore, we primarily considered only information from the *current* searches. Given changes in our evidence tables and quality forms, we reviewed individual studies from the 2004 review in depth *only* if new evidence would seem to change overall conclusions. Because the structure of analysis for KQ 2 changed for this current review, we reorganized the 2004 review findings from KQ 2 to be consistent with our current organizational structure for results.

As part of data synthesis, we paid particular attention to a few issues. First, we closely examined whether studies accounted for relevant confounders in their analyses. Because the goal of etiologic research focuses on understanding the relationship between exposures and outcomes of interest, it is important that confounders are controlled for to determine accurate estimates of effect. Second, we looked closely at studies that reported the relationship between both health literacy and numeracy and the same outcome. This allowed inferences about the relative strengths of the relationships between the variables and the outcome. Third, for intervention studies, we looked at common features of successful interventions and at the impact of interventions on multiple related outcomes. This allows inference about the effective components and mechanisms of health literacy interventions.

Grading the Strength of Available Evidence

We evaluated the strength of evidence based on the AHRQ *Methods Guide for Comparative Effectiveness Research*.[60] To determine overall strength, we first examined several key features contributing to evidence strength: risk of bias, consistency, directness, precision, and the presence of other modifying factors. We then combined these factors to grade the overall strength of evidence. As described in Owens et al., the evaluation of risk of bias includes assessment of study design and aggregate quality of studies.[60] We judged good-quality studies with strong designs to yield evidence with low risk of bias. We graded evidence as consistent when effect sizes across studies were in the same direction and of similar magnitude. For studies addressing KQ1, when the evidence linked differences in health literacy skill level or interventions directly to health outcomes, we graded the evidence as being direct. For studies addressing KQ2, the evidence was graded as direct when at least one study for any given type of intervention or outcome included low literacy specific analyses. We graded evidence as being precise when results were in the same direction and had a narrow range.

Consistent with EPC policy, we independently dually evaluated the overall strength of evidence for each outcome based on a qualitative assessment of strength of evidence for each of the key features listed above. We then reconciled all disagreements through discussion by senior members of the team. The levels of strength of evidence as specified by AHRQ are shown in Table 4. Full results of our strength of evidence reviews are presented in Appendix F.

Table 4. Strength of evidence grades and definitions

Grade	Definition
High	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
Low	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
Insufficient	Evidence either is unavailable or does not permit estimation of an effect.

Applicability of the Evidence

We evaluated the applicability of the evidence based on a qualitative assessment of the population, intensity, or quality of treatment, outcomes, and timing of followup. Specifically, we considered whether enrolled populations differ from target populations, whether studied interventions are comparable with those in routine use, whether measured outcomes are known to reflect the most important clinical outcomes, and whether followup was sufficient.

Peer Review Process

Among the more important activities involved in producing a credible evidence report is conducting an unbiased and broadly based review of the draft report. External reviewers are clinicians, researchers, representatives of professional societies, and potential users of the report, including TEP members (see Appendix G). Peer reviewers provided comments on the content, structure, and format of the evidence report and completed a peer review checklist. We revised the report, as appropriate, based on comments from peer reviewers.

Results: Relationship of Health Literacy to Outcomes and Disparities

This chapter presents the results of our literature search for the project, including results for key questions (KQ s) 1 and 2. It also reports our findings for KQ 1; we illustrated and discussed this KQ in Chapter 2 and Figures 1 and 2. Specifically, KQ 1 asked whether health literacy skills are related to (a) use of health care services, (b) health outcomes, (c) costs, and (d) disparities in outcomes or utilization according to race, ethnicity, culture, or age.

Organization of KQ 1-Related Tables

For ease of navigation, all tables in the chapter related to the KQ 1 results are presented at the end, following the text.

Health literacy tables:
Overview of included studies (Table 5)
Studies grouped by health literacy measurement tool and skill-level groupings used (Table 6)
Aggregate strength of evidence grades (Tables 8, 16, 30, and 32)
Summary information on each included study, sorted by outcome (Tables 7, 9-15, 17-29, and 31)

Numeracy tables:
Overview of included studies (Table 33)
Aggregate strength of evidence grades (Table 35)
Summary information on each included study, sorted by outcome (Tables 34, 36-42)

Detailed evidence tables appear in Appendix D.

Summary tables from the original report (*Literacy and Health Outcomes*, 2004) that briefly describe each of the studies included to answer KQ 1 appear in Appendix J.

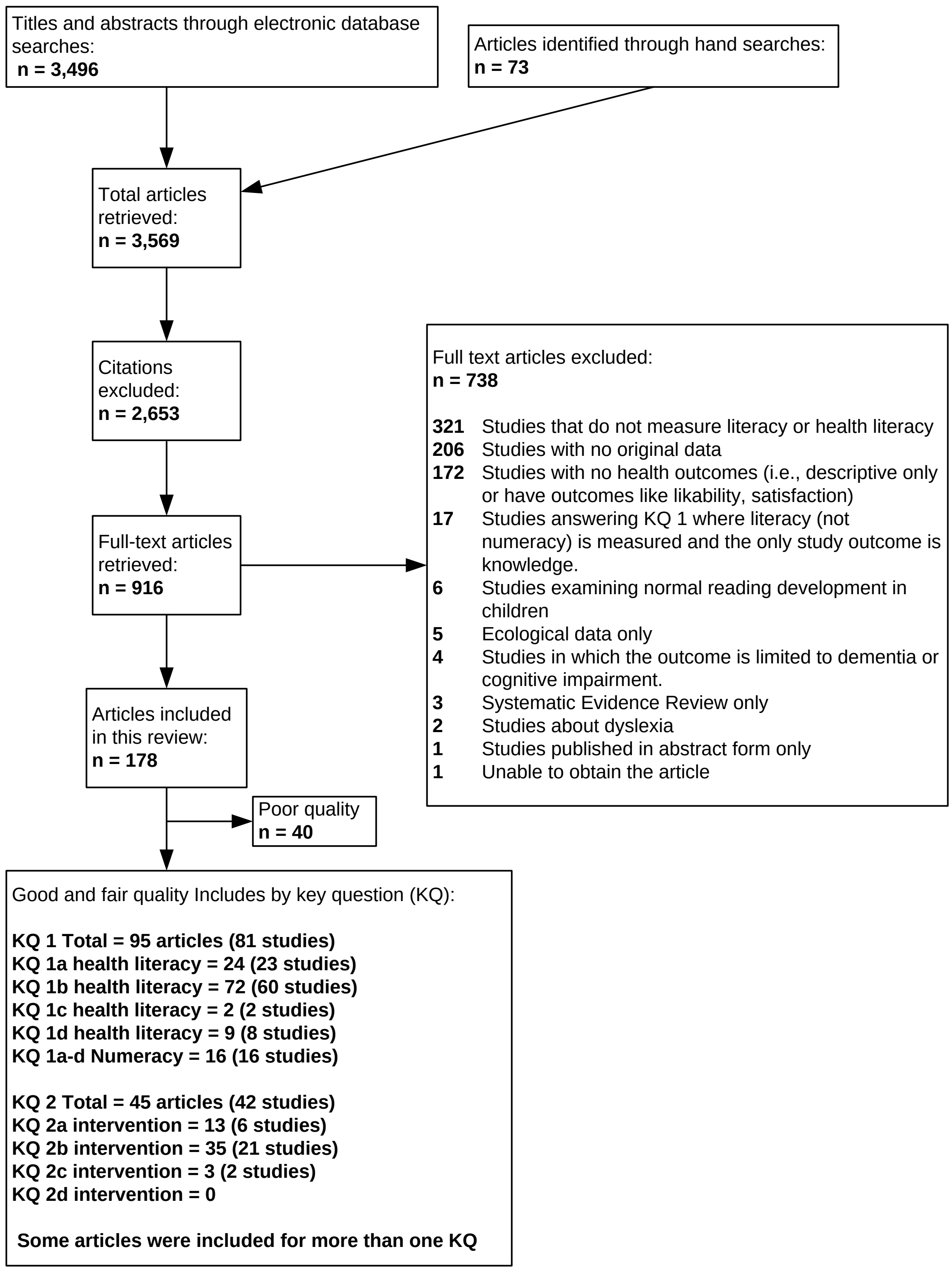
We report our results in three main sections: specific details about the yields of the literature searches and the number of studies meeting our inclusion criteria to answer KQ s 1 and 2, the effects of health literacy on health outcomes, and the effects of numeracy on health outcomes. In studies that measured health literacy, we compared the new results broadly with those found during the earlier review (*Literacy and Health Outcomes*, 2004[1]). All numeracy studies are discussed in this chapter are new; none had been included in the earlier review. We did not find any studies meeting our inclusion criteria addressing outcomes or interventions related to oral health literacy.

References for each study are provided in the summary and evidence tables. By convention, references are not given in tables presenting the strength of evidence. Chapter 2 describes the methods for arriving at strength of evidence grades; Appendix F gives the domain-specific scores used in deriving the overall grades.

Results of Literature Search

Our literature search yielded 3,496 articles (Figure 3). We also conducted full text reviews of 73 articles identified by hand-searching articles and Web-based bibliographies and recommendations from our Technical Expert Panel (TEP). Of the 3,569 articles retrieved, we excluded 2,653 articles after reviewing the abstracts and pulled 916 articles for full text review. The full bibliography is included in Appendix I. Ultimately, for the two main questions, we included studies rated either good or fair quality: 81 studies addressed KQ 1 and 42 studies addressed KQ 2. KQ 1 results are presented separately in relation to health literacy (86 articles) and numeracy (16 articles). Of these, 7 articles address both health literacy and numeracy.

Figure 3. PRISMA tree: Flow diagram depicting review and disposition of articles



Key Question 1. Relationship of Health Literacy to Various Outcomes and Disparities

We identified 86 good- or fair-quality articles reporting on 72 unique studies for this topic. Some studies report on more than one key question. These studies report results about the relationship between health literacy and use of health care services, health outcomes, and costs of health care and disparities between specific racial, ethnic, cultural, or age groups. Fourteen studies were of good quality and 72 of fair quality, according to the criteria described in Chapter 2. In addition, we identified 40 studies which were considered to be of poor quality and therefore not included in the analysis (poor-quality studies are listed in Appendix E; we do not discuss them further in this review.) In the text below, we identify only studies of good quality; all others for which quality is not specifically called out are fair quality. Most studies had a cross-sectional design (N = 64), but 22 were cohort designs (Table 5).

Multiple studies reported results using the same data. For instance, eight articles reported results collected during the "Prudential study." This study was conducted with 3,260 new members in a Prudential Medicare managed care plan of enrollees in Cleveland, Ohio, Houston, Texas, and Tampa and south Florida.[61-68] Other studies reported in multiple articles include four articles reporting on a sample of patients at Chicago, Illinois, and Shreveport, Louisiana, HIV clinics,[69-72] two articles reporting on pharmacy patients in Atlanta, Georgia,[73,74] and three articles reporting on patients in three primary care clinics in Chicago, Illinois; Shreveport, Louisiana; and Jackson, Michigan.[75-77]

Studies examined a variety of outcome measures including use of health care services (hospitalization and emergency department visits and screening and immunizations), access to care, and health outcomes (adherence, self-efficacy, health behaviors, health-care-related skills, disease prevalence and severity, health status, and mortality). Studies also examined differences in costs and disparities related to health literacy level (Table 5).

Table 6 groups KQ 1 health literacy studies based on the health literacy measurement tool used in the analysis and, further, the skill-level groupings used to distinguish study participants. We found that health literacy was mostly measured with the Rapid Estimate of Adult Literacy in Medicine (REALM; 33 articles) or the Test of Functional Health Literacy in Adults (TOFHLA) or Short Test of Functional Health Literacy in Adults (S-TOFHLA; 42 articles). Three articles used the National Assessments of Adult Literacy (NAAL), and, unlike our earlier review, no article used the Wide Range Achievement Test (WRAT; a general literacy measure that was commonly used in studies included in our earlier review *Literacy and Health Outcomes*[1]). Several other literacy measures (in contrast to health literacy measures intended to be used in a health care environment) were included in one study apiece: the Cape Area Panel Study Literacy and Numeracy Evaluation, a reading comprehension instrument in Nepalese, an instrument for the diagnosis of reading, and the Woodcock Language Proficiency Battery. Although the validity and reliability of the Woodcock battery[42] is well known, information about these other literacy measures is quite limited. The health literacy levels used to compare study participants evaluated using the REALM, TOFHLA, or S-TOFHLA varied among studies, ranging from a continuous measure to two, three, or even more groups. In some studies, three groups were identified (i.e., inadequate, marginal, and adequate); in others, two of the three groups were combined in the statistical analysis. Studies varied concerning whether the two lower or the two higher groups were combined. Conceptually, an individual's health literacy level could change over time. However, the instruments included in the reviewed studies capture only static measures of health literacy or numeracy.

In contrast to our earlier review, studies reviewed in the update by and large include multivariate analyses (rather than just unadjusted bivariate analyses) (Table 5). However, the choice of variables controlled for in analyses varied greatly across studies. Potential confounders (related to health literacy and health outcomes) controlled for in many studies include education, age, race, gender, and income.

KQ 1a. Use of Health Care Services

We identified 24 articles reporting on 23 unique studies examining the relationship between health literacy skills and the use of health care services. Three studies were of good quality and 21 were of fair quality. Nine studies included cohort designs; the rest were cross-sectional. These studies focused on emergency department admissions or hospitalizations, general preventive screenings (mammogram, colon, Papanicolau [Pap], sexually transmitted infection testing, and influenza and pneumococcal vaccination), and access to office visits and insurance.

Hospitalization and emergency department rates. Six studies—one good-quality prospective cohort study (hereafter, the Prudential study),[68] two fair-quality prospective cohort study,[78,79] one retrospective cohort study,[80] and two cross-sectional studies[81,82]—examined the risk of hospitalization by health literacy level (Table 7). All but one study showed a statistically significant association of increased hospitalization and use of inpatient services with lower health literacy level. Populations included the elderly,[68,81] patients with asthma,[79,80] and patients with congestive heart failure.[78] The one study that did not find an association with hospitalizations included a cross-sectional subpopulation of HIV-positive adolescents, which may be a healthier population compared to the other studies.[82] One of the larger cohort studies, the Prudential study, examined the impact of low health literacy on medical care use among 3,260 Prudential Medicare managed care enrollees.[68] Patients with low health literacy had higher probabilities of using inpatient services than those with adequate health literacy (mean differences in probability of use, 0.05; 95% confidence interval [CI], 0.00-0.09). Enrollees with marginal and adequate health literacy did not differ in use of inpatient services. The strength of evidence is moderate (Table 8 and Appendix F). These findings are consistent with previous findings in our 2004 systematic review.[1]

Nine studies, including two good-quality prospective analyses from the Prudential study,[62,68] three other prospective cohorts,[78,79,83] one retrospective cohort,[80] and three cross-sectional studies,[81,82,84] examined emergency and urgent care visits by literacy level (Table 7). All but two studies[82,84] showed an association of greater emergency department use and low health literacy. The Prudential study[62] examined the association of emergency department visits with health literacy level. After controlling for multiple confounders, both the inadequate health literacy and the marginal health literacy groups had a higher rate of two or more emergency department visits when compared with those with adequate health literacy (marginal literacy relative risk [RR], 1.44; 95% CI, 1.01-2.02; inadequate literacy RR, 1.34; 95% CI, 1.00-1.79).

The two studies that did not find an association with health literacy examined associations of parent health literacy and child asthma care among children with persistent asthma[84] and the HIV-positive adolescents described above.[82] The other study, a cross sectional study of 499 children with persistent asthma, examined parental health literacy and multiple aspects of asthma care (preventive medicine use, acute care, unmet needs, parental worry, and parental quality of life). Parental health literacy was not associated with children's use of any urgent care. This particular outcome was limited because the outcome of urgent care visits was measured by parental self-report. The strength of evidence is moderate (Table 8 and Appendix F). No studies of emergency department use were reported in our earlier report.

General screening. We found one good[85] and seven fair studies[81,86-91] examining the association of health literacy with general screening services. These services included colon screening (Table 9), Pap testing (Table 10), mammography (Table 11), and testing for sexually transmitted diseases (Table 12).

Colon screening. Five cross-sectional studies found mixed results for the probability of having received colon screening by health literacy level (Table 9).[81,86-89] Of note, the two larger studies found a lower probability of colon screening in patients with lower health literacy.[81,86] The largest study[86] found a decreased probability of colon cancer screening among those 65 years of age and older with below-basic health literacy compared with those with proficient skills in a nationally representative US cross-sectional study of 18,100 individuals examining multiple self-reported preventive services (data not reported [NR]; P < 0.05). The three studies not finding an association with health literacy were smaller in size (samples of 50 to 136) and limited to one geographic area.[87-89] The strength of evidence is low (Table 8 and Appendix F). No studies of colon screening use were reported in the earlier 2004 report.[1]

Pap tests. Three cross-sectional studies found that women with lower health literacy had a lower probability of ever having had a Pap test (Table 10).[81,86,91] However, this result was present only in certain age cohorts. In a nationally representative sample, researchers found that women less than 40 years of age with below-basic health literacy had a lower probability of having a Pap test than women in the same age group with proficient health literacy (NR; $P < 0.05$), but the probabilities did not differ by literacy level in women 40 to 64 years of age.[86] Results also seemed to differ by degree of lower health literacy (inadequate vs. marginal). One study examined Pap screening in 205 low-income Spanish-speaking Latinas in New York City.[91] In adjusted analyses, controlling for age, years in the United States, education, and having a source of care and health insurance, these investigators found that women with inadequate health literacy were less likely to have ever had a Pap test than women with adequate literacy (odds ratio [OR], 0.06; 95% CI, 0.01-0.55). However, the marginal and adequate health literacy groups did not differ significantly (OR, 0.14; 95% CI, 0.01-1.41). This discrepancy in findings between inadequate and marginal groups is consistent with an earlier study[92] in the 2004 report.[1] Thus, the overall strength of evidence is low (Table 8 and Appendix F).

Mammography. Four cross-sectional studies examined use of mammography by health literacy group (Table 11).[81,85,86,90] All studies found a lower use of mammography in the lower health literacy group compared with the adequate group. However, one study found a difference in receipt of mammograms among older women[86] and another found differences between groups by frequency of mammograms.[90] In the Prudential study, women ages 65 and older with low health literacy had a lower probability of having a mammogram than those with adequate health literacy (NR; $P < 0.05$); health literacy was not associated with the probability of having mammography among women ages 40 to 64.[86] Another study evaluated mammography rates in 97 women in three community health clinics in Philadelphia; inadequate health literacy was associated only with significantly lower odds of ever having a mammogram (OR, 0.88; 95% CI, 0.79-0.98), but not with having a mammogram in the past year, past 3 years, or as part of a check-up.[90] The strength of evidence is moderate (Table 8 and Appendix F). These results are consistent with the 2004 report.

Sexually transmitted infection testing. Researchers conducted a cross-sectional study (N = 372) of HIV test acceptors in an inner-city urgent care hospital (Table 12).[93] Subjects with inadequate health literacy had greater odds of accepting an HIV test result than those with adequate health literacy (OR, 2.02; 95% CI, 1.19-3.42). In the 2004 report, the one study about this type of service showed a lower probability of having received a gonorrhea test in the past year among those in the low-literacy group.[94] The strength of evidence is low (Table 8 and Appendix F).

Immunizations. One good cohort[63] and three cross-sectional studies[85,86,95] found inadequate health literacy associated with lower receipt of influenza vaccine (Table 13). In a Prudential study analysis, controlling for age, sex, race, ethnicity, education, income, site, morbidity, and smoking, researchers found lower odds of receiving an influenza vaccine in the inadequate health literacy group than in the adequate group (OR, 0.76; P = 0.020), but no significant differences in the marginal health literacy group compared with the adequate health literacy group.[63] These findings are similar to those in our 2004 report. Age also appears to be a factor in a study[86] that found a lower receipt of influenza vaccine by health literacy level among adults under 40 years of age and 65 or older (NR; P < 0.05), but no differences by health literacy level in adults 40 to 64 years of age (NR; P = nonsignificant [NS]). The strength of evidence is moderate (Table 8 and Appendix F).

Pneumococcal vaccine did not follow a pattern similar to influenza vaccine (Table 13). In the two studies that examined pneumococcal vaccine,[63,86] no significant association between pneumococcal vaccine and health literacy level was found. The strength of evidence is insufficient (Table 8 and Appendix F).

Access to care. Four cohort[62,68,96,97] and five cross-sectional studies[82,86,95,98-100] examined various measures of access to office visits and general care; these types of services included pharmacy visits, dental visits, and vision checkups as well as hospital choice and transplant waitlists (Table 14). Two good cohort analyses from the Prudential study did not find an association of inadequate health literacy level with number of physician visits[62] or pharmacy services used.[68] These results are consistent with the one study[101] described in the 2004 report. Similarly, one prospective cohort of 68 individuals did not find differences in time to follow up after an abnormal Pap test by health literacy level.[96] However, results were mixed for dental and vision visits in one Prudential study analysis.[86] Another large study (N =2,512) of Medicare recipients found less access to medical care by lower health literacy groups.[95]

One interesting retrospective cohort study involved 62 patients in five outpatient dialysis units in San Francisco, California.[97] After controlling for multiple confounders, the investigators found a significantly longer time from start of dialysis to referral to a transplant list in patients with inadequate health literacy (hazard ratio [HR], 4.54; 95% CI, 1.67-12.5). However, they saw no subsequent differences in time from being on a transplant list to making the waitlist for transplant. The strength of evidence is insufficient given the variation among studies (Table 8 and Appendix F).

Access to insurance. One nationally representative cross-sectional study[102] of 6,100 parents examined parental health literacy and their children's access to health insurance. After controlling for multiple confounders, the odds of having at least one child without health insurance in their household was higher among parents with below-basic literacy compared to parents with proficient health literacy (OR, 2.4; 95% CI, 1.1-4.9). The strength of evidence is low because there is only one study and there are biases associated with using self-reported measures as the outcome (Table 8 and Appendix F).

Summary of Outcomes on Use of Health Care Services

Differences in health literacy level were associated with use of some health care services (Table 5). Specifically, lower literacy was associated with increased emergency department and hospital use, less screening for cervical cancer (through a Pap test) and breast cancer (mammography), lower influenza immunization, and less access to insurance. Evidence was mixed for pneumococcal immunization and access to office visits. The strength of evidence to support these findings was moderate for hospitalizations, emergency department visits, mammography, and influenza immunization. Evidence for other health care service use was low or insufficient because of inconsistent findings and outcomes.

KQ 1b. Health Outcomes

We identified 72 articles reporting on 60 unique studies examining the relationship between literacy skills and health outcomes. Of these, 13 articles were of good quality and 59 were fair quality.

Adherence. Eleven studies, reported in 15 articles, evaluated the relationship between health literacy level and adherence in adjusted analyses (Table 15).[61,69-74,81,82,103-108]

Five studies reported in 8 articles examined nonadherence in taking HIV medication and found mixed evidence of a direct relationship.[69-72,82,103-105] Studies found no relationship examining 100 percent adherence to medications over 3 days among patients with a history of alcohol problems,[105] 90 percent adherence over the past 3 days among adolescents,[82] and less than 95 percent adherence over the past 3 months among a small sample (N = 87) of clinic patients.[104] In the last study, the relationship between health literacy level and nonadherence was examined, comparing the unadjusted relationship with an adjusted model, controlling only for the potential mediation of a patient’s norms about an acceptable level of adherence and no potential confounding variables. Norms were found to mediate the relationship.

In contrast, in study using self-reported pill counts and controlling for education and other variables, researchers found a positive relationship between lower health literacy level (measured as a TOFHLA score of less than 90 percent correct rather than more commonly used categories) and probability of nonadherence (OR, 3.77; 95% CI, 1.46-9.93).[103] Similarly, based on findings from a study of 204 patients in clinics in Shreveport, Louisiana, and Chicago, Illinois, researchers found a positive relationship: nonadherence to HIV regimen was higher among those with low health literacy than those with adequate health literacy (OR, 2.12; 95% CI, 1.93-2.32).[69,72] However, this study found no difference between the marginal and adequate groups. In subsequent analyses of this sample, the researchers conducted formal mediation analyses and found that the relationship between low health literacy and nonadherence to HIV medications was mediated by the combination of HIV treatment knowledge and medication self-efficacy in one analysis[69] and by stigma related to taking HIV medications in another.[71]

Medication-taking adherence, refill adherence, and adherence to procedural instructions were examined in various other patient populations with mixed results. Among 110 caregivers of infants in pediatric clinics, a combined group of those with low or marginal health literacy were significantly *more* likely to be adherent in providing vitamins to their infants than those with adequate health literacy (OR, 2.4; 95% CI, 1.37-4.2).[108] However, no significant differences by health literacy level emerged in other patient populations for medication-taking, refill adherence, or adherence to procedural instructions. Studies included patients at an anticoagulation clinic missing doses of warfarin,[106] seniors at two clinics filling any medication prescriptions on time,[81] seniors refilling medications for cardiovascular disease,[61] preoperative clinic patients following fasting and preoperative medication instructions,[107] and adults reporting adherence at hospital pharmacies in Atlanta, Georgia.[74] However, in the Atlanta study, researchers found that the relationship between health literacy and adherence was moderated by social support; at the highest levels of social support, patients with adequate health literacy reported better adherence, and, at the lowest levels of social support, patients with lower health literacy reported better adherence.[74]

Three studies examining the relationship between health literacy level and adherence assessed outcome differences between individuals in the marginal- and adequate-health-literacy groups but found no significant difference.[61,69-72,105]

Our research team found mixed evidence of a relationship between health literacy and health outcomes resulting in a strength of evidence grade of insufficient, which may be the result of differences in adherence measure, disease state, and adjustment for relevant confounders (Table 16 and Appendix F). Our earlier review also found mixed results across studies. One study reported a significant relationship between lower literacy and poorer self-reported adherence; three found no significant relationship.[109-112]

Self-efficacy. Five studies examined the relationship between participant health literacy level and self-efficacy for a variety of behaviors[70,82,87,113,114] (Table 17). One study found greater self-efficacy for taking HIV medications in the adequate-health-literacy group than in the low-health-literacy group, but no difference between the adequate and marginal groups.[70] A second study found greater self-efficacy for colorectal cancer screening among individuals with higher health literacy levels (measured by the UK TOFHLA).[114] In contrast, another study found no difference between groups in relation to self-efficacy for taking medications or keeping appointments among adolescent HIV patients.[82] Furthermore, self-efficacy for obtaining a fecal occult blood test or colonoscopy was not related to limited health literacy level (low and marginal groups combined) compared with a group with adequate literacy in a small, potentially underpowered adjusted analysis of 99 patients at one clinic.[87] Finally, although higher self-efficacy for taking hormone therapy among postmenopausal women was correlated with higher health literacy level, this was in an unadjusted analysis.[113]

Based on the mixed results in these studies, our research team graded the strength of evidence as insufficient (Table 16 and Appendix F). Our earlier review included no self-efficacy studies.

Health Behaviors. We identified studies reporting on a variety of health behaviors including smoking, alcohol and drug use, healthy lifestyle, review of prescription information, HIV risk behaviors, and sexual activity.

Smoking. Two large studies evaluated the relationship between health literacy level and self-report of smoking in adjusted analyses (Table 18); results were statistically different even though odds ratios were fairly similar.[64,115] A study examining current smoking status in a national sample of British adults (N = 719) found that higher health literacy, measured as a continuous variable, was associated with a small increased likelihood of not smoking (OR, 1.02; 95% CI, 1.003-1.03).[115] In contrast, among the Prudential sample of American seniors (N = 2,923), researchers found no relationship between health literacy level and participants' smoking status (never, former, or current).[64] Due to these mixed results, the strength of evidence was graded as insufficient (Table 16 and Appendix F). We reported mixed results in our earlier review through one adjusted analysis of adolescents (boys and girls reported separately) and two unadjusted analyses examining outcomes of smoking in adults; therefore, these studies do not modify our evaluation of the strength of evidence.[116-118]

Alcohol and drug use. The Prudential study also examined the relationship between health literacy level and current alcohol consumption; they found no relationship.[64] Among adolescents with HIV, higher health literacy was associated with greater substance use.[82] Neither study adjusted for comorbid depression. With only one study concerning alcohol consumption and one concerning substance use, strength of evidence was graded as insufficient (Table 16 and Appendix F). In our earlier review, we included one study of alcohol consumption among adolescents and no significant relationship with health literacy was found.[118]

Healthy lifestyle. Eight studies addressed the relationship between health literacy level and various measures of healthy lifestyle, including level of physical activity, eating habits, seat belt use, and weight[9,10,64,65,81,95,115,119] (Table 18).

Two studies, discussed above for smoking outcomes, measured level of physical activity. Neither study found significant differences by health literacy level.[64,115]

Healthy eating, overall healthy lifestyle, and seat belt use were examined in one study each. In a sample of British adults, higher health literacy level was associated with a small but significantly higher probability of eating five or more servings of fruits or vegetables per day (OR, 1.02; 95% CI, 1.003-1.03).[115] Among 489 seniors receiving care at two clinics in Chicago, health literacy level did not have a direct effect on a composite measure, the Health-Promoting Lifestyle Profile, which assesses a combination of exercise, nutrition, and health responsibility.[81] Only one unadjusted analysis examined the relationship between health literacy level and seat belt use. The researchers found no significant differences.[64]

Among obese children, body mass index (BMI) was inversely related to the child's health literacy level, controlling for their parent's health literacy level and other confounders.[119] Four additional studies examined differences in rates of obesity or BMI by health literacy level in unadjusted analyses.[9,10,65,95] Results were mixed.

The research team judged the strength of evidence as insufficient (Table 16 and Appendix F) for the relationship between health literacy and physical activity, eating habits, and seat belt use as a group based on mixed findings. The strength of evidence concerning weight or obesity was also insufficient (Table 16 and Appendix F). Our earlier review included no studies with any healthy lifestyle outcomes.

Review of prescription information. One adjusted analysis examined the relationship between health literacy and review of prescription information (Table 18). Clinic patients (N = 251) in Shreveport, Louisiana, were asked to report on whether they ever looked at the consumer information included with their prescriptions.[120] After controlling for potential confounders, including the number of prescriptions taken, those with low health literacy were less likely to look at the material than persons of adequate health literacy (OR, 2.5; 95% CI, 1.2-5.2). The marginal- and adequate-health-literacy groups did not differ. The strength of evidence was low (Table 16 and Appendix F).

HIV risk behaviors and sexual activity. Two adjusted analyses examined the relationship between health literacy and sexual behaviors (Table 18). One study of female inmates did not find a relationship between health literacy level and HIV risk behaviors (sex without a condom or sharing injecting equipment), controlling for age, race, and problem drinking.[121] A large study of adolescents and young adults (N = 4,751) in Cape Town, South Africa, found that higher literacy level (measured using the Cape Area Panel Study Literacy and Numeracy Evaluation) was associated with a lower probability of sexual debut but not first pregnancy, controlling for socioeconomic variables.[122] The research team judged the strength of evidence to be insufficient based on mixed findings (Table 16 and Appendix F). Our earlier review included no studies with these outcomes.

Health care-related skills. Eleven studies reported in 13 articles included outcomes concerning a variety of health care-related skills (Table 19). Among these were appropriate medication use;[47,123-127] interpreting prescription medication, nutritional labels, and health messages;[9,75-77,102,128] and asthma self-care skills.[79]

Taking medications appropriately. Three studies directly observed whether participants could take prescription medications appropriately; their results generally found a relationship with health literacy level. In one study we rated good quality, researchers required 152 coronary heart disease patients to perform four tasks relating to their medication: identify the appropriate medication, open the container, select the correct dose, and report the appropriate timing of doses.[123] The researchers found no difference across health literacy levels in patients' scores from completing all four tasks in an unadjusted analysis. However, after controlling for age, education, and cognitive functioning, low health literacy (but not marginal health literacy) was associated with poorer performance on one of the tasks—being less likely to identify all of one's medications (OR, 12.00; 95% CI, 2.57-56.08). Using a similar approach, a second team of researchers conducted a mock exercise concerning successful medication management (Medication Management Test) among HIV-positive patients.[47] Patients with higher health literacy scored significantly higher in an adjusted analysis. Similarly, in a small sample of seniors in Texas (N = 57), researchers found that lower health literacy (measured continuously) was associated with poorer ability to open and take one's own medications, in adjusted analysis.[124]

Three additional adjusted analyses examined other measures of whether patients take medications properly, the first through self-report, the second through direct observation, and the third through biologic test results, and found limited evidence of a relationship with health literacy level.[125-127] One study examined whether health literacy level was associated with parents' use of nonstandardized dosing instruments (such as kitchen spoons) when providing medications to their children; they found no relationship in an analysis adjusting for all identified potential confounding variables.[125] However, after removing from the adjusted analysis only the variables in the analysis that were confounded with health literacy level (caregiver's education, country of origin, language, and socio-economic status), participants with marginal/inadequate health literacy (combined into one group) were more likely to use nonstandardized instruments than those with adequate health literacy (OR, 1.9; 95% CI, 1.0-3.5). In a second study, researchers tested parents' health literacy level using the Newest Vital Sign and evaluated whether they made dosing errors using common dosing instruments (i.e., dosing cups, droppers, dosing spoons, and syringes).[127] Parents with a high likelihood of limited health literacy and those with possible limited health literacy were significantly more likely to make a dosing error (greater than 20 percent deviation) than parents with adequate health literacy, in adjusted analyses; parents with a high likelihood of limited health literacy were significantly more likely to make a large dosing error (greater than 40 percent deviation). One study examined warfarin control measured by international normalized ratio (INR) variability. Results did not differ by health literacy level, controlling only for age, in a population of adults 50 years of age and older.[126]

Interpreting labels and health messages. Two studies examined participants' ability to interpret labels (prescription medications and nutrition); both found a positive relationship with health literacy level. One study among 395 adult patients in three primary care clinics in Shreveport, Louisiana, Jackson, Michigan, and Chicago, Illinois, examined interpretation of prescription medication labels.[75-77] Participants demonstrated their ability to understand prescription label instructions by describing to physicians how they would take five medications in adjusted analyses, those with inadequate health literacy (RR, 2.32; 95% CI, 1.26-4.28) as well as those with marginal health literacy (RR, 1.94; 95% CI, 1.14-3.27) had a greater probability of misunderstanding one or more label instructions than those with adequate health literacy.[75] A further (unadjusted) examination of participants' correct interpretation of each of the five primary labels found significant differences in interpretation of four of five primary medication labels. They also found differences in whether participants attended to auxiliary labels in two of five comparisons.[76] Lastly, researchers found in an adjusted analysis that those with lower health literacy (less than high school level) were less likely to understand nutrition labels.[9]

One study examined health literacy and the ability to give an organized oral health narrative. Among a community sample of mothers of young children in Nepal, higher literacy level was associated with greater ability to give an organized health narrative (a skill associated with higher oral health literacy) in an adjusted analysis.[128]

Asthma self-care. One study examined self-care skills relating to asthma among hospitalized adults.[79] In adjusted analysis, those with inadequate health literacy, compared with those with adequate literacy, were less likely to have mastery of their dose inhaler (OR, 0.29; 95% CI, 0.08-1.00). We had found a similar result in our earlier review.[129]

Health care-related skills strength of evidence. The research team separately determined that the strength of evidence concerning taking medications appropriately and interpreting labels and health messages was moderate and the strength of evidence concerning asthma self-care was low (Table 16 and Appendix F). Our earlier review included one health-care-related skills study concerning asthma self-care. [129]

Disease prevalence and severity. We found multiple studies examining the relationship between health literacy level and disease prevalence (specifically, mental health diagnoses and chronic conditions) or disease severity (specifically, HIV, asthma, diabetes, hypertension, and prostate cancer).

Mental health outcomes. Eight of ten studies evaluating the relationship between depression and health literacy level found that patients with lower health literacy were more likely to have symptoms of depression or to be considered depressed; however, the majority of studies controlled for a limited number or no potential confounders.[68,95,103,130-135] One additional study examined the relationship between health literacy level and psychological distress[82] (Table 20). In the most rigorous study of depression (a prospective cohort conducted among 390 patients receiving inpatient detoxification from alcohol and substance abuse), depression symptomatology did not differ between health literacy groups at baseline, but was higher among those with lower health literacy at 2-year followup, controlling for a number of potential confounders including sociodemographic characteristics, primary substance of choice, and mental state.[130] Other analyses were conducted among subpopulations with limited adjustments for potential confounders. One reported that depression was greater in the lower-health-literacy group among HIV-positive adults in five urban clinics, controlling for Hispanic nationality.[131] A second reported that depression was also greater among pregnant patients with lower (but not marginal) health literacy, controlling for Mexican nativity and marijuana use.[132] Finally, a third that depression scores were higher among recent Spanish-speaking immigrants in the low-health-literacy groups, controlling for a scale measuring the demands of immigration.[135] In unadjusted analyses, lower health literacy was also related to depression among rheumatology and diabetes patients[133,134] and among seniors in two community samples.[68,95] However, no difference by health literacy level was found among HIV-positive patients in Atlanta.[103] In relation to psychological distress, differences were not found by health literacy level among HIV-positive adolescents.[82]

The research team judged the strength of evidence to be low because, although studies generally found consistent results, only one rigorously controlled for potential confounders (Table 16 and Appendix F). Results of studies evaluating differences in depression across different levels of health literacy in our earlier review were mixed, including among the two studies that controlled for potential confounders.[136-140]

Chronic disease outcomes and prevalence. Three studies examined differences in rates of chronic disease (defined in a group as any long-term illnesses) by health literacy level (Table 21).[9,65,141]Four additional studies examined differences in rates of specific diseases by health literacy level.[66,68,95,142,143]

Using the large, nationally representative NALS (N = 23,889), researchers found that lower health literacy was associated with higher odds of having a long-term illness (one lasting more than 6 months) and greater odds of having a condition that would keep the individual from working after controlling for various sociodemographic characteristics including education.[141] In other studies with unadjusted analyses, the number of chronic conditions among seniors and the percentage with a chronic disease among adults in a clinic population did not differ by health literacy level.[9,65]

Three studies, discussed in four articles, examined differences in rates of specific diseases by health literacy level; one used a well-designed adjusted analysis and the others used unadjusted analyses.[66,68,95,142] All analyses were limited to senior citizens. In adjusted good-quality analyses of the Prudential sample, inadequate compared with adequate health literacy was associated with significantly higher rates of diabetes and heart failure, but not with higher rates of hypertension, coronary heart disease, bronchitis, asthma, arthritis, or cancer.[66] In contrast, the investigators found no differences in rates of specific diseases between those with marginal and adequate health literacy. Potential limitations of this analysis are that respondents' outcomes are self-reported shortly after joining the health plan and differences in prior access to care may have resulted in differences in knowledge concerning their disease state. Also, by testing multiple outcomes, significant differences were more likely to be found in at least some of the comparisons. Two unadjusted analyses measured the probability of differences in prevalence of chronic disease across three health literacy levels; however, their design was insufficient to determine if differences existed between any two groups (inadequate compared with adequate or marginal compared with adequate).[68,95] A third unadjusted analysis among seniors in Korea found that health literacy was associated with significantly higher rates of arthritis and hypertension, but not sensory disease, diabetes, or pulmonary or heart disease.[142]

Among individuals with diabetes, heart failure rates were higher in the limited health literacy group in one bivariate comparison.[143]

Overall, the body of evidence found mixed results and was limited by differences in outcomes across studies with the majority of studies not controlling for potential confounders. Given these issues, the strength of evidence was graded insufficient (Table 16 and Appendix F). Our earlier review found one study of children with migraines and no relationship was found.[144]

HIV infection severity and symptoms. Three adjusted and one unadjusted analyses of individuals with HIV did not find differences in severity of HIV (measured by viral load suppression, CD4 cell counts, and number of HIV symptoms) by health literacy level (Table 22).[82,103,105,145] In contrast, higher health literacy was associated with greater symptom intensity in one study controlling only for Hispanic ethnicity.[131] In this study, health literacy was measured as a continuous variable among a population with relatively high health literacy (REALM mean score = 59.1). Even though four of five studies found no relationship, the research team evaluated the strength of evidence as low because these studies included limited control for confounding and had small sample sizes (Table 16 and Appendix F). Our earlier review was limited to unadjusted analyses and found mixed results.[138,146,147]

Asthma severity and control. The relationship between health literacy and asthma severity of children was examined in two studies reporting a mix of adjusted and unadjusted analyses (Table 23).[80,84] Both studies measured asthma severity by parent report. In one, an adjusted analysis concluded that lower-health-literacy parents of children with asthma were more likely to report that their children were in fair or poor health; however, in an unadjusted comparison, these same parents' reports of their children's asthma control did not differ by health literacy level.[84] In a different unadjusted analysis, parents with lower health literacy reported greater use of albuterol (a bronchodilator) by their children, indicating poorer asthma control.[80] Overall, the strength of evidence was insufficient (Table 16 and Appendix F).

Diabetes control, complications, and related outcomes. Five adjusted studies examined the relationship between glycosylated hemoglobin (HbA1c) level and health literacy level and found mixed results (Table 24).[134,148-151] One good-quality study measuring the HbA1c levels in 1,002 diabetic adults in Vermont found no relationship with health literacy level after measuring health literacy as a continuous variable using the TOFHLA and controlling for demographic characteristics and several factors related to successful diabetes control, such as duration, diabetes education, medication, and alcohol use.[134] Similarly, a second good-quality study conducted with diabetic patients in the Midwest also found no relationship between HbA1c and health literacy levels after controlling for different factors related to successful diabetes control including patient trust, depression, diabetes knowledge, and performance of self-care activities. The lack of a finding of association between health literacy and the outcome may be due to over-adjustment given that researchers controlled for potentially mediating variables in this analysis.[151] In contrast, a very small study (N = 68) from one general internal medicine clinic found significant differences in HbA1c between the four health literacy levels; each increasingly higher level of health literacy, however, was not associated with better control.[149] In a good-quality study, using a path analysis statistical technique and controlling for potential confounders, researchers found that higher health literacy was related to better glycemic control and that health literacy mediated the direct relationship between education and HbA1c level.[150] Also, in a study conducted in Hong Kong, higher-health-literacy diabetic patients had better glycemic control.[148]

The large study of diabetic patients in Vermont, did not find health literacy level to be related to blood pressure, cholesterol level, or the probability of having other potential side effects of poor diabetes control (retinopathy, nephropathy, foot or leg problems, gastroparesis, cerebrovascular disease, or coronary artery disease) after adjusting for confounders.[134]

The strength of evidence relating to diabetes outcomes from this review was insufficient (Table 16 and Appendix F). In our earlier review, diabetes-related results were mixed.[129,152,153]

Hypertension control. Two studies examined blood pressure control among patients diagnosed with hypertension; results were mixed (Table 25).[154,155] The larger study (N = 1,224), measuring health literacy using the REALM, did not find a significant main effect between systolic blood pressure and health literacy level (limited compared to adequate), controlling for education level, diabetes status, medication adherence, smoking, exercise, and participatory decisionmaking.[154] However, the interaction between health literacy and health care system was significant, indicating that the relationship between blood pressure and health literacy differed in the Veterans Administration vs. the private health care system. A second analysis (N = 330) measured health literacy using the S-TOFHLA subdivided into five categories and found that those in the lowest category were less likely than those in the highest category to have controlled blood pressure (less than 140 mmHg systolic and less than 90 mmHg diastolic [or less than 130 mm Hg systolic and less than 80 mm Hg diastolic among those with diabetes] RR, 2.68; 95% CI, 1.54-4.70) after controlling for sociodemographic characteristics, education level, insurance status, number of comorbid conditions, and years treated for hypertension.[155] In this study, the percentage of patients with controlled blood pressure was not consistently larger with every category of increasingly higher health literacy, and only some comparisons between various other health-literacy-level groups were significantly different. Based on mixed results, the research team judged the strength of evidence to be insufficient (Table 16 and Appendix F). Our earlier review did not find a relationship in hypertensive patients between blood pressure control and health literacy level in an adjusted analysis from the one study reviewed with this outcome.[156,1998]

Prostate cancer control. Prostate cancer patients with low health literacy (sixth grade or less) were more likely than those with adequate health literacy (ninth grade or higher) to have an elevated prostate-specific antigen (PSA) level in an adjusted good-quality study (OR, 2.5; 95% CI, 1.5-4.2) (Table 26).[157] In contrast, the marginal-health-literacy (seventh or eighth grade) group and the functional-health-literacy group did not differ. With only a single study, the strength of evidence was low (Table 16 and Appendix F). In our earlier review, stage of presentation of prostate cancer did not differ by health literacy level, in an adjusted analysis.[158]

Global health status measures. Twelve studies reported in 14 articles examined health status differences by health literacy level among a variety of populations, including all adults, seniors, and adults with various specific disease states (Table 27).[63,65,66,81,85,95,100,131,142,159-163] Health status was measured using an assortment of measures, including self-report of overall health status (excellent/very good/good/fair/poor) and physical and mental health subscales of the 12-Item Short Form Health Survey (SF-12) and SF-36, among others.

Only one study measured self-reported health status among all adults (ages 18 to 85).[159] Limited to one clinic population in Canada, this work indicated that self-reported health status was not related to health literacy level after adjustment for confounders. With only a single study, the strength of evidence was low (Table 16 and Appendix F). Our earlier review found similar results in two adjusted analyses.[101,164]

In studies limited to senior citizens, five studies, reported in six articles, all found differences in self-reported health status by health literacy level.[63,81,85,95,142,160] Within a nationally representative sample (N = 2,668), one good-quality study reported that lower health literacy level measured through the NAAL was related to poorer self-reported health status, after adjusting for potential confounders.[85] Self-reported health status was also poorer in lower health literacy groups in three additional adjusted analyses: among Medicare patients in Chicago, Illinois,[81,160] in the Prudential study comparing differences between the low- and adequate-literacy groups (but not marginal- and adequate-literacy groups),[63,65] and among older Korean adults.[142] The relationship was also found in one unadjusted analysis of 2,512 seniors in Pittsburgh, Pennsylvania, and Memphis, Tennessee.[95] The research team judged the strength of evidence to be moderate (Table 16 and Appendix F). In our earlier review, one unadjusted analysis from the Prudential study also found poorer overall health status among those with lower health literacy.[165]

Three of the studies limited to seniors reported additional health status measures and results were mixed. In adjusted analyses, the Prudential study found lower health literacy to be associated with poorer physical- and mental-health-related quality of life and physical functioning in both the inadequate- and the marginal-literacy groups (SF-36) compared with the adequate group.[63,65,66] In contrast, a sample of Medicare beneficiaries in Chicago, Illinois, was not found to differ in physical or mental functioning by health literacy level.[160] One of these two studies, the Prudential study, also found that persons with inadequate health literacy had higher probabilities of having activity limitations, fewer accomplishments, and greater pain related to physical health than those with adequate health literacy.[66] Among Korean seniors, physical functioning (SF-12) did not differ by health literacy level in adjusted analyses, but significant differences were found in limitations in activities and pain that interfered with normal work.[142] Given mixed results, the research team judged the strength of evidence to be insufficient (Table 16 and Appendix F).

Five studies examined differences in a variety of health status measures in adult populations with various diseases, including persons who were HIV-positive[131] and patients with glaucoma,[161] asthma,[100] spinal cord injuries,[162] and cancer.[163] No more than one study examined each disease state, and results were mixed by disease state and outcome measure (e.g., general health, physical health, mental health, disease-specific quality of life). In HIV patients, better global physical health (using a scale developed by the researchers) was related to lower health literacy.[131] In glaucoma patients, those with lower health literacy had poorer physical, but not vision or mental, quality of life based on quality-of-life scores.[161] Among patients with spinal cord injuries, lower health literacy was associated with poorer physical morbidity, but not with mental health morbidity, physical health, or mental health status (SF-12).[162] In cancer patients of all types, Functional Assessment of Cancer Therapy scores (related to physical and emotional functioning) and general health scores measured by the SF-36 showed no difference by health literacy level.[163] In asthma patients, lower health literacy was associated with poorer asthma quality of life (Asthma Quality of Life Quotient) and physical health status (SF-36), adjusting for asthma severity and asthma self-sufficiency.[100] However, the relationship with both outcomes was no longer significant after the investigators added age, education, depressive symptoms, and knowledge confounders to their analyses. Based on mixed results, the research team judged the strength of evidence as insufficient (Table 16 and Appendix F). In our earlier review of studies of global health measures, two unadjusted studies found no significant relationship.[139,166]

Mortality. Differences in all-cause mortality rates of seniors were related to health literacy in adjusted analyses in two good-quality studies reported in three articles (Table 28).[65,67,167] The Prudential study reported higher mortality rates in the inadequate health literacy group than in the adequate health literacy group—first in an analysis controlling for cognitive functioning[67] and second in an analysis not controlling for cognitive functioning but instead controlling for baseline measures of disease, physical functioning, and healthy lifestyle.[65] Both analyses did not find significant differences between the marginal- and the adequate-health-literacy groups. In a population of seniors in Pittsburgh, Pennsylvania, and Memphis, Tennessee, those with limited health literacy had a higher all-cause mortality rate than those with adequate health literacy.[167] The Prudential study also reported, in adjusted analyses, higher cardiovascular-related mortality in the inadequate- and marginal-health-literacy groups than in the adequate group, but no differences in cancer-related mortality across health literacy levels.[65] The research team graded the strength of evidence as high (Table 16 and Appendix F). No studies examining the association between health literacy and mortality were included in our earlier review.

Summary of Outcomes and Strength of Evidence on Health Outcomes

The effect of health literacy on health outcomes was variable (Table 16). The risk of mortality for seniors was clearly higher with lower health literacy. The strength of evidence to support this finding was high. There was also moderate strength of evidence to support a relationship between lower health literacy and poorer ability to take medications properly, poorer ability to interpret labels and health messages, and poorer overall health status among seniors. In these studies, the evidence consists of all observational studies generally having a medium risk of bias and results generally in a consistent direction. The strength of evidence for all other outcomes was either low or insufficient because the literature consisted of a small number of studies, poorly designed studies, and/or inconsistent results. Strength of evidence evaluations focused on the relationship between the lowest health-literacy group and the highest. The evidence was sparse for evaluating differences between those with marginal (a middle category) health literacy and adequate (the highest category) health literacy. In unreplicated studies, evidence is beginning to emerge that the effect of health literacy on health outcomes may be moderated by social support or the characteristics of the health care system and that it may be mediated by knowledge, patient self-efficacy, and stigma. In addition, health literacy may mediate the effect of education, income, and urbanicity.

KQ 1c. Costs of Health Care

KQ 1c concerns differences in health literacy level and costs of health care (Table 29). The Prudential study of new Medicare managed care enrollees examined costs over a 1-year period.

In adjusted analyses, inadequate- and marginal-health-literacy groups had higher emergency department costs; however, no other patterns of differences were uncovered in relation to overall, inpatient, outpatient, or pharmacy costs.[68] In contrast, total Medicaid costs were higher in the lower literacy group (less than third grade) among a small sample of beneficiaries in Arizona (N = 74).[168] Our earlier review found no relationship between literacy and Medicaid costs.[169]

In summary, the strength of evidence concerning differences by health literacy level in costs of health care (KQ 1c) was insufficient (Table 30 and Appendix F). The two relevant studies examined different payment sources (Medicaid and Medicare), found inconsistent results, and included different patient populations. No studies examined differences in costs among those with private health insurance coverage or no coverage.

KQ 1d. Disparities in Health Outcomes or Health Care Service Use

Eight studies examined whether health literacy mediates the relationship between race/ethnicity and health outcomes or use of health care services, and one study examined whether health literacy moderates the effect between race/ethnicity and health outcomes (Table 31). As described in more detail in Chapter 2, health literacy would be considered a mediator of racial differences in health outcomes, if differences in health literacy level between racial groups explain all or a portion of the outcome differences observed by race. Analytically, health literacy level is determined to be a mediator when health literacy is related to race or ethnicity and an outcome and when the coefficient for the race or ethnicity variable is smaller or becomes statistically insignificant after health literacy is added to the analytic model. Alternatively, the relationships can be observed through a path analysis.[170] Health literacy was found to mediate the effect of race on a variety of health outcomes in a variety of populations: on health conditions that keeps respondents from working and having a long-term illness in a nationally representative sample of adults included in the NALS,[141] on self-reported health status and receipt of an influenza vaccine among seniors included in the nationally representative NAAL sample,[85] on physical and mental-health-related quality of life and self-reported health among seniors included in the Prudential study,[63] PSA levels among newly diagnosed prostate cancer patients in Chicago,[157] on nonadherence to HIV medications in a population of HIV patients,[69] on child health insurance among parents included in the NAAL sample,[102] and misinterpretation of medication label instructions among adults.[77] The relationship was not found in relation to receipt of a mammogram or a dental checkup or parents' difficulty understanding over-the-counter medication labels in the NAAL study,[85,102] rate of receipt of vaccines in the Prudential study,[63] or glycemic control in diabetic adults.[171]

Only the NAAL study examined whether health literacy mediated the effect of ethnicity (Hispanic vs. white) on a health outcome, and this relationship was not found.[85] In contrast, only the study examining misinterpretation of medication label instructions in adults investigated whether health literacy was also a potential mediator of the relationship between gender and the outcome, as well as race; the relationship was found in this comparison as well.[77]

Health literacy is determined to be a moderator of the relationship between race/ethnicity and health outcomes when the relationship is different in magnitude or direction between the two race/ethnicity groups. Only one study examined moderation and found no differences in the relationship between mortality and health literacy level in blacks and whites or males and females.[167]

The strength of evidence was low in relation to health literacy level explaining racial differences in health outcomes based on findings of effect in some outcomes (Table 32 and

Appendix F). The strength of evidence was low in relation to health literacy level explaining differences in health outcomes between Hispanics and whites and between males and females (Table 32 and Appendix F). Data were not available to examine disparities related to cultural or age group differences. In our earlier review, only one study was available to examine this issue, and it did not find that health literacy was a mediator of differences between black and white patients in late-stage prostate cancer diagnosis.[158]

In summary, our research team found that health literacy mediates or partially explains disparities in health outcomes between white and black participants for a variety of outcomes; the strength of evidence for this conclusion is low because only one study examined each outcome (Table 32 and Appendix F). Health literacy was found to mediate outcome differences between blacks and whites in relation to the following outcomes: a health condition that keeps respondents from working or having a long-term illness, self-reported health status, receipt of an influenza vaccine, physical and mental-health-related quality of life, self-reported health among seniors, prostate-specific antigen levels among newly diagnosed prostate cancer patients, nonadherence to HIV medications, children's lack of health insurance, and misinterpretation of medication labels. We cannot know whether health literacy level would also mediate racial disparities for other health outcomes that have not been tested. Only one study examined whether health literacy level mediated the relationship between race and health outcomes for persons of Hispanic ethnicity and whites, and one study examined the relationship between males and females. The strength of evidence for these relationships was low. We found no studies that evaluated disparities related to differences in age, cultural group, or other sociodemographic characteristics.

Key Question 1. Relationship of Numeracy to Various Outcomes and Disparities

We identified 16 unique studies of the relationship between numeracy and outcomes of interest (Table 33). Nearly all studies examining the relationship of numeracy to health outcomes were cross-sectional in design.[9,10,24,47,98,125,171-179] Four studies were randomized controlled trials (RCTs) that analyzed their data in a cross-sectional manner for this analysis,[24,98,172,173] and one used a prospective cohort design.[126] Fifteen studies were of fair quality; only one was of good quality.[171]

Studies employed a wide variety of numeracy measures. These included the WRAT-3, the Lipkus numeracy test, the Schwartz and Woloshin numeracy test (or adaptations thereof), the Diabetes Numeracy Test, the Black and Toteson numeracy test (or adaptations thereof), and the TOFHLA numeracy test. Using these measures, populations studied had a varying proportion of individuals with low numeracy (ranging from 5 percent to 74 percent).

Studies also examined a wide variety of outcome measures. Among them were the accuracy of the use of health care services, accuracy of risk perception, knowledge, self-efficacy, actual behaviors, skills, disease prevalence and severity, and disparities. No studies measured intent for behavior, adherence, quality of life, or costs.

Six studies measured both literacy and numeracy.[9,47,98,125,126,171] This allowed assessment of whether these exposures affect health outcomes differently.

KQ 1a. Use of Health Care Services

One cross-sectional study[178] examined the effect of numeracy on use of health care services (Table 34). This study[178] focused on the effects of numeracy on use of screening services.

Screening services. In adjusted analyses, researchers reported no effect of numeracy level on up-to-date screening for either breast or colon cancer in women presenting for primary care.[178] However, the sample for colon cancer screening was small (N = 152; 58 percent of the total sample due to age ineligibility for screening for colon, but not breast cancer), and the authors provided no power calculations for either analysis.

Summary. In summary, only one study addressed the relationship between numeracy and use of health care services and reported no effect, possibly due to inadequate power. Based on this study, our research team judged the strength of the evidence for the relationship between numeracy and use of health care services to be low (Table 35 and Appendix F).

KQ 1b. Health Outcomes

Accuracy of risk perception. Five studies addressed the effects of numeracy level on accuracy of risk perception (i.e., whether individuals correctly perceived their health risks and treatment benefits) (Table 36). Three were RCTs[24,172,173] and two were cross-sectional studies,[173,176] although all analyzed their data in cross-sectional fashion to answer this question. Two examined the effects of numeracy on the accuracy of perceived risk[175,176] and four on the accuracy of perceived treatment benefit.[24,172,173,176] All used the Schwarz and Woloshin 3-item numeracy test to assess numeracy level.

The two studies examining perceived risk found no effect of numeracy level on the accuracy of perceived risk of breast cancer or breast cancer survival over 5 years.[175,176] One study, however, reported that for every additional numeracy question answered incorrectly (scale range 0-3), participants' error in estimating lifetime risk increased by 18 percent (95% CI, 5-30%).[175]

Four studies examined the effect of numeracy on the accuracy of perceived treatment benefit and found mixed results. Three studies reported lower accuracy of perceived treatment benefit at lower levels of numeracy (0-1 questions correct vs. 3 questions correct).[24,172,173] Notably, the size of the effect was smaller in the one study that adjusted for covariates including age, income, education, and the framing of information about treatment benefit (e.g., relative risk reduction or absolute risk reduction).[24] The fourth study, which also performed adjusted analysis, reported no significant difference between groups,[176] but the authors dichotomized their numeracy exposure variable differently (0-2 questions correct vs. 3 of 3 questions correct).

Interestingly, results varied across studies by how the investigators assessed accuracy. The differences in accuracy of perceived treatment benefit were greater between low- and high-numeracy participants who were asked to calculate an exact treatment benefit than between those who were asked merely to say which of two treatments provided more benefit.[172,173]

Considering all of these studies in aggregate, our research team judged the overall strength of evidence about the relationship between numeracy and accuracy of risk perception to be insufficient due to mixed results by task and study (Table 35 and Appendix F).

Knowledge. We found four cross-sectional studies addressing the effect of numeracy level on knowledge (Table 37).[125,174,177,178] These focused on different types of knowledge as well as different health topics and conditions, including diabetes,[174] general health and HIV,[177] breast and colorectal cancer screening guidelines,[178] and medication dosing.[125] Results were mixed.

Three studies,[174,177,178] including two that adjusted for relevant covariates,[177,178] showed significantly lower knowledge about diabetes, HIV, and breast cancer screening with lower numeracy. These same studies, however, showed no effect of numeracy on general health knowledge or colorectal cancer screening, although nearly half of the sample queried about colorectal cancer screening included individuals who were too young to be eligible for screening. A fourth study showed lower numeracy to be related to lower knowledge about medication dosing in an analysis controlling for some confounders;[125] however, results became nonsignificant after additional adjustment for education, acculturation, and socioeconomic status.

Considering these studies in aggregate, our research team judged the overall strength of evidence regarding the relationship between numeracy and knowledge to be insufficient (Table 35 and Appendix F).

Self-efficacy. One cross-sectional study examined the effects of numeracy level on self-efficacy (Table 38).[174] In an unadjusted analysis, this study found significant reductions in self-efficacy (a 4-point reduction on the Perceived Diabetes Self-management scale ranging from 8 to 40) among those who scored in the lowest vs. the highest quartile of the Diabetes Numeracy Test. Based on this single unadjusted analysis, the overall strength of evidence about the relationship between numeracy and self-efficacy was insufficient (Table 35 and Appendix F).

Intent for behavior. We found no studies that examined the effect of numeracy on intent for behavior.

Behavior. One cross-sectional study examined the effects of numeracy level on behavior (Table 39).[174] In unadjusted analysis, this study found no significant differences in diabetes self-management behaviors in four of five domains of the Diabetes Self-Care Activities Scale, including general diet behavior, specific diet behavior, exercise behavior, or blood glucose testing. However, there were small increases in foot care behavior (+2.25 on a scale of 0-7; $P < 0.001$) among those in the lowest vs. highest quartile of numeracy; these unexpected results (as well as the negative results for analyses of other self-care behaviors) may be the result of confounding. Based on this single unadjusted analysis, our research team judged the overall strength of evidence about the relationship between numeracy and self-efficacy to be insufficient (Table 35 and Appendix F).

Health-related skills. Six studies examined the effects of numeracy level on health-related skills (Table 40). One was a cohort study,[126] four were cross-sectional studies,[9,47,125,179] and one was an RCT that analyzed data in cross-sectional fashion.[98] The skills included taking medication, reading nutrition labels, and assessing health plan materials.

The four studies that focused on skills in taking medication found mixed results. In analyses adjusted for age, one found mixed effects of numeracy on two different but related variables denoting medication-taking skill: the proportion of INR tests within range (adjusted absolute difference, NR; $P = 0.35$) and INR variability (adjusted absolute difference, NR; $P = 0.03$).[126] Other studies measured medication-taking skill more directly and still found mixed effects. One study found a relationship between numeracy and HIV medication management capacity after adjusting for gender, education, health literacy, and time since HIV diagnosis (0.5-point increase in Medication Management skill [range 2-16] for every 1-point increase in the Applied Problems subtest of the Woodcock Johnson Test; $P < 0.01$).[47] Another study reported that, after adjustment for some confounders, poor caregiver numeracy resulted in use of nonstandardized dosing instruments for administering medications to children.[125] Additional adjustment for education, acculturation, and socioeconomic status, however, led to nonsignificant differences between groups, based on TOFHLA numeracy scores split at the median. Finally, a third study found that poor caregiver numeracy (second through eighth grade on the WRAT-math) was associated with (1) an increased likelihood of thinking a potentially harmful over-the-counter medication to be suitable (adjusted OR, 1.25; 95% CI, 0.99-1.58), although results were not statistically significant, and (2) increased intent to use potentially harmful over-the-counter cold medicines in a 13-month-old (adjusted OR for each *decrease* in numeracy skill level, 1.19; 95% CI, 1.01-1.41). This study also reported that, paradoxically, for caregivers with higher numeracy (9th-16th grade), each *increase* in numeracy grade level made them more likely to intend to use over-the-counter cold medicines (adjusted OR for each *increase* in numeracy skill level, 1.78; 95% CI, 1.07-2.96). Investigators attributed this finding to heavier reliance on independent judgment. Importantly, however, analyses were not adjusted for potentially relevant confounders, such as prior physician prescriptions for these medications. Based on these studies, our research team judged the overall strength of evidence regarding the relationship between numeracy and skills in taking medication to be insufficient (Table 35 and Appendix F).

The studies assessing other outcomes—skill at reading nutrition labels[9] and at reviewing health plan materials[98]—found lower comprehension of reviewed materials in participants with lower numeracy. However, only the nutrition label study adjusted for potential confounders. Additionally, the health plan study found fewer participants choosing a higher quality hospital among those with lower numeracy.[98] Interestingly, this result was moderated by patient activation; subjects who were more motivated to process information were also more likely to make higher quality choices, regardless of their numeracy level.

Based on these studies, our research team judged the overall strength of evidence regarding the relationship between numeracy and skill in interpreting health information as insufficient (Table 35 and Appendix F).

Disease prevalence and severity. Three cross-sectional studies examined the effect of numeracy level on disease prevalence and severity (Table 41).[9,10,174] These studies addressed the effects of numeracy on BMI,[9,10] HbA1c,[174] and illness requiring dietary restriction.[9]

The two studies addressing the effect of numeracy (measured by the WRAT-3 numeracy test) on BMI found mixed results in patients drawn from the same academic medicine practice. In one study, those scoring below the ninth-grade level on the WRAT-3 had higher mean BMIs (adjusted beta coefficient, 0.14; $P = 0.01$).[10] By contrast, the other study reported no effect of differential WRAT-3 scores on obesity (BMI greater than 30) in unadjusted analysis.[9] The differences in findings may be attributable to a combination of differences in recruiting (physician referral in the Huizinga study), handling of the outcome variable (continuous in the Huizinga study, categorical in the Rothman study), and adjustment in analysis (adjusted in the Huizinga study, unadjusted in the Rothman study).

Findings on other health outcomes were also mixed. One study reported modest effects of numeracy on HgbA1c (adjusted beta coefficient 0.09 for every 10-percentage-point decrease in the proportion of correct responses on the Diabetes Numeracy Test).[174] A second study, however, reported no effects of numeracy on the proportion of individuals with illness requiring diet restriction in unadjusted analysis.[9]

Given the mixed nature of results, our research team judged the overall strength of evidence regarding the relationship between numeracy and disease prevalence to be insufficient (Table 35 and Appendix F).

Summary. In summary, studies of the relationship between numeracy skill level and many health outcomes (including accuracy of risk perception, knowledge, skills taking medication, and disease prevalence and severity) found mixed results. Based on these findings, we judged overall strength of evidence for its relationship to these outcomes to be insufficient.

The relationship between numeracy skill level and other outcomes is also uncertain. One study suggests a possible relationship between numeracy skill level and label-reading skill. Additionally, only one study each addressed the relationships between numeracy and self-efficacy or behavior (both with unadjusted analyses), making conclusions impossible.

KQ 1c. Costs

We found no study that examined the effect of numeracy level on costs.

KQ 1d. Potential Mediator of Disparities

We found two studies that addressed the effects of numeracy as a potential mediator of disparities in health outcomes.[47,171] One examined numeracy as a potential mediator of the relationship between race and HgbA1c.[171] The other examined numeracy as a potential mediator of the relationship between gender and HIV medication management capacity.[47] Both used formal mediational analyses.

In the study examining numeracy as a potential mediator of the relationship between race and HgbA1c, investigators used path analysis and structural equation models to examine the relationships between race, numeracy, and HgbA1c in a cross-sectional sample of 383 diabetic patients who received care at primary care and diabetes specialty clinics at three medical centers. Investigators demonstrated significant negative relationships between both African-American race and numeracy (standardized path coefficient, -0.46; $P < 0.001$) and numeracy and HgbA1c (standardized path coefficient, -0.15; $P < 0.01$). They additionally demonstrated that the relationship between African-American race and HgbA1c (standardized path coefficient, 0.12; $P < 0.01$) lessens and becomes nonsignificant with the addition of numeracy (standardized path coefficient, 0.10; P = NS), suggesting partial mediation of racial disparities by numeracy.

In the study examining numeracy as a potential mediator of the relationship between gender and HIV medication management capacity, investigators also used path analysis to examine the relationships between gender, numeracy, and HIV medication management capacity in a cross-sectional sample of 155 HIV-positive patients recruited from clinics or drug assistance programs in Miami, Florida. In this study, investigators demonstrated a significant negative relationship between female gender and numeracy (path coefficient, -0.428; $P < 0.01$) and a significant positive relationship between numeracy and medication management capacity (path coefficient, 0.644; $P < 0.01$). They additionally demonstrated that the correlation between female gender and medication management capacity (path coefficient = NR) lessened and became nonsignificant (path coefficient, 0.073; P = NS) with the addition of numeracy to the model. These findings suggest partial mediation of gender disparities in medication management capacity by numeracy. Our research team judged the overall strength of evidence to be low (Table 35 and Appendix F).

Table 5. Overview of health literacy studies

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Bailey et al., 2009[77] Cross-sectional Fair	373 patients at 3 outpatient family medicine clinics serving low-income populations in Shreveport, LA; Chicago, IL; and Jackson, MI	Interpretation of a prescription label for amoxicillin Understanding of dosage measurement and frequency of use	Analysis 1 Race Age Sex Education Analysis 2 Race Age Sex Education Health literacy
Baker et al., 2004[62] Cohort Good	3,260 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Any ED visits 1 ED visit 2 or more ED visits Number of physician visits	Age Gender Race Physical and mental health Chronic diseases Smoking Alcohol use BMI Study site Months enrolled
Baker et al., 2007[65] Prospective cohort Good	3,260 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	All-cause mortality Cardiovascular mortality Cancer mortality Noncardiovascular, noncancer mortality Physical HRQoL (SF-12) Mental HRQoL (SF-12) IADL limitation ADL limitation Number of chronic conditions (unadjusted) BMI (unadjusted)	Age Sex Race/ethnicity Language Study site Income Social class Education Number of chronic conditions Physical health score Mental health score IADL limitation ADL limitation

ADL= activities of daily living; AIDS=acquired immunodeficiency syndrome; ASI-Alc=Addiction Severity Index–Alcohol; ASI-Drug=Addiction Severity Index – Drugs; BMI=body mass index; CD4=cluster of differentiation 4; CHF=congestive heart failure; COPD=Chronic Obstructive Pulmonary Disease; CRC=colorectal cancer; C-SDSCA=Chinese version of the Summary of Diabetes Self-Care Activities measure; DBPdiastolic blood pressure; DRUGS=Drug Regimen Unassisted Grading Scale; ED=emergency department; ER=emergency room; FACT-G=Functional Assessment of Cancer Therapy-General; FOBT=fecal occult blood test; FQHC=federally qualified health center; HADS=hospital anxiety and depression scales; HAQ=health assessment questionnaire; HbA1c=glycosylated hemoglobin; HIV=human immunodeficiency virus; HRQoL=health-related quality of life; IADL=instrumental activities of daily living; INR=International Normalized Ratio; LDL=low density lipoproteins; LVEF=left ventricular ejection fraction; MMT=Medication Management Test; NYHA=New York Hospital Association; OTC=over-the-counter; Pap=Papanicolau test; SBP=systolic blood pressure; SES=socioeconomic status; Serum K=serum potassium; Serum Na=serum sodium; SF=short form; TOFHLA=Test of Functional Health Literacy in Adults; VA=Veteran's Administration; VRQoL=vision-related quality of life.

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Baker et al., 2008[67] Prospective cohort Good	3,260 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Mortality	Age Sex Race Language Income Education SF-36 physical functioning and mental health component scores Number of chronic diseases Number of impairments in ADLs Number of impairments in IADLs City of enrollment
Barragan et al., 2005[93] Cross-sectional Fair	372 patients at an inner-city public hospital urgent care center in Atlanta, GA	HIV test acceptance	Age Education
Bennett et al., 2007[132] Cross-sectional Fair	99 pregnant patients receiving prenatal care in clinics in Philadelphia, PA	Elevated depressive symptomatology	Mexican nativity Recent marijuana use
Bennett et al., 2009[85] Cross-sectional Good	2,668 US adults 65 years and older in a nationally representative sample	Mammography Influenza vaccine Health status	Age Race Gender Income Nativity
Chew et al., 2004[107] Prospective cohort Fair	332 patients at a preoperative clinic of the VA Puget Sound	Nonadherence to fasting instructions Nonadherence to preoperative medication instructions	Age Marital status Number of medications Cognitive functioning

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Cho et al., 2008[81] Cross-sectional Fair	489 elderly outpatients at hospital and an FQHC in Chicago	ER visits Hospitalizations Preventive care FOBT Mammography Health status (self-report) Nonadherence Failed to fill prescriptions on time Health behavior measured through Health Promoting Lifestyle Profile	Race Ethnicity Gender Educational attainment
Coffman and Norton, 2010[135] Cross-sectional Fair	99 participants from 2 Latino service agencies	Depression	Demands of immigration
Davis et al., 2006[75] Cross-sectional Fair	395 adults in primary care clinics in Shreveport, LA; Jackson, MI; and Chicago, IL	Misunderstood ≥1 prescription label instructions Correct demonstration of number of pills	Age Sex Race Education Number of medications currently taken daily Site
DeWalt et al., 2007[80] Retrospective cohort Fair	150 patients at a general, asthma and allergy, and pulmonary clinic at children's hospital	Child ED visits Hospitalizations Albuterol use (unadjusted) Appropriate controller use (unadjusted)	Child age Household income Parental race Parental asthma knowledge Parental smoking Asthma severity classification Controller medication use Site of care
Estrada et al., 2004[126] Prospective cohort Fair	143 adults > 50 years old on warfarin ≥ 1 month in 2 anticoagulation management units	Warfarin control measured through INR variability and INR in the therapeutic range	Age
Fang et al., 2006[106] Cross-sectional Fair	179 patients at an anticoagulation clinic in San Francisco, CA	Adherence to medication as measured by self-report of missed doses over 3 time periods (last 3 days, last 2 weeks, > 3 months) No missed doses > past 3 months	Age Sex Race/ethnicity Education Cognitive impairment Years on warfarin

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Garbers et al., 2004[91] Cross-sectional Fair	205 women recruited through their younger female relatives in 2 women's health centers in New York City	Ever had a Pap test Pap test within past 3 years	Having a source of care Having any health insurance Age Years in the US Education
Gatti et al., 2009[73] Cross-sectional Fair	275 participants recruited from 3 outpatient pharmacies at Grady Memorial Hospital, and from the DeKalb Grady Health Center pharmacy in Atlanta, GA	Self-reported medication adherence	Negative beliefs about medications Age Low self-efficacy Self-report of hyperlipidemia
Gazmararian et al., 2006[61] Prospective cohort Fair	1,549 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Nonadherence to cardiovascular medication refill adherence (1-year period)	Age Race Gender Education Regimen complexity
Graham et al., 2007[104] Retrospective cohort Fair	87 patients at an HIV clinic in Philadelphia, PA	< 95% adherence to HIV medication regimen (self-report of pill counts over past 3 months)	Individual's norm for acceptable adherence (investigator-conceptualized as mediator)
Grubbs et al., 2009[97] Retrospective cohort Fair	62 patients in 5 San Francisco Bay outpatient dialysis units	Time from dialysis date to transplant list referral date Time from transplant list referral date to waitlist date	Race Gender Income Age at start of dialysis Support Hypertension Diabetes Peripheral vascular disease Coronary artery disease HIV Hepatitis C Congestive heart failure Depression Drug abuse
Guerra et al., 2005[88] Cross-sectional Fair	136 patients at 4 community clinics, 2 university practices in Pennsylvania	FOBT Sigmoidoscopy or colonoscopy	Ethnicity Medicaid Education Income

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Guerra et al., 2005[90] Cross-sectional Fair	97 patients at 3 community health plans in Philadelphia, PA	Mammography	Age Education Acculturation Insurance status
Hahn et al., 2007[163] Cross-sectional Good	415 adult cancer patients in 5 Chicago area cancer centers	Physical well-being, emotional well-being, and functional well-being (FACT-G) Physical functioning, role-physical, bodily pain, vitality, mental health, fair/poor health (SF-36) Standard Gamble utility score	Age Gender Race/ethnicity Work status Marital status Living arrangement Socioeconomic status Prior computer experience Cancer diagnosis Stage at diagnosis Months since diagnosis Current chemotherapy treatment Performance status
Hibbard et al., 2007[98] Cross-sectional Fair	303 community participants	Choosing a quality hospital	Age Gender Education Comprehension Activation
Hironaka et al., 2009[108] Prospective cohort Fair	110 caregivers of infants who receive care at 2 pediatric clinics	Days of adherence to giving vitamins to their infants in prior week	Race/ethnicity Caregiver education Caregiver concerns regarding multivitamins and possible side effects Randomized assignment to drops or sprinkle formulation
Hope et al., 2004[83] Prospective cohort Fair	61 control group RCT participants with CHF in Indianapolis, IN	ED visits	Race NYHA classification Medications Reading score
Howard, et al., 2005[68] Prospective cohort Good	3,260 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Use of inpatient, outpatient, ED, or pharmacy services Costs for 1-year period: overall, inpatient, outpatient, pharmacy Depression (unadjusted) Heart attack (unadjusted) Angina (unadjusted) Stroke (unadjusted) COPD (unadjusted)	Age Sex Race/Ethnicity Income Education Tobacco Alcohol Comorbidities

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Howard, 2006[63] Cohort Fair	3,260 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Physical HRQoL (SF-12) Mental HRQoL (SF-12) IADL limitation ADL limitation Physical HRQoL Mental HRQoL Self-reported health good or higher Receipt of influenza vaccine Receipt of pneumococcal vaccine	Age Gender Race/ethnicity Education Income Site Morbidity Smoker
Huizinga et al. 2008[10] Cross-sectional Fair	160 patients at a primary care clinic at Vanderbilt University	BMI (unadjusted)	None
Johnston et al., 2005[162] Cross-sectional Fair	107 adult patients at spinal cord injury clinic in New Jersey	Physical morbidity Mental health morbidity Physical Component score (SF-12) Mental Component score (SF-12) Physical independence Mobility	Motor index Education
Johnson et al., 2010[74] Cross-sectional Fair	275 patients at 3 pharmacies at Grady Memorial Hospital in Atlanta, GA (intervention site) and a community-based satellite pharmacy in Decatur, GA (control site)	Adherence to medication regimens	Age Sex
Kalichman et al., 2008[103] Prospective cohort Fair	145 HIV-positive adults in Atlanta, GA	Antiretroviral therapy pill adherence (pill counts averaged over past 4 months) Depression (unadjusted) HIV symptoms (unadjusted)	Age Education Years since testing HIV positive HIV symptoms Depression Internalized stigma Social support Alcohol use
Kim, 2009[142] Cross-sectional Fair	103 community-dwelling older adults at a community-based senior welfare center in Daegu, Busan, and Kyungpook provinces in Korea	Chronic disease Functional health status Activity limitations	Age Education Income

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Kripalani et al., 2006[123] Cross-sectional Good	152 patients with coronary heart disease at a clinic in Atlanta, GA	DRUGS: Requiring observed completion of 4 tasks: Identify appropriate medication Open container Select correct dose Report appropriate timing of doses	Age Education Cognitive functioning
Laramee et al., 2007[143] Cross-sectional Fair	998 adults with diabetes in primary care practices in Vermont, New Hampshire, and northern New York State	Heart failure	None
Lee, 2009[160] Cross-sectional Fair	489 seniors who are patients at 1 of 2 Chicago, IL clinics	General health (self-report) Physical health (SF-12) Mental health (SF-12)	Age Gender Race Education Marital status Income Social support level
LeVine et al., 2004[128] Cross-sectional Fair	167 mothers of kindergarten-age children in urban and rural Nepal	Comprehension of radio health messages Comprehension of visual print health message Ability to give an organized health-related narrative	Maternal schooling Childhood socioeconomic status Age Current socioeconomic status Husband's schooling Urban/rural
Lincoln et al., 2006[130] Prospective cohort Fair	390 adults in an inner-city short-term inpatient detoxification unit	Depressive symptomatology ASI-Alc ASI-Drug	Time Sex Age Race Education Income Primary language Primary substance of choice Randomization group Mini-mental status exam Outcome variables at baseline
Lindau et al., 2006[96] Cohort Fair	68 patients at clinics in a Chicago-area academic medical center	Patient followed up on time after abnormal Pap Patient followed up within 1 year	Age Race HIV status Cancer Unemployment Insurance

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Mancuso, 2010[151] Cross-sectional Good	102 patients at 2 urban Midwestern US primary care clinics	HbA1c	Patient trust Depression Diabetes knowledge Performance of self-care activities
Mancuso et al., 2006[99,100] Cross-sectional Fair	175 patients at a primary care practice in New York City	Access to asthma care Access to care due to other conditions Asthma-related quality of life Physical health-related quality of life (SF-36)	Age Race/ethnicity Sex Comorbidity Language Asthma duration Asthma severity Asthma control
Marteleto, 2008[122] Prospective cohort Fair	4,751 individuals aged 14-22 years old at time of Wave 1 of study in Cape Town, South Africa	Sexual debut First pregnancy	Grades completed in 2002 Enrolled in 2002 Age Age squared Race Income Household shock Mother's education Father's education Living with mother Living with father
Mayben et al., 2007[145] Cross-sectional Fair	119 adults with HIV receiving care at 4 publicly funded clinics in Houston, TX	CD4 cell count: median (interquartile range)	Gender Reason for getting tested Marijuana use
Miller et al., 2007[89] Cross-sectional Fair	50 patients at a university community-based internal medicine clinic	Last time received colon screening	Age
Morris et al., 2006[134] Cross-sectional Good	1,002 adults with diabetes in primary care practices in Vermont	HbA1c level SBP DBP LDL-cholesterol Retinopathy Nephropathy Foot/leg problems Gastroparesis Cerebrovascular disease Coronary artery disease Depression (unadjusted) Depression, median Patient Health Questionnaire Score (unadjusted)	Age Sex Race Marital status Insurance Income Duration of diabetes Diabetes education Depression Alcohol use Medication use Physician practice

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Muir et al., 2008[161] Cross-sectional Fair	110 glaucoma patients at a Duke eye clinic in Durham, NC	VRQoL Score (mean) Physical HRQoL (SF-12) Mental HRQoL (SF-12)	Age Race Visual acuity Visual field Education
Murphy et al., 2010[82] Cross-sectional Fair	186 patients at 5 US sites, primarily through the Adolescent Trials Network: Ft. Lauderdale, FL; Philadelphia, PA; Baltimore, MD; and Los Angeles, CA; 1 nonnetwork site was located in Detroit, MI	Medication adherence Viral load Self-efficacy to adherence to medication regimens Medical care received	Age Education level
Murray et al., 2009[78] Cohort Fair	192 patients at a university-based public clinic practice in Indianapolis, IN	ED use Hospitalizations	Age Race Insurance NYHA class LVEF Hematocrit CHF score Serum Na, Income Serum K, Cardiomyopathy questionnaire Comparison refill adherence prescription label reading Depression
Nokes et al., 2007[131] Cross-sectional Fair	489 HIV-positive adults receiving care in San Francisco, Fresno, Richmond, NYC, Corpus Christi	Depressive symptomatology Distress over body changes HIV symptom intensity Global physical health scale (unadjusted)	Hispanic
Osborn et al., 2007[69] Cross-sectional Fair	204 patients at 2 HIV clinics, 1 in Chicago, IL, and 1 in Shreveport, LA	Nonadherence to HIV medications in past 4 days (self-report)	Race Gender Age Income Number of medications in HIV regimen Non-HIV comorbid conditions Mental illness

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Osborn et al., 2009[171] Cross-sectional Good	383 patients from 2 primary care and 2 diabetes specialty clinics located at 3 medical clinics	HbA1c: most recent in medical record	Analysis 1 Age Sex Years of education Annual income Insulin use Diabetes type Years of diagnosed diabetes Race Analysis 2 and 3 Age Years of diagnosed diabetes Insulin use African American race
Osborn et al., 2010[72] Cross-sectional Fair	204 patients at outpatient infectious disease clinics at Northwestern Memorial Hospital in Chicago, IL and Louisiana State University Health Sciences Center in Shreveport, LA	Adherence HIV knowledge and action	Age Insurance coverage Employment status Number of medications in HIV regimen Number of non-HIV prescription meds currently taken Presence of a comorbid chronic condition Treatment for a mental health condition in the past 6 months Treatment for alcohol or drug use in past 6 months
Paasche-Orlow et al., 2005[79] Prospective cohort Fair	73 patients at 2 inner-city hospitals for severe asthma	Mastery of metered dose inhaler technique Hospital visits (unadjusted) ED visits (unadjusted)	Age Sex Ethnicity Education Income History of near-fatal asthma Asthma Hospitalization in prior 12 months
Paasche-Orlow, 2005[121] Cross-sectional Fair	423 female inmates in Rhode Island adult correctional institute	HIV risk behavior in past 3 months (self-report of sex without a condom or shared injection drug equipment)	Age Race Problem drinking

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Paasche-Orlow et al., 2006[105] Retrospective cohort Fair	235 patients with HIV and a history of alcohol problems in Boston, MA	100% adherence to HIV medication regimen (self-report for 3-day period) Viral load suppressed	Gender Age Education Randomization group Ethnicity Homeless status Drank to intoxication past 30 days Injected drugs past 6 months Complexity of regimen
Pandit et al., 2009[155] Cross-sectional Fair	330 adults with hypertension receiving primary care from clinics in Grand Rapids, MI, Chicago, IL, and Shreveport, LA	Controlled blood pressure	Age Race Gender Marital status Employment status Insurance coverage Site location Number of comorbid conditions Years treated for hypertension Clinic site Education
Peterson et al., 2007[87] Cross-sectional Fair	99 patients at a community health clinic in Nashville, TN	Up-to-date colon screening Self-efficacy for FOBT Self-efficacy for colonoscopy	Age Sex Race Insurance
Powell et al., 2007[149] Cross-sectional Fair	68 patients with Type 2 diabetes treated in a general medicine clinic	Diabetes Health Belief Model scale score Most recent HbA1c level	Education Age Race Diabetes knowledge Most recent HbA1c

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Powers et al., 2008[154] Cross-sectional Fair	1,224 patients with hypertension receiving primary care in the VA healthcare system and Duke University Healthcare system in Durham, NC	SBP	Age Race Marital status Education Adequacy of income Diabetic status Medication adherence Smoking Exercise Participatory decision-making score
Raehl et al., 2006[124] Cross-sectional Fair	57 seniors in Amarillo, TX	MedTake Test: ability to open and take own medications while observed by pharmacist	Age Number of OTC drugs Owned a car in last 10 years Received food assistance in last 10 years
Rothman et al., 2006[9] Cross-sectional Fair	200 adults in primary care clinic	Understanding nutrition labels Obese (BMI > 30) (unadjusted) Number with chronic illness (unadjusted)	Age Gender Race/ethnicity Income Education Insurance status Presence of chronic disease Status of being on a specific diet Label reading frequency
Schillinger et al., 2006[150] Cross-sectional Good	395 diabetes patients (> 30 years old) treated at 1 of 2 primary care clinics at San Francisco General Hospital	HbA1c	Age Primary language other than English Insurance Education
Sentell and Halpin, 2006[141] Cross-sectional Fair	23,889 adults in a national sample	Physical, mental, or other health condition that keeps respondent from working Long-term illness (> 6 months)	Race Education Understand English Born in US Unemployed Family income Income missing Sex Age Married Get food stamps Live in metropolitan statistical area Region

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Sharif and Blank, 2010[119] Cross-sectional Fair	78 patients at a primary care pediatrics clinic in an inner-city academic community health center in the Bronx, NY	BMI-Z score	Age Parental BMI Child eating self-efficacy Parental eating self-efficacy Parental S-TOFHLA
Shone et al., 2009[84] Cross-sectional Fair	499 children in a New York school district, where over 40% of children live in poverty	Any urgent care use Child fair/poor health (adjusted) Asthma not under good control (unadjusted)	Ethnicity Race Child health Insurance Parent employment
Smith and Haggerty, 2003[159] Cross-sectional Fair	229 adults in university-affiliated family practice center in Montreal, Canada	Perceived general health status	Age Smoking status Maternal language
Sudore et al., 2006[167] Prospective cohort, retrospective analysis Good	2,512 well-functioning Medicare recipients living in the community in Memphis, TN and Pittsburgh, PA	Mortality rate	Demographics: age, race, gender, income, education Health status: self-rated health, cardiac disease, stroke, cancer, hypertension, diabetes, obesity Health-related behaviors: former or current smoker, drinking >1 alcoholic beverage per day Poor health care access: lack of a regular doc or clinic, no flu shot within past 12 months, no insurance for medications Psychosocial status: high depressive symptoms, poor personal mastery
Sudore et al., 2006[95] Cross-sectional Fair	2,512 well-functioning Medicare recipients living in the community in Memphis, TN, and Pittsburgh, PA	Influenza shot Access measures: No doctor/clinic No insurance for medication Composite of access measures Obesity (BMI >30) (unadjusted) Depression (unadjusted) Hypertension (unadjusted) Diabetes (unadjusted)	Age Race Sex Income Study site Health status Cardiac disease Stroke Cancer Hypertension Diabetes Obesity Depressive symptoms

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Tang et al., 2008[148] Cross-sectional survey and medical chart review Fair	149 adults with diabetes in diabetes education management center of a public hospital in Hong Kong	HbA1c level	Gender Insurance Duration of diabetes Patient awareness score C-SDSCA (management of diabetes)
Torres et al., 2009[113] Cross-sectional Fair	106 women patients at a family health center in New York City	Self-efficacy for taking hormone therapy (unadjusted)	None
von Wagner, 2007[115] Cross-sectional Fair	719 individuals in a national sample of British adults	Don't smoke Fruit and vegetable intake > 5/day Any exercise in the last week	Age Education Gender Ethnicity Income
von Wagner et al., 2009[114] Cross-sectional Fair	96 adults in London, England between 50-69 years of age	Self-efficacy for participating in CRC screening	Age Ethnicity Employment Gender Number of computer links open Mean reading time CRC screening knowledge
Waite et al., 2008[71] Cross-sectional Fair	204 patients at 2 HIV clinics, 1 in Chicago, IL and 1 in Shreveport, LA	Nonadherence to HIV medications in past 4 days (self-report)	Stigma concerns related to HIV medications (self-report) (Investigator-conceptualized as mediator) Age Gender Site Employment status Number of medications in HIV regimen Number of non-HIV prescription medications taken Comorbid chronic condition Treatment for mental health condition Treatment for substance abuse

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Waldrop-Valverde et al., 2009[47] Cross-sectional Fair	155 patients from an HIV clinic and participants in AIDS drug assistance program in Miami, FL	Medication Management Test (MMT)	Gender Education Time since HIV diagnosis
Walker et al., 2007[133] Cross-sectional Fair	363 patients at 3 rheumatology clinics in the United Kingdom	Hospital Anxiety and Depression scales (HAQ and HAD)	None
Weiss et al. 2004[168] Retrospective cohort Fair	74 Medicaid beneficiaries in Arizona	Total Medicaid costs, 1-year period	Age Ethnic group Health status
White et al., 2008[86] Cross-sectional Fair	18,100 participants in nationally representative US sample living in households	Colon cancer screening Mammography Had flu shot Vision checkup Dental checkup Prostate screening Osteoporosis screening	Age Gender Race Poverty level Insurance Health status Oral reading fluency
Wolf et al., 2005[66] Cross-sectional Fair	3,260 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Physical functioning (SF-36) Mental health functioning (SF-36) Hypertension Asthma Bronchitis or emphysema Heart failure Coronary artery disease Diabetes Arthritis Cancer IADL Activity limitations Limitations due to physical health Pain interfering with activities	Age Sex Race/ethnicity Income Education Tobacco Alcohol consumption Self-reported comorbid conditions
Wolf et al., 2007[76] Cross-sectional Fair	395 adults in primary care clinics in Shreveport LA; Jackson MI; and Chicago, IL	Correctly interpreted primary prescription label (unadjusted) Correctly attended to auxiliary label (unadjusted)	None

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Wolf et al., 2006[157] Cross-sectional Good	308 patients with newly diagnosed prostate cancer in 4 outpatient oncology and urology clinics in Chicago area	PSA level > 20 ng/mL	Age Race Annual income Marital status
Wolf et al., 2006[120] Cross-sectional Fair	251 adults at a primary care clinic in Shreveport, LA	Read/looked at medication guides and consumer information included with prescription medications	Age Gender Race Education Number of prescriptions taken
Wolf et al., 2007[70] Cross-sectional Fair	204 patients at 2 HIV clinics, 1 in Chicago, IL, and 1 in Shreveport, LA	Nonadherence to HIV medications in past 4 days (self-report) Perception of self-efficacy to properly take and manage HIV medications	HIV treatment knowledge (investigator-conceptualized as mediator) HIV medication self-efficacy (investigator conceptualized as mediator) Age Insurance coverage Employment status Number of medications in HIV regimen Number of non-HIV prescription medications currently taking Presence of comorbid chronic conditions Treatment for mental health condition past 6 months Treatment for alcohol or drug use past 6 months
Wolf, 2007[64] Cross-sectional Fair	2,923 new Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami)	Smoking (never, former, or current) Current alcohol use (none, light to moderate, or heavy) Level of physical activity per week Seat belt use (unadjusted)	Age Gender Race/ethnicity Language (English or Spanish) Site Education Annual income Occupation (white or blue collar)

Table 5. Overview of health literacy studies (continued)

Source Design Quality Score	Population	Outcomes	Covariates Included in Multivariate Analyses
Yin et al., 2007[125] Cross-sectional Fair	292 parents or caregivers of children at an ED in New York City	Self-reported use of nonstandardized dosing instrument	Experience of ever receiving a dosing instrument in a health care setting Child's age Child has regular health care provider Confounders with health literacy: caregiver's education, country of origin, language, socioeconomic status
Yin et al., 2009[102] Cross-sectional Fair	6,100 parents from US households	Parent's self-report of children's health insurance status and difficulty understanding OTC medication labels	Age Gender Number of children living in the home Educational attainment Race/ethnicity Country of birth English proficiency Income Region Metropolitan statistical area
Yin et al., 2010[127] Cross-sectional survey Fair	302 patients at a public hospital (Bellevue) pediatric clinic in New York, NY	Dosing accuracy	Parent's age Relationship to child Marital status Language Ethnicity US birth SES Presence of a child in the house < 8 years old Presence of a child in the house with a chronic medical condition

Table 6. Measurement tools and criteria used to measure health literacy or literacy in KQ 1 articles

Study	Measurement Tool	Measurement Levels (Continuous or Cutpoints)
Marteleto, 2008[122]	Cape Area Panel Study Literacy and Numeracy Evaluation	Continuous
Weiss, 2004[168]	Instrument for the Diagnosis of Reading (IDR- English/Spanish)	< 3rd grade, > 3rd grade
Hope, 2004[83]	Medication Skills Assessment (Reading Score)	0 = no correct answers, 1 = correctly answered some questions, 2 = correctly answered all questions
Sentell, 2006[141]	National Adult Literacy Survey (NALS) literacy and numeracy	Continuous
Bennett, 2009,[85] White, 2008[86], Yin, 2009[102]	National Assessment of Adult Literacy (NAAL)	Below basic, basic, intermediate, proficient
Yin, 2010[127]	Newest Vital Sign	High likelihood of limited, possible limited, adequate
Levine, 2004[128]	Reading comprehension and academic language proficiency (noun definitions) in Nepalese	No school, 1-4 years, 5-9 years, 10+ years
Barragan, 2005[93]	Rapid Estimate of Adult Literacy in Medicine (REALM)	Low or < 6th grade, not low or > 6th grade
Graham, 2007,[104] Huizinga, 2008,[10] Lindau, 2006,[96] Peterson, 2007,[87] Powers, 2008,[154] DeWalt, 2007,[80] Lincoln, 2006,[130] Muir, 2008,[161] Shone, 2009,[84] Sudore, 2006,[167] Miller, 2007,[89] Rothman, 2006,[9] Walker, 2007[133], Gatti, 2008,[73] Johnson, 2010[74]	Rapid Estimate of Adult Literacy in Medicine (REALM)	< 9th grade (score: 0-60), > 9th grade (score: 61-66)
Nokes, 2007,[131] Raehl, 2006,[124] Smith 2003[159]	Rapid Estimate of Adult Literacy in Medicine (REALM)	Continuous
Paasche-Orlow, 2006,[105] Paasche-Orlow, 2005,[121] Davis, 2006,[75] Kripalani, 2006,[123] Wolf, 2006,[157] Osborn, 2007,[69] Wolf, 2006,[120] Wolf, 2007,[70] Sudore, 2006,[95] Waite, 2008,[71] Wolf, 2007,[76] Osborn, 2010[72]	Rapid Estimate of Adult Literacy in Medicine (REALM)	Low or < 6th grade (score: 0-44) Marginal or 7th-8th grade (score: 45-60) Adequate or > 9th grade (score: 61-66)
Powell, 2009,[149] Estrada, 2004[126]	Rapid Estimate of Adult Literacy in Medicine (REALM)	< 3rd grade, 4th-6th grade, 7th-8th grade, > 9th grade
Baker, 2004,[62] Baker, 2007,[65] Wolf, 2007,[64] Baker, 2008,[67] Howard, 2006,[63] Wolf, 2005[66]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Inadequate (0-55), Marginal (56-66), Adequate (67-100)

Table 6. Measurement tools and criteria used to measure health literacy or literacy in KQ 1 articles (continued)

Study	Measurement Tool	Measurement Levels (Continuous or Cutpoints)
Chew, 2004,[107] Murray, 2009[78] Torres, 2009,[113] Raehl, 2006[124]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Inadequate (0-16), Marginal (17-22), Adequate (23-36)
Gazmararian, 2006,[61] Howard, 2005[68]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Inadequate (0-53), Marginal (54-66), Adequate (67-100)
Grubbs, 2009,[97] Cho, 2008,[81] Guerra, 2005,[88] Guerra, 2005,[90] Hironaka, 2009,[108] Laramee, 2007[143] Lee, 2009[160]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Inadequate/Marginal (Limited) (0-22), Adequate (23-36)
Morris, 2006[134]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Inadequate (0-16), Marginal (17-22), Adequate (23-36) and continuous measurement
Paasche-Orlow, 2005[79]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Inadequate (0-16), Marginal/Adequate (17-36)
Pandit, 2009[155]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Category I: 0-30, Category II: 31-50, Category III: 51-70, Category IV: 71-90, Category V: 91-100
Schillinger, 2006,[150] Raehl, 2006,[124] von Wagner, 2007,[115] Hibbard, 2007,[98] Sharif, 2010[119]	Short Test of Functional Health Literacy in Adults (S-TOFHLA)	Continuous
Tang, 2007[148]	Short Test of Functional Health Literacy in Adults (S-TOFHLA) (Chinese)	Continuous
Fang, 2006[106]	Short Test of Functional Health Literacy in Adults (S-TOFHLA) (English or Spanish)	Limited (inadequate/marginal, 0-22), Adequate (23-36)
Bennett, 2007[132]	Short Test of Functional Health Literacy in Adults (S-TOFHLA) (Spanish)	Inadequate (0-55), Marginal (56-66), Adequate (67-100)
Waldrop-Valverde, 2009[47]	Test of Functional Health Literacy in Adults (TOFHLA)	Continuous
Johnston, 2005,[162] Mayben, 2007,[145] Mancuso, 2006,[100] Mancuso, 2006[99] Murphy, 2010[82]	Test of Functional Health Literacy in Adults (TOFHLA)	Inadequate/Marginal (combined; 0-74), Adequate (75-100)
Kalichman, 2008[103]	Test of Functional Health Literacy in Adults (TOFHLA)	Higher literacy (90% correct or 45 of 50 questions correct), Lower literacy (<90% correct or < 45 correct)
Yin, 2007,[125] (English or Spanish), Garbers, 2004[91] (Spanish), Mancuso, 2010[151]	Test of Functional Health Literacy in Adults (TOFHLA)	Inadequate (0-59), Marginal (60-74), Adequate (75-100)

Table 6. Measurement tools and criteria used to measure health literacy or literacy in KQ 1 articles (continued)

Study	Measurement Tool	Measurement Levels (Continuous or Cutpoints)
Kim 2009[142]	Korean Test of Functional Health Literacy in Adults (TOFHLA)	Higher, lower
Von Wagner, 2009[114]	United Kingdom Test of Functional Health Literacy in Adults (TOFHLA)	Continuous
Hahn, 2007[163]	Woodcock Language Proficiency Battery (passage comprehension subtest)	< 7th grade, > 7th grade

Table 7. Summary of studies of the relationship between health literacy and emergency department and hospitalization rates (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Baker et al., 2004[62] Cohort N = 3,260 Good	Enrollees in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 24.5% Marginal: 11.2% Adequate: 64.2%	Age Gender Race Physical and mental health Chronic diseases Smoking Alcohol use BMI Study site Months enrolled	Any ED visits Inadequate: 30.4% Marginal: 27.6% Adequate: 21.8% 1 ED visit Inadequate: 17.0% Marginal: 15.3% Adequate: 15.0% 2 or more ED visits Inadequate: 13.4% Marginal: 12.3% Adequate: 6.8%	Higher rate in inadequate or marginal compared with adequate Any ED visits Marginal: NR; *P* = 0.01 Inadequate: NR; *P* < 0.001 Higher rate in inadequate than adequate; no difference for marginal 1 ED visit Marginal: RR, 1.01; 95% CI, 0.76-1.33 Inadequate: RR, 1.07; 95% CI, 0.86-1.33 Higher rate in inadequate or marginal compared with adequate 2 or more ED visits Marginal: RR, 1.44; 95% CI, 1.01-2.02 Inadequate: RR, 1.34; 95% CI, 1.00-1.79
Howard, et al., 2005[68] Cohort N = 3,260 Good	New Medicare managed-care enrollees in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 24.5% Marginal: 11.2% Adequate: 64.2%	Age Sex Race/ethnicity Income Education Tobacco Alcohol Comorbidities	Inpatient use Inadequate: 35% Marginal: 34% Adequate: 27% ED use Inadequate: 30% Marginal: 28% Adequate: 21%	Higher probability of inpatient and ED services in inadequate than adequate Mean differences in probability of inpatient use in inadequate vs. adequate: 0.05; 95% CI, 0.00-0.09 ED: 0.05; 95% CI, 0.01-0.10 Mean differences in probability of marginal vs. adequate inpatient use: 0.04; 95% CI, -0.01-0.09 ED: 0.04; 95% CI, -0.01-0.09 pharmacy: -0.04; 95% CI, -0.08-0.00

BMI=body mass index; CHF=congestive heart failure; CI=confidence interval; ED=emergency department; FQHC=Federally Qualified Health Center; HIV=human immunodeficiency virus; HL=health literacy; IRR=incidence rate ratio; LVEF=left ventricular ejection fraction; N=number; NR=not reported; NYHA=New York Heart Association; OR=odds ratio; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; RR=relative risk; Serum K=Serum K=serum potassium; S-TOFHLA=Short Test of Functional Health Literacy in Adults.

Table 7. Summary of studies of the relationship between health literacy and emergency department and hospitalization rates (continued)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Hope et al., 2004[83] Cohort N = 61 Fair	Control group RCT participants with CHF in Indianapolis, IN Ability to read standard prescription Literacy level: NR Mean reading score: 1.65 ± 0.56	Race NYHA classification Medications Reading score	ED visits: Data NR	Higher cardiovascular-related ED visits in patients with worse prescription label reading skills NR; *P* = 0.002
Murray et al., 2009[78] Cohort N = 192 Fair	University-based public clinic practice in Indianapolis Indiana S-TOFHLA Inadequate: 29.2% Adequate: 70.8%	Age Race Insurance NYHA class LVEF Hematocrit CHF score Serum Na, Income Serum K, Cardio-myopathy questionnaire Comparison refill adherence prescription label reading Depression	ED use: Data NR Hospitalization: Data NR	Adequate had a lower risk of hospitalization for heart failure than adequate All-cause ED visits (unadjusted) Prescription label reading score, 1-pt increment: IRR, 0.76; 95% CI, 0.59-0.97 Heart-failure-specific ED visits (unadjusted) Prescription label reading score: IRR, 0.36; 95% CI, 0.19-0.69 All-cause hospitalization (unadjusted) Prescription label reading score: IRR, 0.68; 95% CI, 0.54-0.86 Heart-failure-specific hospitalization (unadjusted): IRR, 0.34; 95% CI, 0.15-0.76
DeWalt et al., 2007[80] Retrospective cohort N = 150 Fair	General, asthma and allergy, and pulmonary clinic at children's hospital REALM Low: 24% High:76%	Child age Household income Parental race Parental asthma knowledge Parental smoking Asthma severity classification Controller medication use Site of care	ED visits (per child) Inadequate: 1.53 Adequate: 1.08 Hospitalizations Inadequate: 0.39 Adequate: 0.12	Children of parents with low HL had a greater incidence of ED visits than those with higher HL: IRR, 1.4; 95% CI, 0.97-2.0 Children of parents with low HL had a greater incidence of hospitalizations more than with higher HL: IRR, 4.6; 95%, CI 1.8-12

Table 7. Summary of studies of the relationship between health literacy and emergency department and hospitalization rates (continued)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Cho et al., 2008[81] Cross-sectional N = 489 Fair	Elderly outpatients at a hospital and an FQHC in Chicago S-TOFHLA Inadequate: 50.9% Adequate: 49.1%	Race Ethnicity Gender Educational attainment	ER visits: Data NR Hospitalizations: Data NR Preventive care: Data NR	More ER visits in lower HL group; *P* < 0.05 More hospitalizations in lower HL group*;* *P* < 0.05 Less preventive care in lower health literacy group; *P* < 0.05
Paasche-Orlow et al., 2005[79] Prospective cohort N = 73 Fair	2 inner-city hospitals S-TOFHLA Inadequate: 22% Adequate: 78%	None	Hospital visit past 12 months Inadequate: 81% Adequate: 52% ED visit past 12 months Inadequate: 88% Adequate: 75%	Inadequate HL associated with more hospitalization in past 12 mos.: (unadjusted) NR; *P* = 0.04 Inadequate HL not associated with ED visits in past 12 mos.; (unadjusted) *P* = 0.28
Shone et al., 2009[84] Cross-sectional N = 499 Fair	New York school district, where > 40% of children live in poverty REALM Low: 33% Adequate: 67%	Ethnicity Race Child health Insurance Parent employment	Used any urgent care Low: 40.9% Adequate: 41.2%	Parent HL level not related to urgent care Used any urgent care; (unadjusted) *P* > 0.999
Murphy, 2010[82] Cross-sectional N= 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit S-TOFHLA-modified Inadequate: 12% Marginal: 3% Adequate: 86%	Age Education	ER visits Data by HL: NR Overnight hospital stays Data by HL: NR	HL level not related to ER visits - > 1 compared to none (adjusted): OR, 0.98; 95% CI, 0.96-1.01 HL level not related to overnight hospital stay - > 1 compared to none (adjusted): OR, 0.97; 95% CI, 0.93-1.01

Table 8. KQ 1a health literacy studies: strength of evidence grades by health care service outcomes

Outcome for Health Literacy Studies	Number of Studies	Results	Overall Grade
Hospitalization	6	Low health literacy associated with increased hospitalization	Moderate
Emergency Care Visit	9	Low health literacy associated with greater emergency care use except in 1 study of urgent care visits (measured by self- report)	Moderate
Colon Screening	5	Larger studies found lower health literacy associated with lower probability of screening	Low
Pap Tests	3	Low health literacy associated with decreased probability of ever having a Pap test	Low
Mammogram	4	Low health literacy associated with less use of mammography; measures and populations differed across studies	Moderate
Sexually Transmitted Infection	1	Low health literacy associated with greater odds of accepting HIV testing	Low
Immunization: Influenza	4	Low health literacy associated with lower probability of receipt of influenza vaccine	Moderate
Immunization: Pneumococcal	2	Mixed results	Insufficient
Access to Care	9	Mixed results for association with number of physician visits, dental and vision visits	Insufficient
Access to Insurance	1	Parental low health literacy associated with having child without health insurance	Low

HIV=human immunodeficiency virus; Pap=Papanicolau.

Table 9. Summary of studies of the relationship between health literacy and colon cancer screening (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Miller et al., 2007[89] Cross-sectional N= 50 Fair	University community-based internal medicine clinic REALM Limited: 48% Adequate: 52%	Age	Self-report of last time received colon screening Limited: 54% Adequate: 58%	No difference between limited and adequate groups: RR, 0.99; 95% CI, 0.64 -1.55
Cho et al., 2008[81] Cross-sectional N = 489 Fair	Elderly outpatients at Hospital and an FQHC in Chicago S-TOFHLA Inadequate:50.9% Adequate: 49.1%	Race Ethnicity Gender Education	Self-report FOBT: NR	Decreased probability in inadequate compared with adequate group; $P < 0.05$
Peterson et al., 2007[87] Cross-sectional N = 99 Fair	Community health clinic in Nashville, TN REALM Limited: 29.3% Adequate 70.7%	Age Sex Race Insurance	Self-report of colon screening Inadequate: 51.7% Adequate: 65.7%	No difference between limited and adequate groups: OR, 0.67; 95% CI, 0.24-1.83
Guerra et al., 2005[88] Cross-sectional N = 136 Fair	4 community clinics, 2 university practices in PA S-TOFHLA Inadequate:36% Marginal: 6% Adequate:58%	Ethnicity Medicaid Education Income	Self-report FOBT Inadequate/Marginal: 39% Adequate: 64% Sigmoidoscopy or Colonoscopy Inadequate/Marginal: 30% Adequate: 72%	No differences between inadequate/marginal and adequate groups: FOBT; $P = 0.66$ Sigmoidoscopy or Colonoscopy; $P = 0.52$
White et al., 2008[86] Cross-sectional N = 18,100 Fair	Nationally representative US sample living in households NAAL Basic/below basic: 36% Intermediate: 56% Proficient: 12%	Age Gender Race Poverty level Insurance Health status Oral reading fluency	Self-report of colon screen Below basic: 38% Basic: 41% Intermediate: 41% Proficient: 36%	Adults over 65 years: Decreased probability of having colon cancer screening basic/below basic groups; $P < 0.05$

CI=confidence interval; FOBT=fecal occult blood test; FQHC=federally qualified health center; N=number; NAAL=national assessment of adult literacy; NR=not reported; OR=odds ratio; REALM=Rapid Estimate of Adult Literacy in Medicine; RR=relative risk; S-TOFHLA=Short Test of Functional Health Literacy in Adults.

Table 10. Summary of studies of the relationship between health literacy and Pap tests (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Cho et al., 2008[81] Cross-sectional N = 489 Fair	Elderly outpatients at Hospital and an FQHC in Chicago S-TOFHLA Inadequate: 51% Adequate: 49%	Race Ethnicity Gender Education	Pap: NR	Less Pap screening in inadequate group than adequate group; $P < 0.05$
White et al., 2008[86] Cross-sectional NAAL N = 18,100 Fair	Nationally representative US sample living in households Basic or below basic: 36% Intermediate: 56% Proficient: 12%	Age Race Gender Poverty level Insurance Health status Oral reading fluency	Pap test (age 18-65) Below basic: 63% Basic: 67% Intermediate: 70% Proficient: 74%	Adults under 40 decreased probability of having a Pap test in basic/below basic than higher groups: $P < 0.05$ Adults 40-64 no differences by HL level; $P > 0.05$
Garbers et al., 2004[91] Cross-sectional N = 205 S-TOFHLA Fair	Women recruited through their younger female relatives in 2 women's health centers in New York City Inadequate: 30% Marginal: 19% Adequate: 51%	Having a source of care Having any health insurance Age Years in the US Education	Ever had a Pap test Inadequate: 80% Adequate: 99% Marginal: 92.1% Pap test within past 3 years Inadequate: 62.3% Adequate: 82.9% Marginal: 82.1%	Less likely to ever have had a Pap test in inadequate compared to marginal and adequate Marginal: OR, 0.14; 95% CI, 0.01-1.41 Inadequate: OR, 0.06; 95% CI, 0.01-0.55 No differences in Pap test within past 3 years Marginal: OR, 1.31; 95% CI, 0.44-3.85 Inadequate: OR, 0.53; 95% CI, 0.21-1.35

CI=confidence interval; FQHC=federally qualified health center; HL=health literacy; N=number; NAAL=National Assessment of Adult Literacy; NR=not reported; OR=odds ratio; Pap=Papanicolau, S-TOFHLA=Short Test of Functional Health Literacy in Adults; US=United States.

Table 11. Summary of studies of the relationship between health literacy and mammography (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Bennett et al., 2009[85] Cross-sectional N = 2,668 Good	Nationally representative sample of US population 65 and older NAAL Below basic: 29.0% Basic: 29.5% Intermediate: 38.2 Proficient: 3.3%	Age Race Gender Income Nativity	Mammography: NR	Lower utilization of mammography in the below basic/basic group; *P* < 0.05
Cho et al., 2008[81] Cross-sectional N = 489 Fair	Outpatients at hospital and an FQHC in Chicago S-TOFHLA Inadequate:50.9% Adequate: 49.1%	Race Ethnicity Gender Education	Mammography: NR	Less mammography in inadequate group than adequate group; *P* < 0.05
White et al., 2008[86] Cross-sectional N = 18,100 Fair	Nationally representative US sample living in households NAAL Basic or below basic: 36% Intermediate:56% Proficient: 12%	Age Gender Race Poverty level Insurance status Self-reported health status, Oral reading fluency	Mammogram (age >40) Below basic:58% Basic: 61% Intermediate:62% Proficient: 62%	Adults >65: Decreased probability mammography in below basic or basic group; *P* < 0.05
Guerra et al., 2005[90] Cross-sectional N = 97 Fair	3 community health clinics in Philadelphia S-TOFHLA Inadequate: 70% Adequate: 30%	Age Education Acculturation Insurance status	Mammogram: NR	Inadequate HL associated with only lower odds of ever having a mammogram Ever had a mammogram: OR, 0.88; 95% CI, 0.79-0.98 Had last mammogram within 1 yr: OR, 0.99; 95% CI, 0.92-1.05 Had last mammogram within 2 yrs: OR, 1.02; 95% CI, 0.93- 1.09 Had mammogram as part of check-up: OR, 0.99; 95% CI, 0.92-1.06

CI=confidence interval; FQHC=federally qualified health center; HL=health literacy; N=number; NAAL=National Assessment of Adult Literacy; NR=not reported; OR=odds ratio; S-TOFHLA=Short Test of Functional Health Literacy in Adults; yr=year.

Table 12. Summary of studies of the relationship between health literacy and sexually transmitted infections testing (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Barragan et al., 2005[93] Cross-sectional N = 372 Fair	Inner city public hospital urgent care center, Atlanta, GA REALM Inadequate: 25% Adequate: 75%	Age Education	HIV Test Acceptance: NR	Inadequate HL positively associated with acceptance of HIV test compared with adequate group: OR, 2.017; 95% CI, 1.190-3.418

CI=confidence interval; HIV=human immunodeficiency virus; HL=health literacy; N=number; NR=not reported; OR=odds ratio; REALM=Rapid Estimate of Adult Literacy in Medicine.

Table 13. Summary of studies of the relationship between health literacy and immunizations (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
White et al., 2008[86] Cross-sectional N = 18,100 Fair	Nationally representative US sample living in households NAAL Basic or below basic: 36% Intermediate: 56% Proficient: 12%	Age Gender Race Poverty level Insurance Health status, Oral reading fluency	Pneumonia shot Below basic: 39% Basic: 42% Intermediate: 38% Proficient: 27% Flu shot Below basic: 39% Basic: 37% Intermediate: 32% Proficient: 26%	Increased probability of having a flu shot in basic/below basic group Adults < 40; *P* < 0.05 Adults 40-64; *P* = NS Adults >65: Decreased probability of flu shot; not related to having a pneumonia shot (*P* < 0.05)
Howard et al., 2006[63] Cohort N = 3260 Fair	Prudential Medicare managed care plan in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 24.4% Marginal: 11.5% Adequate: 64.4%	Age Gender Race/Ethnicity Education Income Site Morbidity Smoker	Influenza vaccine: NR Pneumococcal vaccine: NR	Influenza vaccine receipt lower in inadequate than adequate: OR, 0.76; *P* = 0.020 No differences in pneumococcal vaccine receipt between inadequate and adequate: OR, 0.85; *P* = 0.114 No difference between marginal and adequate groups Influenza vaccine: OR, 1.06; *P* = 0.707 Pneumococcal vaccine: OR, 0.91; *P* = 0.445
Sudore et al., 2006[95] Cross-sectional N = 2,512 Fair	Well-functioning, Medicare recipients living in the community in Memphis and Pittsburgh REALM Limited: 24% Adequate: 76%	Age Race Sex Income Study site Health status Cardiac disease Stroke Cancer Hypertension Diabetes Obesity Depressive symptoms	Influenza shot: NR	Inadequate less likely to have influenza shot in 12 months: OR, 0.59; 95% CI, 0.41-0.83 Marginal less likely to have influenza shot in 12 months: OR, 0.94; 95% CI, 0.7-1.25

CI=confidence interval; N=number; NAAL=national assessment of adult literacy; NR=not reported; NS=not significant; OR=odds ratio; REALM=Rapid Estimate of Adult Literacy in Medicine; S-TOFHLA=Short Test of Functional Health Literacy in Adults; US=United States.

Table 13. Summary of studies of the relationship between health literacy and immunizations (KQ 1a) (continued)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Bennett et al., 2009[85] Cross-sectional N = 2668 Good	Nationally representative sample of US population 65 and older NAAL Below basic: 29.0% Basic: 29.5% Intermediate: 38.2 Proficient: 3.3%	Age Race Gender Income Nativity	Influenza vaccination: NR	Lower utilization of influenza vaccination in below basic and basic group; $P < 0.05$

Table 14. Summary of studies of the relationship between health literacy and access to care and access to insurance (KQ 1a)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Baker et al., 2004[62] Cohort N = 3,260 Good	Prudential Medicare managed care enrollees in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 24.5% Marginal: 11.2% Adequate: 64.2%	Age Gender Race Physical and Mental health Chronic-diseases Smoking Alcohol use BMI Study site Months enrolled	Number of physician visits Inadequate: 9.8% Marginal: 9.3% Adequate: 8.1% Total physician visits Inadequate: 13.7 Marginal: 13.5 Adequate: 14.3 Mean physician visits Inadequate: 2.2 Marginal: 2.2 Adequate: 2.2	HL not associated with time to first physician visit, mean number of physician visits, or no physician visit in the first year Number of physician visits Marginal: OR,1.23; 95% CI, 0.82-1.85 Inadequate: OR, 1.23; 95% CI, 0.88-1.72 Time to first visit Marginal: HR, 0.89; 95% CI, 0.78-1.00 Inadequate: HR, 0.94; 95% CI, 0.84-1.04 Mean visits Marginal: NR; $P = 0.34$ Inadequate: NR; $P = 0.38$ Mean visits Marginal: NR; $P = 0.27$ Inadequate: NR; $P = 0.62$

AOR=adjusted odds ratio; BMI=body mass index; CI=confidence interval; ED=emergency department; HIV=human immunodeficiency virus; HL=health literacy; HR=hazard ratio; mos=months; N=number; NAAL=National Assessment of Adult Literacy; NR=not reported; NS=not significant; OR=odds ratio; REALM=Rapid Estimate of Adult Literacy in Medicine; sig=significant; S-TOFHLA=Short Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; vs.=versus.

Table 14. Summary of studies of the relationship between health literacy and access to care and access to insurance (KQ 1a) (continued)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Howard et al., 2005[68] Cohort N = 3,260 Good	New Prudential Medicare managed-care enrollees in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 24.5% Marginal: 11.2% Adequate: 64.2%	Age Sex Race/Ethnicity Income Education Tobacco Alcohol Comorbidities	Overall use Inadequate: 95% Marginal: 96% Adequate: 97% Inpatient use Inadequate: 35% Marginal: 34% Adequate: 27% Outpatient use Inadequate: 90% Marginal: 90% Adequate: 91% ED use Inadequate: 30% Marginal: 28% Adequate: 21% Pharmacy use Inadequate: 85% Marginal: 85% Adequate: 88%	Inadequate HL not related to overall use, outpatient, or pharmacy use Marginal HL used more pharmacy services than those with adequate HL All other use comparisons not significant Mean differences in probability of use Inadequate vs. adequate Overall: 0.00; 95% CI, -0.02-0.02 Outpatient: -0.02; 95% CI, -0.05-0.01 Pharmacy: -0.03; 95% CI, -0.06-0.00 Mean differences in probability of use Marginal vs. adequate Overall: 0.00; 95% CI, -0.02-0.03 Outpatient: -0.01; 95% CI, -0.04-0.02 Pharmacy: -0.04; 95% CI, -0.08-0.00
Lindau et al., 2006[96] Cohort N = 68 Fair	Clinics in Chicago area academic medical center REALM Inadequate: 35% Adequate: 65%	Age Race HIV status Cancer Unemployment Insurance	Patient followed up on time after abnormal Pap Inadequate: 33% Adequate: 66% Patient followed up within one year Inadequate: 67% Adequate: 80%	No differences on-time follow-up after an abnormal Pap smear between inadequate and adequate groups: OR, 2.05; 95% CI, 0.47-8.85 No differences in predicting women's follow-up within one year between inadequate and adequate groups: OR, 3.75; 95% CI, 0.81-17.4
Grubbs et al., 2009[97] Retrospective cohort N = 62 Fair	5 San Francisco bay outpatient dialysis units S-TOFHLA Inadequate: 32.3%	Race Gender Income Age at start of dialysis Support Hypertension Diabetes Peripheral vascular disease	Time from dialysis date to transplant list referral date Inadequate: 23.5 mos Adequate: 15.3 mos Time from transplant	Longer time from dialysis date to transplant referral list date in inadequate group than adequate group: HR 4.54; 95% CI, 1.67-12.5 No difference in time from transplant list referral date to

Table 14. Summary of studies of the relationship between health literacy and access to care and access to insurance (KQ 1a) (continued)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
Grubbs et al., 2009[97] (continued)	Adequate: 67.7%	Coronary artery disease HIV Hepatitis C Congestive heart failure Depression Drug abuse	list referral date to waitlist date Inadequate: 6.6 mos Adequate: 2.1 mos	Waitlist date by HL: HR 1.25; 95% CI, 0.62-3.45
Hibbard et al., 2007[98] Cross-sectional N = 303 Fair	Community TOFHLA (passage B) Low: 45% High: 55%	Age Gender Education Comprehension Activation	Choosing a quality choice hospital: NR	No differences in predicting quality choice of a hospital between inadequate and adequate groups; *P* = NS
Sudore et al., 2006[95] Cross-sectional N = 2,512 Fair	Well-functioning, Medicare recipients living in the community with multiple sources of medical care in Memphis and Pittsburgh REALM Limited: 24% (= 8.8%, 0-6th grade, + 15.2%, marginal/7-8th grade) Adequate: 76%	Age Race Sex Income, Study site Health status Cardiac disease Stroke Cancer Hypertension Diabetes Obesity Depressive symptoms	Doctor/clinic Insurance for meds Composite access measure: NR	Less access in 3 of 4 access measures between limited and adequate group. No doctor/clinic: OR, 0.79; 95% CI, 0.43-1.45 No insurance for medication: OR, 0.58; 95% CI, 0.41-0.81 Composite access measure: OR, 0.51; 95% CI, 0.35-0.75 Marginal group did not differ from adequate group in any access measures No doctor/clinic: OR, 0.90; 95% CI, 0.54-1.49 No insurance for medication: OR, 0.97; 95% CI, 0.75-1.25 Composite access measure: OR, 1.05; 95% CI, 0.81-1.35
Mancuso et al., 2006[99,100] Cross-sectional N = 175 Fair	Primary care practice in New York City TOFHLA Inadequate: 10% Marginal: 8% Adequate: 82%	Age Race/ethnicity Sex Comorbidity Language Asthma duration Asthma severity Asthma control	Access to asthma care: NR Access to care due to other conditions: NR	No difference by HL level More difficult to access asthma care; *P* = 0.58 More difficult access to medical care for other medical conditions; *P* = 0.005

Table 14. Summary of studies of the relationship between health literacy and access to care and access to insurance (KQ 1a) (continued)

Authors, Year, Study Design, Literacy tool, Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Results By Health Literacy Skill Level	Differences in Results Between Health Literacy Skill Levels
White, et al., 2008[86] Cross-sectional N = 18,100 Fair	Nationally representative US sample living in households NAAL Basic or below basic: 36% Intermediate: 56% Proficient: 12%	Age, Gender Race Poverty level Insurance status Self-reported health status, Oral reading fluency	Dental checkup Below basic: 44% Basic: 59% Intermediate: 70% Proficient: 77% Vision checkup Below basic: 54% Basic: 58% Intermediate: 59% Proficient: 58% Prostate screen Below basic: 31% Basic: 34% Intermediate: 31% Proficient: 26% Osteoporosis screen Below basic: 17% Basic: 13% Intermediate: 11% Proficient: 7%	Adults under 40 Decreased probability of having a vision check-up for below basic/basic HL: NR; P < 0.05 No association with dental check-ups, P = NS Adults 40-64 Decreased probability of dental checkup for below basic/basic; P < 0.05 Adults > 65 Decreased probability of dental check-up, vision check-up, osteoporosis screening, and prostate cancer screening in below basic/basic HL group; P < 0.05 No differences by HL related to men's screening for osteoporosis: P = NS
Murphy, 2010[82] Cross-sectional N= 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit TOFHLA-modified Inadequate: 12% Marginal: 3% Adequate: 86%	Age Education	Medical care received Data by HL level: NR	The likelihood of receiving medical care was related to higher HL level Medical care received 3 or more times (adjusted): OR, 1.09; 95% CI, 1.04-1.15 Medical care received once or twice (adjusted): OR, 1.06; 95% CI, 1.02-1.09
Yin, 2009[102] Cross-sectional N = 6,100 Fair	Parents ≥ 16 years old living in a US household (nationally representative sample) NAAL Below basic: 11% Basic: 18% Intermediate: 56% Proficient: 15%	Age Gender Number of children living in the home Education Race/ethnicity Country of birth English proficiency Income Region Metropolitan statistical area	At least 1 child without health insurance Below basic: 24% Basic: 10% Intermediate: 6% Proficient 3%	In comparison to HL proficient group, odds are greater that at least 1 child is without health insurance (adjusted) Below basic: AOR, 2.4; 95% CI, 1.1-4.9 Basic: AOR, 1.7; 95% CI, 0.5-5.7 Intermediate: AOR, 1.4; 95% CI, 0.4-4.2

Table 15. Summary of studies of the relationship between health literacy and adherence (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Graham et al., 2007[104] Retrospective cohort N = 87 Fair	Patients at an HIV clinic in Philadelphia, Pennsylvania REALM Low: 49% Adequate: 51%	Individual's norm for acceptable adherence (investigator controlled as mediator)	< 95% adherence to HIV medication regimen (self-report of pill counts over past 3 months) Low: 60% Adequate: 36%	Norms found to mediate the relationship between HL and nonadherence Difference between low and adequate groups (unadjusted): OR, 0.36; 95% CI, 0.16-0.88 No difference in nonadherence (adjusted): OR, 0.36; 95% CI, 0.17-1.02
Kalichman et al., 2008[103] Prospective cohort N = 145 Fair	HIV positive adults in Atlanta, GA TOFHLA Lower: 49% Higher: 51%	Age Education Years since testing HIV positive HIV symptoms Depression Internalized stigma Social support Alcohol use	Antiretroviral therapy pill adherence < 85% (pills counts averaged over past 4 months) Lower: 84% Higher: 69%	Antiretroviral therapy pill nonadherence greater in lower health literacy group (adjusted): OR, 3.77; 95% CI, 1.46-9.93
Murphy et al., 2010[82] Cross-sectional N = 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit TOFHLA-modified Inadequate/ Marginal: 15% Adequate: 86%	Age Education	Self- reported medication adherence over past 3 days Inadequate/marginal ≥ 90%: 24% > 0 to < 90%: 41% 0%: 35% Adequate ≥ 90%: 36% > 0 to < 90%: 24% 0%: 41%	No difference in medication adherence level by HL (adjusted) ≥ 90% adherent: OR, 1.00; 95% CI, 0.96-1.05 > 0% and < 90% adherent: OR, 1.00; 95% CI, 0.95-1.04

CD4=cluster of differentiation 4; CI=confidence interval; HIV=Human immunodeficiency virus; HL=health literacy; HR=hazard ratio; N=number; NR=not reported; OR=odds ratio; REALM=Rapid estimate of adult literacy in medicine; S-TOFHLA=Short Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; VA=veterans administration.

Table 15. Summary of studies of the relationship between health literacy and adherence (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Osborn et al., 2007[69] (companions: Wolf et al., 2007;[70] Waite et al., 2008[71], Osborn et al., 2010[72]) Cross-sectional N = 204 Fair	Patients at 2 HIV clinics, 1 in Chicago, Illinois and 1 in Shreveport, Louisiana REALM Low: 11% Marginal: 20% Adequate: 69%	Race Gender Age Income Number of medications in HIV regimen Non-HIV comorbid conditions Mental illness	Nonadherence to HIV medications in past 4 days (self-report) Low: 52% Marginal: 19% Adequate: 30%	Nonadherence: Higher in low than adequate group (adjusted): OR, 2.12; 95% CI, 1.93-2.32 No difference between marginal and adequate groups (adjusted): OR, 1.55; 95% CI, 0.93-2.45
Osborn et al., 201072 (companions: Osborne et al., 2007;[69] Wolf et al., 2007;[70] Waite et al., 2008[71] Cross-sectional N = 204 Fair	Patients at 2 HIV clinics, 1 in Chicago, Illinois and 1 in Shreveport, Louisiana REALM Low: 11% Marginal: 20% Adequate: 69%	Age Insurance coverage Employment status Number of medications in HIV regimen Number of non-HIV prescription meds currently taken Presence of a comorbid chronic condition Treatment for a mental health condition Treatment for alcohol or drug use	Nonadherence (<90%-95%) to HIV medications in past 4 days (self-report) Low: 89% Marginal: 80% Adequate: 31%	Nonadherence: Positively associated with being in the low compared to adequate group (adjusted): OR, 3.3; 95% CI, 1.3-8.7 No difference between marginal and adequate group (adjusted): OR, 2.1; 95% CI, 0.8-5.5
Paasche-Orlow et al., 2006[105] Retrospective cohort N = 235 Fair	Patients with HIV and a history of alcohol problems in Boston, Massachusetts REALM: Low: 14% Marginal: 29% Adequate: 57%	Gender Age Education Randomization group Ethnicity Homeless status Drank to intoxication past 30 days Injected drugs past 6 months Complexity of regimen	100% adherence to HIV medication regimen (self-report for 3 day period) Low: 69% Marginal: 63% Adequate: 64%	Total adherence: No difference between low and adequate group (adjusted): OR, 1.93; 95% CI, 0.86-4.31 No difference between marginal and adequate group (adjusted): OR, 1.29; 95% CI, 0.77-2.19

Table 15. Summary of studies of the relationship between health literacy and adherence (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Waite et al., 2008[71] (Companions: Osborn et al., 2007;[69] Wolf et al., 2007[70]; Osborne et al., 2010[72]) Cross-sectional N = 204 Fair	Patients at 2 HIV clinics, 1 in Chicago, Illinois and 1 in Shreveport, Louisiana REALM Low: 11% Marginal: 20% Adequate: 69%	Stigma concerns related to HIV medications (self-report) (investigator controlled as mediator) Age Gender Site Employment status Number of medications in HIV regimen Number of non-HIV prescription medications taken Comorbid chronic condition Treatment for mental health condition Treatment for substance abuse	Nonadherence to HIV medications in past 4 days (self-report) Low: 52% Marginal: 19% Adequate: 30%	Nonadherence (adjusted-not controlling for stigma) Positively related to being in the low compared to the adequate group: OR, 3.3; 95% CI, 1.3-8.7 No difference between marginal and adequate group: OR, 2.1; 95% CI, 0.8-5.5 Nonadherence (adjusted-controlling for stigma) No difference between low and adequate group: OR, 2.1; 95% CI, 0.7-6.5 No difference between low and adequate group: OR, 0.7; 95% CI, 0.2-1.8
Wolf et al., 2007[70] (companions: Osborn et al., 2007;[69] Waite et al., 200871; Osborne et al., 2010[72]) Cross-sectional N = 204 Fair	Patients at 2 HIV clinics, 1 in Chicago, Illinois and 1 in Shreveport, Louisiana REALM Low: 11% Marginal: 20% Adequate: 69%	HIV treatment knowledge (investigator controlled as mediator) HIV medication self-efficacy (investigator controlled as mediator) Age Insurance coverage Employment status Number of medications in HIV regimen Number of non-HIV prescription medications currently taking Presence of comorbid chronic conditions Treatment for mental health condition past 6 months Treatment alcohol or drug use past 6 months	Nonadherence to HIV medications in past 4 days (self-report) Low: 52% Marginal: 19% Adequate: 30%	Nonadherence (adjusted-not controlling for knowledge and self-efficacy) Positively related to being in the low compared to the adequate group: OR, 3.3; 95% CI, 1.3-8.7 No difference between marginal and adequate group: OR, 2.1; 95% CI, 0.8-5.5 Nonadherence mediation analysis (adjusted-controlling for knowledge and self-efficacy) No difference between low and adequate groups: OR, 2.0; 95% CI, 0.8-5.3 No difference between marginal and adequate groups: OR, 1.6; 95% CI, 0.6-4.7

Table 15. Summary of studies of the relationship between health literacy and adherence (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Chew et al., 2004[107] Prospective cohort N = 332 Fair	Preoperative clinic of the VA Puget Sound S-TOFHLA Low (Inadequate/ Marginal): 12% Adequate: 88%	Age Marital status Number of medications Cognitive functioning	Nonadherence to fasting instructions Low: 9% Adequate: 8% Nonadherence to preoperative medication instructions: Low: 37% Adequate: 21%	No difference between groups in nonadherence to fasting instructions (unadjusted): P = 0.80 No difference between groups in nonadherence to preoperative medication instructions (adjusted): OR, 1.9; 95% CI, 0.8-4.8
Cho et al., 2008[81] (companion: Lee et al., 2009[160] Cross-sectional N = 489 Fair	Seniors who are patients at 1 of 2 Chicago, Illinois clinics S-TOFHLA Inadequate/ marginal: 51% Adequate: 49%	Race/ethnicity Gender Education	Nonadherence: failed to fill prescriptions on time (self-report) Inadequate/marginal: NR Adequate: NR	Using path analysis, HL level did not have a significant direct effect on nonadherence (adjusted): β = -0.17, P ≥ 0.05
Fang et al., 2006[106] Cross-sectional N = 179 Fair	Patients at anticoagulation clinic in San Francisco, California S-TOFHLA Limited: 61% Adequate: 39%	Age Sex Race/ethnicity Education Cognitive impairment Years on warfarin	Adherence to medication as measured by self-report of missed doses over 3 time periods (last 3 days, last 2 weeks, > 3 months) No missed doses > past 3 months: Limited: 61% Adequate: 51%	No difference in adherence between groups by any of the measures of missed doses (adjusted) Did not miss a dose in > 3 months (adjusted): OR, 0.9; 95% CI, 0.4-2.0
Gatti et al, 2008[73] (companion Johnson et al., 2010[74]) Cross-sectional N = 275 Fair	Adults who used 3 pharmacies in hospitals in Atlanta REALM Inadequate/ Marginal: 60% Adequate: 40%	Negative beliefs about medications Age Low self-efficacy Self-report of hyperlipidemia	Self-reported low medication adherence - measured by Morisky 8-item Medication Adherence Scale (MMAS-8>2) REALM mean: low adherence group: 52.4 (16.8) high adherence group: 50.1 (17.4)	No difference in medication adherence (adjusted): OR, 0.96; 95% CI, 0.6-1.7

Table 15. Summary of studies of the relationship between health literacy and adherence (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables Used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Gazmararian et al., 2006[61] (companions: Wolf et al., 2007;[64] Baker et al., 2007;[65] Howard et al., 2006;[63] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Prospective cohort N = 1,549 Fair	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Inadequate: 24% Marginal: 12% Adequate: 64%	Age Race Gender Education Regimen complexity	Nonadherence to cardiovascular medication refill adherence (1-year period) Low: 45% Marginal: 42% Adequate: 38%	Nonadherence: No difference between low and adequate groups (adjusted): OR, 1.23; 95% CI, 0.92-1.64 No difference between marginal and adequate groups (adjusted): OR, 1.15; 95% CI, 0.82-1.62
Hironaka et al., 2009[108] Prospective cohort N = 110 Fair	Caregivers of infants who receive care at 2 pediatric clinics S-TOFHLA Inadequate/ Marginal: 18% Adequate: 82%	Race/ethnicity Caregiver education Caregiver concerns regarding multivitamins and possible side effects Randomized assignment to drops or sprinkle formulation	Caregivers' self-reported days of adherence to giving vitamins to their infants in prior week Inadequate/Marginal: 3.7 days Adequate: 2.4 days	Adherence positively related to being in the inadequate/marginal group compared to the adequate group (adjusted): OR, 2.4; 95% CI, 1.37-4.2
Johnson, 2010[74] (companion: Gatti et al., 2008[73]) Cross-sectional N = 275 Fair	Adults who used 3 pharmacies in hospitals in Atlanta REALM Inadequate/ Marginal: 60% Adequate: 40%	Potential moderator: social support Age Sex	Self-reported medication adherence - measured by Morisky 8-item Medication Adherence Scale (MMAS-8): NR	No difference in adherence by HL level: β = 0.072; 95% CI, -0.350-0.494 After adjusting for interaction between HL and social support (moderator): lower HL related to better adherence at lower levels of social support, higher HL better adherence at higher levels of social support HL: β = -1.827; 95% CI, -3.389-0.265 HL x social support: β, 0.086; 95% CI, 0.018-0.154

Table 16. KQ 1b health literacy studies: strength of evidence grades by health outcomes

Outcome for Health Literacy Studies	Number of Studies	Results	Strength of Evidence Grade
Adherence	11	Mixed results depending on adherence measure, disease state, and adjustment for confounding	Insufficient
Self-efficacy	5	Mixed results in studies conducted within various sub-populations	Insufficient
Smoking	2	Mixed results	Insufficient
Alcohol and substance use	2	No effect on current alcohol consumption. Positive relationship between health literacy level and substance use in one study.	Insufficient
Healthy lifestyle (physical activity, eating habits, and seat belt use)	3	Mixed results from studies examining exercise, diet, a composite measure, and seatbelt use	Insufficient
Healthy lifestyle (obesity and weight)	5	Mixed results, 4 of 5 studies unadjusted	Insufficient
Review of prescription information	1	Low health literacy associated with being less likely to read prescription information	Low
HIV risk and sexual behaviors	2	Mixed results	Insufficient
Taking medications appropriately	6	Lower health literacy associated with poorer ability to demonstrate being able to take mediations appropriately	Moderate
Interpreting labels and health messages	3	Low health literacy associated with poorer ability to interpret labels and health messages; smaller likelihood of giving an organized health narrative	Moderate
Asthma self-care	1	Low literacy associated with poorer self-care skill in 1 study	Low
Mental health symptomatology	10	Results in 8 of 10 studies found association between lower health literacy and depression but control for confounding was limited	Low
Chronic disease outcomes	7	Mixed results: 3 studies on association with chronic diseases generally and 4 studies on association with specific diseases	Insufficient
HIV severity and symptoms	5	Results in 3 studies found no relationship but control for confounding was limited and sample sizes were small	Low
Asthma severity and control	2	Mixed results; only unadjusted analysis of asthma control	Insufficient
Diabetes control and related symptoms	5: 5 glycemic control, 1 compli-cations	Glycemic control: mixed results Complications: no relationship	Insufficient

Table 16. KQ 1b health literacy studies: strength of evidence grades by health outcomes (continued)

Outcome for Health Literacy Studies	Number of Studies	Results	Strength of Evidence Grade
Hypertension control	2	Mixed results	Insufficient
Prostate cancer control	1	More likely to have higher prostate-specific antigen (PSA) test results (worse levels)	Low
Health status: all adults	1	No relationship with global health status	Low
Health status and quality of life: seniors	5	Lower overall health status	Overall: Moderate
		Mixed effects mental and physical functioning	Mental and physical: Insufficient
Health status and quality of life: individuals with specific diseases	5	Mixed results: mental and physical functioning by disease state and measure	Insufficient
Mortality: seniors	2	Higher risk of mortality in the lower literacy group; risk not elevated in the marginal literacy group (1 study)	High

Table 17. Summary of studies of the relationship between health literacy and self-efficacy (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Murphy, 2010[82] Cross-sectional N= 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit TOFHLA-modified Inadequate: 12% Marginal: 3% Adequate: 86%	Age Education	Outcomes by HL level: NR	No difference by HL in self-efficacy in taking HIV medication regimen score (adjusted): OR, 0.99; 95% CI, 0.95-1.03 No difference in self-efficacy in keeping medical appointment (adjusted): OR, 1.01; 95% CI, 0.95-1.06
Peterson et al., 2007[87] Cross-sectional N = 99 Fair	Patients with public health care coverage at a community health clinic in Nashville, Tennessee REALM Limited: 29% Adequate: 71%	Age Sex Race Insurance status	Mean perception of self-efficacy score FOBT Limited: 3.87 Adequate: 3.93 Colonoscopy: Limited: 3.92 Adequate: 3.99	No difference between groups in perception of self-efficacy for FOBT (adjusted): P = 0.44 No difference between groups in perception of self-efficacy or colonoscopy: P = 0.52
Torres et al., 2009[113] Cross-sectional N = 106 Fair	Women patients at a family health center in New York City s-TOFHLA Inadequate: 46% Marginal: 18% Adequate: 36%	None	Self-efficacy for taking hormone therapy Self-efficacy by health literacy level: NR	Self-efficacy positively correlated with HL (unadjusted): r = 0.70; P < 0.01
von Wagner et al., 2009[114] Cross-sectional N = 96 Fair	Adults in London, England between 50-69 years of age UK-TOFHLA Mean: 92.2 Range: 26-100	Age Ethnicity Employment Gender Number of computer links open Mean reading time CRC screening knowledge	Self-efficacy for participating in CRC screening Self-efficacy by health literacy level: NR	Higher HL level associated with greater self-efficacy (adjusted): $\beta = 0.061$; 95% CI, 0.009-0.113

CI=confidence interval; CRC=colorectal cancer; FOBT=fecal occult blood test; HL=health literacy; HIV=Human immunodeficiency virus; N=number; NR=not reported; OR=odds ratio; REALM=rapid estimate of adult literacy in medicine; TOFHLA=Test of Functional Health Literacy in Adults; S-TOFHLA=Short Test of Functional Health Literacy in Adults; UK-S-TOFHLA=British version of the Test of Functional Health Literacy in Adults.

Table 17. Summary of studies of the relationship between health literacy and self-efficacy (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Wolf et al., 2007[70] (companions: Osborn et al., 2007;[69] Waite et al., 2008[71] Osborne et al., 2010 [72]) Cross-sectional N = 204 Fair	Patients at 2 HIV clinics, 1 in Chicago, Illinois and 1 in Shreveport, Louisiana REALM Low: 11% Marginal: 20% Adequate: 69%	Age Insurance coverage Employment status Number of medications in HIV regimen Number of non-HIV prescription medications currently taking Presence of comorbid chronic conditions Treatment for mental health condition past 6 months Treatment alcohol or drug use past 6 months	Perception of self-efficacy to properly take and manage HIV medication Low: 61% Marginal: 20% Adequate: 24%	Higher HIV medication self-efficacy greater in adequate than low group (adjusted): OR, 5.8; 95% CI, 2.0-15.7 No difference HIV medication self-efficacy between adequate and marginal groups (adjusted): OR, 1.6; 95% CI, 0.3-3.2

Table 18. Summary of studies of the relationship between health literacy and health behaviors (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
von Wagner, 2007[115] Cross-sectional N = 719 Fair	National sample of British adults Modified TOFHLA Inadequate: 6% Marginal: 6% Adequate: 89% Continuous measure used in analysis	Age Education Gender Ethnicity Income	Don't smoke Inadequate: 29% Marginal: 32% Adequate: 70% Fruit and vegetable intake > 5/day Inadequate: 29% Marginal 39% Adequate: 47% Any exercise in the last week: Inadequate: 22% Marginal: 20% Adequate: 36.6%	Higher HL associated with greater likelihood of not smoking (adjusted): OR, 1.02; 95% CI, 1.003-1.03 Higher HL associated with greater likelihood of eating ≥ 5 fruit/vegetables a day (adjusted): OR, 1.02; 95% CI, 1.003-1.03 HL level not associated with likelihood of having exercised in the last week (adjusted): OR, 1.00; 95% CI, 0.98-1.02
Wolf, 2007[64] (companions: Gazmararian, 2006;[61] Baker et al., 2007;[65] Howard et al., 2006;[63] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Cross-sectional N = 2,923 Fair	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Inadequate: 22% Marginal: 11% Adequate: 66%	Age Gender Race/ethnicity Language (English or Spanish) Site Education Annual income Occupation (white or blue collar)	Smoking (never): Inadequate: 47% Marginal: 42% Adequate: 39% Smoking (former) Inadequate: 42% Marginal: 45% Adequate: 49% Smoking (current) Inadequate: 12% Marginal: 13% Adequate: 12% Current alcohol use (none) Inadequate: 75.6% Marginal: 64.2% None: 57.9% Current alcohol use (light to moderate) Inadequate: 23% Marginal: 34% Adequate: 38% Current alcohol use (heavy) Inadequate: 2% Marginal: 2% Adequate: 4%	Difference in smoking status (adjusted) No difference between groups in ever vs. never smoking Inadequate vs. adequate: OR, 0.9; 95% CI, 0.7-1.1 Marginal vs. adequate: OR, 0.9; 95% CI, 0.7-1.2 No difference between groups in ever vs. quit smoking Inadequate vs. adequate: OR, 0.9; 95% CI, 0.6-1.3 Marginal vs. adequate: OR, 0.7; 95% CI, 0.5-1.0 Difference in alcohol consumption (adjusted) No difference between groups in light/moderate vs. no alcohol consumption Inadequate vs. adequate: OR, 1.1; 95% CI, 0.5-2.5 Marginal vs. adequate: OR, 1.4; 95% CI, 0.6-3.3

BMI=Body Mass Index; CI=confidence interval; HL=health literacy; HIV=Human immunodeficiency virus; INR=International Normalized Ratio; N=number; NR=not reported; OH=Ohio; OR=odds ratio; REALM=rapid estimate of adult literacy in medicine; RR=risk ratio; S-TOFHLA=Short Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; TX=Texas.

Table 18. Summary of studies of the relationship between health literacy and health behaviors (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Wolf, 2007[64] (companions: Gazmararian, 2006;[61] Baker et al., 2007;[65] Howard et al., 2006;[63] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) (continued)			Physical Activity per week (< 1 time) Inadequate: 38% Marginal: 25% Adequate: 22% Physical Activity per week (1-2 times) Inadequate: 15% Marginal: 16% Adequate: 15% Physical Activity per week (3 times) Inadequate: 14% Marginal: 18% Adequate: 15% Physical Activity per week (> 4 times) Inadequate: 33% Marginal: 41% Adequate: 48% Seat belt use (always) Inadequate: 72% Marginal: 78% Adequate: 78% Seat belt use (nearly always, sometimes, or seldom) Inadequate: 28% Marginal: 22% Adequate: 22%	No difference between groups in heavy vs. no alcohol consumption Inadequate vs. adequate: OR, 1.3; 95% CI, 0.6-3.0 Marginal vs. adequate: OR, 1.2; 95% CI, 0.5-2.8 Difference in physical activity (adjusted) No difference between groups in physical activity 1-2 times per week vs. < 1 time Inadequate vs. adequate: OR, 1.0; 95% CI, 0.7-1.4 Marginal vs. adequate: OR, 1.3; 95% CI, 0.9-1.8 No difference between groups in physical activity 3 times per week vs. < 1 time Inadequate vs. adequate: OR, 0.9; 95% CI, 0.7-1.3 Marginal vs. adequate: OR, 1.0; 95% CI, 0.7-1.5 No difference between groups in physical activity greater than 4 times per week vs. less than 1 time Inadequate vs. adequate: OR, 1.3; 95% CI, 0.9-1.7 Marginal vs. adequate: OR, 1.0; 95% CI, 0.7-1.4 No difference between groups in seat belt use (unadjusted): P = 0.13

Table 18. Summary of studies of the relationship between health literacy and health behaviors (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Baker et al., 2007[65] (companions: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Howard et al., 2005;[68] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Cohort N = 3,260 Good	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Inadequate: 24% Marginal: 11% Adequate: 64%	None	BMI < 18.5 Inadequate: 8% Marginal: 4% Adequate: 4% BMI 18.5-24.9 Inadequate: 59% Marginal: 60% Adequate: 58% BMI 25.0-29.9 Inadequate: 23% Marginal: 24% Adequate: 26% BMI > 30.0 Inadequate: 10% Marginal: 12% Adequate: 12%	Difference in BMI across groups (unadjusted): P < 0.005
Huizinga et al. 2008[10] Cross-sectional N = 160 Fair	Patients at primary care clinic at Vanderbilt University REALM < 9th grade: 23% ≥ 9th grade: 77%	None	BMI < 9th: 31.7 (SD 9.9) ≥ 9th: 30.2 (SD 7.8)	No difference between groups in BMI level (unadjusted): P = 0.50
Sudore, 2006[95] (companion: Sudore et al., 2006[167]) Cross-sectional N = 2,512 Fair	Seniors (70-79 year old) in Pittsburgh, Pennsylvania and Memphis, Tennessee REALM 0-6th grade: 8% 7-8th grade: 15% >9th grade: 76%	None	Obesity (BMI > 30) 0-6th grade: 29% 7th-8th grade: 32% > 9th grade: 23%	Difference in probability of obesity across groups (unadjusted): OR, 1.51; 95% CI, 1.23-1.85
Rothman, 2006[9] Cross-sectional N = 200 Fair	Adults in a primary care clinic REALM < HS: 23% > HS: 77%	None	Obese (BMI ≥ 30): < HS: 53% > HS: 43%	No difference between groups in percent obese (unadjusted): P = 0.31

Table 18. Summary of studies of the relationship between health literacy and health behaviors (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Sharif and Blank, 2010[119] Cross-sectional N = 78 Good	Children ages 6-19 BMI ≥ 85th percentile for age and sex who received primary care at in an inner city academic community health center in the Bronx, NY S-TOFHLA Child Adequate: 52% Parent Adequate: 77%	Age Parental BMI Child Eating self-efficacy Parental eating self-efficacy Parental S-TOFHLA	Child BMI No data reported by HL	Higher HL significantly related to decrease in child BMI: B, -0.016; 95% CI, -0.025, -0.008
Cho et al., 2008[81] (companion: Lee et al., 2009[160]) Cross-sectional N = 489 Fair	Seniors who are patients at 1 of 2 Chicago, Illinois clinics s-TOFHLA Inadequate/ marginal: 51% adequate: 49%	Race/ethnicity Gender Education	Health Promoting Lifestyle Profile relating to exercise, nutrition, and health responsibility Data: NR	Using path analysis, HL level did not have a direct effect on health behavior (adjusted): P ≥ 0.05
Wolf et al., 2006[120] Cross-sectional N = 251 Fair	Adults at a primary care clinic in Shreveport, Louisiana REALM Low: 30% Marginal: 31% Adequate: 40%	Age Gender Race Education Number of prescriptions taken	Read/looked at medication guides and consumer information included with prescription medications Low: 17% Marginal: 22% Adequate: 33%	Low HL group more likely than adequate group to not read/look at medication guides: OR, 2.5; 95% CI, 1.2-5.2 No difference between marginal and adequate groups in likelihood of reading/looking at medication guides: P = NS, data NR
Paasche-Orlow, 2005[121] Cross-sectional N = 423 Fair	Female inmates in Rhode Island adult correctional institute REALM ≤ 6th grade: 10% 7th-8th grade: 19% ≥ 9th grade: 71%	Age Race Problem drinking	HIV Risk Behavior in past 3 months (self-report of sex without a condom or shared injection drug equipment) ≤ 6th grade: 9% 7th-8th grade: 19% ≥ 9th grade: 72%	No difference between groups in HIV risk behaviors (adjusted) ≤ 6th grade vs. ≥ 9th grade: OR, 2.02; 95% CI, 0.83-4.92 ≤ 6th grade vs. 7th-8th grade: OR, 1.89; 95% CI, 0.74-4.81

Table 18. Summary of studies of the relationship between health literacy and health behaviors (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Marteleto, 2008[122] Longitudinal N = 4,751 (wave 1) Fair	14-22 years old at time of Wave 1 in Cape Town, South Africa Cape Area Panel Study Literacy evaluation scores: NR	Grades completed in 2002 Enrolled in 2002 Age Age squared Race Income Household shock Mother's education Father's education Living with mother Living with father	Sexual debut: NR First pregnancy: NR	An increase in literacy of one standard deviation associated with a 7.5% reduction in probability of sexual debut (adjusted): P < 0.05 Literacy level not related to first pregnancy in either females or males (adjusted) Probit coefficient Females: 0.41 Males: -0.030
Murphy et al., 2010[82] Cross-sectional N= 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit TOFHLA-modified Inadequate: 12% Marginal: 3% Adequate: 86%	Age Education	Drug and alcohol use over past 3 months No data by HL	Higher HL positively associated with substance use (adjusted): P = 0.0181

Table 19. Summary of studies of the relationship between health literacy and the outcome of health care related skills (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Results By Health Literacy Level	Differences in Results Between Health Literacy Levels
Kripalani et al., 2006[123] Cross-sectional N = 152 Good	Clinic population with coronary heart disease in Atlanta, GA REALM Inadequate: 52% Marginal: 29% Adequate: 20%	Age Education Cognitive functioning	DRUGS: Requiring observed completion of 4 tasks: 1. Identify appropriate medication 2. Open container 3. Select correct dose 4. Report appropriate timing of doses. Mean score: Inadequate: 92.1 Marginal: 96.3 Adequate: 97.7	Difference across groups in overall DRUGS score (unadjusted): *P* = 0.001 Inadequate more likely than adequate to not be able to identify all medications (adjusted): OR, 12.00; 95% CI, 2.57-56.08 No difference between marginal and adequate in ability to identify all medications (adjusted): OR, 4.75; 95% CI, 0.95-23.75
Raehl et al., 2006[124] Cross-sectional N = 57 Fair	Seniors in Amarillo, Texas REALM mean: 55.4	Age Number of over-the-counter drugs Owned a car in last 10 years Received food assistance in last 10 years	MedTake Test: ability to open and take own medications while observed by pharmacist MedTake Test outcomes: NR	A higher MedTake Test score was associated with a higher REALM score (adjusted): *P* < 0.01
Yin et al., 2007[125] Cross-sectional N = 292 Fair	Parents/ caregivers of children at an Emergency Department in New York City TOFHLA Inadequate: 10% Marginal: 16% Adequate: 74%	Experience of ever receiving a dosing instrument in a health care setting Child's age Child has regular health care provider Confounders with health literacy: Caregiver's education, country of origin, language, socio-economic status	Self-reported use of nonstandardized dosing instrument Inadequate/ Marginal: 35% Adequate: 19%	No difference in use of dosing instrument between health literacy groups (adjusted for all control variables): OR, 1.5; 95% CI, 0.8-2.8 Marginal/inadequate greater use than adequate (adjusted for control variables except for confounders with HL): OR, 1.9; 95% CI, 1.0-3.5

AIDS=acquired immune deficiency syndrome; AOR=adjusted odds ratio; BMI=Body Mass Index; CI=confidence interval; DRUGS=Drug Regimen Unassisted Grading Scale; FL=Florida; GA=Georgia; HIV=Human immunodeficiency virus; HL=health literacy; HS=high school; IL=Illinois; INR=International Normalized Ratio; LA=Louisiana; MI=Michigan; N=number; NR=not reported; NY=New York; OR=odds ratio; REALM=rapid estimate of adult literacy in medicine; RR=risk ratio; SD=standard deviation; S-TOFHLA=Short Test of Functional Health Literacy in Adults; SES=socio-economic status; TOFHLA=Test of Functional Health Literacy in Adults; US=United States.

Table 19. Summary of studies of the relationship between health literacy and the outcome of health care related skills (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Results By Health Literacy Level	Differences in Results Between Health Literacy Levels
Estrada et al., 2004[126] Prospective cohort N = 143 Fair	Adults greater than 50 years old on warfarin ≥ 1 month in 2 anticoagulation management units REALM ≤ 3rd: 11% 4th-6th: 15% 7th-8th: 26% >8th: 48%	Age	Warfarin control measured through INR variability: NR Optimal intensity of anticoagulation (time in range): NR	No difference by HL level in INR variability (adjusted): P = 0.06 No difference by HL time INR in therapeutic range (adjusted): P = 0.71
Davis et al., 2006[75] (Analysis 1) Wolf et al., 2007[76] (Analysis 2) Cross-sectional N = 395 Fair	Adults in primary care clinics in Shreveport, LA; Jackson, MI; and Chicago, IL REALM Inadequate: 19% Marginal: 29% Adequate: 52%	Analysis 1 Age Sex Race Education Number of medications currently taken daily Site Analysis 2 None	Misunderstood one or more prescription label instructions: Inadequate: 63% Marginal: 51% Adequate: 38% Correct demonstration of number of pills: Inadequate: 35% Marginal: 63% Adequate: 80%	Analysis 1 Greater misunderstanding in inadequate compared to adequate group (adjusted): RR, 2.32; 95% CI, 1.26-4.28 Greater misunderstanding in marginal compared to adequate group (adjusted): RR, 1.94; 95% CI, 1.14-3.2 Greater demonstration of pills in adequate compared to inadequate group (adjusted): RR, 3.02; 95% CI, 1.70-4.89 No difference between marginal and adequate groups in demonstration of pills: RR = NS, data NR Analysis 2 Difference across literacy groups in correctly interpreting primary label (unadjusted) Amoxicillin: P < 0.001 Trimethoprim: P < 0.001

Table 19. Summary of studies of the relationship between health literacy and the outcome of health care related skills (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Results By Health Literacy Level	Differences in Results Between Health Literacy Levels
Davis et al., 2006[75] (Analysis 1) Wolf et al., 2007[76] (Analysis 2) (continued)				Guaifenesin: P < 0.001 Felodipine: P = 0.03 Furosemide: P = 0.09 Difference across literacy groups in correctly attending to auxiliary label (unadjusted) Amoxicillin: P = 0.13 Trimethoprim: P = 0.14 Guaifenesin: P < 0.001 Felodipine: P = 0.11 Furosemide: P = 0.01
Rothman et al., 2006[9] Cross-sectional N = 200 Fair	Adults in primary care clinic REALM < HS: 23% > HS: 77%	Age Gender Race/ethnicity Income Education Insurance status Presence of chronic disease Status of being on a specific diet Label reading frequency	Understanding nutrition labels measured through Nutrition Label Survey Nutritional Label Survey score mean (SD): < HS: 51 (16) > HS: 75 (19)	Greater understanding of nutrition labels in higher HL group (adjusted): P < 0.001
Bailey et al, 2009[77] (Companions: Davis et al., 2006[75], Wolf et al., 2007[76]) Cross-sectional N = 373 Fair	Adults in Shreveport, La; Chicago, IL, and Jackson, Michigan REALM: Low: ≤ 6th grade: 20% Marginal: 7th-8th grade: 29% Adequate: ≥ 9th grade: 51%	Race Age Sex Education	Misinterpretation of medication label instructions: Low: 43% Marginal: 34% Adequate: 18%	In comparison to group with adequate HL (adjusted): Greater probability of marginal group misinterpreting medication instructions: AOR, 2.20; 95% CI, 1.19-3.97 Greater probability of low group misinterpreting medication instructions: AOR, 2.90; 95% CI, 1.41-6.00

Table 19. Summary of studies of the relationship between health literacy and the outcome of health care related skills (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Results By Health Literacy Level	Differences in Results Between Health Literacy Levels
Yin et al, 2010[127] Cross-sectional N = 302 Good	English- and Spanish-speaking parents whose child received care at public pediatric clinic in NY Newest Vital Sign High likelihood of limited literacy: 40% Possible limited literacy: 38% Adequate literacy: 22%	Parent's age Relationship to child Marital status Language Ethnicity US birth SES Presence of a child in the house <8 years old Presence of child in the household with a chronic medical problem	Accuracy in measuring a dose of medicine using 6 different dosing instruments: NR	In comparison to group with adequate HL, the odds of making any dosing error (>20% deviation) was greater in those with a high likelihood of limited HL: AOR, 1.7; 95% CI, 1.1-2.8 and in those with possible limited HL: AOR, 1.6; 95% CI, 1.02-2.6 In comparison to group with adequate HL, odds of making a large dosing error (>40% deviation) was greater in those with a high likelihood of limited HL: AOR, 2.3; 95% CI, 1.2-4.6 but no difference in those with possible limited HL: AOR, 1.9; 95% CI, 0.95-3.7
LeVine et al., 2004[128] Cross-sectional N = 167 Fair	Mothers of kindergarten age children in urban and rural Nepal Literacy measured as continuous, composite score of reading comprehension and noun definition (in Nepalese) Levels NR	Maternal schooling Childhood socioeconomic status Age Current socioeconomic status Husband's schooling Urban/rural	Comprehension of radio health messages: NR Comprehension of visual print health message: NR Ability to give an organized health-related narrative: NR	Higher literacy level associated with greater probability of giving an organized health narrative (adjusted): $P < 0.05$
Paasche-Orlow et al., 2005[79] Cross-sectional N = 73 Fair	Inpatient adults hospitalized for severe asthma at 2 inner city hospitals s-TOFHLA Inadequate: 22% Adequate: 78%	Age Sex Ethnicity Education Income History of near fatal asthma Asthma hospitalization in prior 12 months	Mastery of metered dose inhaler technique Inadequate: 32% Adequate: 63%	Poorer probability of mastery of metered dose inhaler in inadequate than adequate group (adjusted): OR, 0.29; 95% CI, 0.08-1.00; $P = 0.03$

Table 19. Summary of studies of the relationship between health literacy and the outcome of health care related skills (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Results By Health Literacy Level	Differences in Results Between Health Literacy Levels
Paasche-Orlow et al., 2005[79] (continued)		Having a physician for asthma care Prior emergency department visit for asthma last 12 months (subset of confounders used in final model specification NR)		
Waldrop-Valverde et al, 2009[47] Cross-sectional N = 155 Fair	Adults with HIV in HIV clinics or AIDS drug assistance programs in Miami, FL TOFHLA (% correct) Men: 78% Women: 73%	Gender Education Time since HIV diagnosis Numeracy	Medication Management Test (MMT), a mock trial of medication-taking skills (interpretation of medication labels and a medication insert, counting a week's supply of medication and placing them in an organizer, and determining missed doses and refills) HL data NR	Higher HL related to better MMT score (adjusted): *P* < 0.05

Table 20. Summary of studies of the relationship between health literacy and the outcome of prevalence of depression and other mental health outcomes (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Lincoln et al., 2006[130] Prospective cohort N = 390 Fair	Adults in an inner-city short-term inpatient detoxification unit REALM Low: 46% Higher: 54%	Time Sex Age Race Education Income Primary language Primary substance of choice Randomization group Mini-mental status exam Baseline outcomes variable	Baseline CES-D: mean (SD) Low: 30.9 (11.3) Higher: 34.8 (13.32) ASI-Alc Low: 0.46 (0.34) High: 0.48 (0.34) ASI-Drug Low: 0.26 (0.13) High: 0.26 (0.15)	Depressive symptomatology No difference between groups (adjusted cross-sectional analysis): *P* = 0.09 Lower group greater (adjusted longitudinal analysis): *P* < 0.01 Alcohol addiction severity No difference between groups (adjusted cross-sectional analysis): *P* = 0.88 No difference between groups (adjusted longitudinal analysis): *P* = 0.86 Drug addiction severity No difference between groups (adjusted cross-sectional analysis: *P* = 0.11 No difference between groups (adjusted longitudinal analysis): *P* = 0.35
Nokes et al., 2007[131] Cross-sectional N = 489 Fair	HIV positive adults receiving care in San Francisco, Fresno, Richmond, NYC, Corpus Christi REALM Mean = 59.1 (SD, 12.9)	Hispanic	Depressive symptomatology: NR Distress over body changes: NR	Depressive symptomatology worse in higher health literacy group (adjusted): P < 0.05 Distress over body changes greater in higher health literacy group (adjusted): β= 2.91, P < 0.05

ASI-Alc=Addiction Severity Index - Alcohol; ASI-Drug=Addiction Severity Index - Drugs; BSI=Brief Symptom Index; CES-D=Center for Epidemiology Studies – Depression Scale; COPD=chronic obstructive pulmonary disease; HIV=human immunodeficiency virus; N=number; NALS=national adult literacy survey; NR=not reported; NYC=New York City; OH=Ohio; OR=odds ratio; PHQ=Patient Health Questionnaire; PR=Poisson Regression coefficient; REALM=Rapid Estimate of Adult Literacy in Medicine; SAHSLA=Short Assessment of Health Literacy for Spanish-speaking Adults; S-TOFHLA=Short Test of Functional Health Literacy in Adults, TX=Texas.

Table 20. Summary of studies of the relationship between health literacy and the outcome of prevalence of depression and other mental health outcomes (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Bennett et al., 2007[132] Cross-sectional N = 99 Fair	Pregnant patients Receiving prenatal care in clinics in Philadelphia S-TOFHLA-Spanish Inadequate: 18% Marginal: 15% Adequate: 67%	Mexican nativity Recent marijuana use	Elevated depressive symptomatology (CES-D ≥ 16) Inadequate HL: 44% Marginal HL: 33% Adequate HL: 18%	Inadequate group more likely than adequate group to have depressive symptomatology (adjusted): PR, 2.39; 95% CI, 1.07-5.35 No difference in depressive symptomatology between marginal and adequate groups (adjusted): PR, 1.73; 95% CI, 0.75-4.02
Kalichman et al., 2008[103] Cross-sectional N = 145 Fair	HIV positive adults in Atlanta, GA TOFHLA Lower: 49% Higher: 51%	None	Depression: Mean (SD) Lower: 10.9 (6.6) Higher: 8.7 (7.8)	No difference between groups in rate of depression (unadjusted): OR, 0.95; 95% CI, 0.91-1.00
Walker et al., 2007[133] Cross-sectional N = 363 Fair	Patients at 3 rheumatology clinics in the United Kingdom REALM Lower (< 60): 15% Adequate (≥ 60): 85%	None	Hospital Anxiety and Depression scales (HAQ and HAD) Depression, mean Lower:8.1 Adequate: 6.5 Anxiety, mean Lower: 9.4 Adequate: 7.7	Anxiety higher in lower group (unadjusted): P = 0.03 Depression higher in lower group (unadjusted): P = 0.01
Morris et al., 2006[134] Cross-sectional N = 1,002 Good	Adults with diabetes in primary care practices in Vermont S-TOFHLA Inadequate: 10% Marginal: 7% Adequate: 83%	None	Depression, Patient Health Questionnaire (PHQ) > 5 Inadequate: 40% Marginal: 54% Adequate: 31% Depression, median Patient Health Questionnaire Score Inadequate: 3 Marginal: 5 Adequate: 2	Difference across groups in depression (PHQ > 5) (unadjusted): P = 0.03 Difference across groups in median depression score (unadjusted): P = 0.04

Table 20. Summary of studies of the relationship between health literacy and the outcome of prevalence of depression and other mental health outcomes (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Sudore et al., 2006[95] (companion: Sudore et al., 2006167) Cross-sectional N = 2,512 Fair	Seniors (70-79 year old) in Pittsburgh, Pennsylvania and Memphis, Tennessee REALM 0-6th grade: 8% 7-8th grade: 15% >9th grade: 76%	None	Depression 0-6th grade: 6% 7th-8th grade: 3% > 9th grade: 2%	Difference in probability of depression across groups (unadjusted): OR, 2.54; 95% CI; 1.47-4.42
Howard et al., 2005[68] (companion: Gazmararian, 2006[61]; Wolf et al., 2007[64]; Howard et al., 2006[63]; Wolf et al., 2005[66]; Baker et al., 2008[67]; Baker et al., 2004[62]) Cohort N = 3,260 Good	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Adequate: 64% Marginal: 11% Inadequate: 24%	None	Depression Inadequate: 19% Marginal: 14% Adequate: 12%	Difference between groups in rate of depression (unadjusted): P < 0.0001
Coffman, 2010[135] Cross-sectional N=99 Fair	Spanish speaking adults who are recent immigrants recruited from two Latino service agencies SAHLSA Low HL: ≤ 39 Adequate HL: >39	Demands of immigration	CES-D (mean score) Low HL: 13.9 (9.5) High HL: 9.7 (8.3)	Lower HL related to higher depression scores (adjusted): P = 0.048
Murphy, 2010[82] Cross-sectional N= 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit TOFHLA-modified Inadequate: 12% Marginal: 3% Adequate: 86%	Age Education	Psychological distress as measured by BSI Global Severity Index No data reported by HL	No difference in BSI Global Severity Index by HL level (adjusted): P = 0531

Table 21. Summary of studies of the relationship between health literacy and the outcome of prevalence of chronic diseases (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Sentell and Halpin, 2006[141] Cross-sectional N = 23,889 Fair	National sample of adults Total NALS score Level 1: 20% Level 2: 27% Level 3: 34% Level 4: 18% Level 5: 2%	Race Education Understand English Born in US Unemployed Family income Income missing Sex Age Married Get food stamps Live in Metropolitan Statistical Area Region	Self-report of physical, mental, or other health condition that keeps respondent from working: NR Long-term illness (> 6 months): NR	Lower health literacy associated with greater odds of having a condition that keeps respondent from working (adjusted): OR, 1.11; 95% CI, 1.08-1.14 Lower health literacy associated with greater odds of having a long-term illness (adjusted): OR, 1.04; 95% CI, 1.02-1.04
Baker et al., 2007[65] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Howard et al., 2006;[63] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Prospective cohort N = 3,260 Good	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Inadequate: 24% Marginal: 11% Adequate: 64%	None	Number of chronic conditions Inadequate: mean 1.7 (SD=1.2) Marginal: mean = 1.7 (SD=1.2) Adequate: mean = 1.5 (SD=1.2)	No difference between the groups in number of chronic conditions (unadjusted): P = 0.87
Rothman et al., 2006[9] Cross-sectional N = 200 Fair	Adults in a primary care clinic REALM < HS: 23% > HS: 77%	None	Chronic illness (hypertension, coronary artery disease, high cholesterol, diabetes, or heart failure) < HS: 52% > HS: 38%	No difference between groups in percent with chronic illness (unadjusted): P = 0.08

ASI-Alc=Addiction Severity Index - Alcohol; ASI-Drug=Addiction Severity Index - Drugs; CES-D=Center for Epidemiology Studies – Depression Scale; CI=confidence interval; COPD=Chronic Obstructive Pulmonary Disease; HS=high school; N=number; NALS=National Adult Literacy Survey; NR=not reported; OH=Ohio; PR=Poisson Regression coefficient; REALM=Rapid Estimate of Adult Literacy in Medicine; S-TOFHLA=Short Test of Functional Health Literacy in Adults; SD=standard deviation; TOFHLA=Test of Functional Health Literacy in Adults; TX=Texas; US=United States.

Table 21. Summary of studies of the relationship between health literacy and the outcome of prevalence of chronic diseases (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Wolf et al., 2005[66] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Baker et al., 200;7[65] Howard et al., 2006;[63] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Cross-sectional N = 2,923 Fair	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Adequate: 67% Marginal: 11% Inadequate: 22%	Age Sex Race/ethnicity Income Education Tobacco Alcohol consumption Self-reported comorbid conditions	Hypertension Inadequate:50% Marginal: 46% Adequate: 43% Diabetes Inadequate: 19% Marginal: 15% Adequate: 13% Coronary artery disease Inadequate: 6% Marginal: 7% Adequate: 8% Heart failure Inadequate: 6% Marginal: 4% Adequate: 4% Bronchitis or emphysema Inadequate: 10% Marginal: 10% Adequate: 14% Asthma Inadequate: 7% Marginal: 8% Adequate: 7% Arthritis Inadequate: 57% Marginal: 57% Adequate: 50% Cancer Inadequate: 4% Marginal: 7% Adequate: 6%	Self-reported prevalence of chronic disease (adjusted) No difference in rates of hypertension between inadequate and adequate groups: OR, 1.20; 95% CI, 0.95-1.50 No difference in probability of hypertension between marginal and adequate groups: OR, 1.03; 95% CI, 0.80-1.34 Inadequate group had a significantly higher rate of diabetes than adequate group: OR, 1.48; 95% CI, 1.09-2.02 No difference in probability of diabetes between marginal and adequate groups: OR, 1.10; 95% CI, 0.75-1.59 No difference in coronary artery disease between inadequate and adequate groups: OR, 0.93; 95% CI, 0.59-1.47 No difference in coronary artery disease between marginal and adequate groups: OR, 0.85; 95% CI, 0.51-1.43 Inadequate group has a higher probability of heart failure than adequate group: OR, 1.69; 95% CI, 1.02-2.80 No difference in heart failure between marginal and adequate groups: OR, 0.97; 95% CI, 0.49-1.90 No difference in bronchitis or emphysema between inadequate and adequate groups: OR, 0.75; 95% CI 0.53-1.08

Table 21. Summary of studies of the relationship between health literacy and the outcome of prevalence of chronic diseases (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Wolf et al., 2005[66] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Baker et al., 2007[65] Howard et al., 2006;[63] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) (continued)				No difference in bronchitis or emphysema between marginal and adequate groups: OR, 0.81; 95% CI, 0.53-1.22 No difference in asthma between inadequate and adequate groups: OR, 0.96; 95% CI, 0.62-1.37 No difference in asthma between marginal and adequate groups: OR, 1.26; 95% CI, 0.79-2.01 No difference in arthritis between inadequate and adequate groups: OR, 0.98 95% CI, 0.78-1.23 No difference in arthritis between marginal and adequate groups: OR, 1.11; 95% CI, 0.85-1.44 No difference in cancer between inadequate and adequate groups: OR, 0.91; 95% CI, 0.54-1.52 No difference in cancer between marginal and adequate groups: OR, 1.38; 95% CI, 0.84-2.27
Howard et al., 2005[68] (companion: Gazmararian, 2006;[61] Wolf et al., 2007[64] Baker et al., 2007;[65] Howard et al., 2006;[63] Wolf et al., 2005;[66] Baker et al., 2008;[67] Baker et al., 2004[62]) Cohort N = 3,260 Good	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Adequate: 64% Marginal: 11% Inadequate: 24%	None	Heart Attack Inadequate: 15% Marginal: 18% Adequate: 13% Angina Inadequate: 8% Marginal: 12% Adequate: 8% Stroke Inadequate: 13% Marginal: 9% Adequate: 7% COPD Inadequate: 14% Marginal: 16% Adequate: 18%	Difference between groups in heart attack rate (unadjusted): P = 0.01 No differences between groups in rate of angina (unadjusted): P = 0.06 Difference between groups in rate of stroke (unadjusted): P < 0.0001 No differences between groups in rate of COPD (unadjusted): P = 0.06

Table 21. Summary of studies of the relationship between health literacy and the outcome of prevalence of chronic diseases (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Sudore et al., 2006[95] (companion: Sudore et al., 2006[167]) Cross-sectional N = 2,512 Fair	Seniors (70-79 year old) in Pittsburgh, Pennsylvania and Memphis, Tennessee REALM 0-6th grade: 8% 7-8th grade: 15% > 9th grade: 76%	None	Hypertension 0-6th grade: 62% 7th-8th grade: 63% > 9th grade: 55% Diabetes 0-6th grade: 25% 7th-8th grade: 26% >9th grade: 15%	Difference in probability of hypertension across groups (unadjusted): OR, 1.39; 95% CI, 1.25-1.68 Difference in probability of diabetes across groups (unadjusted): OR, 1.98; 95% CI, 1.58-2.48
Laramee et al., 2007[143] Cross-sectional N = 998 Fair	Adults with diabetes in primary care practices in Vermont, New Hampshire, and northern New York State S-TOFHLA Limited: 17% Adequate: 83%	None	Heart failure Limited: 27% Adequate: 15%	Limited group higher rate of heart failure (unadjusted): OR, 2.05; 95% CI, 1.39-3.02
Kim, 2009[142] Cross-sectional N= 103 Fair	Korean older adults (> 60 years) Korean Functional Health Literacy test (TOFHLA) High literacy (≥5): 58% Low literacy (<5): 42%	None	Self-report of chronic disease Arthritis Low HL: 51.2% High HL: 21.7% Hypertension Low HL: 44.2% High HL: 21.7% Sensory disease Low HL: 39.5% High HL: 23.3% Diabetes mellitus Low HL: 45.5% High HL: 54.5% Pulmonary disease Low HL: 16.3% High HL: 10.0% Heart disease Low HL: 8.3% High HL: 2.3%	Difference in probability of arthritis between groups (unadjusted): P = 0.003 Difference in probability of hypertension between groups (unadjusted): P = 0.018 Difference in probability of sensory disease between groups (unadjusted): P = 0.086 Difference in probability of diabetes mellitus between groups (unadjusted): P = 0.808 Difference in probability of pulmonary disease between groups (unadjusted): P = 0.380 Difference in probability of heart disease between groups (unadjusted): P = 0.397

Table 22. Summary of studies of the relationship between health literacy and HIV patient symptoms (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Paasche-Orlow et al., 2006[105] Retrospective cohort N = 235 Fair	Patients with HIV and a history of alcohol problems in Boston, MA REALM Low: 14% Marginal: 29% Adequate: 57%	Gender Age Education Randomization group Ethnicity Homeless status Drank to intoxication past 30 days Injected drugs past 6 months Complexity of regimen Medication adherence	Viral load suppressed Low: 63% Marginal: 58% Adequate: 61%	Viral load (HIV-RNA) suppression No difference between low and adequate groups (adjusted): OR, 1.70; 95% CI, 0.79-3.65 No difference between marginal and adequate groups (adjusted): OR, 1.29; 95% CI, 0.77-2.18
Mayben et al., 2007[145] Cross-sectional N = 119 Fair	Adults with HIV receiving care at 4 publicly funded clinics in Houston, TX TOFHLA Inadequate: 28% Adequate: 72%	Gender Reason for getting tested Marijuana use	CD4 cell count: median (interquartile range) Inadequate: 175 (69, 272) Adequate: 247(31, 517)	No difference in CD4 cell count between adequate and inadequate groups (adjusted): $P = 0.35$
Nokes et al., 2007[131] Cross-sectional N = 489 Fair	HIV-positive adults receiving care in San Francisco, Fresno, Richmond, NYC, Corpus Christi REALM Mean = 59.1 (SD, 12.9)	Hispanic	HIV-symptom intensity: NR	HIV-symptom intensity greater in higher health literacy group (adjusted): β, 8.62; $P < 0.05$
Kalichman et al., 2008[103] Cross-sectional N = 145 Fair	HIV-positive adults in Atlanta, GA TOFHLA Lower: 49% Higher: 51%	None	HIV symptoms: Mean (SD) Lower: 4.0 (3.2) Higher: 4.7 (3.9)	No difference between groups in number of HIV symptoms (unadjusted): OR, 1.05; 95% CI, 0.95-1.14
Murphy, 2010[82] Cross-sectional N= 186 Fair	HIV-positive individuals ages 16-24 in Fort Lauderdale, Philadelphia, Baltimore, Los Angeles, and Detroit TOFHLA-modified Inadequate: 12% Marginal: 3% Adequate: 86%	Age Education	Viral load (plasma HIV-1 RNA): Mean (SD) Marginal/ Inadequate: 3.82 (1.08) Adequate: 3.69 (1.19) CD4 measures Data NR	No relationship between viral load and HL (adjusted): $P = 0.13$ No relationship between CD4 count and HL (adjusted): $P = 0.15$

CD4=Classification of Disease, Version 4; CES-D=Center for Epidemiology Studies – Depression Scale; CI=confidence interval; COPD=Chronic Obstructive Pulmonary Disease; GA=Georgia; HIV=human immunodeficiency virus; N=number; NR=not reported; NYC=New York City; OR=odds ratio; PR=Poisson Regression coefficient; REALM=Rapid Estimate of Adult Literacy in Medicine; RNA=Ribonucleic Acid; S-TOFHLA=Short Test of Functional Health Literacy in Adults; SD=standard deviation; TOFHLA=Test of Functional Health Literacy in Adults; TX=Texas.

Table 23. Summary of studies of the relationship between health literacy and asthma patient symptoms (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Shone et al., 2009[84] Cross-sectional N = 499 Fair	Parents of children with persistent asthma in Rochester New York School District REALM Low: 33% Adequate: 67%	Child health insurance Parent's employment, ethnicity, and race	Asthma is not under good control Low: 76% Adequate: 82% Child's health is fair/poor Low: 39% Adequate: 17%	No difference between groups in rate of asthma not under good control (unadjusted): P = 0.094 Parents' in low group more likely to have child with fair/poor health (adjusted): OR, 3.96; 95% CI, 2.4-6.4
DeWalt et al., 2007[80] Cross-sectional N = 150 Fair	Parents of children with asthma receiving care at 3 clinics in North Carolina REALM Lower: 24% Higher: 76%	None	Albuterol Use (mean days per week) Lower: 2.7 Higher: 1.5 Albuterol Use (total mean use per week) Lower: 6 doses Higher: 3 doses Appropriate Controller Use Lower: 68% Higher: 82%	Greater Albuterol use in children of parents in lower compared to higher health literacy group (unadjusted): P = 0.01 Greater total weekly Albuterol use in children of parents in lower compared to higher health literacy group (unadjusted): P = 0.03 No difference between groups in appropriate controller use (unadjusted): P = 0.15

CI=confidence interval; N=number; OR=odds ratio; REALM=Rapid Estimate of Adult Literacy in Medicine.

Table 24. Summary of studies of the relationship between health literacy and diabetes control (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Morris et al., 2006[134] Cross-sectional N = 1,002 Good	Adults with diabetes in primary care practices in Vermont S-TOFHLA Inadequate: 10% Marginal: 7% Adequate: 83%	Age Sex Race Marital status Insurance Income Duration of diabetes Diabetes education Depression Alcohol use Medication use Physician practice	HbA1c median Inadequate: 6.9% Marginal: 6.8% Adequate: 6.9% SBP median Inadequate:137 Marginal: 144 Adequate: 138 DBP median Inadequate: 76 Marginal: 77 Adequate: 79 LDL-cholesterol median Inadequate: 99 Marginal: 94 Adequate: 99 Retinopathy Inadequate: 30% Marginal: 34% Adequate: 18% Nephropathy Inadequate: 15% Marginal: 0 Adequate: 9% Gastroparesis Inadequate: 9% Marginal: 6% Adequate: 6% Foot/leg problems Inadequate: 30% Marginal: 30% Adequate: 30% Cerebrovascular disease Inadequate: 21% Marginal: 17% Adequate: 10%	No difference in HbA1c levels across groups (adjusted, continuous TOFHLA scores used): P = 0.88 No difference in SBP across groups (adjusted, continuous TOFHLA scores used): P = 0.78 No difference in DBP across groups (adjusted, continuous TOFHLA scores used): P = 0.39 No difference in LDL-cholesterol across groups (adjusted, continuous TOFHLA scores used): P = 0.59 Retinopathy rates No difference between inadequate and adequate group (adjusted): OR, 1.88; 95% CI, 0.90-3.91 No difference between marginal and adequate groups (adjusted): OR, 2.30; 95% CI, 0.63-8.44 Nephropathy No difference between inadequate and adequate groups (adjusted): OR, 1.05; 95% CI, 0.39-2.80 No difference between marginal and adequate groups (adjusted): OR, 0.99; 95% CI, 0.95-1.03

C-SDSCA=Chinese version of Summary of Diabetes Self-Care Activities; CI=confidence interval; DBP=diastolic blood pressure; Hb=hemoglobin; HL=health literacy; LDL=Low-density lipoprotein; N=number; OR=odds ratio; REALM=Rapid Estimate of Adult Literacy in Medicine; S-TOFHLA-Spanish=Short Test of Functional Health Literacy in Adults–Spanish; SBP=systolic blood pressure; TOFHLA=Test of Functional Health Literacy in Adults.

Table 24. Summary of studies of the relationship between health literacy and diabetes control (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Morris et al., 2006[134] (continued)			Coronary artery disease Inadequate: 30% Marginal: 27% Adequate: 17%	Foot/leg problem rates No difference between inadequate and adequate groups (adjusted): OR, 0.52; 95% CI, 0.24-1.16 No difference between marginal and adequate groups (adjusted): OR, 1.39; 95% CI, 0.47-4.12 Gastroparesis No difference between inadequate and adequate groups (adjusted): OR, 1.92; 95% CI, 0.58-6.36 No difference between marginal and adequate groups (adjusted): OR, 1.98; 95% CI, 0.26-18.07 Cerebrovascular disease No difference between inadequate and adequate groups (adjusted): OR, 0.86; 95% CI, 0.39-1.91 No difference between marginal and adequate groups (adjusted): OR, 0.65; 95% CI, 1.66-2.57 Coronary artery disease No difference between inadequate and adequate groups (adjusted): OR, 0.76; 95% CI, 0.36-1.63

Table 24. Summary of studies of the relationship between health literacy and diabetes control (KQ 1b)(continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Morris et al., 2006[134] (continued)				No difference between marginal and adequate groups (adjusted): OR, 1.12; 95% CI, 0.34-3.70
Tang et al., 2007[148] Cross-sectional survey and medical chart review N = 149 Fair	Adults with diabetes in diabetes education management center of a public hospital in Hong Kong Chinese S-TOFHLA: Levels NR	Gender Insurance Duration of diabetes Patient awareness score C-SDSCA (management of diabetes)	HbA1c levels outcomes: NR	Higher HL associated with lower HbA1c levels (adjusted): *P* < 0.001
Powell et al., 2007[149] Cross-sectional N = 68 Fair	Patients with Type 2 diabetes treated in general internal medicine clinic REALM < 4th grade: 13% 4th-6th grade: 25% 7th-8th grade: 19% High school: 43%	Education Age Race Gender Treatment regimen	HbA1c median <4th grade: 8% 4th-6th grade: 8% 7th-8th grade: 10% HS: Median: 7.9%	Difference in HbA1c level between groups (adjusted): *P* = 0.02
Schillinger et al., 2006[150] Cross-sectional N = 395 Good	Adult diabetes patients (> 30 years old) treated at one of two primary care clinics at San Francisco General Hospital S-TOFHLA Mean = 20.6 (SD=12.1)	Age Primary language other than English Insurance Education	Log HbA1c: NR	HL mediated the direct relationship between education and HbA1c level in a partial mediation model (adjusted path analysis): *P* < 0.05 HL mediated the direct relationship between education and HbA1c level in a full mediation model (adjusted path analysis): *P* = 0.03

Table 24. Summary of studies of the relationship between health literacy and diabetes control (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Mancuso et al, 2010[151] Cross-sectional N=102 Good	Adults with a diagnosis of type 1 or 2 diabetes in 2 urban Midwestern US primary care clinics TOFHLA Inadequate: 16% Marginal: 21% Adequate: 63%	Patient trust depression diabetes knowledge performance of self-care activities	HbA1c by HL level: NR	No difference between HL groups in HbA1c (adjusted): P = 0.436

Table 25. Summary of studies of the relationship between health literacy and hypertension control (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Powers et al., 2008[154] Cross-sectional N = 1,224 Fair	Patients with hypertension receiving primary care in the VA healthcare system and Duke University Healthcare system in Durham, NC. REALM VA Limited: 38% Adequate: 58% Duke Limited: 28% Adequate: 72%	Age Race Marital status Education Adequacy of income Diabetic status Medication Adherence Smoking Exercise Participatory decision-making score	SBP: mean (SD) VA Limited: 138.7 (17.8) Adequate: 138.4 (17.5) Duke Limited: 142 (24.9) Adequate: 133 (17.6)	The relationship between HL and blood pressure level differed in the two healthcare systems (adjusted) (moderator analysis) HL main effect: β = -1.2; 95% CI, -4.8-2.3 Interaction between HL and healthcare system: β = 7.4; 95% CI, 2.5-12.3
Pandit et al., 2009[155] Cross-sectional N = 330 Fair	Adults with hypertension receiving primary care from clinics in Grand Rapids, Michigan, Chicago, Illinois, and Shreveport, Louisiana	Age Race Gender Marital status Employment status Insurance coverage Site location	Controlled Blood Pressure Category I: 34% Category II: 49% Category III: 45% Category IV: 61% Category V: 46% (highest)	Category V group has greater odds of having controlled BP than Category I group (adjusted): RR, 2.68; 95% CI, 1.54-4.70
Pandit et al., 2009[155] (continued)	S-TOFHLA Category I: 17% Category II: 11% Category III: 16% Category IV: 26% Category V: 31%	Number of comorbid conditions Years treated for hypertension Clinic site Education		No difference between Category II and Category V in odds of having controlled BP (adjusted): RR, 1.47; 95% CI, 0.53-4.05 Category V group has greater odds of having controlled BP than Category III group (adjusted): RR, 1.69; 95% CI, 1.08-2.63 No difference between Category IV and Category V in odds of having controlled BP (adjusted): RR, 1.10; 95% CI, 0.40-3.01

BP=blood pressure; CI=confidence interval; PSA=prostate-specific antigen; REALM=Rapid Estimate of Adult Literacy in Medicine; RR=relative risk; S-TOFHLA=Short Test of Functional Health Literacy in Adults; SD=standard deviation; SBP=systolic blood pressure; VA=veterans administration.

Table 26. Summary of studies of the relationship between health literacy and prostate cancer control (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Outcomes Between Health Literacy Levels
Wolf et al., 2006[157] Cross-sectional N = 308 Good	Patients with newly diagnosed prostate cancer in 4 outpatient oncology and urology clinics in Chicago area REALM Low: 18% Marginal: 33% Functional: 50%	Age Race Annual income Marital status	PSA Level > 20 mg/mL Marginal: 24% Low: 33% Functional: 14%	Low group more likely to have elevated PSA than functional group (adjusted): OR, 2.5; 95% CI, 1.5-4.2 No difference in rates of elevated PSA between marginal and functional groups (adjusted): OR, 1.4; 95% CI, 0.9-2.2

CI=confidence interval; mg/mL=milligram/millileter; OR=odds ratio; PSA=prostate-specific antigen; REALM=Rapid Estimate of Adult Literacy in Medicine.

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Smith and Haggerty, 2003[159] Cross-sectional N = 229 Fair	Adults in University-affiliated family practice center in Montreal, Canada REALM Low: 6% Adequate: 94%	Age Smoking status Maternal language	Perceived overall health Low: mean = 3.3 Adequate: mean = 3.0	No difference between groups in perceived general health (adjusted): β = -0.11; 95% CI, -0.25-0.03
Bennett et al., 200985 (companion: White et al., 2008[86]) Cross-sectional N = 2,668 Good	Nationally representative sample of US population, 65 years and older NAAL Below basic: 29.0% Basic: 29.5% Intermediate: 38.2 Proficient: 3.3%	Race Income Gender Age Nativity	Health status levels by health literacy level: NR	Higher health literacy associated with better self-reported health status (adjusted): P < 0.05

ADL=activities of daily living; AQLQ=Asthma Quality of Life Questionnaire; BMI=body mass index; FACT-G=Functional Assessment of Cancer Therapy-General; HR=hazard ratio; HRQoL=health-related quality of life; IADL=instrumental activities of daily living; N=number; NAAL=National Assessment of Adult Literacy; NALS=National Adult Literacy Survey; NR=not reported; OR=odds ratio; PCS=Physical Component Summary; REALM=Rapid Estimate of Adult Literacy in Medicine; SD=standard deviation; SF=short form; S-TOFHLA=Short Test of Functional Health Literacy in Adults; USUnited States; VRQoL=vision-related quality of life.

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Analysis 1 Cho et al., 2008[81] Cross-sectional N = 489 Fair Analysis 2 Lee, 2009[160] Cross-sectional N = 489 Fair	Seniors who are patients at 1 of 2 Chicago clinics S-TOFHLA Inadequate/ marginal: 51% adequate: 49%	Analysis 1 Race/ethnicity Gender Education Analysis 2 Age Gender Race Education Marital status Income Social support level	Health status (self-report) Levels: NR General health (self-report) Levels: NR Physical health (SF-12) Levels: NR Mental health (SF-12) Levels: NR	Analysis 1 Using path analysis, higher health literacy level related to better health status (adjusted): *P* < 0.05 Analysis 2 Low health literacy associated with lower level of general health status(adjusted): *P* < 0.05 No difference between groups in physical health (adjusted): *P* = NS No difference between groups in mental health (adjusted): *P* = NS
Analysis 1 Howard, 2006[63] Prospective cohort N = 3,260 Fair Analysis 2 Baker et al., 2007[65] (companions: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Prospective cohort N = 3,260 Good	New Prudential Medicare managed-care enrollees in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 25% Marginal: 11% Adequate: 64%	Analysis 1 Age Gender Race/ethnicity Education Income Site Morbidity Smoker Analysis 2 None	Physical HRQoL (SF-12) Inadequate: mean = 41.9 (SD=11.9) Marginal: mean = 43.6 (SD=11.7) Adequate: mean = 46.2 (SD=10.7) Mental HRQoL (SF-12) Inadequate: mean 52.1 (SD=10.7) Marginal: mean = 54.9 (SD=9.2) Adequate: mean 55.5 (SD=7.9) IADL limitation Inadequate: 46% Marginal: 37% Adequate: 24% ADL limitation Inadequate: 9% Marginal: 6% Adequate: 3%	Analysis 1 Inadequate group poorer physical HRQoL than adequate (adjusted): *P* < 0.001 Marginal group poorer physical HRQoL than adequate (adjusted): *P* =0.019 Inadequate group poorer mental HRQoL than adequate (adjusted): *P* < 0.001 No difference in mental HRQoL between marginal and adequate groups (adjusted): *P* = 0.304 Inadequate group less likely to self-report health status of good or better than adequate groups (adjusted): OR, 0.71; *P* = 0.004 No differences in self-reported health status of good or better between marginal and adequate groups (adjusted): OR, 0.77; *P* = 0.060

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Analysis 1 Howard, 2006[63] (continued)				Analysis 2 Significant difference between 3 HL groups in IADL limitation (unadjusted): $P < 0.001$ Significant difference between 3 HL groups in ADL limitation (unadjusted): $P < 0.001$
Sudore et al., 2006[95] (companion: Sudore, 2006[167]) Cross-sectional N = 2,512 Fair	Seniors (70-79 year old) in Pittsburgh, Pennsylvania and Memphis, Tennessee REALM 0-6th grade: 8% 7-8th grade: 15% ≥9th grade: 76%	None	Self-report poor health 0-6th grade: 33% 7th-8th grade: 28% ≥ 9th grade: 14%	Difference in probability of poor health across groups (unadjusted): OR, 2.60; 95% CI, 2.09-3.23
Wolf et al., 2005[66] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Baker et al., 2007;[65] Howard et al., 2005;[68] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Cross-sectional N = 2,923 Fair	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Inadequate: 22% Marginal: 11% Adequate: 67%	Age Sex Race/ethnicity Income Education Tobacco Alcohol consumption Self-reported comorbid conditions	Physical function (SF-36) mean (SD) Inadequate: 67.7 (9.7) Marginal: 73.7 (27.5) Adequate: 78.0 (24.6) Mental health functioning (SF-36) mean (SD) Inadequate: 76.2 (20.9) Marginal: 81.8 (18.6) Adequate: 84.0 (16.1)	Inadequate group lower physical function scores than adequate group (adjusted): β, -6; 95% CI, -8.4-3.5 Marginal lower physical function scores than adequate group (adjusted): β, -1.1; 95% CI, -3.9-1.8 Inadequate group lower mental health scores than adequate group (adjusted): β, -4.9; 95% CI, -6.7 to -3.1 Marginal group lower mental health score than adequate group (adjusted including education): β, -0.9; 95% CI, -2.9-1.2 Inadequate group has greater self-reported instrumental activity limitations than adequate group (adjusted including ed): OR, 2.25; 95% CI, 1.74-2.92 Marginal group has greater instrumental activity limitations than adequate group: OR, 1.65; 95% CI, 1.22-2.24

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Wolf et al., 2005[66] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Baker et al., 2007;[65] Howard et al., 2005;[68] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) (continued)				Inadequate group has greater self-reported activity limitations than adequate group (adjusted included): OR, 2.83; 95% CI, 1.62-4.96 Marginal group has greater activity limitations than adequate group (adjusted): OR, 2.05; 95% CI, 1.06-3.97 Inadequate group has greater limitations due to physical health than adequate group (adjusted): OR, 1.79; 95% CI, 1.39-2.32 No differences in limitations because of physical health between adequate and marginal groups (adjusted): OR, 1.35; 95% CI, 1.00-1.84 Inadequate group has fewer accomplishments due to physical health than adequate group (adjusted): OR, 1.90; 95% CI, 1.48-2.45 Marginal has fewer accomplishments than marginal group (adjusted): OR, 1.46; 95% CI, 1.08-1.97 Inadequate group has greater pain interfering with activities than adequate group (adjusted): OR, 2.01; 95% CI, 1.46-2.77 No difference in pain interfering with activities between marginal and adequate groups (adjusted): OR, 1.23; 95% CI, 0.83-1.82

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Muir et al., 2008[161] Cross-sectional N = 110 Fair	Glaucoma patients at a Duke eye clinic in Durham, NC REALM Low: 52% Adequate: 48%	Age Race Visual acuity Visual field Education	VRQoL score (mean) Low: 84 Adequate: 76 Physical HRQoL (SF-12): NR Mental HRQoL (SF-12): NR	No difference between groups in VRQoL (adjusted): P = 0.621 Low HL associated with poorer physical HRQoL (unadjusted): P = 0.002 No difference between groups in mental HRQoL (unadjusted): P = 0.068
Nokes et al., 2007[131] Cross-sectional N = 489 Fair	HIV-positive adults receiving care in San Francisco, Fresno, Richmond, NYC, Corpus Christi REALM Mean = 59.1 (SD, 12.9)	Hispanic	Global physical health (scale developed by investigators): mean (SD) Lower: 7.21, (2.42) Higher: 6.68, (2.22)	Physical health rated lower in higher group (unadjusted): P = 0.02
Mancuso and Rincon, 2006[100] Cross-sectional N = 175 Fair	Adults with asthma enrolled in a primary care practice in New York City TOFHLA Adequate: 82% Marginal: 8% Inadequate: 10%	Asthma severity asthma self-efficacy Age Education Depressive symptoms Asthma knowledge	Outcome data by health literacy level: NR	Lower HL related to poorer AQLQ (adjusting for asthma severity, asthma self-efficacy): P = 0.003 Lower HL related to poorer AQLQ (adjusting for asthma severity, asthma self-efficacy, age and education): P = 0.03 No difference in AQLQ by HL level (adjusting for asthma severity, asthma self-efficacy, age, education, depressive symptoms): P = 0.07 No difference in AQLQ by HL level (adjusting for asthma severity, asthma self-efficacy, age, education, depressive symptoms, asthma knowledge): P = 0.38 Lower HL related to poorer Physical HRQoL (SF-36) (adjusting for asthma severity and asthma self-efficacy): P = 0.0003

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Mancuso and Rincon, 2006[100] (continued)				No difference in physical HRQoL (SF-36) by HL level (adjusting for asthma severity, asthma self-efficacy, age and education): *P* = 0.11 No difference in physical HRQoL (SF-36) by HL level (adjusting for asthma severity, asthma self-efficacy, age, education and depressive symptoms): *P* = 0.22 No difference in SF-36 by HL level (adjusting for asthma severity, asthma self-efficacy, age, education, depressive symptoms and asthma knowledge): *P* = 0.53
Johnston et al., 2005[162] Cross-sectional N = 107 Fair	Adult patients at spinal cord injury clinic in New Jersey TOFHLA Inadequate: 6% Marginal: 8% Adequate: 86%	Motor index Education	Outcome data by health literacy level: NR	Having less than adequate HL associated with poorer physical morbidity (number of days physical health "not good") (adjusted): *P* < = 0.05 No difference between groups in mental health morbidity (number of days mental health "not good") (adjusted): *P* = 0.90 No difference between groups in SF-12 Physical Component score (adjusted): *P* = 0.49 No difference between groups in SF-12 Mental Component score (adjusted): *P* = 0.07 No difference between groups in physical independence (adjusted): *P* = 0.47 No difference between groups in mobility (adjusted): *P* = 0.93

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Hahn et al., 2007[163] Cross-sectional N = 415 Good	Adult cancer patients in 5 Chicago-area cancer centers Passage comprehension subtest of Woodcock Language Proficiency Battery Low: 52% High: 48%	Age Gender Race/ethnicity Work status Marital status Living arrangement Socioeconomic status Prior computer experience Cancer diagnosis Stage at diagnosis Months since diagnosis Current chemotherapy treatment Performance status	FACT-G mean (SD) Physical well-being Low: 17.9 (5.9) High: 18.4 (5.8) Emotional well-being Low: 17.6 (5.2) High:17.5 (4.7) Functional well-being Low: 15.7 (6.5) High: 16.0 (6.3) SF-36 mean (SD) Physical functioning Low: 48.7 (26.7) High: 57.2 (27.5) Role-physical Low: 29.7 (38.2) High: 34.8 (42.4) Bodily pain Low: 55.5 (26.9) High: 56.0 (24.9) General health Low: 49.9 (20.6) High: 53.2 (21.3) Vitality Low: 51.5 (21.4) High: 47.3 (20.5) Mental health Low: 65.5 (19.6) High: 66.9 (20.2) Fair/poor health Low: 53.3% High: 39% Standard Gamble utility score Low: mean = 0.87 (0.20) High: mean = 0.85 (0.23)	No difference between groups on any of the FACT-G scale items (adjusted) No difference between groups on SF-36 including and excluding biased scale items (adjusted) Difference standard Gamble utility score (unadjusted): *P* = 0.561

Table 27. Summary of studies of the relationship between health literacy and health status (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Kim, 2009[142] Cross-sectional N= 103 Fair	Korean older adults (> 60 years) Korean Functional Health Literacy test (TOFHLA) High literacy (≥5): 58% Low literacy (<5): 42%	Age Education Income	Physical function (SF-12) Low HL: 40.34 (10.3) High HL: 46.71 (9.8) Limitations in activity Low HL: 51.11 (8.6) High HL: 44.64 (10.8) Pain that interfered with normal work Low HL: 47.08 (10.6) High HL: 40.37 (12.3) Subjective general health (SF-12) Low HL: 36.97 (11.5) High HL: 44.88 (12.0) Mental health status (SF-12) Low HL: 45.13 (9.82) High HL: 48.88 (6.53)	No difference in physical function by HL level (adjusted): P = 0.06 Limitations in activities worse in low HL group (adjusted): P = 0.025 Pain that interfered with normal work worse in low HL group (adjusted without education): P = 0.044 Subjective general health worse in low HL group (adjusted): P = 0.036 No difference in mental health status by HL level (adjusted): P =0.15

Table 28. Summary of studies on the relationship between health literacy and mortality (KQ 1b)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Baker et al., 2007[65] (Analysis 1) Baker et al., 2008[67] (Analysis 2) (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Howard et al., 2006;[63] Wolf et al., 2005;[66] Howard et al., 2005;[68] Baker et al., 2004[62]) Prospective cohort N = 3,260 Good	New Prudential Medicare managed care enrollees in Cleveland, OH; Houston, TX; and Tampa and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA Inadequate: 24% Marginal: 11% Adequate: 64%	Baseline measures: Number of chronic conditions Physical health score Mental health score IADL limitation ADL limitation Smoking Alcohol use Vigorous physical activity BMI	All-cause mortality rate Inadequate: 39% Marginal: 29% Adequate: 19% Cardiovascular mortality rate Inadequate: 19% Marginal: 17% Adequate: 8% Cancer mortality rate Inadequate: 9% Marginal: 5% Adequate: 6% Noncardiovascular/ noncancer mortality rate Inadequate: 11% Marginal: 7% Adequate: 5%	Analysis 1 All-cause mortality Inadequate group had a greater rate than adequate group (adjusted): HR,1.52; 95% CI, 1.26-1.83 No difference between marginal and adequate groups (adjusted): HR, 1.13; 95% CI, 0.90-1.41 Cardiovascular mortality Inadequate group had a greater rate than the adequate group (adjusted): HR, 1.52; 95% CI, 1.16-2.00 Marginal group had a greater rate than the adequate group (adjusted): HR, 1.39; 95% CI, 1.02-1.90 Cancer mortality No difference between inadequate and adequate groups (adjusted): HR, 1.18; 95% CI, 0.81-1.72 No difference between marginal and adequate groups (adjusted): HR, 0.65; 95% CI, 0.38-1.09 All other causes mortality Inadequate group has a greater rate than the: adequate group (adjusted): HR, 1.87; 95% CI, 1.32-2.67

ADL=activities of daily living; AQLQ=Asthma Quality of Life Questionnaire; BMI=body mass index; CI=confidence interval; HR=hazard ratio; HRQoL=health-related quality of life; IADL=Instrumental activities of daily living; N=number; OH=Ohio; OR=Odds ratio; TN=Tennessee; TX=Texas.

Table 28. Summary of studies on the relationship between health literacy and mortality (KQ 1b) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Baker et al., 2007[65] (Analysis 1) Baker et al., 2008[67] (Analysis 2) (continued)				No difference between marginal and adequate groups (adjusted): HR, 1.18; 95% CI, 0.76-1.85 Analysis 2 All-cause mortality (adjusted for all confounders and level of cognitive functioning) Inadequate group has a greater rate than adequate (adjusted): HR, 1.27; 95% CI, 1.03-1.57 No difference between marginal and adequate group (adjusted): HR, 1.08; 95% CI, 0.85-1.36
Sudore et al., 2006[167] (companion: Sudore et al., 2006[95]) Prospective cohort, retrospective analysis N = 2,512 Good	Seniors (70-79 year old) in Pittsburgh, PA, and Memphis, TN REALM Limited: 24% Adequate: 76%	Demographics: age, race, gender, income, education Health status: self-rated health, cardiac disease, stroke, cancer, hypertension, diabetes, obesity Health-related behaviors: former or current smoker, drinking >1 alcoholic beverage per day Poor health care access: lack of a regular doc or clinic, no flu shot within past 12 months, no insurance for medications Psychosocial status: high depressive symptoms, poor personal mastery	Mortality rate Limited: 20% Adequate: 11%	Limited group greater odds of dying than adequate group (adjusted): HR, 1.75; 95% CI, 1.27-2.41 Limited group greater odds of dying than adequate group (adjusted, excluding participants with cognitive impairment): HR, 1.94; 95% CI, 1.37-2.74

Table 29. Summary of studies of the relationship between health literacy and costs (KQ 1c)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Howard, et al., 2005[68] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Baker et al., 2007;[65] Howard et al., 2006;[63] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Prospective cohort N = 3,260 S-TOFHLA Good	New Medicare managed-care enrollees in Cleveland, Houston, Tampa, and south Florida S-TOFHLA Inadequate: 25% Marginal: 11% Adequate: 64%	Age Sex Race/ethnicity Income Education Tobacco Alcohol consumption Self-reported comorbid conditions	Costs 1-year period Overall mean (SD) Inadequate: $9,614 ± $22,536 Marginal: $8,484 ± $16,646 Adequate: $7,246 ± $17,941 Inpatient mean (SD) Inadequate: $6,817 ± $21,049 Marginal: $5,857 ± $15,240 Adequate: $4,656 ± $16,428 Outpatient mean (SD) Inadequate: $1,970 ± $3,477 Marginal: $1,727 ± $2,954 Adequate: $1,805 ± $3,188 ED mean (SD) Inadequate: $189 ± $551 Marginal: $182 ± $593 Adequate: $100 ± $360 Pharmacy mean (SD) Inadequate: $638 ± $1,267 Marginal: $719 ± $998 Adequate: $684 ± $890	Overall costs (adjusted) No difference between inadequate and adequate groups: β, $1,551; 95% CI, -$166-$3,267 No difference between marginal and adequate groups: β, $596; 95% CI, -$1,437-$2,630 Inpatient costs (adjusted) No difference between inadequate and adequate groups: β, $1,543; 95% CI, -$89-$3,175 No difference between marginal and adequate groups: β, $748; 95% CI, -$1,252-$2,748 Outpatient costs (adjusted) No difference between inadequate and adequate groups: β, -$213; 95% CI, -$481-$55 Costs lower in marginal group: β, -$350; 95% CI, -$679 to -$20 ED costs (adjusted) Higher costs in inadequate group: β, $108; 95% CI, $62-$154 Higher costs in marginal group: β, $80; 95% CI, $28-$132 Pharmacy costs (adjusted) No difference between inadequate and adequate group: β, $27; 95% CI, -$55-$110 No difference between marginal and adequate groups: β, $35; 95% CI, -$62-$132

CI=-confidence interval; ED=-emergency department; IDR=Instrument for the Diagnosis of Reading; N=number; S-TOFHLA=Short Test of Functional Health Literacy in Adults; SD=standard deviation.

Table 29. Summary of studies of the relationship between health literacy and costs (KQ 1c) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Weiss et al. 2004[168] Retrospective cohort N = 74 Fair	Medicaid beneficiaries in Arizona IDR Low: 24% Higher: 76%	Age Ethnic group Health status	Total costs, 1-year period, mean (range) Low: $10,688 ($0-$95,002) Higher: $2,890 ($0-38,957)	Medicaid costs over a 1-year period higher in low group (adjusted) (P = 0.037)

Table 30. KQ 1c health literacy studies: strength of evidence grades by costs of health care

Outcome for Health Literacy Studies	Number of Studies	Results	Strength of Evidence Grade
Costs of health care	2	Mixed results across payment source and patient populations	Insufficient

Table 31. Summary of studies of the relationship between health literacy and disparities (KQ 1d)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure: Outcomes By Health Literacy Level	Outcome Measure: Differences in Results Between Health Literacy Levels
Sentell and Halpin, 2006[141] Cross-sectional N = 23,889 Fair	National sample of adults Total NALS score Level 1: 20% Level 2: 27% Level 3: 34% Level 4: 18% Level 5: 2%	Race Education Understand English Born in U.S.A. Unemployed Family income Income missing Sex Age Married Get food stamps Live in Metropolitan Statistical Area Region	Self report of physical, mental, or other health condition that keeps respondent from working Data: NR Long-term illness (greater than 6 months) Data: NR	Health literacy mediates the association of black race on having a condition that keeps you from work (adjusted): Odds associated with black race, not controlling for health literacy: OR 1.54, 95% CI, 1.29-1.84 Odds associated with black race, controlling for health literacy: OR 1.04; 95% CI, 0.85-1.26 Health literacy mediates the effect of black race on having long-term illness (adjusted) Odds associated with black race, not controlling for health literacy: OR 1.24; 95% CI, 1.03-1.49 Odds associated with black race, controlling for health literacy: OR, 1.07; 95% CI, 0.89-1.30
Howard, 2006[63] (companion: Gazmararian, 2006;[61] Wolf et al., 2007;[64] Baker et al., 2007;[65] Wolf et al., 2005;[66] Baker et al., 2008;[67] Howard et al., 2005;[68] Baker et al., 2004[62]) Cohort N = 3,260 Fair	New Prudential Medicare managed care enrollees in Cleveland, Ohio, Houston, Texas, Tampa, and south Florida (including Ft. Lauderdale and Miami) S-TOFHLA By race: White: Adequate: 71% Marginal: 10% Inadequate: 19% Black: Adequate: 36% Marginal: 12% Inadequate: 52%	Age Gender Race/ethnicity Education Income Site Morbidity Smoker	Physical HRQoL mean (SF-12) White: 44.9 Black: 43.6 Mental HRQoL mean (SF-12) White: 55.7 Black: 53.0 Self-reported health good or higher White: 0.39 Black: 0.23 Receipt of influenza vaccine White: 0.826 Black: 0.701 Receipt of pneumococcal vaccine White: 0.48 Black: 0.29	Physical HRQoL (difference in scores between white and black, adjusted) Not controlling for health literacy: 0.1 Controlling for health literacy: -0.5 Difference between models: (0.6, 95% CI, 0.3-0.9) Mental HRQoL (difference in scores between white and black, adjusted) Not controlling for health literacy: 0.5 Controlling for health literacy: 0.2 Difference between models: (0.3, 95% CI, 0.1-0.5) Self-reported health good or higher (difference in scores between white and black, adjusted) Not controlling for health literacy: 0.8 Controlling for health literacy: 0.6

CI=confidence interval; Hb=hemoglobin; HIV=human immunodeficiency virus; HL=health literacy; HR=hazard ratio; HRQoL=health related quality of life; N=number; NAAL=National Assessment of Adult Literacy; NALS=National Adult Literacy Survey; NR=not reported; NS=not sufficient; OR=odds ratio; OTC=over the counter; PSA=prostate-specific antigen; REALM=Rapid Estimate of Adult Literacy in Medicine; SE=standard error; SF-12=Short Form 12; S-TOFHLA=Short Test of Functional Health Literacy in Adults; US=United States.

Table 31. Summary of studies of the relationship between health literacy and disparities (KQ 1d) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure: Outcomes By Health Literacy Level	Outcome Measure: Differences in Results Between Health Literacy Levels
Wolf et al., 2006[157] Convenience N = 308 Good	Patients with newly diagnosed prostate cancer in 4 outpatient oncology and urology clinics in Chicago area REALM Low: 18% Marginal: 33% Functional: 50%	Age Race Annual income Marital status	PSA Level > 20 ng/mL Marginal: 24% Low: 33% Functional: 14% Outcomes by race: NR	Health literacy mediates the association between race (African American versus white) and PSA level (adjusted). Odds associated with African American, not controlling for health literacy (OR, 4.6; 95% CI, 2.0- 9.5) Odds associated with African American, controlling for health literacy (OR, 3.0; 95% CI, 0.8- 9.1)
Bailey, 2009[77] Cross-sectional N = 373 Fair	Adults in Shreveport, LA; Chicago, IL; and Jackson, MI REALM Low: ≤ 6th grade: 20% Marginal: 7th-8th grade: 29% Adequate: ≥ 9th grade: 51%	Race Age Sex Education	Misinterpretation of medication label instructions Low: 43% Marginal: 34% Adequate: 18%	HL is a mediator between race and gender and misinterpretation of medication instructions Odds associated with being black vs. white (adjusted) Not controlling for HL: OR, 1.63; 95% CI, 1.02-2.61 Controlling for HL: OR, 1.22; 95% CI, 0.73-2.04 Odds associated with being male vs. female (adjusted) Not controlling for HL: OR, 1.67; 95% CI, 1.03-2.72 Controlling for HL: OR, 1.59; 95% CI, 0.97-2.60
Bennett et al., 2009[85] (companion: White et al. 2008[86]) Cross-sectional N = 2,668 Good	Nationally representative sample of US population 65 years and older NAAL Below basic: 29.0% Basic: 29.5% Intermediate: 38.2 Proficient: 3.3%	Race Income Gender Age Nativity	NR	HL mediates the association between race (black vs. white) and self-reported health status (adjusted) Odds associated with being black Not controlling for HL: β, -0.34 (SE, 0.11) (*P* < 0.05) Controlling for HL: β, -0.24 (SE, 0.04) (*P* < 0.05) Odds associated with being Hispanic Not controlling for HL: β, 0.02 (SE, 0.14) (*P* = NS) Controlling for HL: β,0.21 (SE, 0.07) (*P* < 0.05) HL mediates the association between race (black vs. white) and receipt of influenza vaccine (adjusted)

Table 31. Summary of studies of the relationship between health literacy and disparities (KQ 1d) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population and Setting, Health Literacy Level	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Bennett et al., 2009[85] (companion: White et al. 2008[86]) (continued)				Odds associated with being black Not controlling for HL: β,-0.24 (SE, 0.10) (P < 0.05) Controlling for HL: β,-0.18 (SE, 0.04) (P < 0.05) Odds associated with being Hispanic Not controlling for HL: β, -0.04 (SE, 0.16) (P = NS) Controlling for HL: β, 0.08 (SE, 0.07) (P = NS) HL not found to mediate relationship between race/ethnicity and receipt of mammogram (adjusted, comparison is white) Odds associated with being black Not controlling for HL: β, 0.23 (SE, 0.15) (P =NS) Controlling for HL: β, 0.28 (SE, 0.06) (P < 0.05) Odds associated with being Hispanic Not controlling for HL: β, 0.57 (SE, 0.19) (P < 0.05) Controlling for HL: β, 0.70 (SE, 0.07) (P < 0.05) HL not found to mediate the relationship between race/ethnicity and dental checkup (adjusted, comparison is white) Odds associated with being black Not controlling for HL: β, -0.13 (SE, 0.11) (P =NS) Controlling for HL: β, -0.04 (SE, 0.04) (P = NS) Odds associated with being Hispanic Not controlling for HL: β, 0.19 (SE, 0.14) (P = NS) Controlling for HL (β. 0.35 (SE, 0.05) (P < 0.05))

Table 31. Summary of studies of the relationship between health literacy and disparities (KQ 1d) (continued)

Authors, Year, Study Design, Analysis Sample Size, Quality	Population by Health Literacy Level and Setting	Variables used in Multivariate Analysis	Outcome Measure Outcomes By Health Literacy Level	Differences in Results Between Health Literacy Levels
Osborn, 2009[171] Cross-sectional N= 383 Good	Adults with type I or II diabetes REALM < 9th grade = 31% ≥ 9th grade = 69%	Age Year of diagnosed diabetes Insulin use African American race	Data NR	HL not found to be a mediator of relationship between African American race and HbA1C through structural equation modeling
Sudore et al., 2006[167] (companion: Sudore et al., 2006[95]) Prospective cohort, retrospective analysis N = 2,512 Good	Seniors (70-79 year old) in Pittsburgh, PA, and Memphis, TN REALM Limited: 24% Adequate: 76%	NR	Mortality rate Limited: 20% Adequate: 11%	Mortality within subgroups comparing limited group with adequate: Interaction between racial group and HL and sex and HL (P > 0.10 for all comparisons implying no moderator effect) White: HR 2.36; 95% CI, 1.63-3.42 Black: HR 1.66; 95% CI, 1.29-2.29 Male: HR 1.77; 95% CI, 1.20-2.62 Female: HR 2.27; 95% CI, 1.67-3.09
Osborn et al., 2007[69] (companions: Wolf et al., 2007;[70] Waite et al., 2008[71]) Cross-sectional N = 204 Fair	Patients at 2 HIV clinics: 1 in Chicago, IL, and 1 in Shreveport, LA REALM Low: 11% Marginal: 20% Adequate: 69%	Race Gender Age Income Number of medications in HIV regimen Non-HIV comorbid conditions Mental illness	Nonadherence to HIV medications in past 4 days Low: 52% Marginal: 19% Adequate: 30%	HL mediates association of black vs. white race on adherence (adjusted) Odds associated with being black, not controlling for HL: OR, 2.4; 95% CI, 1.14-5.08 Odds associated with being black, controlling for HL: OR, 1.8; 95% CI, 0.51-5.85
Yin, 2009[102] Cross-sectional N = 6,100 Fair	Parents ≥ 16 years old living in a US household (nationally representative sample) NAAL Below basic: 11% Basic: 18% Intermediate: 56% Proficient: 15%	Age Gender Number of children living in the home Educational attainment Race/ethnicity Country of birth English proficiency Income Region Metropolitan statistical area	At least 1 child without health insurance Below basic: 24% Basic: 10% Intermediate: 6% Proficient: 3% Self-reported difficulty understanding OTC medication labels Below basic: 74% Basic: 43% Intermediate/ proficient: 38%	HL is a mediator between race and health insurance coverage (adjusted) Race/ethnicity not controlling for HL: *P* = 0.03 Race/ethnicity controlling for HL: *P* = 0.08 HL is not a mediator between race and self-report of difficulty understanding of medication labels Race/ethnicity not controlling for HL: *P* = 0.04 Race/ethnicity controlling for HL: *P* = 0.05

Table 32. KQ 1d health literacy studies: strength of evidence grades by disparities across health outcomes

Outcome for Health Literacy Studies	Number of Studies	Results	Strength of Evidence Grade
Disparities across health outcomes	8	Health literacy mediates disparities in specific health outcomes between black and white race in selected outcomes. Health literacy not found to mediate the relationship between Hispanic and white race but little data available. Health literacy found to mediate the relationship between males and females in one, study, no other data available.	Black vs. white: Low Hispanic: Insufficient Sex: Insufficient

Table 33. Overview of numeracy studies

Source Design Quality Score	Population	Population Numeracy Levels	Outcomes	Variables Used in Multivariate Analysis	Also examined literacy
Aggarwal et al., 2007[178] Cross-sectional Fair	264 patients at 4 ambulatory care clinics affiliated with an urban academic medical center in the US	74% inadequate numeracy on 5-item numeracy test adapted from Black and Toteson	Knowledge Health care services	Age Race Education Primary care provider FH disease	No
Cavanaugh et al., 2008[174] Cross-sectional Fair	398 patients from 2 primary care clinics and 2 endocrinology clinics at 3 hospitals in the US	69% < 9th grade WRAT-3, numeracy Diabetes Numeracy Test Quartile 1: 27% Quartile 2: 25% Quartile 3: 26% Quartile 4: 23%	Knowledge Self-efficacy Behavior Disease prevalence/ severity	None	Yes
Davids et al., 2004[175] Cross-sectional Fair	254 patients in 2 academic general medicine clinics in the US	% correct on numeracy test adapted from Schwartz and Woloshin 0: 15% 1: 17% 2: 27% 3: 41%	Accuracy of risk perception	Age Race Education Income FH breast cancer Age at menses Age at first live birth Number of breast biopsies	No
Estrada et al., 2004[126] Prospective cohort Fair	143 patients in anticoagulation management clinics in 1 university and 1 VA-based hospital in the US	6 items (including 3 adapted from Schwartz and Woloshin) 0 correct: 13.3% 1-2 correct: 35% 3-4 correct: 34.3% 5-6 correct: 17.5%	Medication skill	Age	No
Haggstrom and Schapira, 2006[176] Cross-sectional Fair	207 patients in a general medicine clinic at an academic medical center in the US	NR % with all correct on Schwartz and Woloshin numeracy test	Accuracy of risk perception	Age Race FH Family income Insurance Education	No
Hibbard et al., 2007[98] RCT Relevant data analyzed cross-sectionally Fair	303 community-dwelling adults in the US	43% low numeracy (less than mean = 9 on 15-item scale adapted from Lipkus)	Skill Use of health care services	None	Yes

AIDS=acquired immune deficiency syndrome; FH=family history; HgbA1c=glycosylated hemoglobin; HIV=human immunodeficiency virus; HS=high school; NOS=not otherwise specified; NR=not reported; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; SES=socioeconomic status; TOFHLA=Test of Functional Health Literacy in Adults; VA=Veterans Administration; WRAT-3=Wide Range Achievement Test-3rd edition.

Table 33. Overview of numeracy studies (continued)

Source Design Quality Score	Population	Population Numeracy Levels	Outcomes	Variables Used in Multivariate Analysis	Also examined literacy
Huizinga et al., 2008[10] Cross-sectional Fair	169 patients in an academic primary care clinic in the US	66% < 9th grade WRAT-3, numeracy	Disease prevalence/ severity	Age Gender Race Income Education REALM	Yes
Lokker et al. 2009[179] Cross-sectional Fair	182 caregivers of patients at general pediatric clinics at 3 academic medical centers	< 6th grade on WRAT-math: 36% 6th-8th grade on WRAT-math: 47%	Medication skill	Age Gender Race Educational attainment	No
Osborn et al., 2009[171] Cross-sectional Good	383 patients at 2 primary care and 2 diabetes specialty clinics located at 3 medical centers	Diabetes Numeracy Test Quartile 1 = 27% Quartile 2 = 25% Quartile 3 = 26% Quartile 4 = 22%	Disease prevalence and severity (Numeracy as a mediator of relationship between race and HgbA1c)	Age Year of diagnosed Diabetes Insulin use African American race	Yes
Rothman et al., 2006[9] Cross-sectional Fair	200 patients at 1 academic primary care clinic in the US	63% < HS on WRAT-3, numeracy	Skill Disease prevalence/ severity	None	Yes
Schwartz et al., 1997[24] RCT Relevant data analyzed cross-sectionally Fair	287 patients at a Veterans hospital in the US who received a mailed survey	% correct on numeracy test from Schwartz and Woloshin 0: 30% 1: 28% 2: 26% 3: 16%	Accuracy of risk perception	Age Income Education Frame of information	No
Sheridan and Pignone, 2002[172] RCT Relevant data analyzed cross-sectionally Fair	62 medical students in 1 US medical school	% correct on numeracy test from Schwartz and Woloshin 0-1: 5% 2: 18% 3: 77%	Accuracy of risk perception	None	No

Table 33. Overview of numeracy studies (continued)

Source Design Quality Score	Population	Population Numeracy Levels	Outcomes	Variables Used in Multivariate Analysis	Also examined literacy
Sheridan et al., 2003[173] RCT Relevant data analyzed cross-sectionally Fair	357 patients in an academic general medicine clinic in the US	% correct on numeracy test from Schwartz and Woloshin 0: 41% 1: 30% 2: 27% 3: 2%	Accuracy of risk perception	None	No
Vavrus, 2006[177] Cross-sectional Fair	277 students from 4 school districts in the United Republic of Tanzania	57% low numeracy (Correctly completed 0-1 of 3 calculations on numeracy test NOS)	Knowledge	Gender Literacy Household spending Parents' education Television in home Siblings Electricity Sewage	No
Waldrop-Vaverde et al., 2009[47] Cross-sectional Fair	155 individuals who are patients at HIV clinics or participants in AIDS drug assistance program in Miami, Florida	57% correct on applied problems subtest of Woodcock-Johnson III Men: 63% correct Women: 50% correct	Medication skill (Numeracy as a mediator of the relationship between gender and medication management capacity)	Gender Time since HIV diagnosis Education Health literacy	Yes
Yin et al., 2007[125] Cross-sectional Fair	292 caregivers of young children at the pediatric emergency department in an urban academic medical center in the US	NR by TOFHLA, numeracy (split at median)	Knowledge, Medication skill	Caregiver education Country of origin Language SES Age of children Regular health care provider Experience in health care setting	No

Table 34. The relationship between numeracy level and use of health care services (KQ 1a)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Aggarwal et al., 2007[178] Cross-sectional survey N = 264 *Note: sample for actual colon screening 152 (women < age 50 who would not be eligible for screening were excluded) Fair	74% inadequate numeracy on 5-item numeracy test adapted from Black and Toteson	% with up-to-date breast cancer screening % with up-to-date colon cancer screening	Age Race Education Primary care provider Familial hypercholes-terolemia disease	Up-to-date with screening for breast cancer Inadequate: 71% Adequate: 77% Up-to-date with colon cancer guidelines Inadequate: 46% Adequate: 51%	OR for up-to-date breast cancer screening (inadequate vs. adequate): OR, 1.43 (0.62-3.33)a OR for up-to-date colon cancer screening (inadequate vs. adequate): OR, 0.91 (0.3-2.0)a

[a]Calculated by research team
OR=odds ratio; RCT=randomized controlled trial; vs.=versus.

Table 35. KQ 1 numeracy studies: strength of evidence grades by use of health care services and health outcomes

Outcome	Number of Studies	Results	Overall Grade
Use of Healthcare Services	1	Mixed results, no adjustment for confounding	Insufficient
Accuracy of Risk Perception	5	Perceived risk (n = 2): mixed results depending on length over which risk estimated Perceived treatment benefit (n = 4): mixed results depending on numeracy level categories, 3 of 4 studies suggested low numeracy reduced accuracy of perceived benefit.	Insufficient
Knowledge	4	Mixed results, partially dependent on type of knowledge, sample size, and adjustment for confounding	Insufficient
Self-Efficacy	1	Lower numeracy associated with lower self-efficacy in unadjusted analysis	Insufficient
Behavior	1	Lower numeracy not related to self-care behavior in unadjusted analysis	Insufficient
Skills	6	Mixed results depending on type of skill Skill in taking medication (n = 4): mixed results Skill in interpreting health information (n = 2) lower numeracy related to lower comprehension	Skill in taking medication: Insufficient Skill in interpreting health information: Low
Disease Prevalence and Severity	3	BMI (n = 2), HbA1c (n = 1), illness requiring dietary restriction (n = 1): Mixed results	Insufficient
Disparities	2	Numeracy appears to partially mediate the relationship between race and HgbA1c (n=1) and between gender and HIV medication management capacity (n=1)	Low

BMI=body mass index; HbA1c=glycosylated hemoglobin; HIV=human immunodeficiency virus

Table 36. The relationship between numeracy level and accuracy of risk perception (KQ 1b)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy levels	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference by Numeracy Level
Davids et al., 2004[175] Cross-Sectional N = 254 Note: 18% of those invited Fair	% of questions correct on numeracy test adapted from Schwartz and Woloshin 0 correct: 15% 1 correct: 17% 2 correct: 27% 3 correct: 41%	Estimation error for breast cancer risk (Absolute difference between perceived and Gail model calculated breast cancer risks over lifetime and 5 years)	Age Race Education Income FH breast cancer Age at menses Age at first live birth Number of breast biopsies	Lifetime risk estimation error Numeracy 0 correct: 40.1 1 correct: 28.3 2 correct: 30.1 3 correct: 25.8 5-year estimation error Numeracy 0 correct: 32.2 1 correct: 24.0 2 correct: 27.8 3 correct: 20.5	Lifetime risk estimation error (adjusted) Beta-coefficient for every additional numeracy question incorrect: 0.18; 95% CI, 0.05-0.30[a] 5-year risk estimation error (adjusted): NR Note: unadjusted correlation NS
Haggstrom and Schapira, 2006[176] Cross-Sectional N = 207 Note: 18% of those invited Fair	NR % with < 3 correct on Schwartz and Woloshin numeracy test	Accurate perception of breast cancer survival (compared with 5-year survival rates) Accurate perception of screening mammography benefit (compared with meta-analysis results)	Age, Race, FH, Family income, Insurance, Education	NR	Accurate perception of breast cancer survival over 5 years (0-2 questions vs. 3 correct; adjusted): OR, 1.19; 95% CI, 0.54–2.63[a] Accurate perception of screening mammography benefit (0-2 correct vs. 3 correct; adjusted): OR, 1.33; 95% CI, 0.50–3.57[a]
Sheridan and Pignone, 2002[172] RCT Relevant data analyzed cross-sectionally N = 62 medical students Fair	% of questions correct on numeracy test from Schwartz and Woloshin 0-1 correct: 5% 2 correct: 18% 3 correct: 77%	Ability to correctly compare treatment benefit presented alternately as ARR, RRR, NNT, combination Ability to correctly calculate treatment benefit presented alternately as ARR, RRR, NNT, combination	None	Correctly stated which treatment provided more benefit 0-1 correct: 33% 2 correct: 91% 3 correct: 94% Correctly calculated treatment benefit 0-1 correct: 0% 2 correct: 36% 3 correct: 71%	Correctly stated which treatment provided more benefit 0-1 vs. 3 correct (unadjusted): - 61%[a], *P* = 0.03 Correctly calculated treatment benefit (unadjusted) 0-1 vs. 3 correct: -71%[a], *P* < 0.01

aCalculated by research team
5-yr survival rate=5-year survival rates; ARR=absolute risk reduction; CI=confidence interval; FH=family history; NNT=number needed to treat; NR=not reported; NS=not significant; OR=odds ratio; RCT=randomized controlled trial; RRR=relative risk ratio; vs.=versus.

Table 36. The relationship between numeracy level and accuracy of risk perception (KQ 1b) (continued)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy levels	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference by Numeracy Level
Sheridan et al., 2003[173] RCT Relevant data analyzed cross-sectionally N = 357 Fair	% of questions correct on numeracy test from Schwartz and Woloshin 0 correct: 41% 1 correct: 30% 2 correct: 27% 3 correct: 2%	Ability to correctly compare treatment benefit presented alternately as ARR, RRR, NNT, combination Ability to correctly calculate treatment benefit presented alternately as ARR, RRR, NNT, combination	None	Correctly stated which treatment provided more benefit 0-1 correct: 35% 2 correct: 63% 3 correct: 88% Correctly calculated treatment benefit 0-1 correct: 5% 2 correct: 30% 3 correct: 50%	Correctly stated which treatment provided more benefit 0-1 vs. 3 correct (unadjusted): - 53%[a]; *P*< 0.001 Correctly calculated treatment benefit (unadjusted) 0-1 vs. 3 correct: -45%[a]; *P*< 0.001
Schwartz et al., 1997[24] RCT Relevant data analyzed cross-sectionally N = 287 Fair	% of questions correct on numeracy test from Schwartz and Woloshin 0 correct: 30% 1 correct: 28% 2 correct: 26% 3 correct: 16%	Ability to correctly perceive treatment benefit presented alternately as ARR +/- baseline risk or as RRR +/- baseline risk	Age, Income, Education, Frame of information	Correctly perceived treatment benefit 0 correct: 5.8% 1 correct: 8.9% 2 correct: 23.7 % 3 correct: 40%	Correctly perceived treatment benefit 0 vs. 1 correct (adjusted) absolute difference: -3.1%a; OR, 0.77; 95% CI, 0.21–3.33a 0 vs. 2 correct (adjusted) absolute difference: -17.9% a; OR, 0.14; 95% CI, 0.04-0.45a 0 vs. 3 correct (adjusted) absolute difference: +34.2%a; OR, 0.08; 95% CI, 0.02-0.28a

Table 37. Relationship between numeracy level and knowledge (KQ 1b)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy levels	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Aggarwal et al., 2007[178] Cross-sectional N = 264 *Note: sample for actual colon screening 152 (women < age 50 who would not be eligible for screening were excluded) Fair	74% inadequate numeracy on 5-item numeracy test adapted from Black and Toteson	Knowledge of breast cancer and colorectal cancer screening guidelines	Age Race Education Primary care provider FH of disease	Knowledge of breast cancer guidelines Inadequate: 25% Adequate: 48% Knowledge of colon cancer guidelines Inadequate: 17% Adequate: 35%	Knowledge of breast cancer guidelines (inadequate vs. adequate, adjusted): 0.37 (0.19-0.71)a Knowledge of colon cancer guidelines (inadequate vs. adequate, adjusted): 0.63 (0.29-1.25)a
Cavanaugh et al., 2008[174] Cross-sectional N = 398 Fair	WRAT-3, numeracy < 9th grade: 69% $\geq$ 9th grade: 31% Diabetes Numeracy Test (DNT: median % correct) Overall: 65% Quartile 1: 27% Quartile 2: 25% Quartile 3: 26% Quartile 4: 23%	Median diabetes knowledge (range 0-100)	None	Median Diabetes knowledge DNT Quartile 1: 52 DNT Quartile 2: 65 DNT Quartile 3: 79 DNT Quartile 4: 86	Median diabetes knowledge DNT Quartile 1 vs. 4 (unadjusted): -34[a]; P for trend: $P < 0.001$
Vavrus, 2006[177] Cross-sectional N = 277 Fair	57% Low Numeracy (correctly completed 0-1 of 3 calculations on numeracy test NOS)	% of 5 knowledge questions about general health correctly answered % of 5 knowledge questions about HIV/AIDS correctly answered	Gender Literacy Household spending Parents' education Television in home Siblings Electricity Sewage	NR	OR for high general health knowledge (low vs. high numeracy, adjusted): 0.66a; P > 0.05 OR for high HIV/AIDS knowledge (low vs. high numeracy, adjusted): 0.36a; P < 0.001

[a]Calculated by research team

CI=confidence interval; DNT=Diabetes Numeracy Test; FH=family history; HIV/AIDS=acquired immunodeficiency syndrome/human immunodeficiency virus; NOS=not otherwise specified; NR=not reported; OR=odds ratio; SES=socioeconomic status; TOFHLA=Test of Functional Health Literacy in Adults; vs.=versus; WRAT-3=Wide Range Achievement Test-3rd edition.

Table 37. Relationship between numeracy level and knowledge (KQ 1b) (continued)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy levels	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Yin et al., 2007[125] Cross-sectional N = 292 caregivers of young children Fair	NR by TOFHLA, numeracy (split at median)	% of caregivers with poor knowledge of weight-based dosing	Caregiver education Country of origin Language SES Age of children Regular healthcare provider Experience in healthcare setting	Poor knowledge of weight based dosing Innumerate: 76% Numerate: 62%	Odds of poor knowledge of weight based dosing (innumerate vs. numerate, adjusted): 1.1; 95% CI, 0.6-2.2 Note: when education, acculturation, and SES are not included in model, result was significant (1.8; 95% CI, 1- 3.1)

Table 38. Relationship between numeracy and self-efficacy (KQ 1b)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Cavanaugh et al., 2008[174] Cross-sectional N = 398 Fair	WRAT-3, numeracy < 9^{th} grade: 69% ≥ 9^{th} grade: 31% Diabetes Numeracy Test (DNT: median % correct) Overall: 65% Quartile 1: 27% Quartile 2: 25% Quartile 3: 26% Quartile 4: 23%	Median self-efficacy for diabetes self-management Measured by Perceived Diabetes Self-Management Scale (range 8-40)	None	Median self-efficacy DNT Quartile 1: 28 DNT Quartile 2: 28 DNT Quartile 3: 31 DNT Quartile 4: 32	Median Self-efficacy DNT Quartile 1 vs. 4: -4[a], *P* for trend: (*P* = 0.003)

[a]Calculated by research team

DNT=Diabetes Numeracy Test; vs.=versus; WRAT-3=Wide Range Achievement Test-3rd edition.

Table 39. Relationship between numeracy level and behavior (KQ 1b)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy	Outcome	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Cavanaugh et al., 2008[174] Cross-sectional N = 398 Fair	WRAT-3, numeracy < 9th grade: 69% ≥ 9th grade: 31% Diabetes Numeracy Test (DNT: median % correct) Overall: 65% Quartile 1: 27% Quartile 2: 25% Quartile 3: 26% Quartile 4: 23%	Median reported use of self-management behaviors using the Summary of Diabetes Self-Care Activities scale (range 0-7) Includes the following behaviors General diet Specific diet Exercise Blood glucose level testing Foot care	None	Self-management behaviors General diet Quartile 1: 5 Quartile 4: 5 Specific diet Quartile 1: 3.5 Quartile 4: 3.5 Exercise Quartile 1: 3.5 Quartile 4: 2.75 Blood glucose level testing Quartile 1: 7 Quartile 4: 6.5 Foot care Quartile 1: 5.5 Quartile 4: 3.25	Absolute difference in general diet behaviors (Quartile 1 vs. 4): 0[a]; *P* = 0.21 Absolute difference in specific diet behaviors (Quartile 1 vs. 4): 0[a]; *P* = 0.82 Absolute difference in exercise behavior (Quartile 1 vs. 4): +0.75[a]; *P* = 0.25 Absolute difference in blood glucose level testing (Quartile 1 vs. 4): 1.5[a]; *P* = 0.44 Absolute difference in foot care behavior (Quartile 1 vs. 4): 2.25[a]; *P* < 0.001

[a]Calculated by research team
DNT=Diabetes Numeracy Test; vs.=versus; WRAT-3=Wide Range Achievement Test- 3rd edition.

Table 40. Relationship between numeracy level and skills (KQ 1b)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy	Outcomes	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
		Medication Taking Skills			
Estrada et al., 2004[126] Prospect cohort N = 143 Note: 11 were proxies for patients Fair	6-items (including 3 adapted from Schwartz and Woloshin) 0 correct: 13.3% 1-2 correct: 35% 3-4 correct: 34.3% 5-6 correct: 17.5%	Correct medication dosing operationalized as: % INR tests within the therapeutic range INR variability (using sigma, a composite capturing number of measurements, time since previous measure, and therapeutic range; higher values are worse)	Age	% INR tests within range 0 correct: 56% 5-6 correct: 66% INR variability using mean sigma score 0 correct: 0.80 5-6 correct: 0.45	Absolute difference in % INR tests within range (adjusted): NR; P = 0.35 Absolute difference in INR variability (adjusted): NR; P = 0.03
Lokker et al., 2009[179] Cross-sectional N = 182 Fair	< 6th grade on WRAT-math: 36% 6th-8th grade on WRAT-math: 47%	Poor caregiver understanding of OTC cold medicine labels (i.e. say product suitable for < 24-month-old) Caregiver intent to use medication in 13-month-old	Age Gender Race Educational attainment	NR	Adjusted odds ratios for each *decrease* in numeracy grade level For caregivers with 2nd-8th grade numeracy score Think suitable: 1.25 (0.99-1.58)[a] Would use: 1.19 (1.01-1.41)* Adjusted odds ratios for each *increase* in numeracy grade level For caregivers with 9th-16th grade numeracy score Think suitable: 1.28 (0.79-2.06) Would use: 1.78 (1.07-2.96)

[a]Calculated by research team

CI=confidence interval; HIV=human immunodeficiency virus; HS=high school; i.e., example; INR=international normalized ratio; NLS=Nutrition Label Survey; N=number; NR=not reported; NS=not significant; OTC=over-the-counter; RCT=randomized controlled trial; SES=socioeconomic status; TOFHLA=Test of Functional Health Literacy in Adults; vs.=versus; WRAT-3=Wide Range Achievement Test-3rd edition.

Table 40. Relationship between numeracy level and skills (KQ 1b) (continued)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy	Outcomes	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Waldrop-Valverde et al., 2009[47] Cross-sectional N = 155 Fair	57% correct on applied problems subtest of Woodcock-Johnson III Men: 63% correct Women: 50% correct	% correct on Medication Management Test (MMT: range 2-16)	Gender Time since HIV diagnosis Education Health literacy	NR	Adjusted beta-coefficient for relationship between numeracy and MMT: 0.538; P < 0.01
Yin et al.,2007[125] Cross-sectional N = 292 caregivers of young children Fair	NR by TOFHLA, numeracy (split at median)	% of caregivers with poor knowledge of correct medication dosing instrument (operationalized as reported use of nonstandardized instrument)	Caregiver education Country of origin Language SES Age of children Regular healthcare provider Experience in healthcare setting	Use of nonstandardized dosing instrument Innumerate: 34% numerate: 19%	Odds of use of nonstandardized dosing instrument (innumerate vs. numerate, fully adjusted): 1.4; 95% CI, 0.8-2.7 Note: when education, acculturation, and SES are not included in model, result was significant: 1.9; 95% CI, 1.1-3.4
Skills in Interpreting Health Information					
Rothman et al., 2006[9] Cross-Sectional N = 200 Fair	63% < HS on WRAT-3, numeracy	% questions correct on 24-item Nutrition Label Survey after being given a nutrition label to read	Age Gender Race Insurance Income Education Clinical disease Specific diet Label reading frequency	Nutrition label comprehension < high school: 61% > high school: 84%	Absolute difference in NLS score (adjusted): NR; P < 0.001
Hibbard et al., 2007[98] RCT However, results of interest in this paper are cross-sectional N = 303 Fair	43% low numeracy (less than mean = 9 on 15-item scale adapted from Lipkus)	% questions correct on 13-item health plan knowledge questionnaire after being given health plan information to review % Choosing higher quality hospital	None	Health Plan Comprehension Low numeracy: 72%a High numeracy: 90.5%a Note: interaction by patient activation (i.e., motivation to engage with material)	Absolute difference in comprehension (low vs. high, unadjusted): -18.5%a; P < 0.05 Absolute difference in choice of higher quality hospital (low vs. high, unadjusted): -11.8%a; P < 0.01

Table 40. Relationship between numeracy level and skills (KQ 1b) (continued)

Author, Year, Study Design, Sample Size, Quality	% Low Numeracy	Outcomes	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Hibbard et al., 2007[98] (continued)				Low numeracy Low activation: 67.7% High activation: 76.3% P for interaction: P < 0.05 High numeracy Low activation: 90.2% High activation: 90.7% P for interaction: NS Choice of higher quality hospital Low numeracy: 59.9% High numeracy: 71.7% Note: interaction by patient activation (i.e., motivation to engage with material) Low numeracy Low activation: 53% High activation: 66.8% P for interaction: P < 0.05 High numeracy Low activation: 66.3% High activation: 77% P for interaction: P < 0.001	

Table 41. Relationship between numeracy level and disease prevalence and severity (KQ 1b)

Author, Year, Study Design, Sample Size Quality	% Low Numeracy	Outcomes	Variables Used in Multivariate Analysis	Results by Numeracy Level	Difference
Cavanaugh et al., 2008[174] Cross-sectional N = 398 Fair	WRAT-3, numeracy < 9th grade: 69% ≥ 9th grade: 31% Diabetes Numeracy Test (DNT: median % correct) Overall: 65% Quartile 1: 27% Quartile 2: 25% Quartile 3: 26% Quartile 4: 23%	Median HbA1c	Age Gender Race Income Type of diabetes Years since diagnosis of diabetes Clinic site	Median HbA1c Quartile 1: 7.6% Quartile 2: 7.1% Quartile 3: 7.1% Quartile 4: 7.1%	Absolute difference in Median HbA1c (quartile 1 vs. 4: +0.5%; *P* = 0.119) In adjusted analysis, every 10% decrease in % correct DNT questions resulted in an increase in HbA1c of 0.09%; 95% CI, 0.01%-0.16%
Huizinga et al., 2008[10] Cross-sectional N = 169 Fair	WRAT-3, numeracy < 9th grade: 66% ≥ 9th grade: 34%	Mean BMI	Age Gender Race Income Education REALM	Mean BMI < 9th grade: 31.8 ≥ 9th grade: 27.9	BMI (< 9th grade vs. ≥ 9th grade, unadjusted): +3.9[a]; *P* = 0.008 Effect of numeracy on BMI: (adjusted): β = -0.14; *P* = 0.01
Rothman et al., 2006[9] Cross-sectional N = 200 Fair	63% < HS on WRAT-3, numeracy	% with self-reported illness requiring dietary restriction % BMI > 30	None	Illness requiring dietary restriction < HS: 44% ≥ HS: 35% % BMI > 30 < HS: 48% ≥ HS: 40%	Absolute difference in percent with illness requiring diet restriction (< HS vs. ≥ HS, unadjusted): +9%; *P* = 0.20 Absolute difference in % with BMI > 30 (< HS vs. ≥ HS, unadjusted): +8%; *P* = 0.30

[a]Calculated by research team
BMI=body mass index; CI=confidence interval; DNT=Diabetes Numeracy Test; HbA1c=glycosylated hemoglobin; HS=high school; REALM=Rapid Estimate of Adult Literacy in Medicine; vs.=versus;WRAT-3=Wide Range Achievement Test-3rd edition.

Table 42. Relationship between numeracy level and disparities (KQ 1d)

Author, Year, Study Design, Sample Size, Quality	% Population with Limited Literacy	Exposure, Outcome, Mediator	Results of Mediational Analysis
Osborn et al., 2009[171] Cross-sectional N = 383 Good	Diabetes Numeracy Test Quartile 1 = 27% Quartile 2 = 25% Quartile 3 = 26% Quartile 4 = 22%	Exposure: race Outcome: HgbA1c Mediator: numeracy	Structural equation model results Correlation between African-American race and numeracy: -0.46 (P < 0.001) Correlation between numeracy and HgbA1c: -0.15 (P < 0.01) Correlation between African-American race and HgbA1c Without mediator: 0.12 (P < 0.01) With mediator: 0.10, NS
Waldrop-Valverde et al, 2009[47] Cross-sectional N = 155 Fair	57% correct on applied problems subtest of Woodcock-Johnson III Men: 63% correct Women: 50% correct	Exposure: gender Outcome: medication management capacity Mediator: numeracy	Path analysis results Correlation between female gender and numeracy: -0.428 (P < 0.01) Correlation between numeracy and medication management capacity: 0.644 (P < 0.01) Correlation between female gender and medication management capacity Without mediator: NR, significant With mediator: 0.073, NS

HgbA1c=glycosylated hemoglobin; NR=not reported; NS=not significant.

The Effect of Interventions To Mitigate the Effects of Low Health Literacy

Introduction

This chapter presents the results of our literature search for key question (KQ) 2. The analytic framework for this question is presented in Chapter 2. In brief, KQ 2 asked about effective interventions to mitigate the effects of low health literacy on (a) use of health care services, (b) health outcomes, (c) costs of health care, and (d) health disparities. As we noted in our methods, the best studies to answer this question would have included analyses specific to individuals with low health literacy. However, much of the research about interventions designed to mitigate the effects of low health literacy has been done in populations that include a combination of low and high health literacy individuals and failed to perform literacy-specific subgroup analyses. Instead of excluding a large portion of the intervention literature, we decided to permit inclusion of studies with a combination of low and high literacy individuals and no subgroup analysis, knowing that they may provide only indirect information about the effect of interventions on an exclusively low literacy population.

For KQ 2, we present our results in two ways. First, where interventions use single strategies to mitigate the effects of low health literacy, we present results by intervention strategy (e.g., alternative document design, alternative numerical presentation, additive or alternative pictorial representation, alternative media, alternative readability, and document design) in an effort to aid intervention developers. The majority of results in this section focus on comprehension following the intervention, although a few[180,181] also focus on the use of health care services. Second, where interventions use multiple strategies (preventing conclusions about the active intervention components), we organize results in accordance with outcomes in our analytic framework.

Tables presenting selected information about KQ 2 studies are presented at the end of the chapter. These tables provide (1) an overview of included intervention studies (Table 43), (2) detail about the interventions tested in included studies (Table 44), (3) the aggregate strength of evidence of included studies (Tables 46 and 53), (4) results of studies using single strategies to mitigate the effects of low health literacy organized by strategy (Tables 44, 47-51), (5) results of studies using multiple strategies to mitigate the effects of low health literacy organized by outcome (Tables 52, 54-61). Detailed evidence tables appear in Appendix D.

Because this report is an update, we needed to integrate findings from our first review in 2004 with those of our current review. To do this, we reorganized findings from the first review using the organizational structure described above and note in each section how results from the first review are similar to or different from current findings and whether they modify our current conclusions.

To facilitate conclusions, we provide insights based on observations about the common features of effective interventions. These "cross-cutting" observations are presented at the end of the chapter.

Search Results

We identified 56 articles reporting on 53 unique studies to include in our updated review.

Study Quality

Of all 53 studies, we rated 3 as good quality[182-184] and 38 studies as fair quality.[79,133,181,185-219] One additional study was rated fair for intermediate outcomes and poor for followup outcomes.[220] Finally, we rated 11 studies as poor quality and excluded them from further review.[221-231]

Characteristics of Included Studies

Below we report on the 42 good- or fair-quality studies identified in our updated review. Included studies had a wide variety of designs (Table 43). Across all 42 studies, 27 were randomized controlled trials (RCTs), two were cluster randomized trials, and 13 were quasi-experimental studies.

With respect to interventions, 21 used one specific strategy to mitigate the effects of low health literacy and 21 used a mixture of strategies combined into one intervention (Table 44). Of intervention studies that used one specific low-literacy strategy to enhance patient comprehension, two focused on alternative document design, three on alternative numerical presentation, eight on additive or alternative pictorial representations, four on alternative media, and seven on a combination of alternative readability and document design. Additionally, one intervention focused on the effects of physician notification about patients' literacy status on health outcomes. A total of 21 studies involved mixed interventions; these included a combination of the strategies noted above and other strategies to promote improvements in patient knowledge, self-efficacy, behavior, adherence, disease, quality of life, and health care services use.

Interventions were tested in study populations with different proportions of individuals with low health literacy or low numeracy. Twenty-one studies examined the effect of interventions specifically in low-health-literacy subgroups, although many were underpowered for these analyses and/or failed to adequately control for confounding. Other studies examined intervention effects in populations that included both low- and high-health-literacy or -numeracy individuals; these studies provide only supportive evidence about the effect of interventions to mitigate the effects of low literacy.

Effects of Health Literacy Interventions Using Single Strategies, by Intervention Type

Intervention: Alternative Document Design

Two fair-quality randomized trials addressed the effects of alternative document design on outcomes, including comprehension and choice of higher quality options (Table 45).[185,188] Both stratified analysis by health literacy subgroups. These studies examined the effects of specific design features including highlighting the common features of comparative information, presenting only essential information, and putting key information first.

One study tested simplifying design features in a convenience sample of 303 adults who were asked to examine comparative information about health plans.[185] This study randomized individuals to six groups, which allowed two major comparisons: (1) the effects of presenting information on 13 features of health plans side by side in random order vs. with common features first, and (2) the effects of presenting a list of information about the plan (no framework) vs. presenting information about four advantages and four disadvantages of the plan (long framework) vs. presenting information about two advantages and two disadvantages of the plan (short framework). The investigators found that presenting common features first provided no improvements over the side-by-side presentation of information in either low- or high-numeracy participants. However, the short framework and the long framework (for high-numeracy participants only) provided small improvement in comprehension (ranging from 0.3-0.7 points on a comprehension scale with scores ranging from 0-6). The long framework provided significantly worse comprehension than no framework for those with low numeracy (-0.5 points on a comprehension scale with scores ranging from 0-6, $P < 0.05$).

In the other study in this category,[188] which was done by the same group of investigators and appears to have used the same participants, the researchers investigated the effects of limiting and focusing information. In this study, participants received varying amounts of health plan information. Some participants received only the information investigators deemed essential to decisions about health plan use (i.e., information on cost and quality). Others, however, received both this essential information as well as other nonessential information (i.e., information on quality of hospital food and number of visiting hours per day). Both high- and low-numeracy participants who received only essential information had better comprehension (high numeracy 0.3 on a scale of 0-3, $P < 0.01$; low numeracy 0.7, $P < 0.01$) and chose higher quality options (high numeracy +19 percentage points, $P < 0.01$; low numeracy +23 percentage points, $P < 0.01$) than individuals who received both essential and nonessential information. When all information was presented, putting the essential information first further improved comprehension for low-numeracy individuals (+0.6 points on a scale of 0-3, $P < 0.01$), but not for high-numeracy individuals. Order had no effect on whether respondents chose higher quality options.

Considering this evidence in aggregate, our research team judged the overall strength of evidence for studies examining alternative document design to be insufficient (Table 46 and Appendix F), indicating that future studies would have a high likelihood of changing estimates of effect. Studies from our previous review did not change overall conclusions. In our previous review, we identified only one study focusing on alternative document design.[232] This RCT compared illustrated narrative text to bulleted text on genital warts and cervical cancer screening and found no overall differences in comprehension among study arms receiving these presentations. Notably, however, low-literacy participants comprehended illustrated materials better than bulleted information.

Intervention: Alternative Numerical Presentation

Three fair-quality randomized trials examined the effects of alternative numerical presentations (Table 47).[188,217,219] Each examined a different strategy to improve numerical presentation. All stratified their analyses by participant numeracy level.

The first study[188] was performed in the same population as the studies in the prior section. It examined the effects of presenting information on hospital quality so that the higher number (rather than the lower number) of any indicator indicated a better quality. In this study, listing information so that the higher number was better improved the mean number of correct responses to comprehension questions (+0.4 on a 0-4 scale, $P < 0.001$) and the proportion of individuals choosing a higher quality option (+13 percentage points, $P < 0.01$). Results varied by numeracy level, however; participants in the low- but not the high-numeracy subgroup achieved benefit from this approach. This study also investigated whether adding symbols to indicate the concepts of "more" or "less" would aid comprehension. We present these results in the next section about pictorial presentations.

The second study[219] examined the effects of presenting information on the baseline risk of heart attack and treatment benefit for a hypothetical cholesterol drug using the same or different denominators. In this factorial randomized trial, a probabilistic sample of 1,047 American and German adults were randomly assigned first to information about the baseline risk of disease and risk following treatment presented alternately with four different sets of denominators (800/800, 100/800, 800/100, and 100/100). They were then secondarily randomized to either receive icon arrays or not. Presenting the numerical information using the same vs. different denominators resulted in appreciable improvements in understanding (P = 0.001), with a greater effect among those with low numeracy (+25 percentage points) vs. high numeracy (+16 percentage points, unadjusted P for numeracy effect = 0.001). The effect of adding icon arrays is discussed below in the section on additive pictorial representation.

The third study[217] examined the effect of presenting information on the positive predictive value of genetic testing for diabetes and trisomy 21 (i.e., the likelihood of disease given a positive test for either of these diseases) in alternate numerical formats. In this study, a convenience sample of 162 adults was randomized to receive genetic testing information as either conditional probabilities or natural frequencies. In the conditional probabilities arm of the study, information on both the baseline rate of disease and the sensitivity and false positive rates of the genetic test was presented in percentages. Participants were then asked to calculate the likelihood of diabetes if genetic testing was positive. In the natural frequency arm, on the other hand, information on the baseline rate of disease was presented as x/10,000 people and sensitivity and false positive rates as y/x and z/10,000-x, respectively; these presentations preserve the base rate of disease and reduce the computations individuals must perform to estimate the likelihood of disease if genetic testing is positive. As hypothesized by investigators, natural frequencies improved the accuracy of participants' estimates of the positive predictive value of genetic testing (effect size not reported, P = 0.001) with similar effects for both high- (+24 percentage points) and low- (+27 percentage points) numeracy individuals. However, these results must be interpreted with caution due to the relatively small sample and lack of reporting of baseline group characteristics.

In considering this evidence, our research team felt that the overall strength of evidence was low (Table 46 and Appendix F), indicating that future research may change estimates of effect. Our prior review found no studies examining this outcome; therefore, it did not modify conclusions.

Intervention: Additive and Alternative Pictorial Representation

Eight fair-quality studies[133,186,188,189,195,216,219] (including two reported by Peters in the same article) investigated the effects of pictorial representation on outcomes, including comprehension, accurate perception of risk, and choice of higher quality options (Table 48). Six were RCTs and two were quasi-experimental studies. Six investigated the additive effects of pictorial information and two examined alternative pictorial representations. Five stratified their analysis by participant health literacy or numeracy level.

Of the six trials addressing the effects of adding pictorial information, two studies (performed by the same group and reported in one article) focused on the effect of adding symbols to numerical information.[188] Both stratified their analyses by numeracy level. One study considered in the preceding section examined the effect of adding symbols to hospital quality information. Numerical information was presented alternately in two formats such that either the higher number indicated better quality (higher-number-better) or the lower number indicated better quality (lower-number-better).[188] Symbols were then added to determine their effect on comprehension of hospital quality information and choice of higher quality hospitals. The symbols included a plus sign to indicate more patients per nurse, a minus sign to indicate fewer patients per nurse, and no symbol to indicate an average number of patients per nurse. These symbols had no effect on comprehension or hospital choice in the overall sample. However, adding symbols to the lower-number-better condition led to poorer choices (although not poorer comprehension) in high-numeracy participants (percentage choosing higher quality hospital -19 percentage points, *P* value not reported) and slightly better choices in the lower-numeracy participants (percentage choosing higher quality hospital +12 percentage points, *P* value not reported). In a similar study from this same group reported in the same article,[188] participants were randomly assigned to one of five conditions to examine two main outcomes: (1) the effect of adding symbols to essential (with or without nonessential) hospital quality information, and (2) the effect of using black and white circles (i.e., all black, half-black half-white, all white) vs. colored traffic light symbols (i.e., green, yellow, red circles) to indicate relative quality. Symbols had no overall effect on comprehension but did increase the number of participants choosing high-quality options (+14 percentage points, $P < 0.05$). Effects varied by whether symbols accompanied only information essential to quality (i.e., death rates) or both essential and nonessential information (i.e., death rates and satisfaction). Adding symbols to both essential and nonessential information reduced the percentage of low-numeracy participants choosing high-quality hospitals, but it made no difference for high-numeracy participants. The effect of using black and white circles vs. colored traffic light symbols also differed by numeracy level. A higher number of high-numeracy participants chose high-quality hospitals with colored symbols (+16 percentage points, $P < 0.05$), while fewer low-numeracy participants chose high-quality hospitals, although the trend was not statistically significant (-11 percentage points, *P* not significant).

Two studies, including one already mentioned above, addressed the effects of adding icon arrays to numerical information about treatment benefit.[216,219] Icon arrays (also known as pictographs) represent the benefits and/or harms of treatment using a series of dots, human figures, or faces that are shaded to represent the proportion of individuals affected by disease. Both studies stratified analyses by participant numeracy level. The first study examined the effects of adding icon arrays to numerical information in three hypothetical treatment scenarios (aspirin for cardiovascular disease, cholesterol drug for cardiovascular disease, and appendicitis screening).[216] This factorial trial randomized a convenience sample of 171 students and older adults first to alternate numerical information (absolute risk reduction vs. relative risk reduction) and then to icon arrays or not. The study confirmed its a priori assumption that presenting treatment benefit information as absolute (rather than relative) risk reduction improved understanding for everyone (unadjusted difference +49 percentage points, adjusted $P = 0.001$). It then showed that adding icon arrays further aided understanding (unadjusted difference +23 percentage points, adjusted $P = 0.002$). However, improvements with icon arrays differed according to numeracy level, with greater improvements among those with low numeracy in unadjusted analyses. The second study, which was mentioned above in the "Alternative Numerical Presentation" section, examined the effects of adding icon arrays to numerical information in a single hypothetical treatment scenario (cholesterol drug for heart attack).[219] In this factorial randomized trial, a probabilistic sample of 1,047 American and German adults were randomly assigned first to information about the baseline risk of disease and risk following treatment presented alternately with four different sets of denominators. They were then secondarily randomized to either receive icon arrays or not. The effects of icon arrays on accuracy of risk perception varied both by the denominators indicating treatment benefit and by participant numeracy. When denominators for the baseline risk and risk following treatment were different, icon arrays improved understanding for both low- (unadjusted difference +32 percentage points) and high- (unadjusted difference +11 percentage points) numeracy participants. However, when denominators for baseline risk and risk following treatment were the same, icon arrays provided a more modest benefit in the accuracy of risk perception for low-literacy participants (unadjusted difference +11 percentage points) and worsened risk perception in high-literacy participants (unadjusted difference -16 percentage points). *P* values for these differences were not reported.

Two other studies examined the effect of adding illustrations to prose.[133,195] Neither of these studies stratified analysis by literacy level, although one reported that literacy predicted outcomes.[133] This study, a randomized trial of 363 participants (only 4 percent of whom had Rapid Estimate of Adult Literacy in Medicine [REALM] scores below 45), found no overall effect of adding a mind map (a pictorial representation linking key concepts and ideas) to standard arthritis education materials.[133] The other study, a quasi-experimental study enrolling a convenience sample of 130 adults from academic family medicine clinics, showed no effect of adding illustrations to the auxiliary prescription labels indicating “take with water,” “may cause drowsiness,” “take with food,” “no alcohol,” or “take on empty stomach.”[195]

The remaining studies examined alternative pictorial representations. Only one stratified analysis by numeracy. In this Internet study randomizing 140 adults (41 percent of whom were deemed to have low numeracy because they incorrectly answered the first numeracy question on the Lipkus numeracy scale) to six different conditions, the researchers could determine the effect of grouped vs. dispersed dot icon arrays for three risk magnitudes (3 percent, 6 percent, 50 percent).[186] They determined that there was no overall effect on comprehension among those who received the grouped dot (rather than dispersed dot) icon arrays; however, those with higher numeracy had significantly greater improvements than those with lower numeracy. A different quasi-experimental study examined seven teratogen warning symbols in comparison with a standard symbol.[189] The researchers found that participants’ understanding that the medication should not be taken if pregnant and that the medication causes birth defects improved if these concepts were represented in separate complementary diagrams rather than single diagrams (*P* value not reported). They also found that adding text stating “causes birth defects” increased understanding of all tested symbols.

In aggregate, our research team considered the overall strength of evidence for alternative pictorial representations to be insufficient (Table 46 and Appendix F). Studies made disparate comparisons and found mixed results, precluding clear conclusions. Our prior review did not modify conclusions; although our prior review found one study of alternative pictorial representations, it was graded as poor quality.

Intervention: Alternative Media

Four randomized trials assessed the effects of various types of media on comprehension and/or intent to seek health care (Table 49).[184,200,212,213] Three focused on the effects of adding or substituting various media (e.g., video, computer, or slide show presentations) for printed materials.[200,212,213] A fourth examined the effects of adding video to verbal narratives.[184] Three of four studies stratified results by health literacy status.[184,200,213]

The first study examining the effects of various media compared to print materials randomized 233 parents or caretakers of children enrolled in Head Start Programs to one of four presentations of informed consent—standard, simplified print, video, computerized—for hypothetical high-risk and low-risk studies.[200] Compared with standard informed consent, the video and computerized versions had little effect on freely remembered recall of information. However, the computerized version showed a trend toward improving prompted recall (percentage of total information remembered +4 percentage points, $P = 0.08$) with no difference by health literacy group. Whether such improvements are clinically meaningful is not clear. The comparison of the standard consent and simplified print version is presented below in the section "Alternative Design and Readability Document."

The second study randomized a convenience sample of 232 men at two university hospitals to two different media for delivery of a symptom score assessment for benign prostatic hypertrophy: print or print plus video (which the authors called "multimedia").[213] The multimedia delivery included a computerized video with reading of the symptom score questions. Questions were shown on the computer screen during reading and color-coded to correspond to written symptom score sheets to be completed by participants. The efficacy of the multimedia version was assessed by two different measures of comprehension: the mean number of errors participants made and the proportion of participants understanding questions (compared to professionally completed scores). Overall, the multimedia version increased comprehension (mean difference in errors -1.51, $P < 0.001$; mean difference in percentage understanding +19 percentage points, P not reported), with larger effects among participants with low health literacy (defined as less than high school reading skills by the REALM; significance of interaction by health literacy status not reported). It also increased the accuracy of categorical classification of symptoms in the overall sample (+13 percentage points, $P = 0.04$).

The third study examining the effects of various media compared to print materials randomized 90 teenage patients and their parents (all of whom had median REALM and Wide Range Achievement Test [WRAT] scores, suggesting reading skill at the high school level) to one of three presentations of informed consent for orthodontic treatment—standard, simplified print, or simplified print plus a slide show that included images and audiovisual cues representing the elements of informed consent.[212] As discussed under the section "Alternative Readability and Document Design" below, compared with standard informed consent (readability not reported), the simplified informed consent (which was written at the seventh-grade level and included large font, white space, active voice, and cues to action) did not improve recall or comprehension for patients or parents. The addition of a slide show, however, improved the proportion of information adequately recalled by patients (unadjusted absolute difference +11 percentage points, $P < 0.05$) and the proportion of information adequately recalled and comprehended by parents (unadjusted absolute differences for recall +9 percentage points, $P < 0.05$; for comprehension +12 percentage points, $P < 0.001$). Results should be interpreted with caution, however, because they did not adjust for potentially meaningful baseline differences between study arms. Furthermore, they were not stratified by literacy level.

A single study examined the effects of adding video to verbal narratives.[184] This study randomized a convenience sample of 200 adults from four primary care practices in the United States to a verbal narrative about advanced dementia or a verbal narrative in combination with a 2-minute video.[184] Participants who received the verbal narrative plus video had improved knowledge compared to the verbal narrative alone (unadjusted mean difference +0.9 on a scale ranging from 0-5, $P < 0.001$) Additionally, those who received the verbal narrative plus video had a greater preference (which we considered a proxy for intent) for comfort care as an end-of-life strategy (adjusted odds ratio [OR] 3.9, 95% confidence interval [CI], 1.8-8.6). Preference for comfort care varied by health literacy level, with those who had higher health literacy having higher preference for comfort care.

Based on findings from the studies above and their mixed results, our research team judged the strength of evidence to be insufficient (Table 46 and Appendix F). Three studies from our prior review contributed additional information, but didn't change overall conclusions.[233-235] In our prior review, one RCT[233] found that both a simple brochure written at the 5-6th grade level and a video written at a similar level improved comprehension of colon cancer screening information more than usual care, although neither was superior to the other overall or in stratified analyses. Two additional nonrandomized trials[234,235] found mixed results. One showed that a brochure plus video plus verbal recommendation about mammography improved mammography rates over either a verbal recommendation alone or a brochure plus verbal recommendation.[234] The other confirmed no differences overall or in literacy subgroups in comprehension of information on sleep disorders with a 12-grade brochure vs. a video based on a script written at the 12th grade level.[235]

Intervention: Alternative Readability and Document Design

We found seven studies examining the effects of interventions that combined simplification of readability with document redesign (Table 50). Six were fair-quality randomized trials (seven articles based on six studies)[191,199,200,204,208,212,214] and one was a fair-quality quasi-experimental study.[204] One focused on an advanced directive,[204,208] one on simplified advice about head trauma,[191] one on a simplified Medicaid health plan comparison chart,[214] and four on simplified informed consent[199,200,204,212] (although one of the latter provided only postintervention data, which limited conclusions[204]). Only three of the six with interpretable data stratified results by health literacy level.[191,200,214]

The first study stratifying results by health literacy level examined the effects of a simplified Medicaid health plan comparison chart.[214] The chart had four key improvements: it listed only the differences between health plans, ordered plans from the most to the least generous, grouped or "chunked" cost-sharing and benefit information in rows to allow comparison across plans, and increased font size. Compared to a standard chart, the modified health plan comparison chart provided no significant improvements in comprehension overall or by health literacy group in a convenience sample of 122 Medicaid recipients in Florida. This might be attributable to the high residual document complexity, which was noted to be at a high school level for the simplified chart.

The second study stratifying results by health literacy level examined the effects of a simplified head trauma advice sheet.[191] This simplified sheet included simplified language, a reduced number of words, grouping or chunking ideas, and the use of large font sizes and plenty of white space. Compared with a standard advice sheet, this simplified sheet resulted in a 1-point improvement on a comprehension scale with possible scores ranging from 0-10. There was no interaction by literacy level.

The third study stratifying results by health literacy level was mentioned above in the section "Alternative Media." This RCT randomized 233 parents or caretakers of children enrolled in Head Start Programs to one of four presentations of informed consent—standard, simplified print, video, computerized—for hypothetical high-risk and low-risk studies.[200] The simplified print version of informed consent included in this study employed simple language, chunking of ideas, and white space to improve participant understanding. Compared with standard informed consent, the simplified print version had little effect on freely remembered recall of information. However, it showed trends toward improving prompted recall in the low-literacy (less than an eighth-grade reading level on the WRAT) subgroup. Whether such improvements are meaningful is not clear.

Results from other studies, which did not stratify data by literacy level, were mixed. Three studies[199,204,208,212] showed no effect on comprehension by three different combinations of reading and document simplification (see Table 44 and Table 50), although one of these showed changes in the proportion of participants completing advanced directives. Both studies had features limiting interpretation of findings.[199,204,208] For instance, in one study,[199] participants had a mean REALM score of 65 out of 66; this raises the possibility that the same intervention tested in a population with more low-literacy individuals might have appreciably different results. Additionally, in the other study,[204,208] results about completion of advanced directives were confounded because of cross-over between study arms with lack of adjustment for relevant confounders.

Based on these findings, our research team judged the overall strength of evidence about alternative readability and document design to be insufficient (Table 46 and Appendix F). Studies found mixed results, which are likely attributable, at least in part, to the components of document redesign and methodological bias. Several studies from our prior review and prior sections of the current review similarly reported mixed results. In our prior review, one study focused on alternative readability alone[236] and showed an association between low readability and improved comprehension. Three other studies focused on a combination of alternative readability and document design and reported mixed results.[237-239] In prior sections of this review (see “Alternative Document Design” above), the benefits of document design varied by the components of redesign.

Intervention: Physician Notification of Patient Literacy Status

One fair-quality cluster randomized trial examined the effects of physician notification of patient literacy status on health outcomes including self-efficacy and hemoglobin A1c (HgbA1c), (Table 51).[181] Despite enrolling a population with a high proportion of low-literacy individuals (74 percent had a Test of Functional Health Literacy in Adults [TOFHLA] score below 16) and increasing physicians’ use of more than three communication-enhancing strategies (adjusted OR 4.7, 95% CI, 1.4-16), neither patients’ self-efficacy nor HgbA1c changed in any material way with physician notification. Based on this single study, our research team graded the overall strength of evidence as low (Table 46 and Appendix F). There were no studies from our prior review to modify this assessment.

Summary of Interventions Using Single Intervention Design Strategies

In summary, the strength of evidence regarding the effect of specific intervention design features for low-health-literacy populations is low (Table 46 and Appendix F). This is attributable, in large part, to differences in the interventions (and subsequent results) for studies broadly grouped as follows: alternative document design, alternative numerical presentation, alternative pictorial representation, alternative media, alternative readability and document design, and physician notification of literacy status.

Looking closely within intervention categories, we noted that several specific design features resulted in improvements in comprehension for low-health-literacy populations in one or a few studies. These features, which bear further study in broader populations, include presenting essential information by itself (i.e., information on hospital death rates without other distracting information, such as information on consumer satisfaction); presenting essential information first (i.e., information on hospital death rates before information about consumer satisfaction); presenting information so that the higher number (rather than the lower number) indicates better quality; using the same denominators to present baseline risk and treatment benefit information; adding icon arrays to numerical presentations of treatment benefit; and adding video to verbal narratives. Additionally, in reexamining data from our 2004 review, we noted potential benefit from other design features tested individually in one or a few studies; these include using reduced reading level and illustrated narratives.

In contrast to the above design features, we noted that a few specific design features resulted in worse comprehension in one or a few studies; these design features also bear further study in broader populations. For instance, one study raised questions about whether colored traffic symbols to denote hospital quality may actually worsen health choices among those with low literacy. Similarly, one study raised questions about whether adding symbols to nonessential quality information (i.e., satisfaction information), may actually draw attention away from the essential information and worsen health choices among those with low health literacy.

Effects of Mixed Strategy Interventions, by Analytic Framework

KQ 2a. Effect of Mixed Interventions on Use of Health Care Services

We found one good-quality study[182] and five fair-quality studies[194,196,202,203,207] addressing the effects of mixed strategy interventions on use of health care services (Table 52). Four were RCTs,[182,194,202,203] one was a cluster randomized trial,[196] and one used a quasi-experimental design.[207] Two studies provided preventive service education and examined rates of preventive services utilization.[196,203] Three others, one promoting adherence[182] and two facilitating self-management,[202,207] examined rates of visits to emergency rooms[182,207] and hospitalizations.[182,202,207] One additional study examined use of recommended services,[194] but the authors did not describe this outcome in sufficient detail to allow interpretation; thus results are not presented here. Four of the six studies stratified analyses by literacy level.

Of two studies providing preventive service education, only one stratified analysis by health literacy level. This cluster randomized trial delivered interventions to both providers and patients. It provided providers with education on literacy and communication strategies and patients with education on colorectal cancer screening. With these interventions, this study showed increases in any colorectal cancer test completion over 18 months (absolute difference 8.9 percentage points, $P = 0.003$). The impact differed by health literacy level, with an absolute difference of 26 percentage points in the low-health-literacy subgroup ($P = 0.002$) and 3 percentage points in the high-health-literacy subgroup ($P = 0.65$) when adjusting only for the clustering of patients within providers.[196] A second trial providing patients with education on prostate cancer screening also increased preventive service use,[203] with significant increases in the number of prostate-specific antigen tests ordered after both low-readability patient education (adjusted OR, 7.62, 95% CI, 1.62-35.83) and cues encouraging patients to talk with their physician (adjusted OR, 5.86, 95% CI, 1.24-27.81). However, the health benefits of additional prostate cancer screening are questionable and the authors do not present information about whether results differed by health literacy level. Rates of digital rectal examinations documented by chart review did not change in this study.

Of two studies examining the effects of interventions on emergency room visits, only one stratified results by health literacy level. This fair-quality quasi-experimental study promoting asthma self-management by children (intervention directed at children) reported an overall reduction in emergency room visits (unadjusted mean difference -30 percentage points, $P < 0.01$), with a striking effect in those who showed improvements in reading compared to those who did not (adjusted OR, 0.34; 95% CI, 0.22-0.52).[207] Smaller reductions in emergency room visits (incidence rate ratio, 0.82; 95% CI, 0.70-0.95) were noted in one good-quality RCT promoting medication adherence for congestive heart failure (CHF); this study was conducted in an undifferentiated population of individuals, 29 percent of whom were designated as "not literate" (not otherwise specified) on the S-TOFHLA.[182]

Of three studies examining the effects of interventions on hospitalizations, two stratified results by health literacy. The best of these two studies was a fair-quality randomized trial focused on CHF self-management.[202] This study reported no overall reduction in hospitalizations but significant reductions in a subgroup of individuals of low health literacy (adjusted incidence rate ratio, 0.39; 95% CI, 0.16-0.91). A fair-quality quasi-experimental study of an asthma self-management intervention also reported reductions in hospitalizations (adjusted mean difference -15 percentage points, $P < 0.001$), although the effect did not differ by literacy level.[207] A third good-quality RCT, which did not stratify results by health literacy, noted a trend toward reduced hospitalizations (incidence rate ratio, 0.39; 95% CI, 0.16-0.91) with a medication adherence for CHF.[182]

Based on these findings, our research team graded the strength of evidence for the effect of mixed interventions on emergency room visits and hospitalizations as moderate. This grade is based on consistent evidence from multiple fair- to good-quality studies that adherence and self-management interventions reduce emergency room visits and hospitalizations in low-literacy subgroups or populations that contain individuals with both low and high numeracy (Table 53 and Appendix F). Our prior review found no studies examining this outcome; it, therefore, did not modify our conclusions.

KQ 2b. Effect of Mixed Interventions on Health Outcomes

Knowledge

We identified 10- fair-quality studies addressing the effects of mixed strategy interventions on knowledge (Table 54).[79,194,197,201,202,205,206,211,215,220] Three were RCTs[194,201,202] and the remaining seven were quasi-experimental studies.[79,197,205,206,211,215,220] Two quasi-experimental studies measured data about knowledge before or after the intervention only, limiting conclusions.[79,206] Of studies with interpretable data, two focused on promoting adherence,[201,220] six on promoting self-management of chronic illness,[194,197,201,202,211,215] and one on promoting weight loss.[205] Only one examined knowledge as the primary outcome.[215] Five examined literacy as a moderator of intervention effect, testing whether the level of effectiveness of the intervention differed by health literacy level.[194,197,211,215]

In aggregate, studies found mixed results; findings did not seem to be related to study design, intervention or disease focus, health literacy level of included participants, or health literacy strategies employed as part of the intervention. Four of eight studies with interpretable data,[202,205,215,220] including one RCT[202] and one study[215] that focused on knowledge as the primary outcome, found positive effects of their intervention on knowledge.[202,205,215,220]

However, which components of these interventions were the effective components remained unclear. Additionally, in the one study that found an effect and stratified results by health literacy level,[215] results were greater in those with high health literacy; this may be in part because the small subgroups for low health literacy had insufficient power to detect differences. One additional quasi-experimental study showed positive effects for the high-health-literacy group but not the low-health-literacy group at 3-month followup.[197]

Given the mixed findings, our research team judged the overall strength of evidence to be insufficient (Table 53 and Appendix F). However, 14 studies from our prior review (including 12 that examined knowledge as their primary outcome) contributed additional information. Eight have been described above because they addressed specific alternative presentations of health information. One additional study is presented below under the effects of mixed interventions on skill. Five additional studies addressed the effect of mixed interventions on knowledge and are described here.[240-245] Four of these five studies, including two RCTs,[243,244] and one study that stratified results by literacy level,[244] found improvements in knowledge with interventions as diverse as an interactive videodisc program about self-care of fatigue in cancer patients, low-literacy nutrition classes, a cholesterol education video, and a CD-ROM on prostate cancer screening. The remaining nonrandomized trial found no improvement in knowledge with the addition of a color medication schedule to verbal teaching. With continued mixed results (9 of 14 studies overall with knowledge improvements), the research team concluded that the overall strength of evidence was still insufficient (Table 53 and Appendix F), with effect estimates that are likely to change substantially with new results.

Self-Efficacy

We identified nine fair-quality studies addressing the effects of mixed strategy interventions on self-efficacy (Table 55). Four were RCTs[187,194,202,209,210] and five were quasi-experimental studies.[190,205,207,211,220] Two focused on promoting adherence,[190,220] five on promoting self-management,[187,194,202,207,210,211] one on arthritis treatment,[209] and one on weight loss.[205] None examined self-efficacy as its primary outcome; only two examined literacy as a moderator of effect.[194,211] One reported self-efficacy results only postintervention, which limited conclusions.[220]

In aggregate, studies found mixed results, which may be related to differences in the intensity of the intervention. Two RCTs[187,202,210] and one quasi-experimental study[207] with intensive self-management interventions including frequent and prolonged participant contact showed improvements in self-efficacy. Additionally, one study that targeted both patients and providers (although with less intensive and less prolonged contact for each than other effective interventions) showed increases in self-efficacy.[205] However, none of these studies stratified analyses by literacy level. Other studies with less intensive interventions, including two randomized trials, showed negative results[190,194,209,211] and no differential effect by health literacy level in the one study that performed stratified analysis.[194] Based on these studies, our research team judged the overall strength of evidence to be insufficient (Table 53 and Appendix F). No studies from our prior review addressed this outcome.

Behavioral Intent

We found no studies addressing the effects of mixed health literacy interventions on patients' intent to perform specific health behaviors. Similarly, our prior review found no studies addressing this outcome.

Skill

We found one study addressing the effects of mixed health literacy interventions on patients' skill (Table 56).[218] This fair-quality randomized trial randomized a convenience sample of 56 individuals to either a standard nutrition label or a nutrition label information card and 8-minute video tutorial. Participants who received the information card and video tutorial correctly answered a higher proportion of questions on a 12-item food label quiz (adjusted absolute difference + 12 percentage points, $P < 0.05$), with a greater effect among those with adequate literacy on the s-TOFHLA in an adjusted analysis. Based on findings from this study, our research team judged the overall strength of evidence to be low (Table 53 and Appendix F). Two studies from our prior review[245,246] addressed label-reading skills and found mixed results. This leaves the overall literature inconclusive.

Behavior

Three fair-quality studies addressed the effect of mixed strategy interventions on actual behaviors (Table 57).[187,197,202,210] Two were RCTs; one was a quasi-experimental study. All involved individual or group counseling that taught self-management behaviors and measured aggregate self-management behaviors. Additionally, two studies measured individual self-management behaviors for diabetes (including diet, physical activity, foot care, medication adherence, and glucose self-monitoring).[187,197,210] Only one analyzed these effects by health literacy level.[197]

In aggregate, these studies suggested that self-management interventions including individual and group counseling improved aggregate self-management behaviors. However, in the only study to examine effects by health literacy status,[197] improvements were sometimes greater for those who had adequate health literacy and at other times greater for those with inadequate health literacy in adjusted analyses. Based on these studies, our research team judged the strength of evidence regarding the effects of self-management interventions on behavior as moderate (Table 53 and Appendix F).

Three studies in our prior review also addressed behavior, although their intervention focus was different.[243,245,247] All three had special diet interventions and measured dietary change and/or caloric intake. These studies found mixed results, precluding definitive conclusions about the effects of low-health-literacy diet interventions on behavior.

Medication Adherence

We found one good-quality[182] and four fair-quality studies[79,197,201,209] addressing the effect of mixed literacy interventions on adherence to medication regimens (Table 58).Three were RCTs[182,201,209] and two were quasi-experimental studies.[79,197] Three included interventions that were designed specifically to promote adherence.[182,197,201] A fourth[79] was a self-management intervention that measured medication adherence only postintervention in a subset of patients, which limited drawing any conclusions. A fifth[209] was designed to promote arthritis management. Of studies with interpretable data, only one stratified results by health literacy level.[197]

In the four studies contributing interpretable data,[182,197,201,209] effects were mixed, which appeared to be related to both the intensity of the intervention and the measure of adherence. The good-quality RCT,[182] which involved an intensive intervention focused at both patients and their providers, found improved adherence (+10.9 percent, 95% CI, 5-16.7) during the intervention period using Medication Event Monitoring Systems (MEMS) to assess adherence. The effect, however, attenuated at 3 months after completion of the intervention (+3.9 percent, 95% CI, -2.8-10.7). Three other studies,[197,201,209] which used less intensive interventions and measured adherence by self-report, found no effect, although one showed a trend toward improved adherence among a subgroup of individuals who were initially nonadherent (+12 percent, P = 0.08, when counting as adherent those who disagreed that they missed medications for any of the four reasons on the Morisky questionnaire).[201] In the study that stratified results by health literacy,[197] results were similar by health literacy group in an adjusted analysis.

Based on the findings above, our research team judged the strength of evidence for the effects of mixed interventions on adherence to be insufficient (Table 53 and Appendix F). Only one study from our previous review measured adherence and found no effect of a color medication schedule.[240] This nonrandomized trial did not change our conclusion about the overall strength of evidence for this outcome.

Disease Prevalence and Severity

We found one good-quality[183] and six fair-quality studies[79,187,193,194,197,198,210] addressing the effects of mixed strategy interventions on disease prevalence and severity (Table 59). Four were RCTs[183,187,193,194,210] and three were quasi-experimental studies.[79,197,198] Five measured biomarkers of disease[183,187,194,197,198,210] and two measured symptoms.[79,193] Five stratified results by level of health literacy. In general, studies reported mixed results, which may be attributable, at least in part, to intervention and study design.

Three studies addressed the effects of diabetes self-management interventions on disease biomarkers (including HgbA1c, blood pressure, and BMI).[187,194,197,210] Two fair-quality RCTs found no effect on HgbA1c, blood pressure, or BMI in participants overall[187,194,210] or in low-health-literacy subgroups in an adjusted analysis.[194] By contrast, a fair-quality quasi-experimental study found a statistically significant decrease in HgbA1c with no difference in effect among health literacy subgroups in an adjusted analysis;[197] without a control group, however, we cannot judge the importance of this finding.

Two other studies addressed the effects of diabetes disease management programs (i.e., self-management plus pharmacist adjustment of medication) on disease biomarkers.[183,198] These studies appeared to test the same intervention in a quasi-experimental[198] and a randomized design.[183] The RCT showed a significant decrease in HgbA1c in the low-health-literacy group (adjusted absolute difference -1.4 percent, 95% CI, -2.3 to -0.6) but not in the high-health-literacy group (adjusted absolute difference -0.5 percent, 95% CI, -1.4 to 0.3), although it should be noted that the sample size may have been too small to detect small differences in the high-literacy subgroup. Systolic blood pressure was also significantly lowered among all participants (adjusted absolute difference -7.6 mmHg, 95% CI, -13 to -2.2 mmHg). Exactly which component of this intervention was efficacious remains unclear, although the lack of efficacy of other self-management interventions suggests that the pharmacist adjustment of medication may be the critical factor. Additionally, the self-management component in this study employed a wider variety of strategies to mitigate low health literacy (e.g., simple language, simple organizational structure, pictures, teach-back, repetition) than other studies.

Two studies addressed the effects of mixed strategy interventions on symptom control,[79,193] although only one had adequate power to test its effects on disease severity and did not stratify results by health literacy level.[193] This fair-quality randomized trial, which tested the effects of adult basic and literacy education as an adjunct to depression management, showed statistically significant reductions in scores on the PHQ-9 (the 9-item depression scale of the Patient Health Questionnaire) over multiple followups.

Based on the findings above, our research team judged the strength of evidence separately for self-management, disease management, and adult basic and literacy interventions. We concluded that the strength of evidence is insufficient for self-management interventions, moderate for disease management interventions, and low for adult basic and literacy education interventions (Table 53 and Appendix F). No studies from our prior review included these types of interventions. However, one RCT from our prior review found reduced depression with case management as an adjunct to a standard Head Start program.[248] Furthermore, two RCTs from our prior review[247,249] found no effect of special nutrition education programs on cholesterol (two studies) or blood pressure (one study).

Quality of Life

One good-quality[182] and three fair-quality[187,202,209,210] RCTs addressed the effects of mixed strategy interventions on quality of life (Table 60); however, none used quality of life as the primary outcome. Two focused on general quality of life[187,209,210] and two focused on disease-specific quality of life.[182,202] One measured quality of life only after the intervention in the intervention group,[182] thereby limiting conclusions. Only one stratified results by health literacy level. [202]

The three studies providing interpretable data yielded mixed results. Two studies reported no effects of self-management interventions on well-validated quality-of-life measures, including the mental and physical health subscales of the Medical Outcomes Study Short Form 12 (SF-12)[187,210] and the Minnesota Living with Heart Failure scale (MLHF).[202] One of the studies, however, reported reductions in the number of bed days in the past month (adjusted absolute difference -1.7 days per month, 95% CI, -3.3 to -0.1 days per month) for people assigned to an intensive telephone counseling intervention with 39 patient contacts.[187,210] A third trial on arthritis management intervention reported mixed effects, with no effects on the Health Assessment Questionnaire (HAQ),[209] but improvements on the mental health subscale of the SF-36.

Based on findings described above, our research team judged the strength of evidence for the effects of mixed interventions on quality of life to be insufficient (Table 53 and Appendix F). Our prior review found no studies examining this outcome; it, therefore, did not modify our conclusions.

KQ 2c. Effect of Mixed Interventions on Health Care Costs

We found two good-quality RCTs examining the health care costs of mixed health literacy interventions. One good-quality RCT examined the cost-effectiveness of its intervention to promote adherence to CHF medication[182] (Table 61). This intensive pharmacist-led intervention, which included patient education and skill building, graphic medication labels, monitoring of adherence, and notification of providers, showed trends toward cost savings (-$2,960, 95% CI, -$7,603 to $1,338) compared with usual care when considering intervention, outpatient, and inpatient costs. Another good-quality RCT examined the labor and total costs (defined as labor plus indirect costs) of its diabetes disease management intervention. This study reported the labor costs for its disease management program, which employed both clinical pharmacists and diabetes care coordinators who provided more than 13 hours of education, skill building, and medication adjustment per patient, were $25.50 per patient per month (range in sensitivity analysis $12.01 to $55.35 per patient per month). Total costs were slightly higher at $36.97 per patient per month (range in sensitivity analysis $16.22 to $88.56 per patient per month).

Based on these studies and their mixed findings, our research team graded the strength of evidence for the effects of mixed interventions on health care costs as insufficient (Table 53 and Appendix F). Our prior review found no studies addressing this outcome and did not modify our conclusions.

KQ 2d. Effect of Mixed Interventions on Disparities

We found no studies addressing the effects of mixed health literacy interventions on patients' intent to perform specific health behaviors. Similarly, our prior review found no studies addressing this outcome.

Summary of Interventions Using Mixed Intervention Strategies

The strength of evidence for studies combining multiple strategies to mitigate the effects of low health literacy on outcomes was more variable than for single-feature interventions. We found moderate strength of evidence that studied interventions change health care service use. Specifically, intensive self-management and adherence interventions appear to be effective in reducing emergency room visits and hospitalizations. Additionally, educational interventions and/or cues for screening increased colorectal cancer and prostate cancer screening. We note, however, that the health benefits of additional prostate cancer screening are questionable and that increased screening rates could be a marker for poor decision making.

Evidence of moderate strength indicates that some interventions change health outcomes. For instance, intensive disease-management programs appear to be effective at reducing disease prevalence. Furthermore, self-management interventions increased self-management behavior; however, in the only study that stratified its analysis by health literacy level, the effect was greater in the high-health-literacy subgroup than in the low-health-literacy subgroup in adjusted analyses. The effects of other interventions on other health outcomes, including knowledge, self-efficacy, adherence, health-related skills, quality of life, and cost, were mixed; thus, the strength of evidence was insufficient.

Too few studies addressed the effects of health literacy interventions on the outcomes of behavioral intent and disparities to draw any meaningful conclusions; the strength of evidence is insufficient.

Cross-Cutting Observations About Interventions Designed To Mitigate Low Health Literacy

Looking at the common features of successful interventions can help illuminate features that may be important in making interventions effective at mitigating the effects of low health literacy. Common features across nearly all of the interventions that improved distal outcomes (e.g., self-management, hospitalizations, mortality) were their high intensity, theory basis, pilot-testing before full implementation, emphasis on skill building, and delivery of the intervention by a health professional (e.g., pharmacist, diabetes educator).[182,183,202,207]

Examining pathways of effect can also help illuminate factors that may be important in making interventions effective. Six studies in our update examined the impact of interventions on three or more outcomes[79,182,187,194,197,202] (Table 44). In addition to changing distal outcomes, these studies reported changes in the following intermediate outcomes: knowledge,[196,197,202] self-efficacy,[187] or behavior.[182,187,197,202] Although these studies did not perform formal mediation analyses, the change in these intermediate outcomes suggests that changing knowledge, increasing self-efficacy, and changing behavior may be important goals in mitigating the effects of low health literacy.

Table 43. Summary of included intervention studies

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Interventions using single strategies for low health literacy							
Bryant et al., 20092[13]	RCT (232)	Fair	28% < high school on REALM Mean REALM score: 59	Standard American Urological Association BPH Symptom Score (AUA-SS)	Multimedia AUA-SS	Comprehension	Yes[a]
Campbell et al., 2004[200]	RCT (233)	Fair	50% Low (< 8th grade reading level on Woodcock Johnson) Average REALM score: 56.3	Standard print consent form	(1) Simplified print consent form (2) Video consent (3) Computerized consent	Knowledge	Yes[a]
Coyne et al., 2003[199]	RCT (226)	Fair	Mean REALM: 65	Standard Consent Form	Simplified consent form	Comprehension	No
Galesic et al., 2009[217]	RCT (162)	Fair	Mean numeracy on 12-pt scale derived from Lipkus & Schwartz: Overall: 9.7 Older adults: 8.6 Younger adults: 10.3	Conditional probabilities (%) Presented to illustrate the positive predictive value of genetic testing for early detection of diabetes or trisomy 21	Natural frequencies (x/10,000) Presented to illustrate the positive predictive value of genetic testing for early detection of diabetes or trisomy 21	Accuracy of positive predictive value estimates	Yes

[a]adjusted for relevant confounders; [b]weighted percents; [c]Read from Table; [d]determined through personal communication with author

12-p= 12-point; ABLE=Adult Basic and Literacy Education; ARR=absolute risk reduction; AUA-SS=American Urological Association-Symptom Score; BPH=benign prostatic hyperplasia; CHD=coronary heart disease; CHF=congestive heart failure; cRCT=cluster randomized controlled trial; FDA=The Federal Drug Administration; HgbA1c=glycosylated hemoglobin; inadeq.inadequate; info.information; MDs= medical doctors; MIC= modified informed consent; MIC + SS=modified informed consent + slide show; NA=not applicable; NOS=not otherwise specified; PDA=personal digital assistant; pt=point; pts=patients; Quasi-=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy for Adults; RRR=relative risk reduction; S-TOFHLA=short form Test of Functional Health literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; US=United States; WRAT=Wide Range Achievement Test.

Table 43. Summary of included intervention studies (continued)

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Galesic et al., 2009[216]	Factorial RCT (171)	Fair	Mean numeracy score on 12-pt scale derived from Lipkus & Schwartz: Older adults: 8.6 Students: 10.3	Numerical Risk (presented alternately as ARR or RRR)	Icon arrays	Accuracy of risk perception	Yes
Garcia-Retamero and Galesic, 2009[219]	RCT (1047)	Fair	49% Low numeracy (> median score on 9-item scale adapted from Lipkus and Schwartz)[b] (Germany: 49%[b], US 48%[a])	Numerical information about RRR (including information with varying size denominators)	Numerical information (RRR) plus icon array (including information presented with varying sizes of denominators)	Accuracy of risk perception	Yes[a]
Greene et al., 2008[185]	RCT (303)	Fair	50% Low (score less than 10 on DR Numeracy Test)	(1) Side-by-side (random) comparison of characteristics (2) No framework	(1) Common/unique presentation of characteristics (2a) Short framework (2b) Long framework	Comprehension	Yes
Greene and Peters, 2009[214]	RCT (122)	Fair	57% TOFHLA Cloze score ≤ 18 (out of 20)	Standard Medicaid health plan comparison chart	Simplified Medicaid health plan comparison chart	Comprehension	Yes
Hwang et al., 2005[195]	Quasi-, pre-post (130)	Fair	5% REALM ≤ 6th grade 22% REALM 7-8th grade	Medication label text: A. Take with water B. May cause drowsiness C. Take with food D. No alcohol E. Take on an empty stomach	Medication label text + illustration	Comprehension	No

Table 43. Summary of included intervention studies (continued)

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Kang et al., 2009[212]	RCT (90)	Fair	Patient: Median REALM and WRAT scores: high school Parent: Median REALM and WRAT score: high school	Standard Consent Form	(1) Modified informed consent for (MIC) (2) Modified informed consent + slide show (MIC + SS) Note: Interventions delivered to both patient and parent	Comprehension	No
Mayhorn and Goldsworthy, 2007[189]	Quasi-, post-only (700)	Fair	42.9% Low literacy (REALM, NOS)	Original teratogen symbol (slash through pregnant woman)	(1) Original symbol, but woman taking pill (2) Cross and skull bones in pregnant belly (4) 2 pictures: Original symbol + skull bones in pregnant belly (5) 2 pictures: #4 but more caricatured (6) 1 picture combining original symbol + skull bones in pregnant belly (7) skull bones in pregnant belly + inlay with slash through person taking pills	Comprehension	No
Peters et al., 2007[188] (Study 1)	RCT (303)	Fair	50% Low (score less than 10 on DR Numeracy Test)	Nonordered, nonquality info.	(1) Ordered cost, quality, non-quality info. (2) Cost and quality info. only	Comprehension, choice of higher quality option	Yes

Table 43. Summary of included intervention studies (continued)

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Peters et al., 2007[188] (Study 2)	RCT (303)	Fair	50% Low (score less than 10 on DR Numeracy Test)	Numbers only	(1) essential info (e.g. death rates) accompanied by black/white symbols (2) essential info (e.g. death rates) accompanied by traffic symbols (3) essential and non-essential info (e.g. death rates and satisfaction) accompanied by black/white symbols (4) essential and non-essential info (e.g. death rates and satisfaction) accompanied by traffic symbols	Comprehension, choice of higher quality option	Yes
Peters et al., 2007[188] (Study 3)	RCT (303)	Fair	50% Low (score less than 10 on DR Numeracy Test)	Lower number is better quality, no symbols	(1) Higher number is better quality, no symbols (2) Lower number is better quality, symbols (3) Higher number is better quality, symbols	Comprehension, choice of higher quality option	Yes
Seligman et al., 2005[181]	cRCT (63 MDs, 182 pts)	Fair	74% TOFHLA inadeq. 16% TOFHLA marginal	Usual Care for Diabetes	Physician notification of patients' health literacy status	Self-efficacy HgbA1c Physician use of effective communication strategies	No

Table 43. Summary of included intervention studies (continued)

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Sudore et al., 2007[204] Sudore et al., 2008[208]	RCT (205)	Fair	40% TOFHLA < 22 (inadeq. or marginal)	Standard Advanced Directive	Simplified Advanced Directive	Comprehension	No
Sudore et al., 2006[192]	Quasi-, post-only (204)	Fair	22% TOFHLA inadeq. 18% TOFHLA marginal	None	Simplified consent form	Comprehension	Yes[a]
Volandes et al., 2009[184]	RCT (200)	Good	18% ≤ 6th grade on REALM 12% 7-8th grade on REALM	Verbal narrative about advanced dementia	Verbal narrative + video showing features of advanced dementia	Knowledge Intent	Yes[a]
Walker et al., 2007[133]	RCT (363)	Fair	15% with REALM < 60 (9th grade)	Standard Arthritis Booklet	Standard Arthritis booklet + Mind Map	Knowledge	No
Wright et al., 2009[186]	RCT (140)	Fair	41% Low (incorrect answer to 1st question on Lipkus numeracy scale)	Dispersed dot icon array (3 different risk magnitudes: 3%, 6%, 50%)	Grouped dot icon array (3 different risk magnitudes: 3%, 6%, 50%)	Comprehension	Yes
Yates and Pena, 2006[191]	RCT (200)	Fair	1.5% REALM < 7th grade[c] 14% REALM 7-8th grade[c]	Standard head trauma advice form	Simplified head trauma advice form	Comprehension	Yes[a]

Table 43. Summary of included intervention studies (continued)

Source	Design (sample size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy
Interventions using mixed interventions for low health literacy							
Bosworth et al., 2005[201]	RCT (588)	Fair	38% low literacyd	Usual care	Tailored adherence intervention	Knowledge Adherence	No
Brock and Smith, 2007[220]	Quasi-, pre-post (51)	Fair (although poor for adherence)	55% REALM < 8th grade	NA	Adherence video on PDA	Knowledge Adherence	No
Davis et al., 2008[205]	Quasi-, pre-post (101)	Fair	49% REALM < 6th grade 22% REALM 7-8th grade	None	Weight loss intervention	Knowledge, Self-efficacy	No
DeWalt et al., 2006[202]	RCT (127)	Fair	41% S-TOFHLA inadeq.	Usual care + low literacy pamphlet on CHF	CHF self-management program	Knowledge Self-efficacy Behavior Quality of life Use of health care services	Yesa
Ferreira et al., 2005[196]	cRCT (113 MDs, 1,978 pts)	Fair	31% Low (< 9th grade on TOFHLA) Note: measured only in 19% of patients	Usual Care	Educational Intervention for Physicians and Patients on Colorectal Cancer screening	Use of Healthcare Services	Yes
Gerber et al., 2005[194]	RCT (144)	Fair	56% S-TOFHLA < 22 (inadeq. or marginal)	Usual care + computerized quizzes on diabetes-related concepts	Diabetes self-management intervention	Knowledge Self-efficacy HgbA1c Use of health care Services	Yes[a]
Jay et al., 2009[218]	RCT (56)	Fair	17% Limited literacy (score ≤ 22) on S-TOFHLA	Standard FDA materials explaining nutrition label	Nutrition label information card and video tutorial	Comprehension	Yes[a]

Table 43. Summary of included intervention studies (continued)

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Kim et al., 2004[197]	Quasi-, pre-post (92)	Fair	23% S-TOFHLA < 22 (inadeq. or marginal) (15% inadeq. on TOFHLA)	None	Diabetes self-management intervention	Knowledge Behavior HgbA1c	Yes[a]
Kripalani et al., 2007[190]	Quasi-, pre-post (242)	Fair	42% REALM < 6th grade 37% REALM 7-8th grade	None	CHD adherence intervention (pill card)	Self-efficacy	No
Kripalani et al., 2007[203]	RCT (303)	Fair	38% REALM < 3rd grade 18% REALM 4-6th grade 23% REALM 7- 8th grade	Handout, NOS Unclear if prostate content or other content	(1) Educational Intervention on Prostate Cancer Screening (2) Cue to Discuss Prostate Cancer screening	Use of Healthcare Services	No
Kripalani et al., 2008[206]	Quasi-, post only (408)	Fair	21% REALM < 3rd grade 25% REALM 4-6th grade 31% REALM 7-8th grade	No control	(1) Modified Print informed Consent with Oral Overview	Knowledge	Yes[a]
Murray et al., 2007[182]	RCT (314)	Good	29% “not literate” on S-TOFHLA (NOS)	Usual care	CHF adherence intervention	Adherence Quality of Life Use of Health care Services Cost	No
Paasche-Orlow et al., 2005[79]	Quasi-, pre-post (73)	Fair	22% S-TOFHLA Inadeq.	NA	Asthma Self-Management Intervention	Knowledge Adherence Asthma symptom control	Yes[a]

Table 43. Summary of included intervention studies (continued)

Source	Design (Sample Size)	Quality Score	Population, Health Literacy Levels	Control	Intervention	Outcomes	Analysis Stratified by Literacy Level
Robinson et al., 2008[207]	Quasi-, pre-post (110)	Fair	Mean Gilmore Oral Reading Test Score: 3.2	NA	Asthma Self-Management Intervention	Self-efficacy Use of Healthcare Services	Yes[a]
Rothman et al., 2004[198]	Quasi-, pre-post (159)	Fair	55% Lower literacy 32% REALM ≤ 3rd grade 23% REALM Score 4-6th grade	NA	Diabetes Self-Management Intervention	HgbA1c (and other biomarkers)	Yes
Rothman et al., 2004[183] Rothman et al., 2006[250]	RCT (217)	Good	38% REALM ≤ 6th grade	1-hour education session	Diabetes Self Management Intervention	HgbA1c (and other biomarkers)	Yes[a]
Rudd et al., 2009[209]	RCT (127)	Fair	19% REALM ≤ high school	Arthritis Management Intervention (arthritis pamphlet, medicine calendar, hospital map)	Arthritis Management Intervention + Individual Counseling	Self-efficacy, Adherence, Quality of Life	No
Schillinger et al., 2008[187] Schillinger et al., 2009[210]	RCT (339)	Fair	59% S-TOFHLA ≤ 22 (inadeq. or marginal)	Usual care	(1) Diabetes Self Management Program (automated telephone delivery) (2) Diabetes Self-Management Program (group medical visit delivery)	Self-efficacy Behavior Hgba1c (and other biomarkers) Quality of life	No
Sobel et al., 2009[215]	Quasi, pre-post (130)	Fair	26% with low literacy (0-44 on REALM) 33% with marginal literacy (45-60 on REALM)	No control	Linear video tutorial about asthma and its management	Knowledge	Yes[a]
Wallace et al., 2009[211]	Quasi-, pre-post (250)	Fair	29% TOFHLA inadeq. 14% TOFHLA marginal	NA	Diabetes Self-Management Intervention	Knowledge Self-efficacy	Yes
Weiss et al., 2006[193]	RCT (70)	Fair	Mean REALM score: 47	Usual care	Adult Basic and Literacy Education (ABLE)	Depression Severity	No

Table 44. Intervention study detail

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Basic Interventions: Alternative Document Design									
Greene et al., 2008[185]	(1) Common presentation of information (vs. random presentation) (2) Short Framework (vs. long or no framework)	Print	1	NR	Researchers	Chunking of ideas	NA	NA	Yes[a]
Peters et al., 2007[188] (study 1)	(1) Ordered info. (vs. unordered info.) (2) Essential info. (vs. nonessential info.)	Print	1	< 1 hour[a]	Researchers	Ordering, Essential info. only	NA	NA	Yes[a]

[a] determined via personal contact with authors

AUA-SS=American Urological Association-Symptom Score; BPH=benign prostatic hyperplasia; avg=average; CHD=coronary heart disease; CHF=congestive heart failure; DM=diabetes; HIV=human immunodeficiency virus; hr=hour; HTN=hypertension; info.=information; med=medicine; min=minute; NA=not applicable; NOS=not otherwise specified; NR=not reported; PCP=primary care provider; PDA=personal digital assistant; Q and A=question and answer; RRR=relative risk reduction; vs.=versus.

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Basic Interventions: Alternative Numerical Presentation									
Galesic et al., 2009[217]	Natural frequencies (x/10,000) Presented to illustrate the positive predictive value of genetic testing for early detection of diabetes or trisomy 21	Print	1	<5 min[a]	Self-administered on computer	Numerical simplification	NA	NA	Yes[a]
Garcia-Retamero and Galesic, 2009[219]	Same (vs. different) denominators for baseline risk and treatment benefit	Print	1	1-2 minutes	Self-administered on Computer	Numerical simplification	NA	NA	Yes[a]
Peters et al., 2007[188] (study (3)	(1) Higher number better quality (vs. lower number better quality)	Print	1	< 1 hour[a]	Researchers	Numerical simplification	NA	NA	Yes[a]

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Basic Interventions: Additive and Alternative Pictorial Presentation									
Galesic et al., 2009[216]	Icon arrays (vs. none)	Print	1	<10 mina	Self-administered on computer	Graphical presentation	NA	NA	Yes
Garcia-Retamero and Galesic, 2009[219]	Icon arrays (vs. none)	Print	1	1-2 minutes	Self-administered on Computer	Graphical presentation	NA	NA	Yes[a]
Hwang et al., 2005[195]	Illustrations (vs. none)	Print	1	NR	Researchers	Graphics	NA	NA	No
Mayhorn and Goldsworthy, 2007[189]	7 alternate teratogen symbols	Print	1	25 min	Researchers	Graphics	NA	NA	Yes
Peters et al., 2007[188] (study (2)	(1) color symbols (vs. black-white or no symbols)	Print	1	< 1 hour[a]	Researchers	Graphics, Color	NA	NA	Yes[a]
Peters et al., 2007[188] (study (3)	(1) symbols to indicate higher/lower quality (vs. none)	Print	1	< 1 hour[a]	Researchers	Graphics	NA	NA	Yes[a]
Walker et al., 2007[133]	Mind map (vs. none)	Print	1	Unknown[a]	Researchers[a]	Conceptual depiction	NA	NA	No
Wright et al., 2009[186]	Grouped dot icon arrays (vs. dispersed dot)	Print	1	NR	Researchers	Graphical simplification	NA	NA	NR

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
				Basic Interventions: Alternative Media					
Bryant et al., 2009[213]	Print + Video BPH Symptom Score (vs. Print Score)	Video, Computer	1	15 min[a]	Researchers	Oral delivery, color-coding of symptom score answers, Visual demonstration of scoring	NA	NA	No[a]
Campbell et al., 2004[200]	(1) Simplified consent form (2) Video consent (3) Compute-rized consent	Print, Video, Computer	1	< 1 hr	Researchers	Simple language, Chunking of ideas, White space, Pictures, Oral delivery	NA	NA	Yes[a]
Kang et al., 2009[212]	(1) Modified informed consent form (2) Modified informed consent + slide show	Print, Slide show	1	10-15 min. for Print; length of slide show NOS	Self-administered, although researchers delivered slide show	7th-grade reading level, large font, white space simple language, active voice, “action” cues Suitability Assessment of Materials score: 69%	NA	NA	Yes
Volandes et al., 2009[184]	Verbal narrative + Video showing features of advanced dementia	Oral, Video	1	2 min.	Researchers	Video	No	Yes[a]	No

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Basic Interventions: Alternative Reading Level and Document Design									
Campbell et al., 2004[200]	(1) Simplified consent form (2) Video consent (3) Computerized consent	Print, Video, Computer	1	< 1 hr	Researchers	Simple language, Chunking of ideas, White space, Pictures, Oral delivery	NA	NA	Yes[a]
Coyne et al., 2003[199]	Simplified consent form (vs. standard form)	Print	1	NR	Researchers	7th-8th grade reading level, Simple language, 1 idea per paragraph, Large font, White space, Pictures	NA	NA	No
Greene and Peters, 2009[214]	Simplified Medicaid health plan comparison chart (vs. standard chart)	Print	1	20 min[a]	Self-administered	Simplified document complexity (high school reading level), font size, focus on differences in information ordering	NA	NA	Yes[a]
Kang et al., 2009[212]	(1) Modified informed consent form (2) Modified informed consent + slide show	Print, Slide show	1	10-15 min. for Print; length of slide show NOS	Self-administered, although researchers delivered slide show	7th-grade reading level, large font, white space simple language, active voice, "action" cues Suitability Assessment of Materials score: 69%	NA	NA	Yes

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Sudore et al., 2007[204] Sudore, 2008[208]	Simplified advanced directive (vs. standard)	Print	1	< 30 min	Researchers	5th-grade reading level, values clarification questions. Large Font, Graphics	NA	NA	No
Sudore et al., 2006[192]	Simplified consent form	Print, Oral	1	10 min	Researchers	6th-grade reading level. Simple language, Large Font, Teach-back	NA	NA	No
Yates and Pena, 2006[191]	Simplified instruction sheet (vs. standard form at same readability)	Print	1	5-10 min	Researchers	Word reduction, Simple language, Chunking of ideas, Large Font, White space	NA	NA	Yes[a]
Basic Interventions: Provider Notification of Patient Literacy Status									
Seligman et al., 2005[181]	Provider notification of patient literacy level	Print	1	NA	Researchers	NA	NA	NA	No
Mixed Interventions: Adherence									
Bosworth et al., 2005[201]	Adherence intervention for HTN (education, skill building)	Telephone	~12	44 min (avg)	Nurses	Oral presentation, key concepts, information given to family/friend[a]	Yes	Yes	No
Brock and Smith, 2007[220]	Adherence intervention for HIV (education, skill building)	Video on PDA	1	17 min	Self	Simple language, Pictures/Graphics	No	NR	Yes
Kripalani et al., 2007[190]	Adherence intervention for CHD (pill card)	Individual Counseling, Print	1[a]	5 min[a]	Pharmacist	Pictures, Large Font	Yes	Social Cognitive Theory[a]	Yes

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Murray et al., 2007[182]	Adherence intervention for CHF (education, graphic med labels, skill building, monitoring and feedback, provider communication)	Patient: Individual counseling, Print Provider: telephone, paging, email	Variable, range not available[a]	~10-20 hours[a]	Pharmacist	6th grade reading level, Organization by mental schema, Lists/short paragraphs, Pictures	Yes	No (but patient-centered principles)	Yes
Mixed Interventions: Self-Management									
DeWalt et al., 2006[202]	Self Management intervention for CHF (education, skill building)	Individual counseling, Print, Telephone	10 to 16	Not measured[a]	Pharmacist or Health Educator	6th grade readability, Teach back	Yes	Social Cognitive Theory[a]	Yes
Gerber et al., 2005[194]	Self Management Intervention for DM (education, feedback)	Computer with audio/video	2.9 on average[a]	53.5 min on average[a]	Self	Audio/Video, Testimonials	Yes	Yes	No
Kim et al., 2004[197]	Self Management Intervention for DM (NR)	Individual and group counseling	4	10 hoursa	Diabetes Educators	6th grade reading level[a]	Noa	None[a]	NA[a]
Paasche-Orlow et al., 2005[79]	Self Management Intervention for Asthma (skill building)	Individual counseling, Print	1	30 min+	Researcher	Teach back	No	N	No

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Robinson et al., 2008[207]	Self Management Intervention for Asthma (literacy education, asthma education, skill building, goal setting, communication training)	Group counseling	29	68 hrs	Trained facilitators, NOS	NR	No	NR	Yes for asthma, no for literacy
Schillinger et al., 2008[187] Schillinger et al., 2009[210]	2 Self Management Interventions for DM (education, skill building)	(1) Telephone (2) Group Counseling	1 39 29	(1) 312 min (2) 810 min	(1) Automated Calls, Nurse (2) PCP, health educator	Oral presentation[a]	Yes[a]	No[a]	Yes[a]
Wallace et al., 2009[211]	Self Management Intervention for DM (education, goal setting)	Individual counseling, Print, Telephone	3	20-45 minutes based on measurement at 1 site	Researcher	Simple language, Conversational tone, Pictures	No	Yes	Yes
Mixed Interventions: Disease Management									
Rothman et al., 2004[198]	Disease Management Intervention for DM (education, trouble-shooting, med adjustment)	Individual counseling, Print, Telephone	~15[a]	~336 min[a]	Pharmacists	Simple language, Pictures, Simple organizational structure, Teach Back	Yes	No (general principles of Social Cognitive Theory applied) [a]	No[a]
Rothman et al., 2004[183]	Disease Management Intervention for DM (education, skill building, med adjustment)	Individual counseling, Print, Telephone	13+	463.2 min[a]	Pharmacists or Diabetes Care Coordinators	Simple language, Pictures, Simplified organizational structure, Teach Back, Repetition	Yes	No (general principles of Social Cognitive Theory applied) [a]	Yes[a]

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Mixed Interventions: Screening									
Ferreira et al., 2005[196]	Educational Intervention on Colorectal Screening	Provider: workshops Patient: Video, Print	Provider: 4-5 Patient: NR	Provider: 5-6 hr Patient: NR	Researchers	Provider: education on low health literacy communication strategies, NOSa Patient: Simple languagea	Providers: Yes Patients: No	Provider: none (although followed quality improvement principals) a Patient: Health Belief Modela	Providers: NR Patients: Yes
Kripalani et al., 2007[203]	(1) Educational Intervention on Prostate Cancer Screening (2) Cue to Discuss Prostate Cancer Screening	Print	1a	Not measureda	Researchers	Simple language, Pictures, Large Font, Key Concepts, Q and A	No	Nonea	Yes
Mixed Interventions: Other									
Davis et al., 2008[205]	Weight loss Intervention	Provider: workshops (education) Patient: Video (education, motivation)	Provider: 2 Patient: 1	Provider: 4 hr Patient: 15 min	Researchers	Physician: specific education interactions with low lit population Patient: 1st-2nd grade readability, teach back	No	Yes	No
Jay et al., 2009[218]	Nutrition label information card and video tutorial	Print, Video	1	~10-15 min	Researchers	Color, Chunking of ideas, Video	No	NR	Card: Yes Video: NR

Table 44. Intervention study detail (continued)

Author	Description	Medium	# of sessions	Contact time	Who Delivered	Literacy Strategies	Individual Tailoring	Theory Driven	Pre-testing
Kripalani et al., 2008[206]	(1) Modified Print Informed Consent with Oral Overview	(1) Print (2) Individual oral education	1	7-8 min on averagea	Researchers	(1) 8th grade readability, Chunking of ideas (2) teach back	No	No	No
Rudd et al., 2009[209]	(1) Arthritis Management Intervention (education, medicine calendar, hospital map) (2) Arthritis Management Intervention + Individual Counseling	Individual Counseling, Print	1+a	~1 hra	Arthritis Educator	5th to 8th grade readability, Avoidance of jargon	Yes (intervention (2)	Social Cognitive Theorya	Yesa
Sobel et al., 2009[215]	Linear video about asthma and its management	Video	1	6-20 min	Researchers	Specific to content, Video, Small number of new concepts	Yes	NR	NA, pilot study
Weiss et al., 2006[193]	Adult Basic and Literacy Education Intervention (education and job skill building)	Individual Counseling, Print, Computer	NR	18.1 hr (range 0-74 hr)	Program Staff	4th-grade readability, Short Sentences, Large Font, White Space, Avoid jargon	No	None (although focus on empowerment and locus of control) a	Yesa

Table 45. Single intervention strategies: alternative document design

Author, Date of Publication, Quality	Study design	Control Group	Intervention	Sample Size	% Population with Limited Literacy/ Numeracy	Outcomes	Difference
Greene et al., 2008[185] Fair	RCT	(1) Side-by-side comparison of characteristics (2) No framework	(1) Common/unique presentation of characteristics (2a) Short framework (2b) Long framework	303	50% Low (score less than 10 on DR Numeracy Test)	Mean # responses to comprehension questions (range 0-6)	Common vs. Side to Side (unadjusted) High Numeracy Subgroup: Comprehension: -0.3, NS Low Numeracy Subgroup: Comprehension: -0.3, NS Short framework vs. No (unadjusted) High Numeracy Subgroup: Comprehension: +0.7, ($P < 0.05$) Low Numeracy Subgroup: Comprehension: +0.3, ($P < 0.05$) Long framework vs. No (unadjusted) High Numeracy Subgroup: Comprehension: +0.5, ($P < 0.05$) Low Numeracy Subgroup: Comprehension: -0.5, ($P < 0.05$)

Info=information; NR=not reported; NS=not significant; RCT=randomized controlled trial; vs.=versus.

Table 45. Single intervention strategies: alternative document design (continued)

Author, Date of Publication, Quality	Study design	Control Group	Intervention	Sample Size	% Population with Limited Literacy/ Numeracy	Outcomes	Difference
Peters et al., 2007[188] (Study 1) Fair	RCT	Non-ordered, non-essential info	(1) Ordered essential and non-essential info (= all) (2) Essential info only	303	50% Low (score less than 10 on DR numeracy test)	Mean # correct responses to comprehension questions (range 0-3) % choosing higher quality hospital	Ordered, all vs. Control (unadjusted) High Literacy Subgroup: Comprehension: +0.1, NS Choice: +5%, NS Low Literacy Subgroup: Comprehension: +0.6, (P < 0.01) Plan Choice: +9%, NS P for literacy interaction: comprehension: (P < 0.05) Choice: NS Essential only, vs. control (unadjusted): Overall: Comprehension: +0.4, (P < 0.01) Choice: +21%, (P < 0.01) High Numeracy Subgroup: Comprehension: +0.3, (P < 0.01) Choice: +19%, NR Low Numeracy Subgroup: Comprehension: +0.7, (P < 0.01) Choice: +23%, NR P for interaction: comprehension: (P < 0.05) Choice: NS

Table 46. KQ 2 specific interventions: strength of evidence grades by type of outcome

Outcome	Number of Studies	Results	Overall Grade
Alternative Document Design	2 RCTs examining multiple simplifications	Highlighting common quality features (n = 1): No effect Providing a framework for quality features (i.e., chunking advantages and disadvantages; n = 1): Improved comprehension for high literacy, worsened comprehension for low literacy if long rather than short list of features Presenting only essential quality info (i.e., death rates, not satisfaction) (n = 1): Improved comprehension and choice of higher quality plans Presenting essential quality info first (n = 1): Improved comprehension for low literacy only, no effect on health plan choice	Insufficient
Alternative Numerical Presentation	3 RCTs examining different numerical presentations	Presenting quality information such that the higher number (vs. lower number) is better: Improved comprehension and choices of higher quality options for low (but not high) numeracy individuals Presenting information about the baseline risk of disease and treatment benefit information with the same vs. different numbers: Improved accuracy of risk perception with greater effect in low vs. high numeracy group Presenting positive predictive values as natural frequencies rather than conditional probabilities: improved comprehension equally for low and high literacy individuals	Low
Alternative Pictorial Representations	6 RCTs and 2 quasi-experimental studies examining (1) adding symbols to numerical information, (2) adding icon arrays to numbers, (3) adding illustrations to prose, (4) using different pictorial representations for same concept	Adding symbols to numerical info (n = 2): Mixed effects depending on the symbols and the information to which they were added. Plus/minus signs to indicate fewer/more had no overall effect, although there was an interaction by whether higher quality was indicated by higher or lower numbers. Black and white and colored traffic light circles had no effect on comprehension, but increased the proportion of individuals choosing high quality hospitals. However, there was an interaction by (1) whether essential (i.e., death rates) or both essential and non-essential (i.e., death rates and satisfaction) quality information was presented, and (2) by numeracy level. Adding icon arrays to numbers (n = 2): Improved understanding of both ARR and RRR presentations when icons were added. Interaction by (1) numeracy level, and (2) whether numbers and icon arrays depicted baseline risk and the risk following treatment with the same or different denominators.	Insufficient

Table 46. KQ 2 specific interventions: strength of evidence grades by type of outcome(continued)

Outcome	Number of Studies	Results	Overall Grade
		Adding illustrations to prose (n = 2): No effect of mind map added to brochure or illustrations added to simple medication label text Using different pictorial representations for the same concept (n = 2): No overall improvement with grouped (vs. random) icon arrays, although interaction by numeracy level. Some teratogen warning symbols	
Alternative Media	4 RCT examining alternate media; 3 examining adding or substituting other media for print and 1 examining adding video to verbal narrative	Effect of adding or substituting for print (n = 3): Effect for adding video, computer, or slide show presentations to print were mixed. Effect for simplified print were mixed depending on the reading level of the printed materials and study design and quality Effect of adding video to verbal narrative (n = 1): Improved knowledge and preference for comfort care.	Insufficient
Alternative Readability and Document Design	6 RCTs, 1 quasi-experimental study with post-only data	Mixed results depending on degree of simplification, literacy level of population, and study quality	Insufficient
Physician Notification of Patient Literacy Status	1 cRCT	No effect on patient level outcomes	Low

RCTs=randomized controlled trials; info=information; vs.=versus; cRCT=cluster randomized controlled trial

Table 47. Single intervention strategies: alternative numerical presentation

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% population with Limited Literacy/ Numeracy	Outcomes	Difference
Peters et al., 2007[188] (Study 3) Fair	RCT	Lower is better, no symbols	(1) higher is better, no symbols (2) lower is better, symbols (3) higher is better, symbols	303	50% (score < 10 on DR Numeracy Test)	Mean # correct responses to comprehension questions (range 0-4) % choosing higher quality hospital	Higher is better vs. Lower is better (unadjusted): Comprehension: Overall: +0.4, (P < 0.001) High literacy Subgroup:+0.2, NS Low literacy Subgroup: +0.7 a, (P < 0.01) Choice: Overall: +13%, (P < 0.01) High Literacy Subgroup: NR (interaction by symbols) Low Numeracy Subgroup: +20% a, (P < 0.05) Symbols vs. No Symbols: Comprehension: Overall: NR, P < 0.10 High Literacy Subgroup: -0.3a, (P < 0.05) Low Literacy Subgroup: -0.1[a], NR Choice: Higher Literacy Subgroup: -7%a, NR Lower Literacy Subgroup: +5%a, NR Higher # better, no symbols vs. Control: High Literacy Subgroup: Comprehension: +0.3, NR Choice: -4%

[a]Calculated by reviewers; [b]Weighted percent; [c]Calculated by research team
12-pt=12-point; NR=not reported; NS=not significant; RCT=randomized controlled trial; vs.=versus.

Table 47. Single intervention strategies: alternative numerical presentation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% population with Limited Literacy/ Numeracy	Outcomes	Difference
							Low Literacy Subgroup: Comprehension: +0.3, NR Choice: +26%, (*P* < 0.05) Lower # better + symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: -0.2, NR Choice: -19% Low Literacy Subgroup: Comprehension: -0.2, NR Choice: +12%, NR Higher # better + symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: -0.1, NR Choice: +1% Low Literacy Subgroup: Comprehension: +0.5, NR Choice: +25%, (*P* < 0.05)
Galesic et al., 2009[217] Fair	RCT	Information about genetic testing for early detection of diabetes or trisomy 21 presented as conditional probabilities (% with condition,	Natural frequencies (x/10,000) Presented to illustrate the positive value of genetic testing for early detection of diabetes or trisomy 21	162 (47 older adults, 115 younger adults)	Mean numeracy on 12-pt scale derived from Lipkus & Schwartz: Overall: 9.7 Older adults: 8.6 Younger adults: 10.3	% Accurately perceiving risk	Natural frequency vs. conditional probability overall (unadjusted): NR, (P = 0.001) High numeracy vs. low numeracy, overall (unadjusted): NR, (P +0.01) Absolute difference in accurate answers (% all correct) by numeracy (unadjusted): High numeracy (natural frequency vs. conditional probability): + 24%[a], NR Low numeracy (natural frequency vs. conditional probability): +27%[a], NR

Table 47. Single intervention strategies: alternative numerical presentation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% population with Limited Literacy/ Numeracy	Outcomes	Difference
		probability of + test with disease, probability of negative test with disease)					Absolute difference (younger vs. older, overall): NR, (*P* = 0.31)
Garcia-Retamero et al., 2009[219] Fair	Factorial RCT	Numerical information with different denominators for baseline risk and treatment benefit (800/100 or 100/800)	Numerical information with the same denominators for baseline risk and treatment benefit (800/800 and 100/100)	1047 (534 from German, 513 from US)	49% Low numeracy (> median score on 9-item scale adapted from Lipkus and Schwartz) (Germany: 49%[b], US: 48%[c])	% Accurate perception of risk reduction	% accurate, same versus different denominators (with or without icon arrays): Low numeracy: +25%[c], P not reported High numeracy: +16%[c], P not reported Overall effect of denominator: not reported, adjusted (*P* = 0.001) Overall effect of numeracy: adjusted (*P* = 0.001)

Table 48. Single intervention strategies: additive and alternative pictorial representation

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Galesic et al., 2009[216] Fair	Factorial RCT	No icon arrays (either ARR or RRR numerical presentation)	Icon arrays	171 (59 older adults, 112 students)	Mean numeracy on 12-pt scale derived from Lipkus & Schwartz: Older adults: 8.6 Students: 10.3	% Accurately perceiving risk	Older adults, high numeracy: Icons vs Numerical RRR (unadjusted): +11%, NS[a] Icons vs Numerical ARR (unadjusted): +5%, NS[a] Older adults, low numeracy: Icons vs Numerical RRR (unadjusted): +75%, sig[a] Icons vs. Numerical ARR (unadjusted): +30%, sig[a] Students, high numeracy: Icons vs Numerical RRR (unadjusted): +23%,sig[a] Icons vs Numerical ARR (unadjusted): -1%, NS[a] Students, low numeracy: Icons vs Numerical RRR (unadjusted): +24%, NS[a] Icons vs Numerical ARR (unadjusted): +21%, NS[a] Overall p for numerical format (ARR vs RRR): +49%[b], (P = 0.001) overall p for icon array (yes/no):+23%[b] (P = 0.002)

[a]difference calculated by research team, significance read from figure; [b]Calculated by research team; [c]Weighted percents; [d]Calculated by research team
12-pt=12-point; ARR=absolute risk ratio; B&W symbols=black and white symbols; CI=confidence interval; e.g.=example; info=information; NOS=not otherwise specified; NR=not reported; NS= not significant; OR=odds ratio; Quasi-=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; RRR=relative risk ratio; sig=significant; US=United States; vs.=versus.

Table 48. Single intervention strategies: additive and alternative pictorial representation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Garcia-Retamero et al., 2009[219] Fair	Factorial RCT	Numerical information only (including varying sizes of denominator)	Numerical information plus icon array (including information presented with varying sizes of denominators)	1047 (534 from German, 513 from US)	49% Low numeracy (> median score on 9-item scale adapted from Lipkus and Schwartz) (Germany: 49%[c,] US: 48%[c])	% Accurate perception of risk reduction	Accurate estimates difference (when size of denominators different; unadjusted): Low numeracy: +32%c, P NR High numeracy: +11%c, P NR Accurate estimates difference (when size of denominator same; unadjusted): Low numeracy: +11%c, P NR High numeracy: -16%c, P NR Interactions between numeracy and icon arrays (P = 0.008) and size of denominators and icon arrays (P = 0.001)
Hwang et al., 2005[195] Fair	Quasi-(post-post)	Medication label text: A. Take with water B. May cause drowsiness C. Take with food D. No alcohol E. Take on an empty stomach	Medication label text + illustration	130	5% REALM ≤ 6th grade 22% REALM 7th-8th grade	% correctly interpreting prescription label	Change in Interpretation of Label B with illustration: Improved: 5 No Change: 87% Worse: 9% (unadjusted P = 0.33) Change in Interpretation of Label E with illustration Improved: 7% No Change: 86% Worse: 7% (unadjusted P = 1.00) Note: change in interpretation of labels A, C, D = 0

Table 48. Single intervention strategies: additive and alternative pictorial representation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Mayhorn and Goldsworthy, 2007[189] Fair	Quasi- (post only)	Original teratogen symbol (slash through pregnant woman)	(1) Original symbol, but woman taking pill (2) Cross and skull bones in pregnant belly (4) 2 pictures: Original symbol + skull bones in pregnant belly (5) 2 pictures: #4 but more caricatured (6) 1 picture combining original symbol + skull bones in pregnant belly (7) skull bones in pregnant belly + inlay with slash through person taking pills	700	42.9% Low literacy (REALM, NOS)	% Who correctly identify symbol meaning as “don’t take if pregnant” % Who correctly identify symbol as “causes birth defect”	"Don't take if pregnant" (x versus original symbol 3) Symbol 1 +4%, NR Symbol 2: -8%, NR Symbol 4: +3%, NR Symbol 5: +8%, NR Symbol 6: -29%, NR Symbol 7: -10%, NR "Causes birth defects" (x versus original symbol 3) Symbol 1: -1%, NR Symbol 2: +14%, NR Symbol 4: +19%, NR Symbol 5: +14%, NR Symbol 6: +4%, NR Symbol 7: +15%, NR Note: addition of text that says “causes birth defects” increase understanding for all

Table 48. Single intervention strategies: additive and alternative pictorial representation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Peters et al., 2007[188] (Study 2) Fair	RCT	Numbers only	(1) essential info (e.g. death rates) accompanied by black/white symbols (2) essential info (e.g. death rates) accompanied by traffic symbols (3) essential and non-essential info (e.g. death rates and satisfaction) accompanied by black/white symbols (4) essential and non-essential info (e.g. death rates and satisfaction) accompanied by traffic symbols	303	50% (Median split)	Mean # of correct comprehension questions (range 0-3) % choosing higher quality hospital	Symbols vs. Numbers (unadjusted): Overall: Comprehension: NR, NS Choice: +14%, (*P* < 0.05) High Numeracy Subgroup: Comprehension: NR Choice: +18%[c], NR Low Numeracy Subgroup: Comprehension: NR Choice: -5%[c], NR p for interaction by numeracy: Comprehension: (*P* < 0.001) Choice: NR Colored vs. B & W symbols (unadjusted): Overall: Comprehension: NR Choice: +3%[d], NS High Literacy Subgroup: Comprehension: NR Choice: 16%[d], (*P* < 0.05) Low Literacy Subgroup: Comprehension: NR Choice: -11%[d], NS

Table 48. Single intervention strategies: additive and alternative pictorial representation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Peters et al., 2007[188] (Study 2) (continued)							Effect of Symbols on Choice: Essential info with B&W symbols (unadjusted): High Literacy Subgroup: +12%, NR Low Literacy Subgroup: +11%, NR Essential info with traffic light symbols (unadjusted): High Literacy Subgroup: +29%, NR Low Literacy Subgroup: +6%, NR Essential and non-essential info with B&W symbols (unadjusted): High Literacy Subgroup: +7%, NR Low Literacy Subgroup: -9%, NR Essential and non-essential info with traffic light symbols (unadjusted): High Literacy Subgroup: +22%, NR Low Literacy Subgroup: -26%, NR p for interaction (essential vs. non-essential): $P < 0.05$ p for interaction (literacy level): $P < 0.05$

Table 48. Single intervention strategies: additive and alternative pictorial representation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Peters et al., 2007[188] (Study 3) Fair	RCT	Lower number is better quality, no symbols	(1) higher number is better quality, no symbols (2) lower number is better quality, symbols (3) higher number is better quality, symbols	303	50% (score < 10 on DR Numeracy Test)	Mean # correct responses to comprehension questions (range 0-4) % choosing higher quality hospital	Symbols vs. No Symbols (unadjusted): Comprehension: Overall: NR, *P* < 0.10 High Literacy Subgroup: -0.3 [c], (*P* < 0.05) Low Literacy Subgroup: -0.1[d], NR Choice: Higher Literacy Subgroup: -7%[c], NR Lower Literacy Subgroup: +5%[c], NR Higher # better, no symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: +0.3, NR Choice: -4% Low Literacy Subgroup: Comprehension: +0.3, NR Choice: +26%, (*P* < 0.05) Lower # better + symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: -0.2, NR Choice: -19%, P not reported Low Literacy Subgroup: Comprehension: -0.2, NR Choice: +12%, *P*, NR

Table 48. Single intervention strategies: additive and alternative pictorial representation (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Peters et al., 2007[188] (Study 3) (continued)							Higher # better + symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: -0.1, NR Choice: +1% Low Literacy Subgroup: Comprehension: +0.5, NR Choice: +25%, (P < 0.05)
Walker et al., 2007[133] Fair	RCT	Standard Arthritis Booklet	Standard Arthritis booklet + Mind Map	363	15% REALM < 60 (9th grade)	Mean Rheumatoid Arthritis Knowledge Score (range -40 to 40)	Overall: -0.11, (unadjusted P > 0.3) Note: REALM score predicts change in knowledge, (adjusted P < 0.003)
Wright et al., 2009[186] Fair	RCT	Dispersed dot icon arrays (3 different risk magnitudes: 3%, 6%, 50%)	Grouped dot icon arrays (3 different risk magnitudes: 3%, 6%, 50%)	140	41% Low (incorrect answer to 1st question on Lipkus numeracy scale)	% correctly identifying largest of 3 displayed risks	Grouped vs. dispersed dot icon arrays, adjusted OR comprehension: 2.26 (95% CI 0.779 to 6.57) [d] Comprehension with grouped dot icon array (unadjusted OR high vs. low numeracy): 3.830 (95% CI, 1.301-11.280) Comprehension with dispersed dot icon array (unadjusted OR high vs. low numeracy): 10.2, CI, NR Interaction term (display by numeracy): NS

Table 49. Single intervention strategies: alternative media

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Sizes	% Population Limited Literacy	Outcomes	Difference
Bryant et al., 2009[213] Fair	RCT		Multimedia computer version of American Urological Association's BPH symptom score AUA-SS	232	28% < high school on REALM Mean REALM score: 59	Mean number of errors on AUA-SS compared with health-professional-administered AUA-SS % understanding AUA-SS questions (i.e. less than 2-pt difference between experimental derived and interviewer derived scores) Accuracy of categorical classification on AUA-SS	Mean symptom score error: Overall (multimedia-written): -1.51 (*P* < 0.001) ≥ HS: -1.24 (*P* <0.001) < HS: -2.31 (*P* 0.03) % understanding of questions overall (multimedia-written): 19% (*P* NR) ≥ HS: +18% (*P* NR) < HS: +25% (*P* NR) Accuracy of classification: +13% (*P* = 0.04)
Campbell et al., 2004[200] Fair	RCT	Standard print consent form	(1) Simplified print consent form (2) Video consent (3) Computerized consent	233	50% Low (≤ 8th grade reading level on Woodcock Johnson) Average REALM score 56.3	% of total information remembered on free recall % of correct answers on prompted recall	% of total information remembered on free recall (adjusted): Simplified vs. standard: +0.1%, NS Video vs. standard: 0.1% < NS Computer vs. standard: -0.1%, NS Note: No interaction by literacy level (unadjusted) % correct answers on prompted recall (adjusted): Simplified vs. standard: +6%, NS Note: Trend toward improvement in low literacy group (unadjusted) Video vs. standard: +3%, NS Computer vs. standard: +4%, (*P* = 0.08)

[a]Calculated by research team

2-pt=2-point; AUA-SS=American Urological Association-Symptom Score; BPH=benign prostatic hyperplasia; CI=confidence interval; HL=health literacy; HS=high school; info=information; MIC=modified informed consent; MIC + SS=modified informed consent + slide show; NR=not reported; NS=not significant; OR=odds ratio; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; ref=reference; vs.=versus; WRAT=Wide Range Achievement Test.

Table 49. Single intervention strategies: alternative media (continued)

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Sizes	% Population Limited Literacy	Outcomes	Difference
Kang et al., 2009[212] Fair	RCT	Standard informed consent	1) MIC form 2) MIC + slide show (MIC + SS)	90	Patient: Median REALM and WRAT scores: high school Parent: Median REALM and WRAT scores: high school Note: Intervention delivered to patient and parent	% with combined recall of info and comprehension	Combined recall and comprehension (unadjusted): Patient: MIC vs. control: +6.5%[a], NS MIC +SS vs. control: -1.2%[a], NS Note: recall improves with MIC + SS (10.5%, $P < 0.05$), comprehension does not (+6.3%, NS) Parent: MIC vs. control: 1.4%[a], NS MIC + SS vs. control: +10.0[a], ($P < 0.05$) Note: recall improves with MIC + SS (+8.9[a], $P < 0.05$), so does comprehension (+11.6%[a], $P < 0.001$)
Volandes et al., 2009[184] Good	RCT		Verbal narrative + Video showing features of advanced dementia	200	18% ≤ 6th grade on REALM 12% 7-8th grade on REALM	Mean knowledge on 5-point scale (higher scores better) % Preferring comfort care	Mean knowledge: Unadjusted difference: +0.9, ($P < 0.001$) Overall preference for comfort care: Unadjusted difference: +22% (95% CI, 11% to 34%) Adjusted OR: 3.9 (1.8-8.6) Preference for comfort care by HL group: Unadjusted differences: ≤ 6th grade HL: ref 7th-8th grade HL: 13% (-13 to 38%) ≥ 9th grade HL: 39% (21% to 56%) Adjusted OR: ≤ 6th grade HL: ref 7th-8th grade HL: 1.7 (0.54-5.3) ≥ 9th grade HL: 4.1 (1.6-10.8)

Table 50. Single intervention strategies: Alternative readability and document design

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Campbell et al., 2004[200] Fair	RCT	Standard print consent form	(1) Simplified print consent form (2) Video consent (3) Computerized consent	233	50% Low (≤ 8th grade reading level on Woodcock Johnson) Average REALM score 56.3	% of total information remembered on free recall % of correct answers on prompted recall	% of total information remembered on free recall (adjusted): Simplified vs. standard: +0.1%, NS Note: No interaction by literacy level % correct answers on prompted recall (adjusted): Simplified vs. standard: +6%, NS Note: Trend toward improvement in low literacy group
Coyne et al., 2003[199] Fair	RCT	Standard Consent Form	Simplified consent form	44 oncology groups 226 patients	Mean REALM: 65	% of answers correct to 23 comprehension questions Note: Also measured decision to participate	Overall difference (unadjusted): 3%, (*P* = 0.21)

[a]Calculated by research team; [b]Read from table
Lit=literacy; NR=not reported; NS=not significant; OR=odds ratio; Quasi-=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; std=standard; TOFHLA=Test of Functional Health Literacy in Adults; WRAT=Wide Range Achievement Test.

Table 50. Single intervention strategies: Alternative readability and document design (continued)

Author, Date of Publication, Quality	Study Design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Greene and Peters, 2009[214] Fair	RCT		Revised Medicaid health plan comparison chart with four key changes: (1) List only the benefits with differences between plans (2) Cost-sharing and benefit information in rows rather than columns (3) Arranged plans from most generous to least generous based on cost-sharing and benefits (instead of alphabetically) (4) Increased font size to 10 (13 for headers)	122	57% TOFHLA Cloze score ≤ 18 (out of 20)	Comprehension (# of correct answers)	Full index (unadjusted, out of 9): Overall: NR Low Lit: +0.1a, NS High Lit: +0.7a, NS Identifying subindex (unadjusted, out of 6): Overall: NR Low Lit: -0.2a, NS High Lit: +0.5a, NS Synthesizing Subindex (unadjusted, out of 3): Overall: NR Low Lit: +0.3a, NS High Lit: +0.1a, NS p for interaction for full and sub-indices < 0.05

Table 50. Single intervention strategies: Alternative readability and document design (continued)

Author, Date of Publication, Quality	Study Design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Kang et al., 2009[212] Fair	RCT	Standard informed consent	1) Modified informed consent form (MIC) 2) Modified informed consent + slide show (MIC + SS)	90	Patient: Median REALM and WRAT scores: high school Parent: Median REALM and WRAT scores: high school Note: Intervention delivered to patient and parent	% with combined recall of info and compre-hension	Combined recall and comprehension (unadjusted difference): Patient: MIC-control: +6.5%[a], NS Parent: MIC-control: 1.4%[a], NS
Sudore et al., 2006[192] Fair	Quasi-(post only)	None	Simplified consent form	204	22% TOFHLA Inadequate 18% TOFHLA Marginal	# of passes through the teach-to-goal consent process required to obtain consent # of compre-hension statements missed on the first pass of questioning	Overall # of passes through teach to goal: 1: 28% 2: 53% 3: 20% Unadjusted P for literacy interaction: 0.02; 11% of those with inadequate literacy required only 1 pass whereas 36% of individuals with adequate literacy required only 1 pass Adjusted OR for requiring more than 1 pass (for each 1-pt decrease in s-TOFHLA): 1.04 (95% CI 1.00 to 1.07) # of comprehension statements missed on first pass questioning: 0: 28% 1: 30% 2 or more: 42% Adjusted OR for missing comprehension (for each 1-pt decrease in s-TOFHLA): 1.04 (95% CI 1.00 to 1.07)

Table 50. Single intervention strategies: Alternative readability and document design (continued)

Author, Date of Publication, Quality	Study Design	Control	Intervention	Sample Size	% Population with Limited Literacy	Outcomes	Difference
Sudore et al., 2007[204] Sudore et al., 2008[208] Fair	RCT	Standard Advanced Directive	Simplified Advanced Directive	205	40% TOFHLA < 22 (Inadequate or Marginal)	Knowledge of advance directive topics, Advance directive completion at 6 months Note: Also measure % of form completed	Knowledge (adjusted for baseline knowledge): +1%, (P = 0.30) Advance directive completed at 6 months (unadjusted): +11%, (P = 0.03)
Yates and Pena, 2006[191] Fair	RCT	Standard head trauma advice form	Simplified head trauma advice form	200	1.5% REALM < 7th gradeb 14% REALM 7th-8th gradeb	Mean comprehension score (range 0-10)	Median score: +1 correct: (unadjusted P < 0.0001) Adjusted OR comprehension (simplified versus std): 4.14 (2.19 - 7.81) No interaction by literacy level

Table 51. Single intervention strategies: physician notification of patient literacy levels[a]

Author, Date of Publication, Quality	Study design	Control	Intervention	Sample Size	% Population Limited Literacy	Outcomes	Difference
Seligman et al., 2005[181] Fair	cRCT	Usual Care for Diabetes	Physician notification of patients' health literacy status	63 MDs 182 pts	74% TOFHLA Inadequate 16% TOFHLA Marginal	% of physicians reporting use of > 3 communication enhancing strategies Mean patient Self-efficacy using Patient Enablement Instrument (range 0-12) Mean HgbA1c	% physicians with intensive use of communication strategies (adjusted OR): 4.7, 95% CI, 1.4-16.0 Note: trends toward differences for individual communication strategies of involving family/friends and referring to a nutritionist Patient Self-efficacy (adjusted): -0.3, (P = 0.61) HbA1c (adjusted): -0.27, 95% CI, -0.80-0.27

[a]Communication strategies include Involving family members or friends; referring to a nutritionist; using pictures of diagrams; referring to a diabetes educator; reviewed understanding of medications; spending time teaching about diabetes

CI=confidence interval; cRCT=cluster randomized controlled trial; HgbA1c=glycosylated hemoglobin; MDs=medical doctors; OR=odds ratio; pts=patients; TOFHLA=Test of Functional Health Literacy in Adults.

Table 52. Effect of mixed interventions on use of health care services

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
DeWalt et al., 2006[202] Fair	RCT	Usual Care + low literacy pamphlet on CHF	CHF Self-Management program	127	41% S-TOFHLA inadequate	Hospitalization	Hospitalization or death: Overall: IRR (unadjusted) = 0.69 (95% CI, 0.40-1.19) Inadequate literacy subgroup: IRR (adjusted) = 0.39 (95% CI, 0.16-0.91) Marginal/adequate literacy subgroup: IRR (adjusted) = 0.56 (95% CI, 0.30-1.04)
Ferreira et al., 2005[196] Fair	cRCT	Usual Care	Educational Intervention for Physicians and Patients on Colorectal Cancer screening	113 MDs 1978 pts	31% Low (< 9th grade on TOFHLA) Note: measured only in 19% of patients	% of patients for whom any CRC screening test[a] is recommended in 18 months following visit % of patients for whom screening is completed within x timeframe	Difference in Any Recommendations: Overall: 6.6%, (*P* = 0.02) Literacy subgroup results NR Difference in Completion of Any Tests: Overall: 8.9%, (*P* = 0.003) Low Literacy Subgroup: 25.7%, (unadjusted *P* = 0.002)[b] High Literacy Subgroup: 3%, (unadjusted *P* =0.65)[b]
Gerber et al., 2005[194] Fair	RCT	Usual Care + computerized quizzes on diabetes-related concepts	Diabetes Self-Management Intervention	144	56% S-TOFHLA < 22 (Inadequate or marginal)	Receipt of Recommended Medical Services (NOS)	Low Literacy Subgroup: Change Medical Care (adjusted): -0.29, NS High Literacy Subgroup: Change Medical Care (adjusted): -0.07, NS

[a] any CRC screening test includes home fecal occult blood testing, sigmoidoscopy, and colonoscopy; [b]adjusted only for effects of clustering of patients within providers
CHF=congestive heart failure; CI=confidence interval; CRC=colorectal cancer; cRCT=cluster randomized controlled trial; DRE=digital rectal examination; ED=emergency department; ER=emergency room; IRR=incidence rate ratio; MDs=medical doctors; NA=not applicable; NOS=not otherwise specified; NR=not reported; NS=not significant; OR=odds ratio; PSA= prostate specific antigen; pts=patients; Quasi=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; S-TOFHLA=short form Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults

Table 52. Effect of mixed interventions on use of health care services (continued)

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Kripalani et al., 2007[203] Fair	RCT	Handout, NOS Unclear if prostate content or other content	(1) Educational Intervention on Prostate Cancer Screening (2) Cue to Discuss Prostate Cancer screening	303	38% REALM < 3rd grade 18% REALM 4th-6th grade 23% REALM 7th-8th grade	PSA test ordered DRE documented	Education PSA test ordered (adjusted OR): 7.62; CI, 1.62-35.83 DRE documented (adjusted OR): 0.85; CI 0.21-3.37 Cue PSA test ordered (adjusted OR): 5.86; CI, 1.24-27.81 DRE documented (adjusted OR): 1.04; CI, 0.29-3.76
Murray et al., 2007[182] Good	RCT	Usual Care	CHF Adherence Intervention	314	29% "not literate" on S-TOFHLA (NOS)	ED visit Hospitalization	ED visits: Absolute difference(unadjusted): -0.52, NR Incidence rate ratio (unadjusted): 0.82 (0.70 to 0.95) Hospitalizations: Absolute difference (unadjusted): -0.21, NR Incidence rate ratio (unadjusted): 0.81 (95%, CI 0.64-1.04)
Robinson et al., 2008[207] Fair	Quasi (pre-post)	NA	Asthma Self-Management Intervention	110	Mean Gilmore Oral Reading Test Score: 3.2	Asthma-related ED visits: Asthma-related hospitalizations:	ED visits (unadjusted): - 29.6%, (*P* < 0.01) Interaction by literacy subgroup: adjusted OR for Effect of reading level on ER visits: 0.34 (0.22 - 0.52) Hospitalizations (unadjusted): -14.9%, (*P* < 0.001) Interaction by literacy subgroup: adjusted OR for effect of reading level on ER visits: 1.31 (0.82 to 2.10)

Table 53. KQ 2 Mixed interventions: strength of evidence grades by type of outcome

Outcome	Number of Studies	Results	Overall Grade
Use of Healthcare Services	4 RCTs, 1cRCT, and 1 quasi-experimental study	Preventive services (n = 2): Increased use across literacy levels ED visits (n = 2): Reduced use across literacy levels Hospitalizations (n = 3): Reduced use (or trends toward reduced use) across literacy levels; greater reductions in low literacy population	Moderate
Knowledge	3 RCTs and 7 quasi-experimental studies (including 2 with post-test only data on knowledge, which precluded conclusions)	Mixed results with 4 of 8 studies with interpretable data showing an effect on knowledge	Insufficient
Self Efficacy	4 RCTs and 5 quasi-experimental studies	Mixed results depending on intensity of intervention; for intensive interventions although these analyses for these interventions weren't stratified by literacy level	Insufficient
Skill	1 RCT	Improved label reading skill with greater effect in those with high literacy (However, 2 studies from 2004 review found mixed results)	Insufficient[a]
Behavior	2 RCTs and 1 quasi-experimental study	Improved self-management behaviors, greater improvement in adequate literacy group in the 1 study that performed analysis stratified by literacy level	Moderate
Adherence	3 RCTs and 2 quasi-experimental studies (1 with post-test only data)	Mixed results related to the intensity of the intervention and measure of adherence	Insufficient
Disease Prevalence and Severity	4 RCTs, 3 quasi-experimental studies	Self-management programs (n = 3): mixed effects on biomarkers depending on study quality Disease management programs (n = 2): improved HbA1c in low literacy group, improved BP across literacy levels Adult Basic and Literacy Education (n = 1): improved depression severity across literacy levels	Self-management programs: Insufficient Disease management programs: moderate Adult basic and literacy education: low
Quality of Life	4 RCTs (1 measured QoL only post-test in intervention group)	Mixed results	Insufficient
Costs	2 RCT	Non-significant trend toward reduced cost across literacy groups	Insufficient

[a]data from 2004 review modified the overall strength of evidence from low to insufficient
RCTs=randomized controlled trials; HbA1c=glycosylated hemoglobin; BP=blood pressure; QoL=quality of Life; cRCT=cluster randomized controlled trial; ED=emergency department

Table 54. Effect of mixed interventions on knowledge

Author, Date of Publication, Quality	Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference Between Control and Intervention Groups
Bosworth et al., 2005[201] Fair	RCT	Usual Care	Tailored Adherence Intervention	588	38% low literacy[a]	Mean Change in Hypertension knowledge (score range 0 - 10)	Overall: 0, (unadjusted P = 0.49)
Brock and Smith, 2007[220] Fair (although poor for adherence)	Quasi- (pre-post)	NA	Adherence Video on PDA	51	55% REALM < 8th grade	Mean HIV and HIV medication Knowledge (9-pt. scale)	Overall: NR, (unadjusted P < 0.005)
Davis et al., 2008[205] Fair	Quasi- (pre-post)	None	Weight loss intervention	101	49% REALM < 6th grade 22% REALM 7th-8th grade	Patient recall of MD recs. to lose weight, increase physical activity or see a dietician	Patient recall of recommendations: Lose weight +43%, (unadjusted P = 0.02) Increase physical activity +41%, (unadjusted P = 0.01) Go to dietician +39%, (unadjusted P = 0.002)
DeWalt et al., 2006[202] Fair	RCT	Usual Care + low literacy pamphlet on CHF	CHF Self-Management program	127	41% S-TOFHLA inadeq.	% CHF Knowledge questions correct	Overall (adjusted): 12% (95% CI, 6-18%)
Gerber et al., 2005[194] Fair	RCT	Usual Care + computerized quizzes on diabetes-related concepts	Diabetes Self-Management Intervention	144	56% S-TOFHLA < 22 (Inadeq. or marginal)	Mean Change in Diabetes Knowledge (scale NR)	Low Literacy Change Knowledge (adjusted): -0.12, NS High Literacy Change Knowledge (adjusted): +0.3, NS

[a]Determined through personal communication with author; [b]absolute difference calculated by research team

9-pt. scale=9-point scale; adeq.=adequate; CHF=congestive heart failure; CI=confidence interval; HIPAA=Health Insurance Portability and Accountability Act of 1996; HIV=human immunodeficiency virus; HL=health literacy; inadeq.=inadequate; MD rec.=physician's recommendations; NA=not applicable; NR=not reported; NS=not significant; PDA=personal digital assistant; Quasi-=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; sig=significant; S-TOFHLA=short form Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; vs.=versus.

Table 54. Effect of mixed interventions on knowledge (continued)

Author, Date of Publication, Quality	Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference Between Control and Intervention Groups
Kripalani et al., 2008[206] Fair	Quasi- (post only)	No control	1) Modified Print informed Consent with Oral Overview	408	21% REALM < 3rd grade 25% REALM 4th - 6th grade 31% REALM 7th - 8th grade	Odds of correctly teaching back consent and HIPAA information on first attempt (relative to those with literacy level < 3rd grade	Correct teach back 1st attempt by literacy subgroup (adjusted): 4th - 6th grade - 2.259 (1.048-4.869) 7th - 8th grade - 2.275 (1.049-4.935) > 9th grade - 4.344 (1.814-10.404)
Kim et al., 2004[197] Fair	Quasi- (pre-post)	None	Diabetes Self-Management Intervention	92	23% S-TOFHLA < 22 (Inadeq. or marginal) (15% inadeq. on TOFHLA)	% Diabetes Knowledge Questions Correct	Overall (adjusted): NR, sig Adeq. vs. Inadeq. HL (adjusted): NR (+), (P < 0.001)
Paasche-Orlow et al., 2005[79] Fair	Quasi- (pre-post; pre-test only for knowledge)	NA	Asthma Self-Management Intervention	73	22% S-TOFHLA Inadeq.	Asthma Knowledge (range 0-10) % Mastering discharge medication regimen	Asthma Knowledge: NR % Mastering discharge medication regimen (baseline- 2 weeks): Overall (unadjusted): + 20%, NR; p for interaction by literacy: (P = 0.40)
Sobel et al., 2009[215] Fair	Quasi-experimental (pre-post)	No control	Linear video tutorial about asthma and its management	130	26% with low literacy (0-44 on REALM) 33% with marginal literacy (45-60 on REALM)	Mean score on 12 asthma knowledge questions (range 0-12)	Mean knowledge score (post-pre, unadjusted): +2.6 b, (P < 0.001) Mean knowledge score (post-pre, adjusted) compared to adequate literacy score: Adequate: reference Marginal: -0.8 (95% CI, -1.5 to -0.1) Low: -1.5 (95% CI, -2.3 to -0.6)
Wallace et al., 2009[211] Fair	Quasi- (pre-post)	NA	Diabetes Self-Management Intervention	250	29% TOFHLA inadeq. 14% TOFHLA marginal	% of Diabetes Knowledge questions correct	Overall (unadjusted): 6.16%, (P <0.001) Adequate Literacy subgroup (unadjusted): +6.94%, NR Marginal/inadequate Literacy subgroup (unadjusted): +5.21%, NR Unadjusted P for interaction by literacy level: 0.23

Table 55. Effect of mixed interventions on self-efficacy

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Davis et al., 2008[205] Fair	Quasi- (pre-post)	None	Weight loss intervention	101	49% REALM < 6th grade 22% REALM 7th-8th grade	% patients reporting confidence in ability to lose weight	Overall (unadjusted): +27%, (*P* = 0.01)
DeWalt et al., 2006[202] Fair	RCT	Usual Care + low literacy pamphlet on CHF	CHF Self-Management program	127	41% S-TOFHLA inadeq.	Mean difference in CHF self-efficacy (range of scores 0-2(4)	Overall (adjusted): 2 (95% CI, 0.7-3.1)
Gerber et al., 2005[194] Fair	RCT	Usual Care + computerized quizzes on diabetes-related concepts	Diabetes Self-Management Intervention	144	56% S-TOFHLA < 22 (Inadeq. or marginal)	Change in Mean Diabetes Self-efficacy – (score range NR)	Low Literacy Change Self-efficacy (adjusted): +0.52, 0.113 High Literacy Change Self-efficacy (adjusted): -0.20, NS
Kripalani et al., 2007[190] Fair	Quasi- (pre-post)	None	CHD adherence intervention (pill card)	242	42% REALM ≤ 6th grade 37% REALM 7th-8th grade	Mean Self Efficacy for Appropriate Medication Use Scale (score range 13-39)	Overall (unadjusted): +2.5, NR
Robinson et al., 2008[207] Fair	Quasi- (pre-post)	NA	Asthma Self-Management Intervention	110	Mean Gilmore Oral Reading Test Score: 3.2	Mean Asthma Self Efficacy Scale (scale 40-100)	Overall (unadjusted): 10.4, (*P* < 0.001)

ATSM=automated telephone self-management support; ATSM-GMV=automated telephone self-management support-group medical visits; CHD=coronary heart disease; CHF=congestive heart failure; CI=confidence interval; GMV=group medical visits; inadeq.=inadequate; mo.=month; NA=not applicable; NR=not reported; NS=not significant; quasi-=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; S-TOFHLA=short form Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults.

Table 55. Effect of mixed interventions on self-efficacy (continued)

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Rudd et al., 2009[209] Fair	RCT	Arthritis Management Intervention (arthritis pamphlet, medicine calendar, hospital map)	Arthritis Management Intervention + Individual Counseling	127	19% REALM ≤ high school	Mean self-efficacy (score range 1-4)	Overall at 12 mo. (adjusted): NR, (*P* = 0.12)
Schillinger et al., 2008[187]; Schillinger et al., 2009[210] Fair	RCT	usual care	(1) Diabetes Self Management Program (automated telephone delivery) (2) Diabetes Self-Management Program (group medical visit delivery)	339	59% S-TOFHLA ≤ 22 (inadeq. or marginal)	Mean Diabetes self-efficacy (0 - 100 scale)	ATSM-Usual Care (adjusted): 6.0 (2.0 to 10.1) GMV-Usual Care (adjusted): 5.5 (1.4 to 9.6) ATSM-GMV (adjusted): 0.5 (-3.6 to 4.6)
Wallace et al., 2009[211] Fair	Quasi- (pre-post)	NA	Diabetes Self-Management Intervention	250	29% TOFHLA inadeq. 14% TOFHLA marginal	Mean diabetes self-care self-efficacy (0–100 scale)	Overall (unadjusted): 4.29, (P < 0.001) Adequate literacy subgroup (unadjusted): 4.8, NR Inadequate literacy subgroup (unadjusted): +3.67, NR Unadjusted P for interaction by literacy subgroup: 0.29

Table 56. Effect of mixed interventions on skills

Author, Date of Publication, Quality	Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference Between Control and Intervention Groups
Jay et al., 2009[218] Fair	RCT	Standard FDA written materials	Nutrition label information card and video tutorial	56	17% limited literacy (score ≤ 22) on S-TOFHLA	% correct on 12-item food label quiz	intervention-control (adjusted): Overall: + 11.8%[b,] ($P < 0.05$) Adequate literacy: +23%[a] Inadequate literacy: +1%[a] p for interaction: < 0.05

[a]absolute difference calculated by research team

FDA=The Food and Drug Administration; RCT=randomized controlled trial; S-TOFHLA=short form Test of Functional Health Literacy in Adults

Table 57. Effect of mixed interventions on behavior

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
DeWalt et al., 2006[202] Fair	RCT	Usual Care + low literacy pamphlet on CHF	CHF Self-Management program	127	41% S-TOFHLA inadequate	% weighing daily at 12 months	Overall (adjusted): NR, (*P* < 0.001)
Kim et al., 2004[197] Fair	Quasi- (Pre-post)	None	Diabetes Self-Management Intervention	92	23% S-TOFHLA < 22 (Inadequate or marginal) (15% inadequate on TOFHLA)	# self-care days in last 7 days	Overall (adjusted): NR, sig Adeq. vs. Inadeq. HL (adjusted): Diet: NR, (*P* < 0.001; Inadeq. better) Exercise: NR, (*P* = 0.022; Adeq. better) Foot care: NR, (*P* = 0.001; Inadeq. better) Medication adherence: NR, (*P* = 0.751) Self-glucose monitoring: NR, (*P* = 0.002; Inadeq. better)
Schillinger et al., 2008[187]; Schillinger et al., 2009[210] Fair	RCT	Usual Care	(1) Diabetes Self Management Program (automated telephone delivery) (2) Diabetes Self-Management Program (group medical visit delivery)	339	59% S-TOFHLA ≤ 22 (inadequate or marginal)	Mean # of days self care behavior performed in last 7 days (score range 0-7) Mean # minutes engaged in moderate or vigorous physical activity/week	Overall # self-care days: ATSM-Usual Care (adjusted): 0.6 (0.4 to 0.9) GMV-Usual Care (adjusted): 0.3 (0.01 to 0.6) ATSM-GMV (adjusted): 0.3 (0.1 to 0.6) Minutes of moderate physical activity: ATSM-Usual Care (adjusted): 123.9 (14.8 to 233.0) GMV-Usual Care (adjusted): 69.1 (-42.1 to 179.4) ATSM-GMV (adjusted): 54.8 (-62.1 to 186.3) Minutes of vigorous physical activity: ATSM-Usual Care (adjusted): 32.2 (-9.8 to 74.2) GMV-Usual Care (adjusted): 23.3 (-19 to 65.5) ATSM-GMV (adjusted): 8.9 (-33.7 to 51.5)

Adeq.=adequate; ATSM=automated telephone self-management support; ATSM-GMV=automated telephone self-management support-group medical visits; CHF=congestive heart failure; GMV=group medical visits; HL=health literacy; inadeq=inadequate; NR=not reported; Quasi=quasi-experimental study; RCT=randomized controlled trial; S-TOFHLA=short form Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults.

Table 58. Effect of mixed interventions on adherence

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% population with Limited Literacy	Outcome	Difference
Bosworth et al., 2005[201] Fair	RCT	Usual care	Tailored Adherence Intervention	588	38% low literacy[a]	Change in % reporting agreement to any question in Morisky adherence scale	Overall change (unadjusted): 0.007% (95% CI, -0.62%-0.076%) Change among those initially adherent (unadjusted): -2%, (*P* = 0.68) Change among those initially non-adherent (unadjusted): +12%, (*P* = 0.08)
Kim et al., 2004[197] Fair	Quasi- (pre-post)	None	Diabetes Self-Management Intervention	92	23% S-TOFHLA < 22 (Inadequate or marginal) (15% inadequate on TOFHLA)	# days of Medication adherence in last week	Overall: +0.7[b], NR Adeq. vs. Inadequate HL (adjusted): NR, (*P* = 0.751)
Murray et al., 2007[182] Good	RCT	Usual Care	CHF Adherence Intervention	314	29% "not literate" on S-TOFHLA (NOS)	% of prescribed medication taken (according to MEMS cap)	% of prescribed medication taken: During intervention (unadjusted): +10.9% (95% CI, 5%-16.7%) Post Intervention (unadjusted): +3.9% (-2.8%-10.7%)
Paasche-Orlow et al., 2005[79] Fair	Quasi- (pre-post)	NA	Asthma Self-Management Intervention	73	22% S-TOFHLA Inadequate	% with adherence less than 50% for inhalers or meds (according to Doser CT or MEMS cap)	Poor adherence, by literacy subgroups (adjusted): NR, p for interaction: (*P* = 0.45)

Table 58. Effect of mixed interventions on adherence (continued)

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% population with Limited Literacy	Outcome	Difference
Rudd et al., 2009[209] Fair	RCT	Arthritis Management Intervention (arthritis pamphlet, medicine calendar, hospital map)	Arthritis Management Intervention + Individual Counseling	127	19% REALM < high school	Mean score on Levine medication adherence assessment (range 0-3, 3 best)	Mean percent change in medication adherence (unadjusted): 6 mo: -5.01%, p 0.33 12 mo: -9.09%, p 0.10

[a]Determined through personal communication with author; [b]Calculated by team

Adeq.=adequate; CHF=congestive heart failure; CI=confidence interval; HL=health literacy; meds=medications; MEMS cap=Medication Event Monitoring System cap; NA=not applicable; NOS=not otherwise specified; NR=not reported; Quasi-=quasi-experimental study; RCT=randomized controlled trial; S-TOFHLA=short form Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; vs.=versus.

Table 59. Effect of mixed interventions on disease prevalence and severity

Author, Date of Publication, Quality	Study design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Gerber et al., 2005[194] Fair	RCT	Usual Care + computerized quizzes on diabetes-related concepts	Diabetes Self-Management Intervention	144	56% S-TOFHLA < 22 (Inadequate or marginal)	Mean Change in Hemoglobin A1C Mean Change in Systolic and Diastolic Blood Pressure (mmHg) Mean Change in Body Mass Index (kg/m2)	Low Literacy Subgroup (adjusted): Change in HgbA1C: -0.1, NS Change in SBP: -1 mmHg, NS Change in DBP: 3 mmHg, NS Change in BMI: NR, NS High Literacy Subgroup (adjusted): Change in HgbA1C: 0.0, NS Change in SBP: +1 mmHg, NS Change in DBP: -7 mmHg, NS Change in BMI: -1 kg/m2, NS Note: in exploratory subgroup analyses of Hgba1c > 9 (n = 26), intervention more effective than control for low literacy (but not high literacy) group
Kim et al., 2004[197] Fair	Quasi- (pre-post)	None	Diabetes Self-Management Intervention	92	23% S-TOFHLA < 22 (Inadequate or marginal) (15% inadequate on TOFHLA)	Mean HgbA1c	Overall (unadjusted): -1.3a, Sig Adeq. vs. Inadeq. HL (adjusted): NR, (P = 0.086)
Paasche-Orlow et al., 2005[79] Fair	Quasi- (pre-post)	NA	Asthma Self-Management Intervention	73	22% S-TOFHLA Inadequate	Mean score on asthma symptom questionnaire (range 0-6)	Overall: NR By subgroup: NR p for interaction: (P = 0.69)

[a]Calculated by team

ABLE=Adult Basic and Literacy Education; Adeq.=adequate; ATSM=automated telephone self-management support; ATSM-GMV=automated telephone self-management support-group medical visists; BMI=body mass index; CI=confidence interval; DBP=diastolic blood pressure; GMV=group medical visit-usual care; HgbA1c=glycosylated hemoglobin; HL=health literacy; inad=inadequate; NA=not applicable; NR=not reported; NS=not significant; Quasi-=quasi-experimental study; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; SBP=systolic blood pressure; sig=significant; S-TOFHLA=short form Test of Functional Health Literacy in Adults; TOFHLA=Test of Functional Health Literacy in Adults; vs.=versus

Table 59. Effect of mixed interventions on disease prevalence and severity (continued)

Author, Date of Publication, Quality	Study design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Rothman et al., 2004[198] Fair	Quasi - (Pre-post)	NA	Diabetes Disease Management Intervention	159	55% Lower Literacy 32% REALM ≤ 3rd grade 23% REALM Score 4th-6th grade	Mean HgbA1c	Lower Literacy Subgroup (unadjusted): -1.9% points (95% CI, -2.5 to -1.2) Higher Literacy Subgroup (unadjusted): -1.8% points (95% CI, -2.5 to -1.0)
Rothman et al., 2004[183] Good	RCT	1-hour education session	Diabetes Disease Management Intervention	217	38% REALM ≤ sixth grade	Mean HgbA1c Systolic blood pressure	Overall (adjusted): SBP -7.6 mmHg (-13 to -2.2 mmHg) Low literacy subgroup: HgbA1c (adjusted): -1.4%; 95% CI, -2.3% to -0.6%) High literacy subgroup): HgbA1c (adjusted): -0.5%; 95% CI, -1.4%-0.3%
Schillinger et al., 2008[187]; Schillinger et al., 2009[210]	RCT	Usual Care	(1) Diabetes Self Management Program (automated telephone delivery) (2) Diabetes Self-Management Program (group medical visit delivery)	339	59% S-TOFHLA ≤ 22 (inadequate or marginal)	Mean Hemoglobin A1C Mean Systolic and diastolic blood pressure (mmHg) Mean Body Mass Index (kg/m^2)	HgbA1C ATSM-Usual Care (adjusted): -0.1 (-0.5 to 0.4) GMV-Usual Care (adjusted): 0.2 (-0.2 to 0.7) ATSM-GMV (adjusted): -0.3 (-0.8 to 0.7) SBP ATSM-Usual Care (adjusted): -3.2 mmHg (-8.3 to 1.9 mmHg) GMV-Usual Care (adjusted): -3.9 mmHg (-9.0 to 1.2 mmHg) ATSM-GMV(adjusted): 0.7 mmHg (-4.5 to 5.9 mmHg)

Table 59. Effect of mixed interventions on disease prevalence and severity (continued)

Author, Date of Publication, Quality	Study design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Schillinger et al., 2008[187]; Schillinger et al., 2009[210] (continued)							DBP ATSM-Usual Care(adjusted): -1.6 mmHg (-5.1 to 2.0 mmHg) GMV-Usual Care (adjusted): -3.1 mmHg (-6.6 to 0.4 mmHg) ATSM-GMV (adjusted): 1.5 mmHg (-2.0 to 5.1 mmHg) BMI ATSM-Usual Care (adjusted): 0.1 kg/m2 (-0.4 to 0.5 kg/m^2) GMV-Usual Care (adjusted): 0.02 kg/m2 (-0.5 to 0.5 kg/m^2) ATSM-GMV (adjusted): 0.1 kg/m^2 (-0.4 to 0.5)
Weiss et al., 2006[193] Fair	RCT	Usual care	Adult Basic and Literacy Education (ABLE)	70	Mean REALM score 47	Mean depression severity score on Patient Health Questionnaire (score range 0-27)	Overall (unadjusted): 1st follow-up: 0, *P* = 0.25 2nd follow-up: -3, *P* = 0.03 3rd follow-up: -4, *P* = 0.04 Note baseline difference in REALM

Table 60. Effect of mixed interventions on quality of life

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% population with Limited Literacy	Outcome	Difference
DeWalt et al., 2006[202] Fair	RCT	Usual Care + low literacy pamphlet on CHF	CHF Self-Management program	127	41% S-TOFHLA inadequate	CHF related Quality of Life by MLHF (range of scores 0-105)	Heart failure-related quality of life (adjusted): 2 (95% CI, 9 to -5) Adequate Health Literacy Subgroup (adjusted): -4.2 (95% CI -14 to 6) Inadequate Health Literacy Subgroup (adjusted): -1.6, 95% CI -15 to 12
Murray et al., 2007[182] Good	RCT	Usual Care	CHF Adherence Intervention	314	29% “not literate” on S-TOFHLA (NOS)	Mean score on Chronic Heart Failure Questionnaire (range from 1 to 7; better functioning = higher)	Within Intervention Group (unadjusted): +0.39
Rudd et al., 2009[209] Fair	RCT	Arthritis Management Intervention (arthritis pamphlet, medicine calendar, hospital map)	Arthritis Management Intervention + Individual Counseling	127	19% REALM $\leq$ high school	HAQ scores (range of scores 0 - 3, 0 best)	Mean percent change in HAQ scores at 12 months: 6 months: -3.60%[a]*, p 0.45 12 months: -2.12%[a]*, p0.64
Schillinger et al., 2008;[187] Schillinger et al., 2009[210]	RCT	Usual Care	(1) Diabetes Self Management Program (automated telephone delivery) (2) Diabetes Self-Management Program (group medical visit delivery)	339	59% S-TOFHLA $\leq$ 22 (inadequate or marginal)	SF12-Mental health scale (score range 0 - 100) SF-12 Physical health scale (score range 0-100) Mean # days in bed in last month due to health problems	SF-12 mental health: ATSM-Usual Care (adjusted): 3.7 (-2 to 9.4) GMV-Usual Care (adjusted): -2.9 (-8.6 to 2.9) ATSM-GMV (adjusted): -6.5 (0.7 to 12.4)

[a]Calculated by research team

ATSM=automated telephone self-management support; ATSM-GMV=automated telephone self-management support-group medical visits; CHF=congestive heart failure; CI=confidence interval; GMV=group medical visits; HAQ=the Health Assessment Questionnaire; MLHF=the Minnesota Living with Heart Failure Questionnaire; NOS=not otherwise specified; NR=not reported; NS=not significant; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; SF-12 Mental health scale=12-item short-form mental health scale; S-TOFHLA=short form Test of Functional Health Literacy in Adults.

Table 60. Effect of mixed interventions on quality of life (continued)

Author, Date of Publication, Quality	Study Design	Control Group	Intervention	Sample Size	% population with Limited Literacy	Outcome	Difference
Schillinger et al., 2008;[187] Schillinger et al., 2009[210] (continued)						Extent to which diabetes limits normal activity (score range 0 - 5, lower = less)	SF-12 physical health: ATSM-Usual Care (adjusted): 2.7 (-4.0 to 9.5) GMV-Usual Care (adjusted): -0.1 (-6.9 to 6.7) ATSM-GMV(adjusted): 2.9 (-4 to 9.7) # Bed Days over prior month: ATSM-Usual Care (adjusted): -1.7 (-3.3 to -0.1) GMV-Usual Care(adjusted): 0.6 (-1.0 to 2.2) ATSM-GMV (adjusted): -2.3 (-3.9 to -0.4) Extent limited activity: ATSM-Usual Care: NR, (*P* = 0.02) GMV-Usual Care: NR, NS ATSM-GMV: NR, NS

[a]Calculated by research team

ATSM, automated telephone self-management support; ATSM-GMV, automated telephone self-management support-group medical visits; CHF, congestive heart failure; CI, confidence interval; GMV, group medical visits; HAQ, the Health Assessment Questionnaire; MLHF, the Minnesota Living with Heart Failure Questionnaire; NOS, not otherwise specified; NR, not reported; NS, not significant; RCT, randomized controlled trial; REALM, Rapid Estimate of Adult Literacy in Medicine; SF-12 Mental health scale, 12-item short-form mental health scale; S-TOFHLA, short form Test of Functional Health Literacy in Adults.

Table 61. Effect of mixed interventions on health care costs

Author, Date of Publication, Quality	Study design	Control Group	Intervention	Sample Size	% Population with Limited Literacy	Outcome	Difference
Murray et al., 2007[182] Good	RCT	Usual Care	CHF Adherence Intervention	314	29% "not literate" on S-TOFHLA (NOS)	Total intervention, outpatient, and inpatient costs	-$2960 (95% CI, -$7603-$1338)
Rothman et al., 2004[183] Rothman et al., 2006[250] Good	RCT	Usual Care + Education Session	Diabetes Disease Management Intervention	217	38% REALM ≤ sixth grade	Labor costs for intervention delivery; Total costs (labor costs + indirect costs)	Labor costs: $25.50 per patient per month (Sens. analysis $12.01 to $55.35 per patient per month) Total costs: $36.97 per patient per month (Sens. Analysis $16.22 to $88.56 per patient per month)

CHF=congestive heart failure; CI=confidence interval; NOS=not otherwise specified; RCT=randomized controlled trial; REALM=Rapid Estimate of Adult Literacy in Medicine; sens.=sensitivity; S-TOFHLA=short form Test of Functional Health Literacy in Adults

Discussion

Overview

During this systematic review update, the RTI International-University of North Carolina Evidence-based Practice Center (RTI-UNC EPC) identified a moderately large body of literature addressing the relationship between health literacy (including numeracy) and health outcomes. Our two key questions (KQ s) and subquestions were as follows.

1. Outcomes: Are health literacy skills related to (a) use of health care services, (b) health outcomes, (c) costs of health care, and (d) disparities in health outcomes or health care service use?
2. Interventions: For individuals with low health literacy skills, what are effective interventions to (a) improve use of health care services, (b) improve health outcomes, (c) affect the costs of care, and (d) improve health care service use and/or health outcomes among different racial, ethnic, cultural, or age groups?

These issues parallel the questions addressed in the initial review, published in 2004.[1,50,51]

The amount of research being published in the field has expanded substantially. The initial review was limited to the relationship between literacy and health outcomes (or interventions); it included a total of 73 articles, 44 addressing outcomes, and 29 addressing interventions. The updated review expanded the scope of studies; it included 103 new good- or fair-quality studies reported in a total of 132 unduplicated articles. Of these, 86 articles addressed the relationship between health literacy and outcomes and 16 examined the relationship between numeracy and outcomes. In addition, 45 articles reported on interventions for individuals with low health literacy, split between those testing a single intervention strategy and those testing a mix (combination) of intervention strategies.

In this chapter, we recap the principal findings for KQ 1 and KQ 2 and comment on the applicability of the available bodies of evidence. We then discuss the limitations of both the literature reviewed and our own update. Finally, we present recommendations for future research.

Principal Findings

KQ 1. Health Literacy and Outcomes

Literacy Studies

For examining the association between health literacy and health outcomes (KQ 1), we included 86 fair- or good-quality articles (72 studies) in this update. Of these, 24 articles addressed the effect of health literacy on health care service use, 72 on health outcomes, 9 on disparities, and 2 on costs. Overall, the majority of studies were assessed as being of fair quality.

Differences in health literacy level were associated with use of health care services. Specifically, lower literacy was associated with increased emergency department and hospital use, and breast cancer (mammography), and lower influenza immunization, based on moderate strength of evidence. Evidence for other health care service use was low or insufficient because of inconsistent or limited findings and outcomes.

The relationship between health literacy and health outcomes was variable. The risk of mortality for seniors was clearly higher with lower health literacy. There was also moderate evidence to support a relationship between lower health literacy and poorer ability to take medications appropriately or interpret labels and health messages and poorer overall health status among seniors. In these studies, the evidence consists of all observational studies generally having a medium risk of bias and results generally in a consistent direction. The evidence for all other outcomes was either low or insufficient because the literature consisted of a small number of studies, poorly designed studies, and/or inconsistent results. These evaluations focused on the relationship between the lowest and highest health literacy groups. The evidence was sparse for evaluating differences between those with marginal (a middle category) health literacy and adequate (the highest category) health literacy.

The evidence concerning differences by health literacy level in costs of health care (KQ 1c) was low. The two relevant studies examined different payment sources (Medicaid and Medicare), found inconsistent results, and included different patient populations. No studies examined differences in costs among those with private health insurance coverage or no coverage.

Health literacy was found to mediate the relationship between race and health for a variety of outcomes. Outcomes studied included a condition that keeps respondents from working or having a long-term illness; misinterpretation of medication labels; prostate-specific antigen levels among newly diagnosed prostate cancer patients; nonadherence to HIV medications; children having health insurance; and, among seniors, self-reported health status, physical and mental health-related quality of life, and receipt of an influenza vaccine. We cannot know whether health literacy level would also be a mediator of the relationship between race and other health outcomes that have not been tested. Only one study examined whether health literacy level mediated the relationship between Hispanic ethnicity and health outcomes and no relationship was found. In contrast, one study found that health literacy level mediated the relationship between gender and misinterpretation of medication labels. We found no studies that evaluated the relationship between age, cultural group, or other sociodemographic characteristics and health outcomes.

Numeracy Studies

In this update we reviewed 16 fair-quality studies that examined the relationship between numeracy and various outcomes, including use of health care services, health outcomes, costs, and disparities. Most studies examining the relationship of numeracy to health outcomes were cross-sectional in design. Four studies were randomized controlled trials that analyzed their data in a cross-sectional manner for this analysis; one used a prospective cohort design.

In general, the strength of evidence for the relationship between numeracy and outcomes was insufficient or low given the small number of studies, which often had a high risk of bias or collectively gave mixed results. Only one study addressed the relationship between numeracy and use of health care services; this study reported no effect of numeracy on up-to-date screening for breast and colon cancer, but appears to be limited by inadequate power. Similarly, several studies demonstrated that the relationships between numeracy level and accuracy of risk perception (five studies), knowledge (four studies), skill in taking medication (six studies), and disease prevalence and severity (three studies) are mixed. The evidence for the relationship between numeracy and other health outcomes (e.g., self-efficacy, behavior) was insufficient to draw conclusions. No studies addressed the costs associated with differences in numeracy level.

However, two studies examined whether numeracy level mediates health disparities and found that numeracy appeared to mediate the relationship between race and hemoglobin A1c and between gender and HIV medication management capacity.

Health Literacy and Numeracy Studies

Seven studies addressed the effects of both health literacy and numeracy on various outcomes.[9,10,47,98,125,126,171] Of these seven studies, six performed adjusted analyses on the same outcomes, thereby allowing assessment of whether these exposures affect health outcomes differently.[9,47,98,125,126,171] All of these studies must be interpreted with caution, however, because the proportion of individuals with low health literacy was small, raising the possibility of ceiling effects, which could obscure effects in the health literacy analyses. One study showed that ability to read nutrition labels was lower in both those with low health literacy skills (less than ninth grade) measured by the Rapid Estimate of Adult Literacy in Medicine (REALM) and low numeracy skills (less than ninth grade) measured by the Wide Range Achievement Test for mathematics (WRAT-math).[9] However, it noted that the outcome was more highly correlated with numeracy (ρ 0.67) than health literacy (ρ 0.52). Similarly, another study showed that both health literacy skills (percent correct on the Short Test of Functional Health Literacy in Adults [S-TOFHLA]) and numeracy (percent correct on the Applied Problems Subtest of the Woodcock-Johnson Test) were related to HIV medication management capacity,[47] although the beta-coefficient was higher for numeracy in a regression model including both literacy and numeracy skill. A third study[126] showed that both health literacy skills (measured by the REALM) and numeracy (measured by a 6-item hybrid test including 3-items from Schwarz and Woloshin and 3 additional items from investigators) were related to the proportion of INR tests within range, although the correlation was higher for numeracy (r 0.12) than for health literacy (r 0.02). In contrast, two other studies found relationships between numeracy and health outcomes, but not between literacy and health outcomes. One of these studies found a relationship between numeracy (measured by the WRAT-math) and body mass index (BMI), but no relationship between literacy (measured by the REALM) and BMI.[10] The other found a relationship between diabetes-specific numeracy (measured by the Diabetes Numeracy Test) and HgbA1c, but no relationship between literacy and HgbA1c.[171] Only a single study[125] suggested a stronger relationship between literacy and health outcomes than numeracy and health outcomes. This study showed a greater likelihood of parent's using nonstandard dosing instruments to dose children's medicines related to their TOFHLA reading comprehension score (split at the median; adjusted OR, 2.4; 95% CI, 1.3-4.7) compared with their TOFHLA numeracy score (split at the median; OR, 1.4; 95% CI, 0.8 to 2.7).

KQ 2. Interventions To Improve Health Literacy

In this update we identified 42 new fair- or good-quality studies addressing the effect of interventions designed to mitigate the effects of low health literacy. Twenty-one used one specific strategy to mitigate the effects of low health literacy, and21 used a mixture of strategies combined into one intervention.

Interventions With Single Design Features

In general, the strength of evidence regarding the effect of specific design features of interventions for low-health-literacy populations is low or insufficient. This is attributable, in large part, to differences in the interventions (and subsequently results) for studies broadly grouped in the following design feature categories: alternative document design, alternative numerical presentation, additive and alternative pictorial representation, and improved readability and alternative document design.

Looking closely within categories, however, we noted that several specific design features resulted in improvements in comprehension for low-health-literacy populations in one or a few studies. These features, which bear further study in broader populations, include: presenting essential information by itself (i.e., information on hospital death rates without other distracting information, such as information on consumer satisfaction);[188] presenting essential information first (i.e., information on hospital death rates before information about consumer satisfaction);[188] presenting quality information with the higher number (rather than the lower number) indicating better quality;[188] using the same denominators to present the baseline risk of disease and treatment benefit;[219] adding icon arrays to numerical presentations of treatment benefit;[216,219] and adding video to verbal narratives.[184] Additionally, reexamining data from our 2004 review within these categories further suggests potential benefit from using reduced reading level and/or illustrated narratives.[232,236] In contrast, one study raised questions about whether certain design features, such as colored traffic symbols to denote death rates in hospitals of varying quality or symbols accompanying nonessential quality information, may actually worsen health choices among those with low health literacy.[188]

Interventions With a Combination of Features

The strength of evidence for studies combining multiple strategies to mitigate the effects of low health literacy on outcomes was more variable that it was for single-feature interventions. We found consistent moderate strength of evidence that studied interventions change health care service use. Specifically, intensive self-management and adherence interventions appear to be effective in reducing emergency department visits and hospitalizations. Additionally, educational interventions and/or cues for screening increased colorectal cancer and prostate cancer screening. We note, however, that the health benefits of additional prostate cancer screening are questionable[251,252] and that increased screening rates could be a marker for poor decisionmaking.

We additionally found consistent evidence of moderate strength that some interventions change health outcomes. For instance, intensive disease-management programs appear to be effective at reducing disease prevalence. Furthermore, self-management interventions increased self-management behavior; however, in the only study that stratified its analysis by health literacy level, improvements were sometimes greater for those who had adequate health literacy and at other times greater for those with inadequate health literacy in adjusted analyses. The effects of other interventions on other health outcomes, including knowledge, self-efficacy, adherence, health-related skills, quality of life, and cost were mixed; thus, the strength of evidence was insufficient.

Components of effective interventions were their high intensity, theory basis, pilottesting before full implementation, emphasis on skill building, and delivery of the intervention by a health professional. Interventions that changed distal outcomes appeared to work by intermediately increasing knowledge or self-efficacy or by changing behavior.

Too few studies addressed the effects of literacy interventions on the outcomes of behavioral intent, or disparities to draw any meaningful conclusions; the strength of evidence is insufficient.

What This Update Adds to the Literature Included in the 2004 Review

Our results expand findings from our 2004 review in several ways. The size of the literature in the 2010 update review, examining the relationship between health literature and health outcomes (KQ 1) is larger than was available for the earlier review and encompasses a larger variety of outcomes (Table 62). In the 2004 review, we found that lower health literacy level was related to poorer knowledge of matters related to health outcomes and use of health services. Therefore, we did not reexamine this relationship during the update. In the earlier review, we recommended that future research examining the relationship between health literacy and health outcomes consistently control for potential confounding variables to more accurately measure the strength of the relationship between health literacy and the outcome. Unlike the earlier review, in the update, primary study outcomes are generally evaluated using multivariate analysis and control for potential confounding variables, providing a better and less biased estimate of the direction and magnitude of effect for our findings. Based on these more rigorous studies, we identified a relationship between health literacy level and additional health related outcomes. In 2004, we also recommended that studies more closely examine the factors that mediate the relationship between health literacy and health outcomes. In 2004, we had found only one study that directly examined racial disparities.[158] For the update, we found a limited body of research that begins to provide evidence of variables that may be on the pathway of effect between health literacy and health outcomes; these include factors such as knowledge, self-efficacy, and beliefs such as stigma related to their disease. New studies suggest that health literacy could be a mediator of racial disparities in health outcomes.

In 2004, we also recommended that studies stratify outcomes by numeracy level to gain a greater understanding of how these skills may uniquely affect health outcomes and under what conditions numeracy would be a useful indicator for targeting individuals for interventions. For the update, we found a small body of evidence concerning the relationship between numeracy level and health outcomes (Table 63). This is not only useful in and of itself, but it also is the next step in expanding our understanding of the skills that are needed to be health literate.

For KQ 2, our findings also expand findings from the 2004 review in several ways. In the 2004 review, we recommended that additional and more varied studies of interventions be pursued and that all studies measure the interventions' effects in a broader range of outcomes and by literacy subgroup. Studies in the current report have largely addressed these recommendations (see Table 64 and Table 65).

First, they address more varied interventions and provide insights into the utility of particular intervention design features. In our 2004 report, there were relatively few interventions of any type. Thus, we focused on how interventions affected outcomes rather than attempting to parse interventions into specific elements. In the current report, we reviewed studies by the specific intervention design features studied (see Table 64); only when that was not possible (i.e., because interventions used multiple design features) did we review studies by the outcomes involved (see Table 65). Using this new organizational structure, we identified several intervention design features that bear further study, including some identified through our 2004 review; these include presenting essential information by itself (i.e., information on hospital death rates without other distracting information, such as information on consumer satisfaction);[188] presenting essential information first (i.e., information on hospital death rates before information about consumer satisfaction);[188] presenting quality information with the higher number (rather than the lower number) indicating better quality;[188] adding icon arrays to numerical presentations of treatment benefit;[216,219] adding video to verbal narratives;[184] and using reduced reading level and/or illustrated narratives.[232,236] We also were able to illuminate what factors may be key in making the mixed interventions effective. Common features across nearly all of the mixed interventions that improved distal outcomes (e.g., self-management, hospitalizations, mortality) were their high intensity, theory basis, pilottesting before full implementation, emphasis on skill building, and delivery of the intervention by a health professional (e.g., pharmacist, diabetes educator; see intervention studies evidence tables in Appendix D).[182,183,202,207]

Second, studies in the current report provide insight into the impact of interventions on a broader spectrum of outcomes. In our 2004 review, the majority of studies focused only on the outcome of knowledge (see Table 64 and Table 65). In the current review, studies focused on a broader range of outcomes, including disease self-efficacy, behavior, adherence, disease prevalence and severity, quality of life, preventive services use, emergency department visits, hospitalizations, and costs. Additionally, six studies in our update examined the impact of interventions on three or more outcomes[79,182,187,194,197,202] (see intervention studies evidence tables in Appendix D); they preliminarily suggest that effective interventions to mitigate the effects of low health literacy may work by increasing knowledge,[197,202] increasing self-efficacy,[187] or changing behavior.[182,187,197,202]

Third, a little over half the studies examined the effect of interventions by health literacy subgroup. This allows investigators to determine whether the intervention is more or less effective among those with low health literacy and whether interventions might ameliorate health disparities.

Limitations

Limitations of the Literature

Readers should interpret the findings from our systematic review in the context of several limitations. As with all systematic reviews, our results and conclusions depend on the quality of the published literature. A limitation across KQ s was heterogeneity in outcomes, populations, and study designs; this level of diversity in the knowledge base precluded us from pooling results statistically.

Specific limitations of the literature for studies addressing KQ 1 (i.e., the effects of health literacy and/or numeracy on health outcomes) included the following:

- Lack of specification of thresholds for distinguishing levels of health literacy that consider the relevance of those levels to (1) the outcomes and population being studied and (2) the body of similar work in the field.[253]
- Lack of an analytic framework or logic model for determining the appropriate set of potential confounding variables that need to be included in multivariate models. While studies generally controlled for some sociodemographic variables and other factors, the choice of variables varies across studies.
- The potential for over controlling. Many studies included education (which is highly correlated with health literacy) as part of their multivariate model. Additionally, some studies included mediators of the effect of health literacy in their model; this may result in underestimating the aggregate effect of health literacy.

Small sample sizes, making it impossible to determine whether null findings represented a true lack of effect or simply reflected limitations in statistical power.

Studies conducted in just one clinic or in other narrowly defined patient populations, rendering the applicability of findings to other settings or populations unknown. Only two studies were conducted within nationally representative samples: the National Assessment of Adult Literacy conducted in 2003 and the earlier National Adult Literacy Survey in 1992.

Health literacy tools that continue to focus primarily on reading ability despite the Institute of Medicine's call for skills-based health literacy tools[53] (i.e., tools focused on a combination of oral or verbal, navigational, computer, or other skills necessary for individuals to manage their health).At the time of this update review, we identified none in the literature. Thus, we could not determine the relationship between a wider array of skills or abilities and health outcomes. We did, however, find evidence that development of tools that can measure these additional skills has begun.[254]

A limited number of studies examining the role of health literacy on health disparities. Most research focused on whether health literacy mediated the relationship between race and health outcomes.

The limitations of the literature for studies addressing KQ 2 (i.e., the effects of interventions to mitigate low health literacy) included the following:

- Lack of an adequate control or comparator group in many studies, limiting the ability to determine the true effect(s) of the intervention.
- Measurement of multiple outcomes with insufficient attention to ensure that each is adequately powered to detect a difference.
- Testing interventions that combined various design features to mitigate the effect of low health literacy but offering no way to determine the effectiveness of individual components.
- Failure to perform adequately controlled subgroup analyses that would elucidate differential effects of interventions in low- and high-health-literacy populations. This is important to the extent that the field's overall goal is to reduce disparities related to the impact of low health literacy rather than simply to improve outcomes for individuals at all health literacy levels.
- Failure to report adequately the design features that would allow future content analyses of effective interventions.

Limitations of Our Review

In addition to clarifying the limitations of the overall body of literature, we must also acknowledge the limitations of our systematic review and update of the 2004 report. First, we included only those studies in which investigators quantitatively measured the literacy of their populations. We may have missed some important studies addressing the relationship of health literacy on health outcomes or important interventions that either did not measure health literacy or measured it only by self-report. Second, we excluded studies that included only outcomes focused on communication or decisionmaking.[255-260] Our reasoning was that, in our judgment, patient-physician communication likely moderated rather than mediated the effect of intent for behavior on health outcomes. However, this may have meant we missed outcomes or interventions important to some researchers, clinicians, and policymakers. Third, we did not conduct dual *independent* abstraction of all information for review. Rather, a single reviewer abstracted information and a second reviewer checked it; we feel this process was sufficiently rigorous to allow accurate conclusions, and it is the basic strategy the RTI–UNC EPC has used for this step for more than a decade. We did, however, perform dual review for article inclusion and dual rating of the risk of bias of individual studies and the strength of evidence in relation to outcomes, highlighting an overall rigorous process. Fourth, we did not formally integrate the analyses from our 2004 and current reviews, although based on our review of summary materials, we suspect this would have a minimum impact on our overall conclusions.

Opportunities for Future Research

This update shows that the field of health literacy has advanced since our 2004 review. However, many opportunities remain for important future research. The need for such investigations is considerable for gaining a better understanding of the outcomes of health care, given levels of health literacy, and for expanding the knowledge base about the impact of interventions intended to improve health literacy.

Future Research Into the Relationship Between Health Literacy and Health Outcomes

Instrument Cutpoints

The field will greatly benefit from researchers prespecifying the most relevant cutpoints for distinguishing levels of health literacy within the population being studied, considering how the cutpoints selected compare to those that have been used in measuring similar populations and outcomes. Currently, investigators use cutpoints inconsistently, such that "adequate" and "inadequate" or "low" health literacy levels have different definitions across studies. This problem makes comparing results from these studies difficult. Additionally, the literature as a whole does not lend itself to explaining at what particular level lower health literacy is related to significantly poorer outcomes of health care.

Furthermore, sometimes a middle group, often referred to as having "marginal health literacy," is identified; other times, no such group is specified. Sometimes research teams combine the middle health literacy group with the higher health literacy group; sometimes they combine it with the lower health literacy group.

In short, those conducting work in this area in the future should more rigorously defend their choice of inadequate, marginal, and adequate levels of health literacy.

Skills-Based Measures

Testing skills-based health literacy measures will be an important focus of future research. Our current review expanded the tools that measure health literacy to include those that focus on numeracy. However, we found no tools that measure oral health literacy. New instruments are likely to be available in the near future that can be used as alternative measures of health literacy that capture additional and potentially critical skills. For example, a 2009 Institute of Medicine workshop and resulting report, Measures of Health Literacy, highlight several skills-based measurement tools that are under development—one designed for use in clinics and a second for population-based surveillance.261 Future research should consider these and other measures that may explain the interplay of a wider range of health literacy skills and outcomes.

Future research should also consider capturing changing competencies over time based on greater knowledge or experience (or both), resulting in health literacy levels changing over time. For this type of measurement, prospective research designs will be critical, allowing researchers to measure health literacy at different times while in treatment or after different amounts of experience managing a chronic condition.

Links Between Low Health Literacy and Outcomes

Additional work is needed to help us understand the pathways between low health literacy and health outcomes. A few studies examined variables that may be in the analytic pathway between health literacy and health outcomes and mediate the relationship between the two—including knowledge, self-efficacy, and beliefs. More research is needed investigating these potential mediators in relation to a wider range of outcomes and populations. Other potential variables that warrant serious attention as mediators or moderators of the relationship include measures of education, social support, cultural competency, decisionmaking skills, and trust in the information source.

Population Subgroups

Additional research is needed to understand whether health literacy has a differential effect in various subgroups of the population. For example, we lack data evaluating whether the effect of low health literacy would be significantly different in different groups defined by various sociodemographic factors. Of particular interest are the following comparisons: white populations vs. various racial and/or ethnic minority populations, nonelderly vs. elderly individuals, and male vs. female patients.

Methodologic Limitations

Current work should continue to address the basic methodological deficiencies we found during this update and the problems we noted in the previous review. For instance, researchers need to determine a minimal set of confounding variables to be considered for all multivariate analyses; sample sizes need to be larger so that investigators truly have sufficient power to detect differences among the three health literacy levels.

Applicability of Research

The degree to which results from the studies done to date can be applied broadly is limited. Considering the "PICOTS" framework (patients/populations, interventions, comparators, outcomes, timeframes, and settings) for considering the generalizability of a body of research, we conclude that the ability of decisionmakers to generalize results from the current body of work is not great. Most current studies were limited to one clinic or one geographic area; thus, we lack evidence that the results would apply in more broadly defined populations or settings. The field needs to examine the relationships between health literacy and health outcomes in more diverse and representative populations.

Future Research Into Interventions to Mitigate the Effects of Low Health Literacy

Opportunities to study interventions to mitigate the effects of low health literacy are also substantial.

Effective Design of Health-Related Documents

Additional work is needed on the design features of documents. As discussed above, we identified several design features of health-related interventions that could mitigate the effects of low health literacy. However, the majority have been examined in only one or a few studies in clinical populations; thus, they warrant further investigation.

An important question to answer is, "What needs study and what does not?" Our review failed to turn up evidence regarding several document design features widely recommended by experts in the field of health literacy; these include grouping or "chunking" of ideas and teach-back.[262] However, whether these features require specific investigation in relation to health literacy when they have been well studied in other fields is not clear. For instance, the field of psycholinguistics has done extensive testing of simplified sentence and document structure and the cohesiveness of concepts in the text; this body of work, albeit not necessarily stemming from the health sector, may obviate the need for specific testing of these approaches in the health literacy field per se.[263] Furthermore, the educational literature has tested techniques of explicit instruction that are recommended for poor readers—i.e., instruction that has a clear task and is broken into small steps with practice and feedback at every step—and determined that they are effective.[263] Rather than spending time and energy on additional testing, exploring the extent to which other fields can inform the work of health literacy may be more appropriate.

Some design features, however, may warrant explicit testing. Given the evidence from multiple areas of study that motivation increases the effects of comprehension and behavior,[98,263,264] more study of the impact of illustrations, videos, fotonovelas, and other novel approaches that may increase motivation for information-processing through their visual appeal seems warranted. Researchers in health literacy should seek guidance from the health communication literature to guide these efforts.[265]

Further testing of techniques based on oral and numerical delivery of information will also be useful. Oral information receives different cognitive processing than written information and has a naturally simpler syntax that may help low-literacy individuals.[263] Numbers and graphical numerical information have many alternative forms of presentation. These have been shown to affect understanding in high-literacy individuals; they should be tested for comprehension among those with lower literacy.[266-271]

Finally, investigation of "work-around" interventions should be undertaken. These can include use of patient advocates, who could accompany individuals to medical appointments and facilitate subsequent care.

Effective Components of Combination Interventions

Additional work is also needed to determine the effective components of already-tested interventions that have employed a combination of features to mitigate the effects of low health literacy. While a combination of intervention features has repeatedly been shown to ensure the success of interventions, paring away ineffective features could save delivery time and result in more cost-effective delivery. Several possibilities for accomplishing this task exist. For instance, one approach is to conduct a qualitative content analysis of existing interventions. Another approach is to conduct additional trials to test components of effective interventions. A final approach is to conduct a meta-regression; in such analyses, investigators enter data about the features of existing interventions into a statistical program to determine their relative impact on relevant outcomes. While the field may be too young for this now, meta-regression could be a very useful technique as additional studies with similar intervention features and outcomes become available. To prepare for such a meta-regression, investigators in the field might agree on a useful set of intervention design features to be tested and consistently report on the incorporation of these features into multicomponent interventions.

Effective Practice and Policy Interventions

Additional work is also needed to determine the effect of practice and policy interventions. We found almost no studies that addressed such interventions.

Implications of This Report for Clinicians and Policymakers

In addition to identifying areas for future research, this report informs clinicians and policymakers. First, it continues to raise awareness that low health literacy has a substantial impact on healthcare service use, health outcomes, cost, and disparities and warrants the attention of both clinicians and policymakers. Second, it highlights effective interventions that could be implemented in clinical practice now and/or supported by policy. These interventions have been rated as having moderate strength of evidence in our review and include intensive adherence, self-management, and disease management interventions delivered by clinical practitioners. Finally, for policymakers, our update highlights the critical need for research funding to test practice and policy interventions, which to date have gone largely untested. The recent Department of Health and Human Services National Action Plan to Improve Health Literacy helps enumerate these and other critical actions for clinicians and policymakers addressing health literacy.[52]

Conclusions

Our systematic review update confirms that lower health literacy as measured by poorer reading skills is associated with a range of adverse health outcomes. Evidence is beginning to emerge concerning the relationship between poorer numeracy skills and health outcomes but the evidence is still too weak to be confident of an association. We found no evidence evaluating oral (verbal) health literacy and health outcomes.

Rigorous, well-designed studies of interventions to mitigate the effects of low health literacy have been conducted since our earlier review. Future studies isolating one measurable and replicable component of an intervention will, however, be particularly helpful in building this body of evidence. Many studies have now been conducted with a variety of clinic populations. Future research could enhance our confidence in the more universal applicability of results by including more broadly based and representative samples.

Table 62. Health outcome study results (KQ 1): summary and comparison of 2004 and 2010 systematic reviews

Outcome	Study design	Number of articles: 2004 (Number controlling for confounding)	Number of articles: 2010 (Number controlling for confounding)	Low Health Literacy Related Results: 2004	Low Health Literacy Related Results: 2010	Strength of Evidence: 2010
Hospitalization	Cohort Cross-sectional	2 (2) 0	4 (3) 2 (2)	Increase	Increase	Moderate
Emergency care visits	Cohort Cross-sectional	0 0	4 (3) 3 (3)	NA: no studies	Increase	Moderate
Colon screening	Cross-sectional	0	5(5)	NA: no studies	Decrease	Insufficient
Pap tests	Cross-sectional	1(1)	3(3)	Decrease	Decrease	Low
Mammogram	Cross-sectional	1(1)	4(4)	Decrease	Decrease	Moderate
STI (testing)	Cross-sectional	1(1)	1(1)	Increase	Increase	Low
Immunization: Influenza	Cohort Cross-sectional	0 1(1)	1(1) 3(3)	Decrease	Decrease	Moderate
Immunization: Pneumococcal	Cohort Cross-sectional	0 1(1)	1(1) 1(1)	Decrease	Mixed	Insufficient
Access to care	Cohort Cross-sectional	0 1(1)	4(4) 5(5)	No difference	Mixed	Insufficient
Access to insurance	Cross-sectional	0	1(1)	NA: no studies	Decrease	Low
Knowledge	Cohort Cross-sectional	1 (0) 9 (7)	NA	Decrease	NA: analysis not repeated	Not re-evaluated
Adherence	Cohort Cross-sectional	2 (0) 2 (1)	6 (6) 9 (9)	Mixed	Mixed	Insufficient
Self-efficacy	Cross-sectional	0	5 (4)	NA: no studies	Mixed	Insufficient
Smoking	Cross-sectional	3 (1)	2 (2)	Mixed	Mixed	Insufficient
Alcohol and drug use	Cross-sectional	1 (1)	2 (2)	No difference	Mixed	Insufficient
Healthy lifestyle (physical activity, eating habits, and seat belt use)	Cross-sectional	0	3 (3-for some outcomes)	NA: no studies	Mixed	Insufficient
Obesity and weight	Cohort Cross-sectional	0 0	1 (0) 4 (1)	NA: no studies	Mixed	Insufficient
Review of prescription information	Cross-sectional	0	1 (1)	NA: no studies	Decrease	Low
HIV risk and sexual behavior	Cohort Cross-sectional	0 0	1 (1) 1 (1)	NA: no studies	Mixed	Insufficient
Taking medications appropriately	Cohort Cross-sectional	0 0	1 (1) 4 (4)	NA: no studies	Decrease	Moderate
Interpreting labels and health messages	Cross-sectional	0	5 (4)	NA: no studies	Decrease	Moderate
Asthma self care	Cross-sectional	1 (1)	1 (1)	Decrease	Decrease	Low
Mental health symptomatology	Cohort Cross-sectional	1 (0) 4 (2)	2 (1) 8 (4)	Decrease	Greater in 8 studies	Low
Chronic disease	Cohort Cross-sectional	1 (1)	2 (0) 5 (3)	No difference	Mixed	Insufficient

HL=health literacy; NA=not applicable; QoL=quality of life; STI=sexually transmitted infection

Table 62. Health outcome study results (KQ 1): summary and comparison of 2004 and 2010 systematic reviews (continued)

Outcome	Study design	Number of articles: 2004 (Number controlling for confounding)	Number of articles: 2010 (Number controlling for confounding)	Low Health Literacy Related Results: 2004	Low Health Literacy Related Results: 2010	Strength of Evidence: 2010
HIV severity and symptoms	Cohort Cross-sectional	 3 (0)	1 (1) 4 (3)	Mixed	No difference in 4 studies	Low
Asthma severity and control	Cross-sectional	0	2 (1)	NA: no studies	Mixed	Insufficient
Diabetes control and related symptoms	Cross-sectional	3 (2)	6 (5)	Mixed	Mixed	Insufficient
Hypertension control	Cross-sectional	1 (1)	2 (2)	No difference	Mixed	Insufficient
Prostate cancer control	Cross-sectional	1 (1)	1 (1)	No difference	Decrease	Low
Health status: all adults	Cross-sectional	2 (2)	1 (1)	Decrease	No difference	Low
Health status and QoL seniors:	Cohort Cross-sectional	0 1 (0)	1 (1) 5 (4)	Decrease	Decrease	Moderate
Mental & physical functioning: seniors	Cohort Cross-sectional	 0	3 (2) 2 (2)	NA: no studies	Mixed	Insufficient
Health status and QoL: specific diseases	Cross-sectional	2 (0)	5 (5)	No difference	Mixed	Insufficient
Mortality: seniors	Cohort	0	3 (3)	NA: no studies	Greater	High
Costs	Cohort	1 (1)	2(2)	No difference	Mixed	Insufficient
Disparities	Cohort Cross-sectional	0 1 (1)	1 (1) 5 (5)	HL mediates racial disparity in 1 study	HL partially mediates: racial disparities in some outcomes, no differences in Hispanic ethnicity, sex differences for 1 outcome	Race: Low Hispanic ethnicity: Low Sex: Low

Table 63. Numeracy outcome study results (KQ 1): summary of 2010 systematic review*

Outcome	Study design	Number of articles: 2010 (Number controlling for confounding)	Low Numeracy Literacy Related Results: 2010	Strength of Evidence: 2010
Use of health care services	Cross-sectional	1(1)	No effect	Low
Accuracy of risk perception	Cross-sectional	5(3)	Mixed	Insufficient
Knowledge	Cross-sectional	4(3)	Mixed	Insufficient
Self-efficacy	Cross-sectional	1(0)	Decrease	Insufficient
Behavior	Cross-sectional	1(0)	No effect	Insufficient
Skills	Cohort Cross-sectional	1(1) 5(4)	Taking medication (n=4): Mixed Interpreting health information (n=2): Decrease	Taking medication: Insufficient Interpreting health information: Low
Disease prevalence and severity	Cross-sectional	3(2)	Mixed	Insufficient
Disparities	Cross-sectional	2(2)	Numeracy partially mediates the relationship between race and 1 outcome and between gender and 1 outcome	Low

*Numeracy studies were not included in the 2004 review
n=number

Table 64. Results of intervention studies with single design strategies (KQ 2): summary and comparison of 2004 and 2010 systematic reviews *

Design Strategy	Study design	Number of articles (Number stratifying results by HL level): 2004	Number of articles (Number stratifying results by HL level): 2010	Low Health Literacy Related Results: 2004	Low Health Literacy Related Results: 2010	Strength of Evidence: 2010
Alternative Document Design	RCT	1(1)	2(2)	Increased	Increased	Low
Alternative Numerical Presentation	RCT	0	3(3)	NA	Increased	Low
Additive and Alternative Pictorial Representation	RCT Quasi (pre/post)	0 0	8(5)	NA	Mixed	Insufficient
Alternative Media	RCT NRCT	1(1) 2(1)	4(3)	Mixed	Mixed	Insufficient
Alternative Readability and Document Design	RCT Quasi (post) NRCT	2(0) 0 3(3)	6(3) 1(1)	Mixed	Mixed	Insufficient
Physician Notification of HL Level	cRCT	0	1(1)	NA	No effect (patient outcomes)	Low

*Studies in 2004 report reorganized into 2010 framework (e.g. single vs. multiple design strategy interventions) for reporting
cRCT=cluster randomized controlled trial; HL=health literacy; NA=not applicable; NRCT=non-randomized controlled trial; quasi=quasi-experimental study; RCT=randomized controlled trial

Table 65. Results of interventions with multiple design strategies: summary and comparison of 2004 and 2010 systematic reviews*

Outcome	Study design	Number of articles (Number stratifying results by HL level): 2004	Number of articles (Number stratifying results by HL level): 2010	Low Health Literacy Related Results: 2004	Low Health Literacy Related Results: 2010	Strength of Evidence: 2010
Knowledge	RCT	2(1)	3(1)	Mixed	Mixed	Insufficient
	Quasi (pre/post)	1(0)	5(2)			
	Quasi (post)	1(0)	2(2)			
	NRCT	1(0)	0			
Self-efficacy	RCT	0	4(1)	NA	Mixed	Insufficient
	Quasi (pre/post)	0	4(0)			
	Quasi (post)	0	1(0)			
Behavioral Intent		0	0	NA	NA	NA
Skill	RCT	0	1(1)	Mixed	Increased	Insufficient*
	Quasi (pre/post)	1(1)	0			
	NRCT	1(0)	0			
Behavior	RCT	2 (0)	2(0)	Nutrition interventions: Mixed	Self-management interventions: Increased	Self-management interventions: Moderate Nutrition interventions: Insufficient
	Quasi (pre/post)	0	1(1)			
	NRCT	1	0			
Adherence	RCT	0	2(0)	No effect	Mixed	Insufficient
	Quasi (pre/post)	0	1(1)			
	Quasi (post)	0	1(1)			
	NRCT	1 (0)	0			
Disease Prevalence and Severity	RCT	3(0)	4(2)	No effect	Self-management: Insufficient Disease management: Moderate Adult basic and Lit. Education: Low	Self-management: Insufficient Disease management: Moderate Adult Basic and Education: Low
	Quasi	0	3(3)			
Quality of Life	RCT	0	4(0)	NA	Mixed	Insufficient
Preventive service use	RCT	0	1(0)	NA	Increased	Moderate
	cRCT	0	1(1)			
Emergency Room Visits	RCT	0	1(0)	NA	Reduced	Moderate
	Quasi (pre/post)	0	1(1)			
Hospitalization	RCT	0	2(1)	NA	Reduced	Moderate
	Quasi (pre/post)	0	1(1)			
Cost	RCT	0	2(0)	NA	Mixed	Insufficient
Disparities		0	0	NA	NA	Insufficient

*Studies in 2004 report reorganized into 2010 framework (e.g. single vs. multiple design strategy interventions) for reporting
cRCT=cluster randomized controlled trial; NA=not applicable; NRCT=non-randomized controlled trial; quasi=quasi-experimental study; RCT=randomized controlled trial

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Appendix A. Author Queries

Queries to Authors for Additional Information

Author	Research Objective	Questions for Authors
Bosworth et al., 2005[1]	To determine if a nurse administered patient-tailored intervention can improve blood pressure control	What strategies did you employ in your intervention specifically to address the problem of low health literacy?
Brock & Smith, 2007[2]	To evaluate the effects of using an audiovisual animation displayed on a PDA for patient education in a clinical setting	What behavioral theory did you use in the design of your intervention?
Bryant et al., 2009[3]	To determine whether a novel multimedia computer version of the AUA-SS would be better understood by patients than the original form, and to see whether improvement in understanding varied by literacy level	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention? What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention? Did you tailor your intervention to address individual patient characteristics? If so, how?
Campbell et al., 2004[4]	To compare comprehension of consent information (for a hypothetical research study) as a function of the medium of presentation, mostly among a low-literacy population	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
DeWalt et al., 2006[5]	To compare the efficacy of a heart failure self-management program designed for patients with low literacy versus usual care	What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention?
Ferreira et al., 2005[6]	To test whether health-care provider directed intervention increased colorectal cancer screening rates	What strategies did you employ in your intervention specifically to address the problem of low health literacy? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Galesic et al., 2009[7]	Experiment 1: To investigate whether icon arrays increase accuracy of understanding medical risks (either ARR or RRR) Experiment 2: To investigate whether icon arrays and alternate denominators affect perceived seriousness of risks and helpfulness of treatments; this experiment is not of interest to SER	What was the total contact time with participants during the delivery of your intervention?
Galesic et al., 2009[8]	To examine whether natural frequencies can improve posterior probability judgments of older adults and of people with lower numeracy skills	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention? What was the total contact time with participants during the delivery of your intervention?

Author	Research Objective	Questions for Authors
Garcia-Retamero and Galesic, 2009[9]	1) To determine whether participants show denominator neglect in their estimates of risk reduction and whether those with low numeracy show more denominator neglect than those with high numeracy 2) To evaluate whether icon array presentation helps reduce misunderstanding of risk reduction information due to denominator neglect 3) To determine whether US participants show more denominator neglect than German participants	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Gerber et al., 2005[10]	To evaluate a multimedia intervention for diabetes education targeting low literacy individuals from a diverse population	How many intervention sessions did you provide for study participants? What was the total contact time with participants during the delivery of your intervention?
Greene and Peters, 2009[11]	To test whether simplifying official Medicaid comparison chart improved comprehension and to examine how important literacy and numeracy skills were for comprehension	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention? What was the total contact time with participants during the delivery of your intervention?
Greene et al., 2008[12]	1) To test whether comprehension could be improved by varying the way information was presented 2) To examine the effect of numeracy on comprehension of CDHP design and informed decision making (i.e. is numeracy of moderator)	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Jay et al., 2009[13]	To determine whether a multimedia intervention can improve food label comprehension in a sample of low-income patients	What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Kang et al, 2009[14]	1) To investigate the recall and comprehension of orthodontic informed consent among patients and their parents with the traditional AAO informed consent form and other methods with improved readability and processability 2) To investigate the association between reading ability, anxiety, and sociodemographic variables, and recall and comprehension 3) To determine how different domains of information are affected by varying degrees of readability and processability	What was the total contact time with participants during the delivery of your intervention?

Author	Research Objective	Questions for Authors
Kim et al., 2004[15]	To examine the association between health literacy and self management behaviors in patients with diabetes and to determine whether diabetes education improves self-management behaviors in patients with limited compared with adequate health literacy	What was the total contact time with participants during the delivery of your intervention? What strategies did you employ in your intervention specifically to address the problem of low health literacy? Did you tailor your intervention to address individual patient characteristics? If so, how? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Kripalani et al., 2007[16]	To design and evaluate an illustrated medication schedule (pill card) that depicts a patient's daily medication regimen using pill images and icons	How many intervention sessions did you provide for study participants? What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention?
Kripalani et al., 2007[17]	To determine the effects of two low-literacy educational handouts on the frequency of subsequent prostate cancer discussion and screening	How many intervention sessions did you provide for study participants? What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention?
Kripalani et al., 2008[18]	To determine whether simplified written documents, a short verbal description of the study, and a visual aid to describe the randomization process improved participant comprehension of informed consent and HIPAA Privacy Rule requirements regarding authorization for use and disclosure of protected health information	What was the total contact time with participants during the delivery of your intervention?
Murray et al., 2007[19]	To determine whether a pharmacist intervention improves medication adherence and health outcomes compared with usual care for low-income patients with heart failure	How many intervention sessions did you provide for study participants? What was the total contact time with participants during the delivery of your intervention?
Peters et al., 2007[20]	Examine whether simpler presentations of quantitative information have a larger influence on (on comprehension) among consumers with low numeracy compared to those higher in numeracy	What was the total contact time with participants during the delivery of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Robinson et al., 2008[21]	To determine the effects of literacy classes given to asthmatic pediatric patients in an urban area on reading level, asthma treatment self-efficacy, ED visits and hospitalizations	What strategies did you employ in your intervention specifically to address the problem of low health literacy? What behavioral theory did you use in the design of your intervention?

Author	Research Objective	Questions for Authors
Rothman et al., 2004[22]	To examine the role of literacy in glycemic control in a cohort of patients with type 2 diabetes	How many intervention sessions did you provide for study participants? What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Rothman et al., 2004[23]	To examine the role of literacy on the effectiveness of a comprehensive disease management program for patients with diabetes	What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Rudd et al., 2009[24]	To test the efficacy of educational interventions to reduce literacy barriers and enhance health outcomes among patients with inflammatory arthritis	How many intervention sessions did you provide for study participants? What was the total contact time with participants during the delivery of your intervention? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Schillinger et al., 2009[25] Schillinger et al., 2008[26]	Examined the effects of 2 self-management support (SMS) strategies (automated telephone self-management support (ATSM) and group medical visits (GMV)) across outcomes corresponding to the Chronic Care Model	What strategies did you employ in your intervention specifically to address the problem of low health literacy? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Seligman et al., 2005[27]	To determine if notifying physicians of their patients' limited health literacy affects physician behavior, physician satisfaction, or patient self-efficacy	What behavioral theory did you use in the design of your intervention?
Sobel et al., 2009[28]	To determine whether a low-literacy multimedia tool can improve asthma knowledge in African-American adults	What behavioral theory did you use in the design of your intervention?
Volandes et al., 2009[29]	To evaluate the effect of a video decision support tool on preferences for future medical care in older people if they develop advanced dementia, and stability of preferences after 6 weeks	What behavioral theory did you use in the design of your intervention? Did you tailor your intervention to address individual patient characteristics? If so, how?
Walker et al., 2007[30]	Intervention: To determine the effectiveness of a pictorial 'mind map' together with the Arthritis Research Campaign (ARC) booklet for imparting knowledge to participants with rheumatoid arthritis, and to relate this to participant reading ability Health outcome: To investigate the relationship between anxiety/depression and HL	What was the total contact time with participants during the delivery of your intervention? Who delivered your intervention?

Author	Research Objective	Questions for Authors
Wallace et al., 2009[31]	To evaluate the impact of providing patients with a literacy-appropriate diabetes education guide accompanied by brief counseling designed for use in primary care	What was the total contact time with participants during the delivery of your intervention?
Weiss et al., 2006[32]	To determine whether literacy education, provided along with standard depression treatment to adults with depression and limited literacy, would result in greater improvement in depression than would standard depression treatment alone	How many intervention sessions did you provide for study participants? What behavioral theory did you use in the design of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Wright et al., 2009[33]	To determine whether low numeracy participants would better understand risks presented using grouped dot or dispersed dot displays	What was the total contact time with participants during the delivery of your intervention? Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?
Yates & Pena, 2006[34]	To assess differences in comprehension between standard and simplified head injury advice sheets	Did you perform any pre-testing (either cognitive and usability testing or pilot testing) of your intervention?

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Appendix B. Search Strings

May 2009 Search

PubMed

#1	Search numeracy	173
#2	Search numeracy Limits: Humans, English	146
#3	Search "health literacy"	789
#4	Search "health literacy" Limits: Entrez Date from 2003, Humans, English	586
#5	Search #2 OR #4	716
#6	Search literacy	39075
#7	Search "rapid estimate of adult literacy" OR real*	215538
#8	Search #6 AND #7	920
#9	Search "test of functional health literacy" OR tofhl*	295
#10	Search #6 AND #9	295
#11	Search "Hebrew health literacy test" OR HHLT	6
#12	Search "medical achievement reading test" OR MART	1202
#13	Search #6 AND #12	23
#14	Search "newest vital signs" OR NVS	203
#15	Search #6 AND #14	6
#16	Search "short assessment of health literacy" OR SAHLSA	170
#17	Search #6 AND #16	170
#18	Search "wide range achievement test" OR WRAT	290
#19	Search #6 AND #18	77
#20	Search "nutritional literacy" OR "literacy assessment for diabetes" OR LAD OR SIL OR "single item numeracy screener" OR DAHL OR "demographic assessment" OR BEHKA OR "brief estimate" OR "diabetes numeracy" OR "medical data interpretation" OR "subjective numeracy" OR "numeracy test"	18220
#21	Search #6 AND #20	264
#22	Search #8 OR #10 OR #11 OR #13 OR #15 OR #17 OR #19 OR #21	1661
#23	Search #8 OR #10 OR #11 OR #13 OR #15 OR #17 OR #19 OR #21 Limits: Entrez Date from 2003, Humans, English	729
#24	Search #5 OR #23	1310
#25	Search #5 OR #23 Limits: Editorial, Letter, Case Reports	58
#26	Search #24 NOT #25	1252

PubMed

#1	Search "rapid estimate of adult literacy"	104
#2	Search "test of functional health literacy"	290

#3	Search "Hebrew health literacy test"	6
#4	Search "medical achievement reading test	0
#5	Search medical achievements reading test	68
#6	Search "newest vital signs"	1
#7	Search "short assessment of health literacy"	170
#8	Search "wide range achievement test"	219
#9	Search "literacy assessment for diabetes"	225
#10	Search "nutritional literacy"	3
#11	Search "single item numeracy screener"	0
#12	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11	991
#13	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 Limits: Entrez Date from 2003, Humans, English	473
#14	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 Limits: Entrez Date from 2003, Humans, Editorial, Letter, Case Reports, English	5
#15	Search #13 NOT #14	468

PubMed

#1 Search literacy [tw]	5516
#2 Search literacy [tw] Limits: Entrez Date from 2003, Humans, English	2337
#3 Search literacy [tw] Limits: Editorial, Letter, Case Reports	243
#4 Search #2 NOT #3	2226

Term used in other databases:
“health literacy”

CINAHL = 34 = 22 NEW

Cochrane = 61 = 34 NEW

PsycINFO = 65 = 26

ERIC = 34 = 31

Total Unduplicated Database = 2855

December 2009 Search

PubMed

Search	Queries	Result
#1	Search numeracy	213
#2	Search numeracy Limits: Humans, English	169
#3	Search "health literacy"	964
#4	Search ("2009/01/01"[Entrez Date] : "3000"[Entrez Date]) AND ("health literacy") Limits: Humans, English	110
#5	Search #2 OR #4 Limits: Humans, English	273
#6	Search literacy	41096
#7	Search "rapid estimate of adult literacy" OR real*	232562
#8	Search #6 AND #7	968
#9	Search "test of functional health literacy" OR tofhl*	326
#10	Search #6 AND #9	326
#11	Search "Hebrew health literacy test" OR HHLT	7
#12	Search "medical achievement reading test" OR MART	1300
#13	Search #6 AND #12	26
#14	Search "newest vital signs" OR NVS	220
#15	Search #6 AND #14	8
#16	Search "short assessment of health literacy" OR SAHLSA	187
#17	Search #6 AND #16	187
#18	Search "wide range achievement test" OR WRAT	302
#19	Search #6 AND #18	83
#20	Search "nutritional literacy" OR "literacy assessment for diabetes" OR LAD OR SIL OR "single item numeracy screener" OR DAHL OR "demographic assessment" OR BEHKA OR "brief estimate" OR "diabetes numeracy" OR "medical data interpretation" OR "subjective numeracy" OR "numeracy test"	18849
#21	Search #6 AND #20	282
#22	Search #8 OR #10 OR #11 OR #13 OR #15 OR #17 OR #19 OR #21	1773
#23	Search ("2009/01/01"[Entrez Date] : "3000"[Entrez Date]) AND (#8 OR #10 OR #11 OR #13 OR #15 OR #17 OR #19 OR #21) Limits: Humans, English	86
#24	Search #5 OR #23	342
#25	Search #5 OR #23 Limits: Editorial, Letter, Case Reports	24
#26	Search #24 NOT #25	318

CINAHL
"health literacy" limited to English language and non-Medline = 37 :
"health literacy" Limiters - Published Date from: 20090101-20101231; Exclude MEDLINE records; Language: English
Search modes - Boolean/Phrase
(**37**)

Cochrane Library
"health literacy" 2009-present= 1 review; 4 clinical trials = 5 total.

PsycINFO
"health literacy", 2009-present, English language, no editorials, no letters = 74
"health literacy" Limiters - Published Date from: 20090101-20101231; Language: English
Search modes - Boolean/Phrase
(**74**)

ERIC
Main Search:
"health literacy", 2009-present, **English language = 9**

May 2010 Search

PubMed

Search	Most Recent Queries	Result
#1	Search numeracy	243
#2	Search "health literacy"	1084
#3	Search #1 OR #2	1285
#4	Search literacy	42702
#5	Search "rapid estimate of adult literacy" OR real*	245476
#6	Search #4 AND #5	1000
#7	Search "test of functional health literacy" OR tofhl*	154
#8	Search #4 AND #7	154
#9	Search "Hebrew health literacy test" OR HHLT	1
#10	Search #4 AND #9	1
#11	Search "medical achievement reading test" OR MART	1358
#12	Search #4 AND #11	28
#13	Search "newest vital signs" OR NVS	261
#14	Search #4 AND #13	11
#15	Search "short assessment of health literacy" OR SAHLSA	49
#16	Search #4 AND #15	49
#17	Search "wide range achievement test" OR WRAT	303
#18	Search #4 AND #17	84
#19	Search "nutritional literacy" OR "literacy assessment for diabetes" OR LAD OR SIL OR "single item numeracy screener" OR DAHL OR "demographic assessment" OR BEHKA OR "brief estimate" OR "diabetes numeracy" OR "medical data interpretation" OR "subjective numeracy" OR "numeracy test"	19266
#20	Search #4 AND #19	303
#21	Search #6 OR #8 OR #10 OR #12 OR #14 OR #16 OR #18 OR #20	1522
#22	Search #3 OR #21	2561
#23	Search #22 Limits: Humans, English	2042
#24	Search #23 Limits: Editorial, Letter, Case Reports	93
#25	Search #23 NOT #24	1949
#26	Search (#25) AND "2009/10/01"[Entrez Date] : "3000"[Entrez Date] Sort by: PublicationDate	106

Analogous terms were used to conduct searches in the following databases:

CINAHL
39 initially imported
38 after duplicates removed

PsycINFO
68 initially imported
53 after duplicates removed

Cochrane Library
44 initially imported
41 after duplicates removed

ERIC
8 initially imported
6 after duplicates removed

Total records = 24

Appendix C. Inclusion/Exclusion Criteria and Study Internal Validity Quality Form

Inclusion/Exclusion Criteria:

Please mark each abstract or article IN/OUT based on following criteria. For those excluded, provide exclusion reason and any additional pertinent codes listed below. Insert space below

Inclusions:

1. Prospective and cross-sectional observational studies of literacy levels and health. Studies must measure literacy at the individual level.
2. Trials of materials developed for low literacy populations or trials of interventions that compare easier to read/understand material versus standard materials.

Exclusion Criteria:

1. Studies with no original data
2. SER only
3. Studies that do not measure literacy or health literacy
4. Studies with no health outcomes (ie. descriptive only or have outcomes like likability, satisfaction)
5. Studies examining normal reading development in children
6. Studies about dyslexia
7. Studies on the basic experimental science of reading ability (e.g., studies of brain function, MRI, EEG)
8. Non-English language studies
9. Studies answering KQ1 where literacy is measured (not numeracy) and the only study outcome is knowledge.
10. Studies in which the outcome is limited to dementia or cognitive impairment.
11. Studies published in abstract form only
12. Case-report only
13. Ecological data only
14. Sample size less than 10
15. Unable to obtain the article
16. Intervention studies that do not address low health literacy

Study Internal Validity (Risk of Bias) Review Form

REF #, Author, Year:________________________________ **Reviewer**_____________________

Short Title:____

Question	Response	Criteria	Comments
Internal Validity			
1. Method of Randomization (KQ2-RCT only)	Good ☐	Computer generated random allocation.	
	Fair ☐	Flipped coin	
	Poor ☐	Pseudo randomization (ie. alternate allocation, by days of week, etc) or randomization approach cannot be determined	
	NA ☐	Participants not randomized	
2. Allocation Concealment (KQ2-RCT only)	Good ☐	Central randomization	
	Fair ☐	Opaque envelopes	
	Poor ☐	No concealment	
	NA ☐	Participants not randomized	
3. Creation of Comparable Groups	Good ☐	No baseline differences (>20% qualitatively) among groups regarding inclusion/exclusion criteria	
	Fair ☐	Few baseline difference among groups, probably related to chance	
	Poor ☐	Multiple differences among groups	
	NA ☐☐	Cross-sectional, case-control or single arm study	
4. Maintenance of Comparable Groups. If there is only one study arm than consider the overall attrition only.	Good ☐	Low attrition (< 20%) and Low differential loss (<5%)	
	Fair ☐	Moderate attrition (20-40%) or Moderate differential loss (5-15%)	
	Poor ☐	High Attrition (>40%) or High differential loss (>15%)	
	NA ☐	Cross-sectional, case-control.	
5. Health Literacy Measurement (health literacy, literacy, numeracy, or other)	Good ☐	Measure valid and reliable. (unless the HL measure is one of the well known and applied measures (REALM, TOFHLA,WRAT etc., measurement validation should be discussed in the text)	
	Fair ☐	Some of the above features	

	Poor ☐	None of the above features	
6. Outcome Measurement	Good ☐	Measure valid and reliable (i.e. mortality, clinical measure, well validated scale)	
	Fair ☐	Some of the above features (Chart review, partially validated scale)	
	Poor ☐	None of the above features. (self-report, pain may be an exception, non-validated scale)	
7. Outcome Measurement Equally Applied	Good ☐	Same measurement applied to each group. Measurement at same point in time in each group	
	Fair ☐	Some of the above features.	
	Poor ☐	None of the above features.	
	NA ☐	Study includes only one group	
8. Blinding of patients and providers (KQ2 only)	Good ☐	Blinding of patients and providers	
	Fair ☐	Blinding of one of the above.	
	Poor ☐	Blinding of none of the above.	
	NA ☐	Study was not an RCT/Intervention study: Patients and providers could not be blinded to the treatment arm	
9. Blinding of outcome assessors to intervention or exposure status of participants	Good ☐	Yes	
	Poor ☐	No	
	NR ☐		
	NA ☐		
10. Appropriate statistical testing	Good ☐	Statistical tests appropriate to the data. Appropriate accounting for clustering, if RCT or naturally clustered environment, and multiple comparisons.	
	Fair ☐	Some of the above features.	
	Poor ☐	None of the above features.	
11. Intent to Treat Analysis or Sensitivity Analysis done to assess impact of loss to follow-up	Good ☐	Intent to treat or other analysis done	
	Poor ☐	No analysis completed	
	NA ☐	Cross sectional, single arm study or case-control selected on outcome measure	
12 Appropriate control of confounding	Good ☐	Addressed through study design (e.g., randomization) and/or analysis (e.g., through matching, stratification, multivariate analysis or other statistical adjustment)	
	Fair ☐	Attempt made to control confounding, but doesn't address all relevant confounders.	

	Poor ☐	No attempt to control confounders.	
13. Sample sufficient by power analysis	Good ☐	Yes, for all outcomes reported	
	Fair ☐	Yes, for some outcomes	
	Poor ☐	No, not done	
Overall Assessment			
14. Overall study assessment	Good ☐	Conclusions are very likely to be correct given degree of bias	
	Fair ☐	Conclusions are probably correct given degree of bias	
	Poor ☐	Conclusions aren't certain because bias too large	

Appendix D. Evidence Tables

Glossary of Abbreviations and Acronyms Used in Evidence Tables

Abbreviation/ Acronym	Definition
*	Calculated by evidence report authors
AA	African-American
ABCD	Assessment of Body Change Distress Scale
ABLE	Adult Basic Learning Examination
ABMT	Autologous bone marrow transplant
AC	Asthma clinic
ACE	Angiotensin-converting enzyme
ADEPT	Adherence and Efficacy to Protease Inhibitor Therapy study
ADL	Activities of daily living
AdLit	Adolescent Literacy
AFDC	Aid for Families with Dependent Children
AIDS	Acquired immune deficiency syndrome
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AOR	adjusted odds ratio
AQLQ	Asthma Quality of Life Questionnaire
ARB	Angiotensin II receptor blockers
ARC	Arthritis Research Campaign
ARR	Absolute Risk Reduction
ART	Antiretrovial therapy
ASI-Aic	Addition Severity Index-alcohol scale
ASI-drug	Addition Severity Index-drug scale
Avg	average
b/c	because
BA/BS	Bachelor of Arts/Bachelor of Science
BCT	breast-conservation therapy
BDI	Beck Depression Inventory
BMI	Body mass index
BMQ	Beliefs about Medicines Questionnaire
BP	blood pressure
BSE	Breast self-exam
BSI	Brief Symptom Inventory
CA	cancer
CAD	coronary artery disease
CAGE	Capillary Affinity Gel Electrophoresis
CARDES	Cardiovascular Dietary Education System
CASI	computer-assisted self interview
CBE	Clinical breast exam
CD	Compact disc
CD4	Cluster Difference 4
CD-ROM	Compact disc—read-only memory
CES-D	Center for Epidemiology Studies Depression Scale
CHART	Craig Handicap Assessment and Reporting Technique
CHD	coronary heart disease
CHF	congestive heart failure
CI	Confidence interval
cigs	cigarettes
COMBO	combination of 3 risk reduction presentations (RRR + ARR + NNT)
COOP/WONCA	Dartmouth Primary Care Cooperative Information Project/World Organization of National Colleges, Academies
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CRC	colorectal cancer

Abbreviation/ Acronym	Definition
C-SDSCA	Chinese version of the Summary of Diabetes Self-Care Activities
CT	Computed Tomography
dB	Decibel
DBP	Diastolic blood pressure
DDS	Diabetes Distress Scale
DICCT	Deaconess Informed Consent Comprehension Test
dl	Deciliter
DM	Diabetes mellitus
DMHDS	Dunedin Multidisciplinary Health and Development Study
DNA	Deoxyribonucleic Acid
DNR	Do Not Resuscitate
DRUGS	Drug Regimen Unassisted Grading Scale
E or S	English or Spanish
ED	Emergency department
EFNEP	Expanded Food and Nutrition Education Program
FACT-G	Functional Assessment of Cancer Therapy-General
FOBT	fecal occult blood testing
FQHC	Federally Qualified Health Centers
FSC	Family Service Center
G	Group
GA	Georgia
GED	General equivalency degree
GEE	Generalized Estimating Equation
Grady	Grady Memorial Hospital, Atlanta, GA
HAART	Highly active antiretroviral therapy
HAQ/HAD	Hospital Anxiety and Depression Scale
Harbor	Harbor-UCLA Medical Center, Torrance, CA
HbA1c	Glycosylated hemoglobin
Hep C	hepatitis C
Hg	Mercury
HIV	Human immunodeficiency virus
HIV/AIDS	Human immunodeficiency virus/Acquired Immune Deficiency Syndrome
HL	health literacy
HMO	Health maintenance organization
HRQoL	health related quality of life
HS	high school
HTN	Hypertension
IADL	Instrumental activities of daily living
ICD-9	International Classification of Disease-Ninth Revision
ICD-9-CM	International Classification of Disease-Ninth Revision, Clinical Modification
IDL	Instrument for the diagnosis of reading
IDR	Instrument for the Diagnosis of Reading
IEP	Individualized Educational Plan
INR	International Normalized Ratio
IQ	Intelligence quotient
IQR	Individual Qualification Record
IRR	Incidence rate ratio
IUD	Intra-uterine device
kcal	Kilocalories
kg	Kilogram
KMS	Knowledge of Medication Subtest
KQ	key question
KSQ	Knowledge Scale Questionnaire
l	Liter
LA	Louisiana
LAE	Los Angeles English speaking (Harbor-UCLA Medical Center)
LAS	Los Angeles Spanish speaking (Harbor-UCLA Medical Center)
LDL	Low Density Lipoprotein

Abbreviation/ Acronym	Definition
MCS	Mental Component Summary of SF-36
MD	medical doctor
MDI	Metered dose inhaler
med	medical
MEMS	Medical Equipment Management System
mg	Milligrams
MHMC	Mercy Hospital and Medical Center
MHP	mental health problem
MKS	Medication Knowledge Score
mL	Milliliter
mm	Millimeters
MMC	Medication management capacity
MML	Marginal Maximum Likelihood
mmol	Millimoles
MMSE	Mini-Mental State Examination
MUSP	Mater–University of Queensland Study of Pregnancy
N	Number
NA	Not applicable
NAAL	National Assessment of Adult Literacy
NALS	National Adult Literacy Survey
NART	National Adult Reading Test
NC	North Carolina
ng/mL	Nanograms per mililiter
NH	New Hampshire
NLS	Nutrition Label Survey
NNT	number needed to treat
NOS	not otherwise specified
NR	Not reported
NS	Not significant
NY	New York
OAD	oral anti-diabetic drug
OCP	Oral contraceptive pill
OLS	Ordinary Least Squares
OR	Odds ratio
P	Probability
PA	Pennsylvania
PACE	Pima County adult education program, Tucson, AZ
PACQLQ	Pediatric Asthma Caregiver’s Quality of Life Questionnaire
PAG	Pictorial anticipatory guidance
PAM	Patient Activiation Measure
Pap test	Papanicolaou smear
PCKQ	Prostate Cancer Knowledge Questionnaire
PCP	primary care physician
PMAQ	Patient Medication Adherence Questionnaire
PORT	Patient Outcomes Research Team
PR	prevalence ratio
PSA	Prostate-Specific Antigen
QLS	Questionnaire Literacy Screen
r	Correlation coefficient
RA	Research assistant
RCT	Randomized controlled trial
REALM	Rapid Estimate of Adult Literacy in Medicine
RNA	Ribonucleic Acid
RR	Relative risk
RRR	Relative risk ratio
RSPM	Raven Standard Progressive Matrices
SBP	Systolic blood pressure
SD	Standard deviation

Abbreviation/ Acronym	Definition
SDSCA	Summary of Diabetes Self-Care Activities Measure
SES	Socio-economic status
SF-12	Short Form 12
SF-36	Short Form 36
SF-36 PCS	Medical Outcomes Study Physical Component
SGUQ	Standard Gamble Utility Questionnaire
Sig	Significant
SIP	Sickness Impact Profile
SMOG	Readability formula
SNAP	Stanford Nutrition Action Program
SPMSQ	Short Portable Mental Status Questionnaire
SSC-HIVrev	Revised Sign and Symptom Checklist for persons with HIV Disease
STD	Sexually transmitted diseases
STIFLE	
S-TOFHLA	Short Test of Functional Health Literacy in Adults
SWOG	Southwestern Oncology Group
TABE	Test of Adult Basic Education
TALS	Test of Applied Literacy Skills
TIPP	The Injury Prevention Program
TN	Tennessee
TOFHLA	Test of Functional Health Literacy in Adults
TOFHLS-S	Test of Functional Health Literacy in Adults in Spanish
TT	Talking Touchscreen
t-tests	Statistical hypothesis test
TX	Texas
UCLA	University of California, Los Angeles
UHS	Duke University Healthcare System
UK	United Kingdom
U-PENN	University of Pennsylvania
US	United States
VA	Veterans Affairs
VAHS	Veterans Affairs Healthcare System
VFQ-25	25-item Visual Function Questionnaire
VRQoL	vision-related quality of life
vs.	versus
VT	Vermont
WAIS-R	Wechsler Adult Intelligence Scale–Revised
WIC	Women, Infants, and Children
wk	week
WRAT	Wide Range Achievement Test
WRAT3	Wide Range Achievement Test, 3rd edition
WRAT-R	Wide Range Achievement Test–Revised
yr(s)	Year(s)

Evidence Table 1. Key Question 1: Health literacy outcome studies

Study Description	Participant Characteristics
Author, year: Bailey et al., 2009[1] Research objective: To determine the level of adult understanding of dosage instructions for a liquid medication commonly prescribed for children. Study design: Cross-sectional Study setting: 3 Outpatient family medicine clinics serving low-income populations in Shreveport, La; Chicago, IL, and Jackson, Mich Measurement period: July 2003 - August 2004 Measurement tools including cutpoints, %: REALM: Low: ≤ 6th grade Marginal: 7th-8th grade Adequate: ≥ 9th grade	Eligibility criteria: Inclusion: 18-75 years of age Exclusion: Self-reported severe impaired vision, hearing problems, acute illness or limited English proficiency Sampling strategy: Convenience Sample-consecutive adults waiting for an appointment for themselves or their children in clinic waiting rooms. Sample size: N = 373 Age (mean and range), %: 44 (SD = 13.2) Gender, %: Female: 67.8% Race/Ethnicity, %: African-American: 58 White: 42 Income, %: NR Insurance status, %: NR Education, %: More than HL or GED: 27.8 HS or GED: 43.1 Less than HS: 29.1 Other characteristics, %: NR Health literacy/numeracy levels, %: Literacy Level: Low: 19.8 Marginal: 28.9 Adequate: 51.2

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Intrepretation of a prescription label for amoxicillin Understanding of dosage measurement and frequency of use Covariates used in multivariate analysis: Multivariate analysis 1: Race, age, sex, and education Multivariate analysis 2: Race, age, sex, and education and HL Description of outcome measures: To assess subjects' understanding of prescription labels, each patient was presented with a series of mock prescription bottles, including one for an oral suspension medication and asked "How would you give this medicine?" Data source(s) for outcomes: Interview Attempts for control for confounding: Multivariate logistic regression models Blinding: Yes; panel of blinded physician reviewers determined whether or not the interpretations were correct Statistical measures used: Bivariate analyses between demographic variables, literacy level, and incorrect interpretation of dosage instructions Mediational analysis, a form of regression, was used to explore the relationship between literacy, race, and the outcome	Describe results: Those with lower HL levels were more likely to misunderstand dosing instructions, controlling for other characteristics. HL mediates the relationship between racial differences and medication label understanding. Effect in no exposure (i.e., adequate literacy) or control group: Misunderstanding of Medication Label Instructions, %: Literacy level, adequate: 18.3 Effect in exposure (i.e., low/moderate literacy) or intervention: Misunderstanding of Medication Label Instructions, %: Literacy level, low: 43.2 Literacy level, marginal: 34.3 Difference: Difference in Medication Understanding (adjusted): Marginal v Adequate: AOR, 2.20; 95% CI 1.19-3.97 Low v Adequate: AOR, 2.90; 95% CI 1.41-6.00 Mediation analysis: race and gender sig in Model 1 (not controlling for HL) and not in Model 2 (controlling for HL)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Baker et al., 2004[2] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8] Howard et al., 2005;[9]) Research objective: Determine whether individuals with inadequate HL who are newly enrolled in Medicare managed care plans in 4 US cities had lower rates of outpatient physician visits than enrollees with adequate HL. Study design: Cohort Study setting: In-person in-home interviews with and subsequent claims data for enrollees in Cleveland, Houston, Tampa, and south Florida (including Ft. Lauderdale and Miami) Measurement period: Interviews occurred May 1997-December 1997 Claims data from within 1 year of date of enrollment into plan (usually 3 months prior to study enrollment) Follow-up duration: 1 year Completeness of follow-up: N = 3260 completed interview and S-TOFHLA	Eligibility criteria: Included: Medicare managed-care enrollee 65+ Enrolled in Prudential HealthCare 3 months or more Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Missed 1 or more screening questions for severe cognitive impairment (not able to correctly identify year, month, state, year of their birth, or home address) Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: 3,260 Age (mean and range), % (SD): 65-69: 37.0 70-74: 27.3 75-79: 19.3 80-84: 11.0 >85: 5.4 Adequate HL: 71.6 (5.6) Marginal HL: 74.1 (6.3) Inadequate HL: 75.6 (7.2) Gender, %: Male: 42.6 Male by HL status, %: Adequate: 42.1 Marginal: 46.2 Inadequate: 42.2 Race/Ethnicity, %: White: 76.0 Black: 11.8 English-speaking Hispanic: 2.0 Spanish-speaking Hispanic: 9.2 Other: 1.0 Adequate: White: 84 AA: 6.6 Hispanic English-speaking: 1.6 Hispanic Spanish-speaking: 6.6 Other: 1.2

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Access to Care: Time to first physician visit following enrollment Number of outpatient visits first year, enrolled No physician visit first year ED frequency Covariates used in multivariate analysis: Age Gender Race Self-reported physical and mental health # chronic diseases Smoking Current alcohol use Study site Months enrolled first year Description of outcome measures: No outpatient visits Total number of outpatient visits Time to first visit Total number of ED visits Current alcohol use: categorical None, Light to moderate, Heavy Problem Drinking: >2 Positive Responses on CAGE: Number of Chronic Conditions: (hypertension, diabetes, heart disease, chronic obstructive pulmonary disease or asthma, arthritis, or cancer) Depression: Geriatric Depression Scale Physical Health Summary Scale: SF-12 Mental Health Summary Scale: Mini Mental State Exam Data source(s) for outcomes: Medicare claims data and in-person orally administered survey Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Chi-square Multivariate logistic regression ANOVA Kaplan-Meier curves and unadjusted Cox proportional hazards models Multivariate survival analysis Linear regression Multivariate polytomous logistic regression	Describe results: After adjusting for covariates, healthy literacy was not significantly associated with time to first physician visit, mean number of physician visits, or no physician visit in the first year. Inadequate health literacy was associated with a significantly higher rate of ED visits, after adjusting for covariates. Effect in no exposure (i.e., adequate literacy) or control group, %: Total Outpatient Visits, mean (CI): No Physician visit: 8.1 Time to first visit: see Kaplan-Meier Curves, Figure 1 Total physician visits: 14.3 (13.7-15.0) Mean ln (visits): Mean 2.23 (2.19-2.28) ED Visits: Any ED visit: 21.8 1 ED visit: 15.0 2 or more ED visits: 6.8 Smoking, %: Never: 38.3 Former: 49.2 Current: 12.6 Current alcohol use, %: None: 58.5 Light to moderate: 37.5 Heavy: 4.0 >2 Positive Responses on CAGE:7.9 Number of chronic conditions, mean (SD): Number of chronic conditions: 1.9 (1.4) Physical Health Summary Scale: 46.4 (10.7) Mental Health Summary Scale: 55.6 (8.0) Effect in exposure (i.e., low/moderate literacy) or intervention: Total Outpatient Visits (marginal), mean (CI) No Physician visit: 9.3 Time to first visit: see Kaplan-Meier Curves, Figure 1 Total physician visits: 13.5 (12.1-15.0) Mean ln (visits): 2.17 (2.07-2.27) Total Outpatient Visits (inadequate), mean (CI) No Physician visit: 9.8 Time to first visit: see Kaplan-Meier Curves, Figure 1 Total physician visits: 13.7 (12.7-14.8) Mean ln(visits): 2.21 (2.14-2.28) ED Visits (marginal), % Any ED visit: 27.6 1 ED visit: 15.3 2 or more ED visits: 12.3 ED Visits (inadequate), % Any ED visit: 30.4 1 ED visit: 17.0 2 or more ED visits: 13.4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Baker et al., 2004[2] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8] Howard et al., 2005;[9]) (continued)	Marginal: White: 68 AA: 12.6 Hispanic English-speaking: 2.5 Hispanic Spanish-speaking: 16.4 Other: 0.6 Inadequate : White: 25.2 AA: 58.6 Hispanic English-speaking: 2.3 Hispanic Spanish-speaking: 13 Other: 1 Income, %: <$10 000: 18.2 $10 000-14 999: 21.6 $15 000-24 999: 25.6 $25 000-34 999: 8.7 $35 000: 10.2 Did not answer/did not know: 15.7 By HL status, %: Adequate: 36.6 <$15,000 Marginal 56 <$15,000 Inadequate 67.1 <$15,000 Insurance status: Medicare: 100% Education, %: Grade school or less: 17.3 Some high school: 18.4 High school: 33.6 More than high school: 30.7 By health literacy status: Adequate: 0-8 years: 7.1 9-11 years: 14.9 12 or GED: 38.3 >12 years: 39.7 Marginal: 0-8 years: 24.2 9-11 years: 25.6 12 or GED: 30.2 >12 years: 20.0 Inadequate: 0-8 years: 40.9 9-11 years: 24.3 12 or GED: 22.8 >12 years: 12.0

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Smoking (marginal), %: Never: 42.6 Former: 44.8 Current: 12.6 Smoking (inadequate), %: Never: 45.1 Former: 42.9 Current: 12.0 Current alcohol use (marginal): None: 64.7 Light to moderate: 33.3 Heavy: 1.9 Current alcohol use (inadequate): None: 75.1 Light to moderate: 23.3 Heavy: 1.6 > 2 Positive Responses on CAGE, % Marginal: 7.9 Inadequate: 13.7 Number of chronic conditions, mean (SD): Marginal: 2.1 (1.5) Inadequate: 2.2 (1.5) Physical Health Summary Scale, mean (SD): Marginal: 43.7 (11.7) Inadequate): Mean (SD) = 41.9 (11.9) Marginal: 55.1 (9.2) Mental Health Summary Scale (inadequate): Mean (SD) = 52.1 (10.7) Difference: Total Outpatient Visits: Difference in no physician visit (adjusted), OR (CI): Marginal: 1.23 (0.82-1.85) Inadequate: 1.23 (0.88-1.72) Time to first visit, days (adjusted), HR (CI): Marginal: 0.89 (0.78-1.00) Inadequate: 0.94.84-1.04) Mean visits (adjusted): Marginal: (*P* = 0.34) Inadequate: (*P* = 0.38) Mean visits, natural log (adjusted): Marginal: (*P* = 0.27) Inadequate: (*P* = 0.62) ED Visits: Any ED Visit (adjusted): Marginal: (*P* = 0.01) Inadequate: (*P* < 0.001)

Study Description	Participant Characteristics
Author, year: Baker et al., 2004[2] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8] Howard et al., 2005;[9]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	1 ED visit (adjusted), RR (CI): Marginal: 1.01 (0.76-1.33) Inadequate: 1.07 (0.86-1.33) 2 or more ED visits (adjusted): Marginal: 1.44 (1.01-2.02) Inadequate:1.34 (1.00-1.79) Smoking: Diff across all 3 HL groups (unadjusted): *(P* < 0.01) Current Alcohol Use: Diff across all 3 HL groups (unadjusted): *(P* < 0.01) > 2 Positive Responses on CAGE: Diff across all 3 HL groups (unadjusted): *(P* = NS) Number of Chronic Conditions: Diff across all 3 HL groups (unadjusted): *(P* = NS) Physical Health Summary Scale: Diff across all 3 HL groups (unadjusted):*(P* = NS) Mental Health Summary Scale: Diff across all 3 HL groups (unadjusted): *(P* = NS)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Baker et al., 2008[8] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Howard et al., 2005[9]; Baker et al., 2004[2]) Measurement tools including cutpoints: S-TOFHLA: Adequate Marginal Inadequate (cut points NR) Cut points used in other publications from the same study: Adequate: 67-100 Marginal: 56-66 Inadequate: 0-55	Eligibility criteria: Included: Medicare managed-care enrollee 65+ Enrolled in Prudential HealthCare 3 months or more Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Missed 1 or more screening questions for severe cognitive impairment (not able to correctly identify year, month, state, year of their birth, or home address) Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: 3191 (69 of original 3620 excluded because of missing data on cognitive functioning) Age (mean and range): NR: not exactly same as full sample in Baker et al. (2004) since sample analysis excludes 69 participants Gender: NR: not exactly same as Baker et al. (2004) since sample analysis excludes 69 participants Race/Ethnicity: NR: not exactly same as Baker et al. (2004) above since sample analysis excludes 69 participants Income: NR: not exactly same as Baker et al. (2004) since sample analysis excludes 69 participants Insurance status, %: Medicare: 100 Education: NR: not exactly same as Baker et al. (2004) since sample analysis excludes 69 participants Other characteristics: NR Health literacy/numeracy levels: NR

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Mortality Covariates used in multivariate analysis: Age Sex Race Language Income Education SF-36 physical functioning and mental health component scores # of chronic diseases # of impairments in ADLs # of impairments in IADLs City of enrollment Description of outcome measures: Deaths were identified using matches from the National Death Index Data source(s) for outcomes: One-hour in-person orally administered survey and National Death Index data Attempts for control for confounding: Multivariate Cox models Blinding: NR Statistical measures used: Kaplan-Meier curves, Cox proportional hazards model, chi square, multivariate Cox models	Describe results: Participants with inadequate HL had sig higher mortality rates than those with adequate literacy, after adjusting for demographic characteristics, socioeconomic status, and baseline health; when cognitive function was included in model, association Effect in no exposure (i.e., adequate literacy) or control group: Unadjusted (crude) mortality rates, %: Adequate: 18.9 Effect in exposure (i.e., low/moderate literacy) or intervention: Unadjusted (crude) mortality rates, % : Inadequate: 38.4 Marginal: 28.4 Difference: Difference in mortality rate (adjusted for control variables but not cognitive functioning), HR (CI): Inadequate vs. Adequate: 1.50 (1.24-1.81) Marginal vs. adequate: 1.13 (0.90-1.42) Difference in mortality rate (adjusted for control variables and cognitive functioning), HR (CI): Inadequate vs. adequate: 1.27 (1.03-1.57) Marginal vs. adequate: 1.08 (0.85-1.36)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Baker et al., 2007[5] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) Research objective: Determine whether low literacy levels independently predict overall and cause-specific mortality Study design: Prospective cohort Study setting: Cleveland, Houston, Tampa, and South Florida Measurement period: Baseline measurement: July 1 - December 31, 1997 Follow-up duration: Through 2003 Completeness of follow-up: NR Measurement tools including cutpoints: S-TOFHLA: Adequate: 67-100 Marginal: 56-66 Inadequate: 0-55	Eligibility criteria: Included: New Medicare enrollees in 4 health plans 65+ English or Spanish speaking Adequate vision Knew year, month, state, year born, address Excluded: Could not complete S-TOFHLA for reasons other than poor vision or illiterate Sampling strategy: Consecutive series of new enrollees Sample size: 3,260 Age, mean (SD): Adequate HL: 71.6 (5.6) Marginal HL: 74.1 (6.3) Inadequate HL: 75.6 (7.2) Gender, %: Male Overall: 42.6 Adequate HL: 42.1 Marginal HL: 46.2 Inadequate HL: 42.2% Race/Ethnicity, %: Adequate HL: White: 83.7 AA: 6.6 Hispanic, English-speaking: 1.6 Hispanic, Spanish-speaking: 6.5 Other: 1.6 Marginal HL: White: 68 AA: 12.6 Hispanic English Speaking: 2.5 Hispanic Spanish Speaking: 16.4 Other: 0.5 Inadequate HL: White: 58.1 AA: 25.0 Hispanic, English-speaking: 2.3 Hispanic, Spanish-speaking: 12.9 Other: 1.8% Income, %: <$10,000 Adequate HL: 12.0 Marginal HL: 26.2 Inadequate HL: 34.1

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Mortality; Cause-specific mortality (cardiovascular, Cancer, other) Covariates used in multivariate analysis: Age Sex Race/ethnicity Primary language (E or S) Income Education # Chronic conditions Self-reported mental and physical health Instrumental activities of daily living Activities of daily living Description of outcome measures: National Death Index to identify deaths of individuals in study and matched to Medicare enrollees in study; ICD-9 codes to determine cause of death (cardiovascular death, cancer death, other) Data source(s) for outcomes: National Death Index, death certificates Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Multivariate analysis, Kaplan-Meier curves, multivariate Cox proportional hazards model	Describe results: Inadequate HL compared to adequate (adjusted) significantly predicts all-cause mortality, cardiovascular death and death due to all other causes than cardiovascular or cancer but is not significantly related to cancer death. In analyses stratified by race/ethnicity, hazard ratio for relationship between HL and mortality was significant among white and black participants but not Latino. Marginal HL compared to adequate (adjusted) significantly related to higher cardiovascular death but not significantly related to cancer death or death due to all other causes than cardiovascular or cancer. Effect in no exposure (i.e., adequate literacy) or control group, % (SD): All cause mortality: 18.9 Cardiovascular death: 7.9 Cancer death: 5.8 Death due to other causes: 5.2 Number of chronic conditions, mean: 1.5 (1.2) Physical function score, mean: 46.2 (10.7) Mental health score, mean: 55.5 (7.9) IADL limitation: 23.6 ADL limitation: 3.0 Smoking, %: Never: 38.3 Former: 49.2 Current: 12.6 Current alcohol use, %: None: 58.5 Light to moderate: 37.4 Heavy: 4.0 Vigorous physical activity, times per week, %: >4: 47.2 3: 15.0 1-2: 15.5 <1: 22.3 BMI, %: <18.5: 4.2 18.5-24.9: 57.8 25.0-29.9: 25.9 >30.0: 12.1 Effect in exposure (i.e., low/moderate literacy) or intervention, %: All cause mortality (marginal), %: 8.7 All cause mortality (inadequate), %: 39.5 Cardiovascular death (marginal), %: 16.7 Cardiovascular death (inadequate), %: 19.3 Cancer death (marginal), %: 4.6 Cancer death (inadequate), %: 8.8 Death due to other causes (marginal), %: 7.4 Death due to other causes (inadequate), %: 11.4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Baker et al., 2007[5] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	Insurance status, %: Medicare: 100 Education, %: >12 years: Adequate HL: 39.7 Marginal HL: 20 Inadequate HL: 12 Other characteristics: NA Health literacy/numeracy levels, %: Adequate: 64.1 Marginal: 11.2 Inadequate: 24.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Number of chronic conditions (marginal) mean (SD): 1.7 (1.2) Number of chronic conditions (inadequate) mean (SD): 1.7 (1.2) Physical function score (marginal) mean (SD): 43.6 (11.7) Physical function score (inadequate) mean (SD): Mean: 41.9 (11.9) Mental health score (marginal) mean (SD): 54.9 (9.2) Mental health score (inadequate) mean (SD): 52.1 (10.7) IADL limitation (marginal), %: 37.4 IADL limitation (inadequate), %: 46.0 ADL limitation (marginal), %: 5.7 ADL limitation (inadequate), %: 8.8 Smoking (marginal), %: Never: 42.6 Former: 44.8 Current: 12.6 Smoking (inadequate), %: Never: 45.1 Former: 42.9 Current: 12.0 Current alcohol use (marginal), %: None: 65.0 Light to moderate: 33.1 Heavy: 1.9 Current alcohol use (inadequate), %: None: 75.1 Light to moderate: 23.3 Heavy: 1.6 Vigorous physical activity, times per week (marginal), %: >4: 41.0 3: 16.7 1-2: 15.3 <1: 27.0 Vigorous physical activity, times per week (inadequate), %: >4: 31.8 3: 13.8 1-2: 14.1 <1: 40.4 BMI (marginal), %: <18.5: 3.6 18.5-24.9: 59.8 25.0-29.9: 23.8 >30.0: 12.8 BMI (inadequate), %: <18.5: 7.8 18.5-24.9: 59.0 25.0-29.9: 23.1 >30.0: 10.1

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Baker et al., 2007[5] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Difference: Difference all-cause mortality (adjusted), HR (CI): Marginal HL vs. Adequate HL: 1.13 (0.90-1.41) Inadequate HL vs. Adequate HL: 1.52 (1.26-1.83) Difference Cardiovascular death (adjusted): Marginal HL vs. Adequate HL: 1.39 (1.02-1.90) Inadequate HL vs. Adequate HL; 1.52 (1.16-2.00) Difference Cancer death (adjusted), HR (CI): Marginal HL vs. Adequate HL: 0.65 (0.38-1.09) Inadequate HL vs. Adequate HL: 1.18 (0.81-1.72) Difference All other causes death (adjusted), HR (CI): Marginal HL vs. Adequate HL: 1.18 (0.76-1.85) Inadequate HL vs. Adequate HL: 1.87 (1.32-2.67) Difference in No. Chronic Conditions (unadjusted): ($P = 0.87$). Difference in Physical Function Score (unadjusted): Inadequate HL worse physical health than adequate HL: ($P < 0.001$). Difference in Mental Health Score (unadjusted): Inadequate HL worse mental health than adequate HL: ($P < 0.001$). Difference in IADL limitation (unadjusted): Inadequate HL more likely to have IADL limitations than adequate HL: ($P < 0.001$). Difference in ADL limitation (unadjusted): Inadequate HL more likely to have ADL limitations than adequate HL: ($P < 0.001$). Difference in Smoking (unadjusted): Inadequate HL less likely to have ever smoked than adequate HL: ($P < 0.05$). Difference in Current Alcohol Use (unadjusted): Inadequate HL less likely to have used alcohol in the past month than adequate HL: ($P < 0.001$). Difference in Vigorous Physical Activity (unadjusted): Inadequate HL less likely to participate in frequent vigorous physical activity than adequate HL: ($P < 0.001$). Difference in BMI by Health Literacy Status (unadjusted): Individuals with inadequate HL were more likely to be underweight than individuals with adequate HL: ($P < 0.005$).

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Barragan et al., 2005[10] Research objective: Evaluate association between patients' health literacy and acceptance of HIV testing Study design: Cross-sectional, HIV test acceptors "cases" and refusers "controls" Study setting: Inner city public hospital urgent care center, Atlanta GA Measurement period: 6 months from March to Sept 2000 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: High health literacy: > 6th grade Low health literacy: ≤ 6th grade	Eligibility criteria: Included: 18-65 years Offered HIV test by provider No known HIV infection Not tested for HIV in past 6 months Well enough to participate Able to give consent Excluded: NA Sampling strategy: Convenience: Patients seen at urgent care center during 6-month study period and meeting eligibility criteria Sample size: 372 n=200 accepted HIV test, n=172 refused HIV test Age (mean and range): Under 40 years, %: Acceptors: 61 Refusers: 48.8 Gender, % : Acceptors, Females: 44 Refusers, Females: 50.6 Race/Ethnicity, % AA: Acceptors: 93.5 Refusers: 94.8 Income, %: < $10,000/yr: Acceptors: 55.5 Refusers: 60.5 Insurance status, %: Private: Acceptors: 13 Refusers:11.6 Public: Acceptors: 18.5 Refusers: 22.1 None: Acceptors: 68.5 Refusers: 66.3 Education, %: ≥High School Acceptors: 67 Refusers: 67.4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Independent: Literacy Dependent: HIV testing refusal or acceptance Covariates used in multivariate analysis: Age and education Description of outcome measures: One-time survey which gathered demographic information and asked HIV test acceptors and refusers questions relating to HIV test knowledge, HIV transmission knowledge, HIV treatment knowledge, HIV risk perception, and HIV attitudes and beliefs Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Univariate analysis: OR and 95% CI Multivariate analysis: OR and 95% CI	Describe results: In multivariate analysis test acceptors were more likely to have lower health literacy (adjusted for age and education) Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference, OR (CI): 2.017 (1.190-3.418)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Barragan et al., 2005[10] (continued)	Other characteristics, %: High HIV Risk Perception: Acceptors: 66.5 Refusers:72.7 High Health literacy/numeracy levels, %: Acceptors: 70.5 Refusers: 80.8

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Bennett et al., 2009[11] (Companion: White et al., 2008[12]) Research objective: Assess whether health literacy contributes, through mediation, to racial/ethnic and education-related disparities in self-rated health status and preventive health behaviors among older adults. Study design: Cross-sectional Study setting: Household data collection of nationally representative sample of US population. Measurement period: March 2003-January 2004 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: National Assessment of Adult Literacy (NAAL) health literacy component. Continuous scale collapsed into 4 categories: Below basic Basic Intermediate Proficient. Cut-points not provided. Health Literacy enters regression model as a continuous variable by transforming Item Response Theory Theta scale to a 0-500 metric.	Eligibility criteria: Included: NAAL respondent Nonincarcerated 65 years and older Excluded: Could not be interviewed because of language barriers or mental disabilities Sampling strategy: 4-stage stratified area design (area segments w/ >25% population black or Hispanic over sampled) Sample size: 2,668 Age (mean and range), %: Weighted Percentage: 65-74: 55.2 75-84: 36.5 85+: 8.3 Gender, %: Weighted Percentage: Male: 44.9 Race/Ethnicity, weighted %: White: 85.3 AA: 7.3 Latino: 5.1 Other: 2.3 Income, weighted %: >175% poverty threshold: 58.6 100%-175%: 23.0 Below pov threshold: 18.4 Insurance status: NR Education, weighted %: >High School: 37.3 High School: 38.5 >High School: 24.3 Nativity, weighted % (SD): US born: 92.2 (0.9) Foreign Born: 7.8 (0.9) Health literacy/numeracy levels, %: NAAL Categories: Below Basic: 29.0 Basic: 29.5 Intermediate: 38.2 Proficient 3.3

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Health Outcome: Self-rated health status - Fair/poor vs. Excellent/very good/good Preventive Measures: Influenza vaccination, mammogram, dental visit in preceding year (dichotomous) Covariates used in multivariate analysis: Race Income Gender Age Nativity Description of outcome measures: Self-rated health status: self report on 5-point scale of Poor, Fair, Good, Very Good, Excellent; converted to dichotomous Fair/poor vs. Excellent/very good/good. Preventive Measures: dichotomous-self reported Data source(s) for outcomes: Face to Face interviews for NAAL Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Marginal Maximum Likelihood Probit analysis Probit analysis Baron and Kenney mediation criteria Sobel tests	Describe results: Health literacy is significantly related to self-rated health status, obtaining an influenza vaccination, a mammogram and a dental checkup in a nationally representative senior population in adjusted models. Health Literacy significantly mediates disparities between blacks and whites in relation to self-reported health status and obtaining an influenza vaccine but not other outcomes. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: Difference: Adjusted: Self-reported health status (adjusted): Beta 0.23, $P < 0.05$ Utilization of influenza vaccination: Beta 0.14, $P < 0.05$ Mammography: Beta 0.17, $P < 0.05$ Dental checkup: Beta 0.20, $P < 0.05$ Mediation of race, education by Health Literacy

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Bennett et al., 2007[13] Research objective: Assess association between low literacy and depressive symptomatology in pregnant Latinas with limited English language proficiency in US inner-city setting. Study design: Cross-sectional Study setting: Patients recruited from Philadelphia District Health Centers and 4 hospital-based prenatal care clinics serving primarily Medicaid recipients Measurement period: 11/2003 - 9/2004 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: S-TOFHLA (Spanish): Inadequate: 0-55 Marginal: 56-66 Adequate: >67	Eligibility criteria: Included: Singleton pregnancy English or Spanish speaking Chose to have the interview conducted in Spanish (indicator of limited English proficiency) Excluded: NR Sampling strategy: Convenience sample Sample size (n = 99): Inadequate HL (n = 18) Marginal HL, (n = 15) Adequate HL, (n = 66) Age, mean (SD): Total: 26.1 (5.44) Inadequate HL: 25.8 (4.91) Marginal HL: 26.2 (6.63) Adequate HL: 26.2 (5.38) Gender, %: Females: 100 Race/Ethnicity, %: Total: Latina: 100 Mexican: 23 Other Hispanic Nativity: 77 Inadequate HL: Mexican: 50 Marginal HL, %: Mexican: 27 Adequate HL: Mexican: 15 Income, mean in $ (SD): Total: 7,251 (6762) Inadequate HL: 7,631 (9104) Marginal HL: 6,869 (6925) Adequate HL: 7,240 (6294) Insurance status: NR Education, %: < HS education: Total: 47 Inadequate HL: 78 Marginal HL: 53 Adequate HL: 36

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Depressive symptoms (CES-D scale) Covariates used in multivariate analysis: Mexican nativity Recent marijuana use Description of outcome measures: Depressive symptomatology was assessed with a Spanish translation of the CES-D. This 20-item instrument has scores ranging from 0 to 60. Standard categorical cut-point of >16 was used to indicate elevated depressive symptomatology. Data source(s) for outcomes: Self-reported data collected by in-person interview Attempts for control for confounding: Logistic regression used to estimate risk of elevated depressive symptomatology among women at different literacy levels, controlling for variables found to be effect modifiers of health literacy—nativity and recent marijuana use—but not associated with depression symptomatology. Other sociodemographic variables identified through literature as known to be related to depressive symptoms among Latinas were excluded from equation. Blinding: NA Statistical measures used: Bivariate associations: assessed using one-way analysis of variance or chi-square statistic. Fisher's exact test was used whenever any cell contained fewer than 5 respondents. Poisson regression used in multivariate analysis, calculation of PR (instead of standard logistic regression) to avoid inflation of RR estimate	Describe results: Controlling for 2 effect modifiers, women with inadequate HL were more likely to have depressive symptoms compared to those with adequate HL. A significant difference was not found between women with marginal and adequate HL. Effect in no exposure (i.e., adequate literacy) or control group: Elevated depressive symptomatology (CES-D ≥ 16) Adequate HL: N = 12 (18%) Effect in exposure (i.e., low/moderate literacy) or intervention: Elevated depressive symptomatology (CES-D ≥ 16) Inadequate HL, N)%): 8 (44%) Marginal HL, N (%): 5 (33%) Difference: Difference in elevated depressive symptomatology (CES-D ≥ 16) Inadequate HL, PR (CI): 2.39 (1.07–5.35) Marginal HL, PR (CI): 1.73 (0.75-4.02)

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Bennett et al., 2007[13] (continued)	Other characteristics: Foreign born, N (%): Total: 91 (92) Inadequate HL: 17 (94) Marginal HL: 14 (93) Adequate: 60 (91) Mean years living in United States (SD): Total: 5.34 (5.22) Inadequate HL: 4.47 (5.70) Marginal HL: 5.07 (3.58) Adequate HL: 5.65 (5.44) Parity, N (%): 0 previous births: Total: 31 (31) Inadequate HL: 6 (33) Marginal HL: 4 (27) Adequate HL: 21 (32) ≥ 1 previous births Total: 68 (69) Inadequate HL: 13 (67) Marginal HL: 11 (73) Adequate: 45 (68) Married or living as married, N (%): Total: 59 (60) Inadequate HL: 12 (67) Marginal HL: 8 (53) Adequate HL: 39 (59) Ever homeless, N (%): Total: 4 (4) Inadequate HL: 1 (6) Marginal HL: 0 (0) Adequate HL: 3 (5) Risk indicators Ever used marijuana, N (%): Total: 4 (4.0) Inadequate HL: 0 (0.0) Marginal HL: 1 (6.7) Adequate HL: 3 (4.5) Intimate partner violence, N (%): Total: 9 (9.0) Inadequate HL: 2 (10.5) Marginal HL: 0 (0.0) Adequate HL: 7 (10.6) Elevated depressive symptomatology (CES-D _ 16), N (%): Total: 25 (25) Inadequate HL: 8 (44) Marginal HL: 5 (33) Adequate HL: 12 (18) Health literacy/numeracy levels, %: Inadequate: 18 Marginal: 15 Adequate: 67

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Chew et al., 2004[14] Research objective: Determine association between low HL and adherence to preoperative instructions. Study design: Prospective cohort Study setting: Preoperative clinic of VA Puget Sound Health Care System Measurement period: Oct 2001 to Jan 2002 Follow-up duration: NR Completeness of follow-up: NR Measurement tools including cutpoints: sTOFHLA Inadequate HL: 0-16 Marginal HL: 17-22 Adequate HL: 23-36	Eligibility criteria: Included: English speaking Excluded: Poor vision Severe dementia Sampling strategy: Attempted to enroll all patients who presented at clinic during time period Sample size: 332 Adherence to preoperative fasting instructions: n = 271 Adherence to preoperative medication adherence: n = 217 Age, mean (SD): 58.2 (13.1) Significantly different between low and adequate HL Gender, %: Females: 5 Race/Ethnicity, %: White: 81 Black: 10 Other: 9 Income, %: < $20,000: 34 $20,000 - $39,000: 33 > $40,000: 24 Did not Know/Refused: 9 Significantly different between low and adequate HL Insurance status: NR Education, %: ≤ 8th grade: 7 Some HS: 8 High school/GED: 38 > HS: 48 Significantly different between low and adequate HL Other characteristics: Self report excellent/good health, %: Adequate HL: 82 Low HL: 10 Self report fair/poor health, %: Low HL: 82 Inadequate HL: 18 Sig different between low and adequate HL groups Health literacy/numeracy levels, %: Adequate: 88 Marginal: 7.5 Inadequate: 4.5

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Non-adherence to preoperative fasting instructions Non-adherence to preoperative medication instructions Covariates used in multivariate analysis: Age Marital status Number of medications Cognitive function Description of outcome measures: Adherent to preoperative fasting instructions: Self report of adherence to instructions on day of surgical procedure Adherent to preoperative medication instructions: Self report adherence to instructions as directed at preoperative clinic visit Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis Blinding: Preoperative nurses were masked to patient's literacy test results for pre-op interview Statistical measures used: Multivariate analyses	Describe results: Patients with low HL were more likely to be non-adherent to preoperative medication adherence instructions but this did not reach statistical significance Effect in no exposure (i.e., adequate literacy) or control group, %: Non-adherent to fasting instructions (unadjusted): 8 Non-adherent to medication instructions (unadjusted): 21 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Non-adherent to fasting instructions (unadjusted): 9 Non-adherent to medication instructions, (unadjusted): 37 Difference: Adherent to fasting instructions (unadjusted): ($P = 0.80$) Adherent to medication instructions (adjusted), OR (CI): 1.9 (0.8-4.8)

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Cho et al., 2008[15] (Companion: Lee et al., 2009[16]) Research objective: Examine whether 4 intermediate factors (disease knowledge, health behavior, preventive care, and compliance) explain association between health literacy and health status or utilization Study design: Cross-sectional Study setting: Outpatients at MHMC in Chicago, or at Mercy Family Health Center, an FQHC associated with MHMC; interviews occurred in participants' homes or in medical center Measurement period: March 2003-February 2004 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: s-TOFHLA: Inadequate (0-16) Marginal (17-22) Adequate (23-36)	Eligibility criteria: Included: Age > 65 Medicare recipient > 1 visit to MHMC-affiliated outpatient clinic between 1999 and 2003 Mentally competent Good vision Currently living at home in Illinois Good hearing Able to conduct the interview in English Excluded: NR Sampling strategy: NR Sample size: 489 participants Age (mean and range): NR Gender, %: Females: 78.7 Race/Ethnicity, %: AA: 59.1 Income: NR Insurance status: NR Education (SD): 2.95 (1.49) Scale: 1 = grade/elementary school 2 = some high school 3 = high school diploma/GED 4 = some college 5 = college graduate 6 = graduate degree Other characteristics: Social support Medical co morbidities Functional status Attitudes toward health care Risk and healthy behaviors Access Health literacy/numeracy levels, %: Inadequate/marginal: 50.89 Adequate: 49.11

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Health status Hospitalizations ER visits Disease knowledge Health behavior Preventive care Compliance Covariates used in multivariate analysis: Race/ethnicity Gender Educational attainment Description of outcome measures: Health status: Self-rated 5 point Likert scale Hospitalizations: Self-report of hospitalizations in the past year; dichotomized to 1 (>1 hospitalization) or 0 (0 hospitalizations) ER visits: - Self-report of visits in the past year; dichotomized to 1 (>1 visit) or 0 (0 visits) Disease knowledge 17 question survey Health behavior 9 Likert scale items from Health Promoting Lifestyle Profile Preventive care FOBT/prostate screening in past two years if male, mammography/Pap smear in past two years if female Compliance Self-report of how often participants forgot to fill prescriptions on time; dichotomized to 1 (always) and 0 (not always) Data source(s) for outcomes: Participant self-report during interview Attempts for control for confounding: Yes - control variables added to path analyses Blinding: NA Statistical measures used: Path analyses using weighted least-squared method with asymptotic covariance matrix	Describe results: Higher health literacy significantly associated with fewer ER visits, fewer hospitalizations, higher self-reported health status, higher disease knowledge, and more preventive care Health literacy had direct rather than indirect effect on health outcomes including health status, hospitalization and ER visits Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: (Standardized beta coefficients; results in bold/italics are statistically significant at $P < .05$) Health status: 0.48 Hospitalizations: -0.24 ER visits: -0.35 Disease knowledge: 0.61 Health behavior: 0.07 Preventive care: 0.42 Compliance: -0.17 *Health literacy dichotomized as 1 (adequate) or 0 (inadequate or marginal)

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Coffman and Norton, 2010[17] Research objective: To explore the relationships of immigration demands, health literacy, and depression in a sample of recent immigrants. Study design: Cross sectional Study setting: NR Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: 50- item Short Assessment of Health Literacy for Spanish-speaking Adults (SAHLSA), Spanish language REALM, Highest score: 50 (Low Health Literacy: the lowest quartile).	Eligibility criteria: Inclusion: Self-identification as a Latino Age 18 years or older Spanish speaking Recent immigrant status (15 years or less in the United States) Exclusion: NA Sampling strategy: Convenience Sample recruited from two Latino service agencies through newspaper advertisements, walk-ins, and networking Sample size: N = 99 Age (mean and range), % (SD): 35.7 (3.7) Gender, %: Female: 76.8 Race/Ethnicity, %: 100% Latino Mexican descent: 54.5 8 countries in South America (n = 29) and 4 countries in Central America (n = 16). Income, %: Household income, %: < $20,000: 43.5 $20,000 to $30,000: 30.3 > $30,000: 21.2 Insurance status, %: Insurance: Insurance: 14.1 No Insurance: 85.9 Education, %: Mean years of education: 11.4 (SD = 4.3) < high school education: 49.4% Other characteristics, %: Mean years of residence in the United States: 5.1 (SD = 3.7) Little to no written or spoken English proficiency, low: 95% Undocumented legal status: 70% Employed: 66.7% Housewives not seeking employment: 22% Health literacy/numeracy levels, %: Mean SAHLSA Score: 42.0 (SD = 7.5) Low HL: ≤ 39; n = 27

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Depression Covariates used in multivariate analysis: Demands of immigration Description of outcome measures: Depression: Participants completed the 20- item Spanish language Center for Epidemiologic Studies Depression Scale (CES-D). Participants were asked to rate how often they experienced depressive symptoms in the past week from 0 to 3: 0: Rarely or none of the time 1: Some or a little of the time 2: Occassionally or a moderate amount of time 3: Most or all of the time Lower scores indicated less depression, and a score of 16 or greater was indicative of clinical depression. Data source(s) for outcomes: Self-report: Questionnaire Attempts for control for confounding: Regression Blinding: No Statistical measures used: Regression model	Describe results: Low health literacy, controlling for greater immigration demands predicted higher depression scores. Effect in no exposure (i.e., adequate literacy) or control group: Mean CES-D score for participants with high health literacy (SD): 9.7 (8.3) Effect in exposure (i.e., low/moderate literacy) or intervention: Mean depression score for participants with low health literacy: 13.9 (9.5) Reported depression symptoms, low health literacy: 42.3% Reported depression symptoms among those with low health literacy that were not depressed: 21.9% CES-D items that were significantly correlated to lower health literacy score included not feeling hopeful about the futere (r = .3; *P* = .004) and thinking that life had been a failure (r = .3; *P* = .002). Difference: Difference in depression score (adjusted): Lower HL vs higher: B = -.22 (SE .11) (*P* = 0.048)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Davis et al., 2006[18] (Companion: Wolf et al., 2007[19]) Research objective: Examine relationship between patients' HL and abilities to understand and demonstrate instructions found on container labels of common prescription medications Study design: Cross-sectional Study setting: 3 primary care clinics in Shreveport LA (public hospital), Jackson MI (FQHC), and Chicago, IL (FQHC) Measurement period: July 2003 (Shreveport) July 2004 (Jackson and Chicago) Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM 0-44: sixth grade or less (low literacy) 45-60: seventh to eighth grade (marginal) 61-66: ninth grade and above (adequate)	Eligibility criteria: Included: ≥ 18 years old Excluded: Severely impaired vision Hearing problems Illness too severe to participate Inability to speak English Sampling strategy: Convenience sample of consecutive patients presenting to the clinics Sample size: 395 Age (range): 44.8 (19-85) Gender, %: Female: 67.8 Race/Ethnicity, %: AA: 47.4 White: 48.4 Income: NR Insurance status, %: Uninsured for medication: 22.8 Education, %: < HS: 28.4 Other characteristics: Mean # prescription medications: 1.4 Health literacy/numeracy levels, %: Inadequate: 19.0 Marginal: 28.6 Adequate: 52.4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Understanding medication label instructions Attention to auxiliary warning label instructions Demonstration of correct administration Covariates used in multivariate analysis: Age Sex Race Education Number of medications currently taken daily Site Description of outcome measures: Understanding medication label instructions: response to the question "How would you take this medicine?" as rated (correct or incorrect) by three physicians Attention to auxiliary warning label instructions: "yes" or "no," based on whether behavior was noted by reviewer Demonstration of correct administration: response to the question “Show me how many pills you would take [of this medicine] in one day” using candy pills for demonstration Data source(s) for outcomes: Structured interview and patient-demonstrated interpretation of medication labels Attempts for control for confounding: Logistic regression Blinding: Outcomes assessors blinded Statistical measures used: Chi square Multivariate analysis	Describe results: Compared with those who had adequate HL, participants with low or marginal HL were sig more likely to misunderstand one or more prescription labels and participants with low literacy were significantly less likely to correctly demonstrate how to follow label instructions. Effect in no exposure (i.e., adequate literacy) or control group, %: Misunderstood one or more prescription labels: Adequate: 37.7 Correct demonstration of number of pills: Adequate: 80.2 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Misunderstood one or more prescription labels, %: Marginal: 51.3 Low: 62.7 Correct demonstration of number of pills: Marginal: 62.8 Low: 34.7 Difference: Difference misunderstanding prescription medication label instructions (adjusted) RR (CI): Marginal vs. adequate: 1.94 (1.14-3.27) Low vs adequate: 2.32 (1.26-4.28) Difference in correct demonstration of label instructions (adjusted) RR (CI): Low vs. adequate: 3.02 (1.70-4.89) Marginal vs. adequate: RR NS (data not reported)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: DeWalt et al., 2007[20] Research objective: Determine if parental literacy is related to ED visits, hospitalizations, and days of school missed for children with asthma. Study design: Retrospective cohort study Study setting: Study conducted in 3 outpatient pediatrics clinics (general, asthma and allergy, and pulmonary) at NC Children's Hospital, public children's hospital of NC Measurement period: January 2004 to March 2005 Follow-up duration: NR Completeness of follow-up: NR Measurement tools including cutpoints: REALM Higher literacy: > 8th grade literacy level Low literacy: ≤ 8th grade literacy level	Eligibility criteria: Included: Child 3 to 12 yrs old Clinical diagnosis of asthma for 3+ months History of recurrent episodes of wheezing or coughing Previous visit with physician in clinic no more than 12 months prior to index visit Undergoing treatment for asthma with 1 or more of following: inhaled bronchodilators, inhaled cortico-steroids or oral leukotriene inhibitors Excluded: Diagnosis of severe developmental delay Cystic fibrosis Severe neurological impairment Those not accompanied by primary caregiver on day of study Sampling strategy: Convenience Sample size: N = 150 Higher Parental Literacy, n = 114 Low Parental Literacy, n = 36 Age, mean (SD): Entire sample Child: 7.7 (2.8) Parent: 35 (8.7) Higher Parental Literacy: Child: 7.7 (2.8) Parent: 35 (7.5) Low Parental literacy: Child: 7.7 (2.8) Parent: 35 (12) Gender: NR Race/Ethnicity, %: Parental Race: Entire sample: AA: 47 Caucasian: 45 Higher Parental Literacy: AA: 39 Caucasian: 52 Low Parental Literacy: AA: 69 Caucasian: 25 Income, %: Household income of < $15,000/yr Entire Sample: 27 Higher Health Literacy: 21 Low Health Literacy: 44

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Classification of Asthma Severity Albuterol Use Controller Medication Use ED Visits Hospitalization Covariates used in multivariate analysis: Child age Household income Parental race Parental asthma knowledge Parental smoking Asthma severity classification Controller medication use Site of care Description of outcome measures: Questions were asked with an open-ended response format. Severity and medication use were based on recall over past 2 weeks. ED visits and hospitalizations were based on recall over past 12 months. RA classified severity of illness based on self-reported symptoms using questions based on NHLBI asthma severity guidelines from 2002. Sociodemographic data were self-reported. Data source(s) for outcomes: Self-report by interviewer Administered questionnaire Attempts for control for confounding: Multivariate Poisson regression Blinding: NR Statistical measures used: Multivariate Poisson regression.	Describe results: Children of parents with low literacy were more likely to have moderate or severe persistent asthma and had greater use of rescue medications. They were also more likely to require ED visits or hospitalization than children of parents with higher literacy Effect in no exposure (i.e., adequate literacy) or control group: Moderate/Severe Persistent Asthma: 35% Albuterol Use (mean days per week): 1.5 Albuterol Use (total mean use per week): 3 doses Appropriate Controller Use: 82% ED Visits (per child): 1.08 Hospitalizations: 0.12 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Moderate/Severe Persistent Asthma: 56 Albuterol Use (mean days per week): 2.7 Albuterol Use (total mean use per week: 6 doses Appropriate Controller Use: 68 ED Visits (per child): 1.53 Hospitalizations: 0.39 Difference: Difference Moderate/Severe Persistent Asthma (unadjusted): (*P* = 0.03) Difference Albuterol Use (unadjusted): (*P* = 0.01) Difference Total Weekly Albuterol Use: (*P* = 0.03) Difference Appropriate controller use: (*P* = 0.15) ED Visits (adjusted): IRR, 1.

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: DeWalt et al., 2007[20] (continued)	Insurance status, %: Child's Insurance: Entire sample: Medicaid: 57 Private: 43 Higher Parental Literacy: Medicaid: 43 Private: 57 Low Parental Literacy: Medicaid: 86 Private: 14 Education: NR Other characteristics, %: Parental smoking: Entire sample: 28 Higher Parental Literacy: 26 Low Parental Literacy: 33 Controller medication use if persistent Asthma: Entire sample: 80 Higher Parental Literacy: 68 Low Parental literacy: 82 Health literacy/numeracy levels, %: Low Parental Literacy: 24 Higher Parental Literacy: 76

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Estrada et al., 2004[21] Research objective: Examine association between low literacy and numeracy in patients taking warfarin with anticoagulation control and other processes of care Study design: Prospective cohort Study setting: Anticoagulation management units: 1 based at a university and 1 based at a VA hospital Measurement period: November 1998-May 1999 Follow-up duration: Mean: 91 days (SD 18.9) Completeness of follow-up: 100% Measurement tools including cutpoints: Literacy: REALM Numeracy: 6 item test; Schwartz 3-item (1997) and 3 items developed by study researches specific to anticoagulation therapy	Eligibility criteria: Included: > 50 years old Been on warfarin ≥ 1 month Excluded: Unable to speak Non-English speaking Did not consent to participate Sampling strategy: Convenience Sample size: N=143 Participants were 3.9 years younger than eligible patients who refused or were excluded, $P = 0.03$ Age, mean (SD): 65.3 (9.8) Gender, %: Female: 37.8 Race/Ethnicity, %: Nonwhite: 29.4 Income: NR Insurance status: VA patients: 36 University-based clinic: 4 patients said they could not afford medication, so it was provided to them. Education, %: ≤ 3rd grade: 3.5 4-6th grad: 7.0 7-8th grade: 10.5 >8th grade: 79.0 Other characteristics, %: Indications for anticoagulation therapy: Atrial fibrillation: 39.2 Valvular heart disease: 16.8 Venous thrombosis: 16.8 Neurologic condition: 11.2 Length of time on wafarin: < 6 months: 19.6 6 - 12 months: 14 > 1 yr: 66.4 INR goal: 2-3: 79.7 of patients 2.5-3.5 or other: 20.3 of patients

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Primary outcomes: Variability of the INR Optimal intensity of anticoagulation Secondary outcomes: % INR tests within patients therapeutic range Maximum INR value # dose changes Dose change # missed visits Covariates used in multivariate analysis: Age Description of outcome measures: INR variability: measured by computing the deviation in the patient's INR from his/her therapeutic range over time. A wider INR range indicates poorer anticoagulation and is one of the strongest predictors of bleeding risk. Optimal intensity of anticoagulation (time in range): estimates the amount of time a patients INR is within his/her therapeutic range Data source(s) for outcomes: Self-report and medical record review Attempts for control for confounding: Multiple linear regression Blinding: Provider's making adjustments to warfarin dosage were not informed of patients' literacy or numeracy assessments Statistical measures used: Relationship between literacy or numeracy levels and INR variability, time in range, and secondary outcomes was measured with the Spearman rank test. Multiple linear regression	Describe results: After adjusting for age, low numeracy skills were associated with greater INR variability, while the optimal intensity of anticoagulation (time in range) was similar among patients at different literacy or numeracy levels Numeracy skills were associated with the time spent above the patients therapeutic INR range (unadjusted). Neither low literacy nor numeracy were associated with any other secondary outcomes examined. Effect in no exposure (i.e., adequate literacy) or control group: % INR tests within range: 5-6 correct: 56% INR variability using mean sigma score: 5-6 correct: 0.45 Effect in exposure (i.e., low/moderate literacy) or intervention: % INR tests within range: 0 correct: 56% INR variability using mean sigma score: 0 correct:0.80 Difference: Difference in INR variability: Higher among patients at lower literacy levels (adjusted): $P = 0.06$ Higher among patients with lower numeracy skills (adjusted): $P = 0.03$ Optimal intensity of anticoagulation (time in range): The optimal intensity of anticoagulation (time in range) (adjusted) was similar among patients at different literacy, $P = 0.71$ or numeracy levels, $P = 0.35$

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Estrada et al., 2004[21] (continued)	Health literacy/numeracy levels, %: 6-items (including 3 adapted from Schwarz and Woloshin): 0 correct: 13.3 1-2 correct: 35 3-4 correct: 34.3 5-6 correct: 17.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Fang et al., 2006[22] Research objective: Assess if literacy is associated with warfarin knowledge, adherence and control Study design: Cross-sectional Study setting: Anticoagulation clinic at San Francisco General Hospital Measurement period: March 2002 to June 2003 Follow-up duration: NA Completeness of follow-up: NR Measurement tools including cutpoints: Numeracy: 4 warfarin-specific questions developed by investigators Literacy: s-TOFHLA (English or Spanish) Limited health literacy: 0-22 Adequate health literacy: 23-26	Eligibility criteria: Included: ≥ 18 years Visual acuity Basic reading ability Excluded: NR Sampling strategy: Consecutive Eligible patients receiving care in an anticoagulation clinic Sample size: 179 Limited literacy: n = 109 Adequate literacy: n = 70 Age, mean (range): Limited literacy: 63.3 (61.0-65.6) Adequate literacy: 53.8 (50.4-57.1) Gender, %: Females: Limited literacy: 52.3 Adequate literacy: 38.6 Race/Ethnicity, %: Latino: Limited literacy: 45.9 Adequate literacy: 15.7 Asian-Pacific Islander: Limited literacy: 28.4 Adequate literacy:18.6 White: Limited literacy: 10.1 Adequate literacy: 35.7 AA: Limited literacy:12.8 Adequate literacy: 22.9 Income: NR Insurance status: NR Education, %: ≤8th grade: Limited literacy: 50.5 Adequate literacy: 7.1 High school (some/all): Limited literacy: 30.3 Adequate literacy: 30

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Warfarin (numeracy) knowledge Self reported adherence to medication International Normalized Ratio (INR) control Covariates used in multivariate analysis: Age Sex Race/ethnicity Education Cognitive impairment Number of years on warfarin Description of outcome measures: Numeracy 4 warfarin-specific numeracy-related questions Adherence Validated questionnaire reporting 1) last time a pill was missed, 2) any missed dose with the last 2 weeks, 3) any missed dose within the last 3 days INR control Proportion of person-time within target therapeutic range over total person-time of follow-up Data source(s) for outcomes: Warfarin target range was obtained from clinic database all other data was self-report Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Bivariate analysis: t-tests for continuous variables and chi squared tests for categorical variables Univariate analysis: Simple logistic regression to determine the association between health literacy and warfarin knowledge as well as self-reported adherence to medication Multivariate analysis: multivariate logistic regression to control for confounders Generalized linear models: To determine if health literacy was related to INR range (i.e., to warfarin control)	Describe results: Knowledge (adjusted) Limited literacy was significantly associated with 3 of 4 numeracy questions Adherence and INR control (adjusted) Limited health literacy was not significantly associated with self-Reported adherence or INR control Effect in no exposure (i.e., adequate literacy) or control group, %: Knowledge (adjusted): Numeracy Question 1: 25.7 Numeracy Question 2: 35.7 Numeracy Question 3: 18.6 Numeracy Question 4: 18.6 Self-reported adherence (adjusted): Missed a dose within the last 3 d: 17.1 Missed a dose within the last 2wk: 14.3 Did not miss a dose in >3 mo: 51.4 INR control (adjusted): Person-time in therapeutic INR range: 43.2 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Knowledge (adjusted): Numeracy Question 1: 70.6 Numeracy Question 2: 73.4 Numeracy Question 3: 50.5 Numeracy Question 4: 71.6 Self-reported adherence (adjusted): Missed a dose within the last 3 d: 6.5 Missed a dose within the last 2wk: 12.0 Did not miss a dose in > 3 mo: 61.1 INR control (adjusted): Person-time in therapeutic INR range: 45.0 Difference(adjusted), OR (CI): Knowledge: Numeracy Question 1: 2.6 (1.1-6.1) Numeracy Question 2: 1.9 (0.8- 4.4) Numeracy Question 3: 3.2 (1.3-7.7) Numeracy Question 4: 5.7,(2.3-14.0) Self-reported adherence: Missed a dose within the last 3 days: 0.5 (0.1-2.1) Missed a dose within the last 2 weeks: 0.7 (0.3-2.2) Did not miss a dose in >3 months: 0.9 (0.4-2.0) INR control (adjusted): Person-time in therapeutic INR range: 1.0 (0.7-1.4)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Fang et al., 2006[22] (continued)	≥College: Limited literacy: 19.3 Adequate literacy: 62.9 Other characteristics: Low cognitive function (s-CASI <17): Limited literacy, %: 19.3 Adequate literacy, %: 1.4 Years on warfarin: Limited literacy: 4.4 Adequate literacy: 2.9 Health literacy/numeracy levels, %: Limited: 60.9 Adequate: 39.1

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Garbers and Chiasson, 2004[23] Research objective: Examine independent association between inadequate functional health literacy in Spanish among low-income Latinas aged 40 and older and cervical cancer screening behavior. Study design: Cross-sectional Study setting: In-person interview at participants' homes. Women were recruited for study through younger female relatives who were approached as they waited for prenatal or family planning appointments at 2 women's health centers in New York City Measurement period: Nov 2002 - July 2003 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: TOFHLA-S Inadequate score 0 - 59 Marginal score 60 - 74 Adequate score 75 - 100	Eligibility criteria: Included: For young female relatives: Self-identified as Latina or Hispanic ≥ 18 yrs Had a female relative ≥ 40 living in New York city For participants: Self-identified as Latina or Hispanic ≥ 40 yrs Spoke Spanish as primary language Excluded: For participants Refusal to complete the Spanish S-TOFHLA Sampling strategy: Convenience Sample size: 205 Age, mean: 51 Significant difference between inadequate, marginal and adequate literacy groups Gender, %: Females: 100 Race/Ethnicity, %: Hispanic: 100 Income: NR Insurance status, %: Uninsured: 57.8 Medicaid/Medicare: 32.3 Private insurance: 9.8 Education, %: No formal education: 5.9 Elementary school only: 44.4 Some high school: 18.5 High school graduate or more: 31.2 Significant difference between inadequate, marginal and adequate literacy groups Other characteristics: Years in the US: 17.9 Significant difference between inadequate, marginal and adequate literacy groups No regular source of health care, %: 40.5 No visit to health care provider in the last yr, %: 22 Health literacy/numeracy levels, n (%): Inadequate Literacy: 61 (30) Marginal Literacy: 39 (19) Adequate literacy: 105 (51)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Ever had a Pap test Pap test within past 3 years Covariates used in multivariate analysis: Having source of care Having any health insurance Age Years in US Education Description of outcome measures: 20 minute survey developed for purposes of study plus medical record review for randomly selected subset of 10% of participants Data source(s) for outcomes: Self-report Medical chart review for 10% of participants Attempts for control for confounding: Logistic regression Blinding: NA Statistical measures used: Chi square tests for categorical variables Analysis of variance for continuous variables Bivariate analysis Logistic regression	Describe results: Compared to those with adequate and marginal health literacy, women with inadequate functional health literacy in Spanish were significantly less likely to ever have had a pap test Effect in no exposure (i.e., adequate literacy) or control group: Ever had a Pap test (unadjusted), n (%): Adequate HL: 104 (99) Marginal HL: 35 (92.1) Pap test within past three years (unadjusted), n (%): Adequate HL: 87 (82.9) Marginal HL: 32 (82.1) Effect in exposure (i.e., low/moderate literacy) or intervention: Ever had a Pap test (unadjusted), n (%): Inadequate HL: 48 (80) Pap test within past three years (Unadjusted), n (%): Inadequate HL: 38 (62.3) Difference: Ever had a Pap test (Adjusted), OR (CI): Adequate HL: Ref Marginal HL: 0.14 (0.01-1.41) Inadequate HL: 0.06 (0.01-0.55) Pap test within past three years (Adjusted), OR (CI): Adequate HL: Ref Marginal HL: 1.31 (0.44-3.85) Inadequate HL: 0.53 (0.21-1.35)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Gatti et al., 2009[24] Research objective: To examine the relationships among health literacy, beliefs about medications, and medication adherence in a population with inadequate health literacy skills Study design: Cross-sectional Study setting: Participants recruited from three outpatient pharmacies at Grady Memorial Hospital, and from the DeKalb Grady Health Center pharmacy in Atlanta, GA Measurement period: June 2006 - October 2006 Follow-up duration: N/A Completeness of follow-up: 275/301 (91.4%) Measurement tools including cutpoints, %: REALM (0-66) < high school reading level: 0-60 high school reading level: 61-66	Eligibility criteria: Replied when their number was called at pharmacy Had a phone number ≥ 18 years old Were picking up a prescription for themselves Used the GMH or DGHC pharmacy as their primary pharmacy Had been a patient at GMH or DGHC for at least 6 months Were comfortable speaking English Did not have a vision impairment beyond 20/200 Were able to pass the mini-Cog Sampling strategy: Convenience sample Sample size: N = 275 Age (mean): 54 Gender, %: Female: 73.1 Race/Ethnicity, %: African American: 86.2 Caucasian or white: 5.1 Other: 8.7 Income, %: < $10,000/yr: 63.7 Insurance status, %: NR Education, %: At least a HL diploma or GED: 72.4% Other characteristics, %: Married: 17.2% Divorced/separated: 39.2% Widowed: 18.3% Single/never married: 25.3% Unemployed: 26.8% Employed full-time: 8.5% Employed part-time: 15.8% Other: 48.9% Number of prescriptions: 3.5 (SD 2.5) Coronary artery disease: 20.1% Hypertension: 72.1% Diabetes: 31.2% Hyperlipidemia: 43.9% Cancer: 3.9% Depression: 44.7% Health literacy/numeracy levels, %: High school: 40.3% < high school: 59.7% (mean REALM score of 51.3, SD 17.1)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Self-reported medication adherence Covariates used in multivariate analysis: Health literacy and "patient and regimen characteristic covariates" including negative beliefs about medications, age, low self-efficacy, self-report of hyperlipidemia Description of outcome measures: Self-reported medication adherence - measured by Morisky 8-item Medication Adherence Scale (MMAS-8), which has a score range of 0-8, with lower score representing better adherence; score dichotomized into high adherence: 0-2 and low adherence: 3-8 Data source(s) for outcomes: Patient self-report via survey instruments during 50 minute interview Attempts for control for confounding: Multivariable logistic regression Blinding: N/A Statistical measures used: Chi-square Wilcoxon tests Multivariable logistic regression	Describe results: Health literacy was not a significant predictor of medication adherence in bivariate relationships and when other potential predictors of adherence were controlled in the model. Effect in no exposure (i.e., adequate literacy) or control group: REALM mean in high adherence group: 50.1 (17.4) Effect in exposure (i.e., low/moderate literacy) or intervention: REALM mean in low adherence group: 52.4 (16.8) Difference: Difference in medication adherence (adjusted): OR = 0.96; 95%CI, 0.6-1.7 (*P* =0.88)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Gazmararian, 2006[3] (Companions: Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8] Howard et al., 2005;[9] Baker et al., 2004[2]) Research objective: Examine relationship between HL and medication refill adherence among Medicare managed care enrollees with cardiovascular-related conditions Study design: Cohort Study setting: In-person in-home interviews with and subsequent claims data for enrollees in Cleveland, Houston, Tampa, and south Florida (including Ft. Lauderdale and Miami) Measurement period: Interviews occurred May 1997-December 1997 Claims data from within 1 year of date of enrollment into plan (usually 3 months prior to study enrollment) Follow-up duration: 1 year Completeness of follow-up: 3260 completed both S-TOFHLA and interview; of these, 1711 were excluded because they did not meet criteria for this sub-analysis Measurement tools including cutpoints: S-TOFHLA: Adequate: 67-100 Marginal: 54-66 Inadequate: 0-53	Eligibility criteria: Included: Medicare managed-care enrollee 65+ Enrolled in Prudential HealthCare 3 months or more ICD-9-CM code and pharmacy claims related to 1 of 4 diagnoses: coronary heart disease, hypertension, diabetes mellitus, or hyperlipidemia Inpatient and outpatient claims Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Missed 1 or more screening questions for severe cognitive impairment (not able to correctly identify year, month, state, year of their birth, or home address) Continuously enrolled < 1 year Spent prolonged period in the hospital (> 100 days) Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: 1,549 Age (mean and range), %: 65-69: 34.5 70-74: 28.0 75-79: 19.7 80-84: 12.1 >85: 5.6 Gender, %: Female: 58 Race/Ethnicity, %: White: 76.7 Black: 11.9 Hispanic: 10.3 Other: 1.2 Income: NR Insurance status, %: Medicare: 100 Education, %: Grade school or less: 17.5 Some HS: 19.5 HS: 33.1 > HS: 29.8 Other characteristics, %: Regimen complexity: < 3: 48.5 > 3: 51.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Cardiovascular medication refill adherence Covariates used in multivariate analysis: Age Race Gender Education Regimen complexity Description of outcome measures: Cardiovascular medication refill adherence - measured by CMG from pharmacy claims data during 1 yr after enrollment; CMG: # of days medication unavailable between prescription fills, divided by number of days between the first Data source(s) for outcomes: Medicare and pharmacy claims data and one-hour in-person orally administered survey Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Chi-square, logistic regression	Describe results: In adjusted analysis, a sig association between HL level and refill adherence was not found. Effect in no exposure (i.e., adequate literacy) or control group, %: Adequate: Low Adherence (CMG > 20%): 37.8 Adequate Adherence (CMG < 20%): 62.2 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Marginal: Low Adherence (CMG > 20%): 41.2 Adequate Adherence (CMG < 20%): 58.8 Inadequate: Low Adherence (CMG > 20%): 45.4 Adequate Adherence (CMG < 20%): 54.6 Difference: Difference in refill adherence (adjusted), OR (CI): Marginal vs. adequate: 1.15 (0.82-1.61) Inadequate vs. adequate: 1.21(0.91-1.62) Difference in refill adherence (adjusted controlling for adherence complexity), OR (CI): Marginal vs adequate: 1.15 (0.82-1.62) Inadequate vs. adequate: 1.23 (0.92-1.64)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Gazmararian, 2006[3] (Companions: Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8] Howard et al., 2005;[9] Baker et al., 2004[2]) (continued)	Cognitive health: Severe dementia: 1.6 Mild dementia: 22.4 Normal: 76.0 Health literacy/numeracy levels, %: Adequate: 64.2 Marginal: 11.8 Inadequate: 24.0

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Graham et al., 2007[25] Research objective: Assess relationship between literacy and HIV medication adherence Study design: Cross-sectional Study setting: Recruited from U-Penn HIV clinics in Philadelphia, PA Measurement period: Feb to June 2003. A retrospective examination of the previous 3-month pharmacy records Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM ≤61: Low health literacy (i.e., <9th grade level)	Eligibility criteria: Included: ≥ 18 years-old On antiretroviral therapy for ≥ 3 months Receiving treatment from 1 of 2 U- Penn HIV clinics Excluded: NR Sampling strategy: Pharmacy records examined for those recruited sequentially on arrival for regular clinic appointments Sample size: 87 Age, median (IQR): <95% adherence: 44 (37-48) ≥95% adherence: 46 (37-53) Gender, %: Females: <95% adherence: 24 ≥95% adherence: 27 Race/Ethnicity, %: <95% adherence: Black: 88 White: 12 ≥95% adherence: Black: 69 White: 31 Income, %: <$10,0000: <95% adherence: 64 ≥95% adherence: 47 Insurance status: NR Education, %: High school <95% adherence: 60 ≥95% adherence: 69 Other characteristics: Median CD4 count (interquartile range) <95% adherence: 303 cells/cm3 (163-537) ≥95% adherence: 363 cells/cm3 (248-470) Undetectable viral load (<50 c/ml), %: <95% adherence: 45 ≥95% adherence: 73 Health literacy/numeracy levels: NR

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Independent: Literacy Dependent: Adherence to HIV medication Covariates used in multivariate analysis: NA Description of outcome measures: Adherence assessed via a validated time to pharmacy refill surrogate measure to a single index drug over the prior 3 months Adherence defined as: (days supply dispensed / # days between refills) x 100% Data source(s) for outcomes: Pharmacy records Attempts for control for confounding: Demographic variables assessed: Age Race History of drug and alcohol use Cognitive function Level of schooling completed Income Insurance type Social support Medical factors assessed: Current HIV viral loads CD4 counts Prior and current psychiatric diagnoses Blinding: NA Statistical measures used: Adherence was include as a continuous variable and dichotomized as ≥95% or not. Association between health literacy and adherence was assessed using chi squared and a REALM cut off of 61 representing a 9th grade reading level Wilcoxon rank sum tests Logistic regression	Describe results: Individuals with adequate literacy had significantly better medication adherence than those with low literacy in unadjusted analysis. In multivariate model, literacy was not found to be significantly related to adherence, controlling for potential mediating effect of adherence norm (knowledge). Effect in no exposure (i.e., adequate literacy) or control group, %: ≥95% adherence: 64 Effect in exposure (i.e., low/moderate literacy) or intervention, %: ≥95% adherence: 40 Difference: Difference in 95% adherence (unadjusted): ($P < 0.05$) Difference in 95% Adherence (adjusted) controlling for adherence norm (possible mediator): ≥ 9th grade literacy, OR (CI): 2.38 (0.98-5.79)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Grubbs et al., 2009[26] Research objective: Determine relationship between health literacy and referral for transplant evaluation in patients on hemodialysis Study design: Retrospective chart review, interview Study setting: 5 San Francisco Bay area outpatient dialysis units Measurement period: July 2007- April 2008 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA: Inadequate health literacy: 0-22 Adequate health literacy: 23-36	Eligibility criteria: Included: Patients on maintenance hemodialysis (at least 9 months) Self identified as black or white Between 21-75 yrs old Never had a kidney transplant Excluded: Mini Mental Status <18 Vision impaired (<20/100) Sampling strategy: Convenience sample Sample size: 62 Age, mean (SD): 52.4 (12.2) Gender, %: Males: 66.1 Race/Ethnicity, %: Black:72.6 White: 27.4 Income, %: < 30,000: 54.8 Insurance status, %: Medicaid: 11.3 Medicare: 11.3 Medicare/Medicaid: 41.9 Private: 12.9 Private +Medicare: 14.5 VA: 8.1 Education, %: >HS: 61.3 HS equiv: 25.8 <HS: 12.9 Other characteristics, %: HTN: 90.3 Diabetes: 35.5 Hep C: 12.9 CHF: 9.7 Health literacy/numeracy levels: sTOFHLA mean (SD): 25.6 (9.4) Inadequate health literacy (sTOFHLA<23): 32.3

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Access to kidney transplant wait-list Covariates used in multivariate analysis: Demographics (race, gender, income age at start of dialysis) Comorbid conditions (HTN, diabetes, peripheral vascular disease, CAD, HIV, Hep c, CHF, depression, drug abuse) Support (someone to help with appointments or medications) Description of outcome measures: Dichotomous for referral for transplant evaluation Mean time from dialysis to referral date Data source(s) for outcomes: Chart review, transplant center staff Attempts for control for confounding: Multivariate analyses Blinding: NA Statistical measures used: Cox proportional Hazards modeling	Describe results: Inadequate health literacy was associated with lower hazard of being referred for transplant evaluation but not for being wait-listed Effect in no exposure (i.e., adequate literacy) or control group, mean time (SD): Time from dialysis date to referral date: 15.3 (44.7) mos Time from referral date to waitlist date: 2.1 (4.1) mos Effect in exposure (i.e., low/moderate literacy) or intervention, mean time (SD): Time from dialysis date to referral date: 23.5 (44.8) mos Time from referral date to waitlist date: 6.6 (9.2) mos Difference, HR (CI): Difference in mean time from dialysis date to referral date (adjusted): 8.2 mos, 0.22 (0.08-0.60) Difference in time from referral date to waitlist (adjusted): 4 mos, 0.80 (0.39-1.61)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Guerra et al., 2005[27] Research objective: Explore association between functional health literacy and reported usage of colorectal cancer screening tests Study design: Cross-sectional Study setting: 4 community clinics, 2 university-based practices in Pennsylvania Measurement period: June 2001-August 2002 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA: Inadequate Health Literacy: 0-16 Marginal Health Literacy: 17-22 Adequate Health Literacy: 23-36	Eligibility criteria: Included: 50 yrs and older No prior history of colorectal cancer Excluded: NR Sampling strategy: Convenience Sample size: 136 Age (range): Total: 61 (50-98) Inadequate or Marginal Health Literacy, %: 50-59: 37 60-69: 39 ≥70: 25 Adequate Health Literacy, %: 50-59: 46 60-69: 34 ≥70: 20 Gender, %: Female: Total: 49 Inadequate or Marginal Health Literacy: 42 Adequate Health Literacy: 46 Race/Ethnicity, %: Total: Latino: 47 AA: 20 White: 33 Inadequate or Marginal Health Literacy: Latino: 84 AA: 14 White: 2 Adequate Health Literacy: Latino: 21 AA: 24 White: 55 Income, %: Total: Income < 10,000: 39 Inadequate or Marginal Health Literacy: 79 Adequate Health Literacy: 14 Insurance status, %: Total: Insured: 89 Uninsured: 11 Medicaid: 18

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Had colorectal screening tests Covariates used in multivariate analysis: Ethnicity Medicaid Insurance status Education Income Description of outcome measures: Colorectal screening instrument (self report) adapted from an instrument to measure knowledge, attitudes, beliefs, and influences about screening mammography developed for low literate women Data source(s) for outcomes: Interview Attempts for control for confounding: Multivariate analyses Blinding: NR Statistical measures used: ANCOVA	Describe results: sTOFHLA scores were not significant predictors of colon screening behaviors after adjustment. Effect in no exposure (i.e., adequate literacy) or control group, %: FOBT: 64 Sigmoidoscopy or Colonoscopy: 72 Effect in exposure (i.e., low/moderate literacy) or intervention, %: FOBT: 39 Sigmoidoscopy or Colonoscopy: 30 Difference: FOBT: (Unadjusted) OR (CI): 2.75 (1.28-5.97), (adjusted) (*P* = 0.66) Sigmoidoscopy or Colonoscopy (Unadjusted) OR (CI): 6.15 (2.69-14.24) (adjusted): (*P* = 0.52)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Guerra et al., 2005[27] (continued)	Inadequate or Marginal Health Literacy: Insured:79 Uninsured: 21 Medicaid: 37 Adequate Health Literacy: Insured: 95 Uninsured: 5 Medicaid: 5 Education, %: Total: 8th grade or less: 27 Inadequate or Marginal Health Literacy: 57 Adequate Health Literacy: 6 Other characteristics: NA Health literacy/numeracy levels: Mean STIFLE: 25.9 (0-36) Inadequate Health Literacy (N=36), %: 36 Marginal Health Literacy, %: 6 Adequate Health Literacy, %: 58

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Guerra et al., 2005[28] Research objective: Explored association between functional health literacy and behavior about mammography and self-breast examination in a sample of Latinas attending community health clinics in Philadelphia. Study design: Cross-sectional Study setting: 3 Community health clinics in Philadelphia Measurement period: April to September 2001 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA: Inadequate score 0-16 Marginal score 17-22 Adequate score 23-36	Eligibility criteria: Included: Women > 40 years Hispanic ethnicity No history of breast cancer Spanish or English speaking Excluded: NR Sampling strategy: Convenience Sample size: 97 Age mean (range): All women: 58.0 (41-85) Significant difference between adequate and Inadequate literacy groups Gender, %: Females: 100 Race/Ethnicity, %: Hispanic:100 Income (N = 71), %: <$10,000: 63 >$10,000 37 Insurance status (N = 97), %: Uninsured: 26 Education (N = 94), %: < high school: 75 High school diploma or GED: 12 Some education beyond high school: 13 Significant difference between adequate and inadequate groups Other characteristics: Acculturation scale 1-5 (SD), (N=85): 1.69 (0.5) Significant difference between adequate and inadequate groups Health literacy/numeracy levels, %: Mean sTOFHLA score: 17 Inadequate functional health literacy: 70 Adequate functional health literacy: 30

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Ever had a mammogram Had last mammogram within 1 yr Had last mammogram within 2 yrs Had mammogram as part of check-up Check own breasts for lumps Perform self breast exam at least monthly Covariates used in multivariate analysis: Education Age Acculturation Insurance status Description of outcome measures: Structured 60-item breast cancer screening questionnaire Data source(s) for outcomes: Self-report Attempts for control for confounding: Logistic regression adjusted for education, age, acculturation, insurance status Blinding: NA Statistical measures used: Adjusted logistic regression models	Describe results: After adjusting for demographic characteristics, functional health literacy was only associated with a greater odds of having ever had a mammogram Difference, OR (CI): Adjusted results: Ever had a mammogram: 1.14 (1.02-1.27) Had last mammogram within 1 yr: 1.01 (0.95-1.08) Had last mammogram within 2 yrs: 0.98 (0.91-1.07) Had mammogram as part of check-up: 1.01 (0.94-1)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Hahn et al., 2007[29] Research objective: Examine relationship between literacy and HRQoL using a multimedia touch screen program that assesses HRQoL. Study design: Cross-sectional Study setting: Five Chicago-area cancer centers Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: Passage comprehension subtest of Woodcock Language Proficiency Battery: Low < 7th grade High ≥ 7th grade	Eligibility criteria: Included: ≥ 18 yrs old Cancer diagnosis English language preference Adequate visual, auditory and physical capabilities Excluded: < 20/70 vision when tested with a Rosenbaum vision card Sampling strategy: Convenience Sample size: 415 Low, n = 214 High, n = 201 Age, mean (SD): Total: 54.3 (13.4) Low: 56.3 (12.9) High: 52.1 (13.8) Gender, %: Total: Female: 66.9 Low: 67.8 High: 66.2 Race/Ethnicity, %: Total: White: 29.8 Black: 57.6 Other: 12.6 Low: White: 18.2 Black: 71.5 Other: 10.3 High: White: 42.3 Black: 43.3 Other: 14.4 Income: NR Insurance status: NR Education, %: Total: <HS: 36.4 HS/GED: 29.3 Some college: 34.3

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: HRQoL (measured by 3 different tests) Covariates used in multivariate analysis: Age Gender Race/ethnicity Work status Marital status Living arrangement SES Prior computer experience Cancer diagnosis Stage at diagnosis Months since diagnosis Current chemotherapy treatment Performance status Description of outcome measures: Three measures of HRQoL: The FACT-G: 27-item questionnaire with 5 Likert-type response categories. Scores total HRQoL and dimensions of physical, social/ family, emotional and functional well-being. Higher scores = better HRQoL. SF-36: 36-item measure of 8 health concepts: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and Mental Health, and two higher order dimensions. It contains multiple response formats (yes/no, Likert-type, true/false). Higher scores = better HRQoL. The SGUQ: a preference-based measure of HRQoL that reflects the patient's value for her/his current health state. Utility scores range from 0 (current health = to death) to 1 (current health = to perfect health). Negative scores are possible. Data source(s) for outcomes: Multimedia TT: participants self-administer questionnaires. As text appears on the screen, it is also read out loud as patients listen through their headset. Attempts for control for confounding: Multivariable linear regression *Covariates that met a screening criterion of (*P* < 0.25) in bivariate regressions were selected for a multivariable model, and then removed individually using backward elimination (retention criterion, *P* < 0.05) Blinding: NA	Describe results: There were no statistically significant differences in any of the HRQoL scores between the high and low literacy groups. Effect in no exposure (i.e., adequate literacy) or control group, mean (SD): FACT-G: Physical well-being: 18.4 (5.8) Social/family well-being: 20.8 (5.6) Emotional well-being: 17.5 (4.7) Functional well-being: 16.0 (6.3) SF-36: Physical functioning: 57.2 (27.5) Role-physical: 34.8 (42.4) Bodily pain: 56.0 (24.9) General health: 53.2 (21.3) Vitality: 47.3 (20.5) Social functioning: 59.5 (26.2) Role-emotional: 48.7 (43.9) Mental health 66.9 (20.2) Number (%) with fair/poor health: 79 (39.3) Standard gamble utility score: 0.85 (0.23) Effect in exposure (i.e., low/moderate literacy) or intervention, mean (SD): FACT-G: Physical well-being: 17.9 (5.9) Social/family well-being: 20.3 (5.9) Emotional well-being: 17.6 (5.2) Functional well-being: 15.7 (6.5) SF-36: Physical functioning: 48.7 (26.7) Role-physical: 29.7 (38.2) bodily pain: 55.5 (26.9) General health: 49.9 (20.6) Vitality: 51.5 (21.4) Social functioning: 61.4 (25.7) Role-emotional: 49.3 (43.9) Mental health: 65.5 (19.6) Number (%) with fair/poor health: 114 (53.3) Standard gamble utility score, mean (sd): 0.87 (0.20) Difference: Difference FACT-G (adjusted): no sig difference between groups including and excluding biased scale items Difference SF-36 (adjusted): no sig difference between groups including and excluding biased scale items Difference Standard Gamble utility score (unadjusted): (*P* = 0.561) Difference mean Vitality score (adjusted): 4.6, (*P* = 0.023). Sig difference does not hold when biased scale items removed Difference mean Social functioning score (adjusted): 5.1, (*P* = 0.030)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Hahn et al., 2007[29] (continued)	Low: <HS: 60.3 HS/GED: 27.1 Some college: 12.6 High: <HS: 11 HS/GED: 31.3 Some college: 57.5 Other characteristics, %: Currently working: Total: 16.9 Low: 10.3 High: 24.4 Socioeconomic Status: Total: Lowest SES: 18.1 Low SES: 32.6 Middle SES: 21.2 High SES: 21.7 Highest SES: 6.4 Low: Lowest SES: 31.8 Low SES: 16.4 Middle SES: 18.7 High SES: 7.5 Highest SES: 2.3 High: Lowest SES: 3.5 Low SES: 24.9 Middle SES: 23.9 High SES: 36.8 Highest SES: 10.9 Health literacy/numeracy levels, %: High: 48.43 Low: 51.57

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Statistical measures used: Bivariate relationships: t-test or Wilcoxon rank-sum test for continuous variables, Pearson chi-square statistic or Fisher's exact test for nominal variables, and Mantel-Haenszel chi-square statistic for ordinal variables. HRQoL scores by literacy level	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Hibbard et al., 2007[30] Research objective: Examine contribution of health literacy, numeracy, and patient activation to the comprehension of comparative health care performance reports and their use in making an informed choice Study design: Cross-sectional Study setting: Community Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: TOFHLA (passage B only) Numeracy: 11 item measure from Lipkus, Samsa and Rimer, plus 4 items on interpreting risk magnitude	Eligibility criteria: Included: Adults (18-64 years of age) Excluded: NR Sampling strategy: Convenience Sample size: 303 Age (range): 37 (18-64) Gender: Females: 48% Race/Ethnicity: NR Income, %: < 25,000: 74 Insurance status, %: Health Insurance: 45 Education, %: High school or less: 45 Some college or more: 55 Other characteristics, %: Good to excellent health: 40 Fair to poor health: 24 Health literacy/numeracy levels, %: (Calculated) TOFHLA Low Health Literacy: 45 High Health Literacy: 55 Low Numeracy: 43 High Numeracy: 57

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Choosing a high performing hospital Covariates used in multivariate analysis: Age Gender Education Comprehension Activation Description of outcome measures: Quality Choice: Experiment of choosing a higher quality hospital based on performance measures Comprehension: how well a patient understood information in the data display Data source(s) for outcomes: Interview Attempts for control for confounding: Multivariate analyses Blinding: NA Statistical measures used: Multivariate Logistic regression Path analysis	Describe results: Numeracy and literacy predict comprehension but do not predict quality choice. In a path analysis, higher numeracy and literacy predict better comprehension, which in turn predicts a better quality choice. Making a better quality hospital choices is related to activation level, separate from comprehension. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Quality Choice (adjusted): Literacy: -0.023, *P* = NS Numeracy: 0.032, *P* = NS Activation X Numeracy: (*P* = NS) Activation X HL: (*P* = NS) Path analysis (adjusted): HL predicts comprehension: (*P* < 0.001) Numeracy predicts comprehension: (*P* < 0.001) Comprehension predicts Quality Choice: (*P* < 0.001)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Hironaka et al., 2009[31] Research objective: Determine whether limited caregiver HL is associated with adherence to a daily multi-vitamin with iron regimen in infants. Study design: Nested Cohort Study setting: Phone calls and home visits to caregivers using 2 urban pediatric primary care clinics Measurement period: June 2005-March 2006 Follow-up duration: 3 months Completeness of follow-up: NR Measurement tools including cutpoints: sTOFHLA: Limited HL = marginal or inadequate HL Inadequate HL: 0-16 Marginal HL: 17-22 Adequate HL: 23-36	Eligibility criteria: Included: Caregivers and infants age 5-7 months English or Spanish Excluded: History of conditions associated with iron deficiency anemia Use of vitamin or iron supplements within 1 month prior to enrollment Premature, multiple gestations BW < 2500 g Sampling strategy: Convenience, drawn from 150 in RCT (67% of those eligible) Sample size: Total: 110 dyad Families: Limited HL:20 Adequate HL: 90 Age, mean (SD): Caregiver: 30.2 (6.55) Limited HL: 30.2 (6.17) Adequate HL: 30.1 (6.67) Gender, %: Female: Caregiver: 91.8 Limited HL: 95.0 Adequate HL: 91.1 Race/Ethnicity, %: (Child's race) Black: 48.2 Hispanic: 30.0 Other: 17.3 White: 4.6 Limited HL: Black: 55.0 Hispanic: 20.0 Other: 20.0 White: 5.0 Adequate HL: Black: 46.7 Hispanic: 32.2 Other: 16.7 White: 4.4 Income: NR Insurance status, %: Public: 86.4 Limited HL: 80.0 Adequate HL: 87.8

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Adherence to administration of Multivitamin with iron: 32.7% Covariates used in multivariate analysis: Race/ethnicity Caregiver ed Caregiver concerns regarding multivitamins, side effects Randomized assignment to drops or sprinkle formulation Description of outcome measures: Answer to questions regarding Infant's adherence to multi-vitamin and iron regimen on 5-7 days of preceding week. High adherence: administration of vitamin and iron on 5-7 days of preceding wk. Data source(s) for outcomes: Interview from biweekly data collection over the 3-mo period Attempts for control for confounding: Multivariate analyses Blinding: NA Statistical measures used: GEE multiple Logistic regression	Describe results: Caregivers with limited HL were twice as likely to report high adherence to a daily multivitamin with iron regimen in infants as caregivers with adequate HL Effect in no exposure (i.e., adequate literacy) or control group: Avg # of days adherent per wk: 2.4 Effect in exposure (i.e., low/moderate literacy) or intervention: Avg # of days adherent per wk: 3.7 Difference, OR (CI): High adherence (adjusted): limited HL versus adequate HL: 2.13 (1.2-3.78 0) High adherence (adjusted-adding control for concerns to model): 2.4 (1.37-4.2)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Hironaka et al., 2009[31] Research objective: Determine whether limited caregiver HL is associated with adherence to a daily multi-vitamin with iron regimen in infants. Study design: Nested Cohort Study setting: Phone calls and home visits to caregivers using 2 urban pediatric primary care clinics Measurement period: June 2005-March 2006 Follow-up duration: 3 months Completeness of follow-up: NA	Education, %: Caregiver < HS: 17.3 Limited HL: 25.0 Adequate HL: 15.6 Other characteristics, %: Caregiver born outside US: 66.4 Limited HL: 90.0 Adequate HL: 61.1 Health literacy/numeracy levels, %: Limited HL: 18.2

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Hope et al., 2004[32] Research objective: Study association of medication adherence, knowledge, and skills (including literacy - ability to read labels) with ED visits Study design: Cohort Study setting: Patients in study enrolled in control group of an ongoing randomized trial of participants with CHF in Indianapolis, Indiana Measurement period: 3/2/2001 - 6/30/2004 Follow-up duration: 6 months Completeness of follow-up: NR Measurement tools including cutpoints: Literacy was defined as the ability to read standard prescription and auxiliary labels, and was 1 of 3 components of medication skills measure. Other components of this measure were: dexterity (ability to open child-resistant and easy open 40-dr containers and a child resistant 4-oz bottle) and ability to distinguish Colors of tablets and capsules	Eligibility criteria: Included: Diagnosis of CHF by a patient's primary care physician 50 years or older Ability to speak English Ability to hear at normal speaking levels, access to a telephone Plans to receive medical care and prescription medications at Wishard Health Service Excluded: Dementia or 5+ errors on the Short Portable Mental Status Questionnaire Not prescribed 1+ medication from common drug classes used to treat CHF Unwilling to respond to health-related questions about their quality of life and adherence Sampling strategy: NR Sample size: 61 Age, mean (SD): 65.4 (8.7) Gender, %: Females: 72.1 Race/Ethnicity, %: AA: 49.2 White: 49.2 American IndiaNAlaska Native: 1.6 Income: NR Insurance status: NR Education, %: More than 12 years: 8.9 12 years: 28.6 Less than 12 years: 62.5 Other characteristics, %: NYHA Classification I = 35 II = 46.7 III/IV = 18.3 No. medications 1 - 10 = 60.7 11+ = 39.3 Health literacy/numeracy levels: NR Mean reading score (SD): 1.65 (0.56)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: All-cause cardiovascular-related and CHF-specific ED visits Covariates used in multivariate analysis: NYHA classification Number of medications Race Reading score Description of outcome measures: The primary outcomes were all-cause cardiovascular-related and CHF-specific ED visits during the six-month period. ICD-9 codes were used to determine ED visits with a diagnosis of CHF and a cardiac diagnosis Data source(s) for outcomes: NR (medical records?) Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Multivariate log-linear regression	Describe results: Better prescription-label-reading skills (literacy) were associated with fewer ED visits, $P = 0.002$. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: ($P = 0.002$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2005[9] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) Research objective: Examine impact of low health literacy on medical care use and costs Study design: Cohort Study setting: In-person in-home interviews with and subsequent claims data for new Medicare managed-care enrollees in Cleveland, Houston, Tampa, and south Florida (including Ft. Lauderdale and Miami) Measurement period: New enrollees in Prudential Medicare managed care plans between December 1996 and August 1997. Interviews occurred 3 months following enrollment. Claims data from within 1 year of date of enrollment into the managed-care plan (usually 3 months prior to study enrollment) Follow-up duration: 1 year Completeness of follow-up: 3487 enrolled, 3,260 completed sTOFHLA and interview Measurement tools (cutpoints NR): S-TOFHLA: Adequate Marginal Inadequate	Eligibility criteria: Included: Medicare managed-care enrollees 65 years or older 3 months after he/she enrolled in Prudential HealthCare Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Severe cognitive impairment Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: 3,260 Age (range), %: 65-69: 37.0 70-74: 27.3 75-79: 19.3 80-84: 11.0 >85: 5.4 Mean by HL level (SD): Adequate: 71.6 (7.2) Marginal: 74.1 (6.3) Inadequate: 75.6 (5.6) Gender: Female: 57.4 By HL status, %: Female: Adequate: 57.9 Marginal: 53.8% Inadequate: 57.8% Race/Ethnicity,%: White: 76.0 Black: 11.8 English-speaking Hispanic: 2.0 Spanish-speaking Hispanic: 9.2 Other: 1.0 By HL status: Adequate: White: 84 AA: 6.6 Hispanic English-speaking: 1.6 Hispanic Spanish-speaking: 6.6 Other: 1.2

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Healthcare utilization Healthcare costs Covariates used in multivariate analysis: Age Sex Race/ethnicity Income Education Tobacco Alcohol consumption Self-reported comorbid conditions (heart attack, angina, stroke, high blood pressure, chronic obstructive pulmonary disease, cancer, diabetes, arthritis, depression) Description of outcome measures: Healthcare utilization: percent using any inpatient, outpatient, ED, or pharmacy services. Healthcare costs: total, inpatient, outpatient, ED, and pharmacy services. Data source(s) for outcomes: Medicare claims data and one-hour in-person orally administered survey Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: 1-way ANOVA Chi-square Modified 2-part regression model (Mullahy)	Describe results: Participants with inadequate HL used sig more inpatient and ED services than those with adequate HL but no sig differences were found in overall use outpatient or pharmacy use (adjusted). Patients with marginal HL used sig more pharmacy services than those with adequate HL. All other use comparisons were not sig (adjusted). Participants with inadequate and marginal HL had sig higher ED costs than those with adequate HL. Participants with marginal HL had sig lower outpatient costs than participants with adequate literacy (after adjusting for covariates). All other comparisons were not sig. Similar results were found in models comparing inadequate and adequate groups not controlling for education or comorbid conditions. Effect in no exposure (i.e., adequate literacy) or control group, %: Adequate Use: Overall: 97 Inpatient: 27 Outpatient: 91 ED: 21 Pharmacy: 88 Costs (SD): Overall: $7,246 ($17 941) Inpatient: $4,656 ($16 428) Outpatient:$,1805 ($3188) ED: $100 ($360) Pharmacy: $684 ($890) Smoking: Never: 38 Former: 49 Current: 13 Drinking, %: None: 58 Light to Moderate: 37 Heavy: 4 Comorbid Conditions, %: Heart Attack: 13 Angina: 8 Stroke: 7 High Blood Pressure: 45 COPD: 18 Asthma: 7 Cancer: 6 Diabetes: 13 Arthritis: 50 Depression: 12

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2005[9] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	Marginal: White: 68 AA: 12.6 Hispanic English-speaking: 2.5 Hispanic Spanish-speaking: 16.4 Other: 0.6 Inadequate: White: 25.2 AA: 58.6 Hispanic English-speaking: 2.3 Hispanic Spanish-speaking: 13 Other: 1 Income, %: <$10 000: 18.2 $10 000-14 999: 21.6 $15 000-24 999: 25.6 $25 000-34 999: 8.7 $35 000: 10.2 Did not answer/did not know: 15.7 By HL status: Adequate, <$15,000: 33 Marginal, <15,000: 47 Inadequate, <$15,000: 54 Insurance status, %: Medicare: 100 Education, %: Grade school or less: 17.3 Some high school: 18.4 High school: 33.6 More than high school: 30.7 By HL status: >12 years of school completed: Adequate: 39.7 Marginal: 20 Inadequate: 12 0-8 years of school completed: Adequate: 7.1 Marginal: 24.2 Inadequate: 40.9 Other characteristics: NR Health literacy/numeracy levels, %: Adequate: 64.2 Marginal: 11.2 Inadequate: 24.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Inadequate All: 95 Effect in exposure (i.e., low/moderate literacy) or intervention: Inpatient: 35 Outpatient: 90 ED: 30 Pharmacy: 85 Costs (SD): Overall: $9,614 ($22536) Inpatient: $6,817 ($21049) Outpatient: $1,970 ($3477) ED: $189 ($551) Pharmacy:$638 ($1267) Smoking, %: Never: 45 Former: 43 Current: 12 Drinking, %: None: 75 Light to Moderate: 23 Heavy: 2 Comorbid Conditions: Heart Attack: 15 Angina: 8 Stroke: 13 High Blood Pressure: 51 COPD: 14 Asthma: 7 Cancer: 5 Diabetes: 19 Arthritis: 58 Depression: 19 Marginal - Use, %: Overall: 96 Inpatient: 34 Outpatient: 90 ED: 28 Pharmacy: 85 Marginal - Costs (SD): Overall: $8,484 ($16646) Inpatient: $5,857 ($15240) Outpatient: $1,727 ($2954) ED: $182 ($593) Pharmacy: $719 ($998) Smoking, %: Never: 43 Former: 45 Current: 13

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2005[9] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Drinking, %: None: 64 Light to Moderate: 33 Heavy: 2 Comorbid Conditions, %: Heart Attack: 18 Angina:12 Stroke: 9 High Blood Pressure: 48 COPD: 16 Asthma: 8 Cancer: 7 Diabetes: 16 Arthritis: 58 Depression: 14 +AU1 Difference (CI): Differences in probability of use (adjusted) Inadequate vs adequate overall: 0.00 (-0.02-0.02) Inpatient use: 0.05 (0.00-0.09) Outpatient: -0.02 (-0.05-0.01) ED: 0.05 (0.01-0.10) Pharmacy: -0.03; 95% CI, -0.06-0.00 Differences in probability of use (adjusted) Marginal vs adequate overall: 0.00 (-0.02-0.03) Inpatient use: 0.04 (-0.01-0.09) Outpatient: -0.01 (-0.04-0.02) ED: 0.04 (-0.01-0.09) Pharmacy: -0.04 (-0.08-0.00) Differences in costs (adjusted) - Inadequate vs adequate: Overall: $1,551 (-$166-$3267) Inpatient use: $1,543 (-$89-$3175) Outpatient: -$213 (-$481-$55) ED: $108 ($62-$154) Pharmacy $27; 95% CI, -$55-$110 Differences in costs (adjusted) - Marginal vs adequate: Overall: $596 (-$1437-$2630) Inpatient use: $748 (-$1252-$2748) outpatient: -$350 (-$679--$20) ED: $80 ($28-$132) Pharmacy: $35 (-$62-$132) Comparisons across 3 groups (unadjusted): Smoking: (*P* = 0.01) Drinking: (*P* = 0.23)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2005[9] (Companions: Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Howard et al., 2006[6]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Comorbid conditions: Heart Attack: (*P* = 0.01) Angina: (*P* = 0.06) Stroke: (*P* < 0.0001) High Blood Pressure: (*P* = 0.01) COPD: (*P* = 0.06) Asthma: (*P* = 0.65) Cancer: (*P* = 0.15) Diabetes: (*P* = 0.0002) Arthritis: (*P* = 0.0002) Depression: (*P* < 0.0001)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2006[6] (Companions:Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) Research objective: Explore impact of HL on differences in health status and vaccination by educational attainment and race Study design: Cohort Study setting: In-person in-home interviews with and subsequent claims data for enrollees in Cleveland, Houston, Tampa, and south Florida (including Ft. Lauderdale and Miami) Measurement period: Interviews occurred May 1997-December 1997 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: S-TOFHLA: Adequate Marginal Inadequate	Eligibility criteria: Included: Medicare managed-care enrollee 65+ Enrolled in Prudential HealthCare 3 months or more Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Missed 1 or more screening questions for severe cognitive impairment (not able to correctly identify year, month, state, year of their birth, or home address) Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: Analysis by educational level, N: 3,260 Analysis by race (limited to black and white), N: 2,850 Age (mean and range), %: Full sample: 65-69: 37.0 70-74: 27.3 75-79: 19.3 80-84: 11.0 >85: 5.4 White: 65-74: 61 75-84: 33 85+: 6 Black: 65-74: 66 75-84: 29 85+: 5 Gender, %: Male by education: HS degree: 42 No HS degree: 44 Male by race: White: 42 Black: 34 Race/Ethnicity, %: By education: HS degree: White: 86 Black: 7 Hispanic: 4 Other: 3

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Physical and mental health status receipt of vaccinations Covariates used in multivariate analysis: Age Gender Race/ethnicity Education Income Site Morbidity Smoker Description of outcome measures: Health status: Physical health SF-12 Mental health SF-12 Self-reported health status (fair or poor vs. good, very good, or excellent) Receipt of vaccination: Self-reported receipt of influenza vaccination Self-reported receipt of pneumococcal vaccination Data source(s) for outcomes: In-person survey Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Chi-square, multivariate logistic regression, ordinary least squares regression	Describe results: Compared to those with adequate HL, enrollees with inadequate HL had sig worse physical and mental health status and were sig less likely to report receiving an influenza vaccine. No sig differences were found between marginal and adequate HL groups. Difference: Difference in Physical Health SF-12 (adjusted), β: Inadequate/Adequate: -2.53, *P* < 0.001 Marginal/Adequate: -1.35, *P* =0.019 Difference in Mental Health SF-12 (adjusted), β: Inadequate/Adequate: -1.41, *P* < 0.001 Marginal/Adequate: 0.46, *P* = 0.304 Difference in self-reported health status of good or better (adjusted), OR: Inadequate/Adequate: 0.71, *P* = 0.004 Marginal/Adequate: 0.77, *P* = 0.060 Difference in receipt of influenza vaccine (adjusted), OR: Inadequate/Adequate: 0.76, *P* = 0.020 Marginal/Adequate: 1.06, *P* = 0.707 Difference in recipt of pneumodoccal vaccine (adjusted), OR: Inadequate/Adequate: 0.85, *P* = 0.114 Marginal/Adequate: 0.91, *P* = 0.445 Difference in Physical Health SF-12 score (adjusted) between model not controlling for HL vs model controlling for HL (CI): By education level: 0.7 points (0.4-0.9) By race: 0.6 points (0.3-0.9) Difference in Mental Health SF-12 score (adjusted) between model not controlling for HL vs model controlling for HL (CI): By education level: 0.3 points (0.1-0.5) By race: 0.3 points (0.1-0.5) Difference in probability of self-reported health status of good or better (adjusted) between model not controlling for HL vs model controlling for HL (CI): By education level: 0.02 (0.01-0.03) By race: 0.02 (0.01-0.03) Difference in probability of receipt of influenza vaccine (adjusted) between model not controlling for HL vs model controlling for HL (CI): By education level: 0.010 (0.001-0.020) By race: 0.009 (-0.001-0.020) Difference in probability of receipt of pneumococcal vaccine (adjusted) between model not controlling for HL vs model controlling for HL (CI): By education level: 0.010 (-0.002-0.022) By race: 0.003 (-0.007-0.013)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2006[6] (Companions:Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	No HS degree: White: 59 Black: 20 Hispanic: 18 Other: 3 Income, %: By education HS degree: Missing: 16 0-10,000: 11 10,000-15,000: 19 15,000-25,000: 28 25,000-35,000: 11 35,000+: 14 No HS degree: Missing: 16 0-10,000: 30 10,000-15,000: 25 15,000-25,000: 21 25,000-35,000: 4 35,000+: 3 Insurance status, %: Medicare: 100 Education, %: Full sample: Grade school or less: 17.3 Some HS: 18.4 HS grad: 33.6 More than HS: 30.7 White: Grade school or less: 10 Some HS: 18 HS grad: 38 More than HS: 35 Black: Grade school or less: 33 Some HS: 28 HS grad: 24 More than HS: 15 Health literacy/numeracy levels,%: By education: HS degree: Adequate: 78 Marginal: 9 Inadequate: 13

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Howard et al., 2006[6] (Companions:Gazmararian, 2006[3]; Wolf et al., 2007[4]; Baker et al., 2007[5]; Wolf et al., 2005[7]; Baker et al., 2008[8]; Howard et al., 2005[9]; Baker et al., 2004[2]) (continued)	No HS degree: Adequate: 40 Marginal: 16 Inadequate: 45 By race: White: Adequate: 71 Marginal: 10 Inadequate: 19 Black: Adequate: 36 Marginal: 12 Inadequate: 52

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Huizinga et al., 2008[33] Research objective: Examine association between numeracy skills and weight status as measured by BMI Study design: Cross-sectional Study setting: Academic primary care clinic at Vanderbilt University Medical Center Measurement period: July 2006 - August 2007 Follow-up duration: NA Completeness of follow-up, (%): 160/169 (95) Measurement tools including cutpoints: Numeracy: WRAT-3 Literacy: REALM	Eligibility criteria: Included: N Excluded: Age < 18 years Non-English speaking Dementia Corrected visual acuity equal to or worse than 20/50 by Rosenbaum Pocket Vision Screener Sampling strategy: Convenience sample (referred by clinic staff) Sample size: 169, no comparisons Age, mean (SD): 46 (16) Low Numeracy: 45.1 High Numeracy: 47.6 Gender, %: Female: 70 Low Numeracy: 70 High Numeracy: 70 Race/Ethnicity, %: White: 66 Low Numeracy: 52 High Numeracy: 93 Income, %: <$20,000: 16 Low Numeracy: 23 High Numeracy: 4 Insurance status: NR Education, %: High-school or GED: 91 Low Numeracy: 87 High Numeracy: 98 Other characteristics, %: Dyslipidemia: 26 Hypertension: 38 CAD: 8 Diabetes: 17 NR by numeracy subgroup Health literacy/numeracy levels: Numeracy: All participants, mean (SD): 89.1 (16) < 9th grade (66% of participants), mean (SD): 80.9 (11) > 9th grade (34% of participants), mean (SD): 105 (9.1)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: BMI Covariates used in multivariate analysis: Age Sex Race Income Years of education REALM score Description of outcome measures: BMI calculated from height and weight Data source(s) for outcomes: Self-report by patient after measurement by clinic staff Attempts for control for confounding: Linear regression Blinding: NR Statistical measures used: Spearman's rank correlation Wilcoxon rank sum Linear regression	Describe results: Lower numeracy was significantly associated with higher BMI. Literacy was not significantly associated with BMI Effect in no exposure (i.e., adequate literacy) or control group: Numeracy > 9th grade: BMI (SD): 27.9 (6.0) Literacy > 9th grade: BMI (SD): 30.2 (7.8) Effect in exposure (i.e., low/moderate literacy) or intervention: Numeracy < 9th grade: BMI (SD): 31.8 (9.0) Literacy < 9th grade: BMI (SD): 31.7 (9.9) Difference: BMI (low versus high Num) (unadjusted): +3.9, P = 0.008 Beta coefficient for effect of Numeracy on BMI: (adjusted for age, sex, race, income, and years of education): -0.14, P = 0.01 BMI (low versus high Lit) (unadjusted): +1.5, P = 0.50

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Huizinga et al., 2008[33] (continued)	Health Literacy: All participants, mean (SD): 61.0 (8.7) < 9th grade (22.5% of participants) > 9th grade (77.5% of participants)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Johnson et al., 2010[34] Research objective: To explore whether social support helps patients with limited HL adhere to their medication regimens. Study design: Cross-sectional Study setting: 3 pharmacies at Grady Memorial Hospital in Atlanta, GA (intervention site) and a community-based satellite pharmacy in Decatur, GA (control site) Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: REALM: 0-44: limited health literacy 45-66: adequate health literacy	Eligibility criteria: Inclusion: NA Exclusion: Cognitive impairment (Mini-Cog Assessment) Had poor vision (worse than 20/100) <18 years of age Had not been a pharmacy patient for ≥6 months. Sampling strategy: Convenience sample; A standardized telephone script was used to recruit patients already enrolled in the PILL Study. Pharmacy supervisors helped identify pharmacists who might be available for interviews Sample size: 275 Pharmacy Patients Age (mean and range), % (SD): Mean: 53.91 (12.50) Gender, %: Female: 73.1 Race/Ethnicity, %: Race: Black/African American: 86.2 White: 5.1 Other: 8.7 Ethnicity: Hispanic: 1.8 Non-Hispanic: 98.2 Income, %: Annual household income, %: <$10,000: 63.7 ≥$10,000: 36.3 Insurance status, %: NR Education, %: <High school: 27.6 High school or more: 72.4 High school graduate of GED: 36.4 Technical school or some college: 24.0 College graduate, graduate school, or professional school: 12.0 Other characteristics, %: Employment statuse: Unemployed: 26.7 Employed full time: 8.5 Employed part time: 15.9 Retired, disabled, or in school: 48.9

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Adherence to medication regimens Covariates used in multivariate analysis: Age Sex Description of outcome measures: Adherence: A modified 8-item version of the Morisky Adherence Scale. Social support: the Enriched Social Support Instrument (ESSI), which measures different types of social support. Data source(s) for outcomes: Researchers conducted four focus groups with patients (two at the intervention site and two at the control site) and face-to-face interviews with pharmacists. Researched conducted 30-min interviews at the pharmacies. Attempts for control for confounding: Linear regression analyses Blinding: NR Statistical measures used: Regression Descriptive statistics Chi-square tests	Describe results: Social support was associated with better medication adherence for patients with adequate HL but not those with limited HL (P< 0.05). Effect in no exposure (i.e., adequate literacy) or control group: Multiple linear regression Analyses: Greater social support was associated with better medication adherence, but only for patients with adequate health literacy (β = -1.827; SE = 0.793; R^2 = 0.000; CI, -3.389 to -0.265; *P* < 0.05). At the highest level of social support, patients with adequate health literacy reported better medication adherence than those reporting inadequate/marginal health literacy. Effect in exposure (i.e., low/moderate literacy) or intervention: Having as much contact as you would like with someone in whom you can trust and confide was associated with better medication adherence for inadequate/marginal-literacy patients (*P* < 0.05). Patients in both of the limited-literacy focus groups said relatives began helping them after they were hospitalized for medication overdoses or interactions. Difference: The difference between inadequate/marginal and adequate health literacy changed for different values of social support, as indicated by the interaction observed between social support and health literacy (β = 0.086; SE, 0.035; R^2 change = 0.020; CI, 0.018 to 0.154; *P* < 0.05)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Johnson et al., 2010[34] (continued)	Social support: Low: 48.0 High: 52.0 Mean (SD): 22.24 (6.18) Medication adherence (n = 272): Low: 68.4 High: 31.6 Mean (SD): 4.95 (1.82) Health literacy/numeracy levels, %: REALM, n = 273 Inadequate/marginal, %: 59.7 Adequate, %: 40.3 Mean (SD): 51.31 (17.09)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Johnston et al., 2005[35] Research objective: Describe levels of health literacy in spinal cord injury patients and to investigate its possible associations with morbidity, health-related quality of life, functional independence, community participation, and life satisfaction. Study design: Cross-sectional Study setting: New Jersey outpatient Spinal Cord Injury center Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: Adequate: 75 and above Inadequate/Marginal: 74 and below	Eligibility criteria: Included: Spinal Cord Injury (prioritizing those that do not currently have comobidity) 18+ years old Community living Excluded: Less than 6 months after injury Extremely poor vision Inability to speak English or Spanish Unintelligible speech Uncontrolled psychiatric illness Lack of cooperation Sampling strategy: Convenience Sample size: 107 Age, mean (SD): 39.1 (11.16) Gender, %: Males: 82.2 Race/Ethnicity, %: White: 66.4 AA: 26.2 Asian/Pacific Islander: 2.8 Other/Unclassified: 4.7 Income, median annual income (n = 104): $10,000-$14,999 Insurance status: NR Education, %: 1st-8th grade: 1.9 9th-11th grade: 16.8 Grade 12 or GED: 26.2 College 1 to 3 years: 29 College 4 yrs or more: 26.2 Other characteristics, %: Marital status: Never been married: 65.4 Married: 19.6 Divorced: 10.3 Separated: 1.9 Widowed: 2.8 Years since injury, mean/median (SD): 11.36/8.71 (9.56) ASIA Impairment Scale: Motor complete, sensory and motor 56.4 Motor complete, sensory complete: 20.2 Motor incomplete, major deficit: 14.9 Motor incomplete, less deficit: 8.5 Normal 0.0

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Mobidity (days limited per month) Physical Mental SF-12 Physical Component Summary Mental Component Summary CHART (handicap/participation) Physical independence Mobility Occupation Social Integration Economic self-suf Covariates used in multivariate analysis: Motor index Education Description of outcome measures: Mobidity (days limited per month) - # of days that physical or mental health "not good" in the last 30 days SF-12: Physical and Mental sub-scales - questionnaire to assess health-related QoL Physical Component Summary Raw summative - raw scores transformed to create mean of 50 and standard deviation of 10 Mental Component Summary Raw Summative- raw scores transformed to create mean of 50 and standard deviation of 10 CHART (handicap/participation) - includes subscales listed below; ranging between 0 and 100; and a total score. Physical independence Mobility Occupation Social Integration Economic self-sufficiency CHART total Satisfaction with Life Scale Mean - Diener's Satisfaction with Life Scale, 5 statements on overall life satisfaction with responses ranging from 1 (strongly disagree to 7 (strongly disagree). Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis (Linear regression)	Describe results: HL was related to physical health mobidity, but associations with other outcomes were not significant. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Mobidity (days limited per month) Difference in number of days physical health "not good", β: -0.25, *P* < =0.05 Difference in number of days mental health "not good", β: -0.02, *P* = 0.90 SF-12 Difference in Physical Component Summary Scale, β: -0.09, *P* = 0.49 Difference in Mental Component Summary Scale, β: 0.23, *P* = 0.07 CHART (handicap/participation) Difference in Physical independence, β: -0.09, *P* = 0.47 Difference in Physical independence(curvilinear): -0.04, *P* = 0.70 Difference in Mobility, β: -0.01, *P* = 0.93 Difference in Occupation, β: 0.23, *P* = 0.06 Difference in Social Integration, β: 0.21, *P* = 0.11 Difference in Economic self-sufficiency, β: 0.06, *P* = 0.64 Difference in CHART total, β: 0.13, *P* = 0.28 Difference in Satisfaction with Life Scale Mean, β: -0.04, *P* = 0.78

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Johnston et al., 2005[35] (continued)	Health literacy/numeracy levels, mean/median (SD): Inadequate: 6.5 Marginal: 7.5 Adequate: 86 Numeracy: 39.6/42.0 (9.4) Literacy: 44.1/47.0 (8.6)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Kalichman et al., 2008[36] Research objective: Examine relationship between health literacy and antiretroviral treatment adherence among HIV patients. Study design: Cross-sectional Study setting: Research program office in Atlanta, GA and follow-up phone calls Measurement period: NR Follow-up duration: 4 months Completeness of follow-up: NR Measurement tools including cutpoints: TOFHLA (Scores divided into higher and lower literacy; specific cut points not specified, but used median scores of 90% correct to define higher/lower)	Eligibility criteria: Included: 18 years old Proof of positive HIV status Antiretroviral prescription bottle Currently taking antiretroviral meds Excluded: NR Sampling strategy: Convenience Sample size: 145 Age, mean (SD): 44.9 (6.3) Gender, %: Males: 69 Race/Ethnicity, %: AA: 93 White: 6 Other: 1 Income: NR Insurance status: NR Education, mean years (SD): 12.3 (2.1) Other characteristics: NR Health literacy/numeracy levels: TOFHLA median score, % correct: 90

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Antiretroviral therapy adherence Covariates used in multivariate analysis: Age Education Years since testing HIV positive HIV symptoms Depression Internalized stigma Social support Alcohol use Description of outcome measures: HIV symptoms: experience with 14 common HIV symptoms (symptoms not described) Depression: frequency of 13 cognitive and affective symptoms of depression during past 7 days using items from Centers for Epidemiological Studies Depression Scale Data source(s) for outcomes: HIV symptoms: self-report Depression: self-report Alcohol Use: self-report Antiretroviral Therapy adherence: Monthly unannounced telephone-based pill counts to patients, pharmacy information from pill bottles. Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Hierarchical logistic regression	Describe results: HL level not significantly related to HIV symptoms, depression, or alcohol score (unadjusted). Lower health literacy was associated with poorer antiretroviral treatment adherence, after adjusting for other factors including education. Effect in no exposure (i.e., adequate literacy) or control group, mean (SD): HIV symptoms: 4.7 (3.9) Depression: 8.7 (7.8) Alcohol Score: 1.4 (1.9) Antiretroviral Therapy adherence, %: <80% pills taken: 60 <85% pills taken: 69 <90% pills taken: 77 Effect in exposure (i.e., low/moderate literacy) or intervention, mean (SD): HIV symptoms: 4.0 (3.2) Depression: 10.9 (6.6) Alcohol Score: 0.95 (1.5) Antiretroviral Therapy adherence: Pills taken: <80%: 78 <85%: 84 <90%: 91 Difference, OR (CI): Difference HIV symptoms (unadjusted): 1.05 (0.95-1.14) Difference Depression (unadjusted): 0.95 (0.91-1.00) Difference Alcohol Score (unadjusted): 1.16 (0.96-1.41) Difference < 80% pills taken (unadjusted): 2.45 (1.17-5.12) Difference 85% Adherence (adjusted): 3.77 (1.46-9.93) Difference < 90% pills taken (unadjusted): 3.18 (1.17-8.62)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Kim, 2009[37] Research objective: To investigate the relationships of health literacy to chronic medical conditions and the functional health status among community-dwelling Korean older adults Study design: Cross-sectional Study setting: Community-dwelling older adults recruited at community-based senior welfare centers in Daegu, Busan, and Kyungpook provinces in Korea Measurement period: June 2007 - September 2007 Follow-up duration: N/A Completeness of follow-up: NA Measurement tools including cutpoints, %: Korean Functional Health Literacy test (based on the TOFHLA and previously validated) score ranges from 0-15 (cutpoints not defined)	Eligibility criteria: Inclusion: Age ≥ 60 No apparent communicative or cognitive impairment problems Willing to participate in the study Exclusion: Severe vision problem not correctable with glasses Did not know year they were born, current month, year, and place they live Sampling strategy: Convenience sample Sample size: N =103 Age (mean and range), %: High literacy: 70.98 (SD 4.28) Low literacy: 73.15 (SD 5.14) Gender, %: Female: 58.3 Race/Ethnicity, %: NR Income, % (SD): Korean currency: Won High literacy: 809,000 Won (632,000 Won) Low literacy: 397,000 Won, (425,000 Won) Insurance status, %: NR Education, % (SD): High literacy: 10.22 years (2.74) Low literacy: 7.05 years (4.17) Health literacy/numeracy levels, %: Mean score 5.48 (SD 3.53) Score categories: > 5: 41 = 5: 19 < 5: 43 High literacy (≥5): 60 Low literacy (<5): 43

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Chronic disease Functional health status Activity limitations Covariates used in multivariate analysis: Age Education Income Description of outcome measures: chronic disease - measured by self-report functional health status - divided into physical health status, mental health status, functional status, and subjective general health status; measured using the subscales of the Medical Outcomes Study 12-item Short-Form Health Survey activity limitations - measured by assessing IADLs, ADLS, and limited activities because of physical health in the past four weeks scores for all of the scales were converted to a normalized score with mean of 50 and SD of 10 Data source(s) for outcomes: Patient self-report via survey instruments Attempts for control for confounding: Linear regression Blinding: NA Statistical measures used: Chi-square Linear regression	Describe results: Older individuals with low health literacy had higher rates of arthritis and hypertension (unadjusted). They were more likely to have limitations in activity and lower subjective health controlling for all confounders including education. In adjusted models not controlling for education, lower health literacy was also associated with poorer physical function and pain that interferred with normal work activity. Effect in no exposure (i.e., adequate literacy) or control group: Arthritis: 21.7% Hypertension: 21.7% Sensory disease: 23.3% Diabetes mellitus: 54.5% Pulmonary disease: 10.0% Heart disease: 2.3% Physical function: 46.71, SD 9.81 Mental health status: 48.88, SD 6.53 Limitations in activity: 44.64, SD 10.75 Pain that interfered with normal work activities: 40.37, SD 12.33 Subjective general health: 44.88, SD 12.01 Effect in exposure (i.e., low/moderate literacy) or intervention: Arthritis: 51.2% Hypertension: 44.2% Sensory disease: 39.5% Diabetes mellitus: 45.5% Pulmonary disease: 16.3% Heart disease: 8.3% Physical function: 40.34, SD 10.29 Mental health status: 45.13, SD 9.82 Limitations in activity: 51.11, SD 8.59 Pain that interfered with normal work activities: 47.08, SD 10.62 Subjective general health: 36.97, SD 11.46 Difference: difference in rates of chronic conditions (unadjusted): Arthritis: (P = 0.003) Hypertension: (P = 0.018) All other chronic conditions: (P = NS) Adjusted for age, education and income: Difference in physical function: (P = 0.06) Difference in mental health status: (P = 0.15) Difference in limitations in activity: (P = 0.025) Difference in pain that interfered with normal work activities: (P = 0.215) Difference in subjective general health: (P = 0.036) Adjusted for age and income: Difference in physical function: (P = 0.006) Difference in mental health status: (P = 0.18) Difference in limitations in activity: (P = 0.005) Difference in pain that interfered with normal work activities: (P = 0.044) Difference in subjective general health: (P = 0.010)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Kripalani et al., 2006[38] Research objective: Evaluate effects of low literacy, medication regimen complexity, and sociodemographic characteristics on MMC Study design: Cross-sectional Study setting: Patients served at General Medical Clinic at Grady Memorial Hospital in Atlanta, GA Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: ≤ 6th grade (score 0 to 44): inadequate literacy 7th-8th grade (score 45 to 60): marginal literacy ≥ 9th grade (61 to 66): high literacy	Eligibility criteria: Included: Documented diagnosis of CHD or a history of coronary artery Bypass graft surgery, percutaneous transluminal coronary angioplasty, or myocardial infarction Excluded: Currently participating in another adherence study Too ill to complete the enrollment interview Does not manage own medications Already using a medication pill card that graphically illustrated their regimen No mailing address or telephone number Routinely filled prescriptions outside of the Grady pharmacy system Unable to communicate in English Worse than 20/60 vision Significant psychiatric illnesses, overt delirium, or dementia Sampling strategy: Convenience Sample size: 152 Age (mean and range): Gender, %: Females: 54.6 Race/Ethnicity, %: AA: 94.1 Caucasian: 3.9 Hispanic/Latino: 1.3 Other: 0.7 Income: NR Insurance status: NR Education: Years of education (SD): 10.7 (3.6), Range 0-20 Other characteristics, %: Employment: Unemployed: 17.1 Full-time: 0.7 Part-time: 5.9 Retired/disabled: 76.3 Marital status: Married: 16.4 Separated: 11.8 Divorced: 23.7 Widowed: 30.9 Single/never married: 16.4%

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: MMC Covariates used in multivariate analysis: Age Years of schooling Cognitive function (MMSE) Description of outcome measures: MMC assessed using Drug Regimen Unassisted Grading Scale (DRUGS). DRUGS requires subjects to perform 4 tasks with each of their medications: Identify appropriate medication Open container Select correct dose Report appropriate timing of doses. Scores range from 0 to 100, weighting each of 4 tasks equally. DRUGS provides an overall measure of management capacity but can also indicates specific areas of difficulty. Data source(s) for outcomes: DRUGS assessment (participant performs tasks and interviewer records score) Attempts for control for confounding: Multivariable logistic regression Blinding: Yes Statistical measures used: DRUGS score and its 4 components and patient characteristics and regimen size were compared using Mann-Whitney and Kruskal-Wallis tests for nonparametric data. DRUGS scores were dichotomized and compared them across patient and regimen characteristics using chi-square and or Fisher's exact tests. Significant factors from univariate analyses included in multivariable logistic regression models. Full models were reduced using a backward elimination approach with likelihood ratio tests. Two alternate modeling strategies were also preformed: one without years of schooling and another treated continuous variables as such.	Describe results: In univariate analyses, total DRUGS scores and specifically, ability to identify medications, increased with literacy level. Literacy was not related to other 3 components of DRUGS (open container, indicate dose, and report timing). In logistic regression models, those with inadequate literacy were significantly less likely to identify all of their medications, compared with those with adequate literacy skills, while a sig difference was not found between those with marginal and adequate scores. Effect in no exposure (i.e., adequate literacy) or control group, mean (SD): Adequate literacy Overall DRUGS score: Mean (SD): 97.7 (4.3) Components of DRUGS: Identify: 99.2 (2.9) Open: 99.2 (4.5) Dose: 98.3 (7.5) Timing: 94 (12) Unable to identify all medications: 7% Effect in exposure (i.e., low/moderate literacy) or intervention, mean (SD): Marginal literacy Overall DRUGS score: Marginal HL: 96.3 (4.9) Inadequate HL: 92.1 (8.7) Components of DRUGS: Marginal HL: Identify: 92 (17) Open: 100 (0) Dose: 97.6 (7.3) Timing: 95.4 (8.1) Inadequate HL: Identify, mean: 76.9 (28.4) Open, mean: 99.7 (1.7) Dose, mean: 96.1 (10.2) Timing, mean: 95.6 (8.3) Unable to identify all medications: Marginal HL: 25 Inadequate HL: 57 Difference: Difference in overall DRUG score: (Unadjusted): (*P* = 0.001) DRUG components separately measured (Open, Dose,Timing) (Unadjusted): (*P* = NS) Difference inability to identify all medications, (adjusted including ed): Marginal, OR (CI): 4.75 (0.95-23)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Laramee et al., 2007[39] Research objective: Assess relationship between HL and heart failure among diabetics Study design: Cross-sectional Study setting: Patients attending non-academic primary care practices in VT, northern NY and northern NH interviewed in their homes Measurement period: 7/2003 - 3/2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA Limited (inadequate or marginal): 0-22 Adequate 23-36 Limited literacy includes sTOFHLA score <23, blind or otherwise unable to complete test	Eligibility criteria: Included: Adults with diabetes Excluded: Significant cognitive impairments Sampling strategy: Convenience sample Sample size: 998 Limited HL (n = 171) Adequate HL (n = 827) Age (range): 65 (22-93) Gender, %: Females: 54 Race/Ethnicity, %: White: 97 Income, %: < $30,000: 59 Insurance status, %: Uninsured: 2 Education, %: HS grad: 75 Other characteristics, %: Married or living as married: 63 Health literacy/numeracy levels, %: Limited: 17 Adequate: 83

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Heart failure Covariates used in multivariate analysis: NA Description of outcome measures: Heart failure measured through Self-administered Comorbidity Questionnaire, modified from the Charlson Index Data source(s) for outcomes: Self-report Attempts for control for confounding: None Blinding: NA Statistical measures used: Chi-square tests	Describe results: Diabetes patients with limited literacy were significantly more likely to have heart failure than those with adequate literacy. Effect in no exposure (i.e., adequate literacy) or control group, %: Heart failure: 15 Effect in exposure (i.e., low/moderate literacy) or intervention: inadequate/marginal Heart failure: 27 Difference: Difference in Heart failure rate (unadjusted), OR (CI): 2.05 (1.39-3.02)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Lee et al., 2009[16] (Companion: Cho et al., 2008[15]) Research objective: Examine whether social support interacts with HL in affecting the health status of older adults Study design: Cross-sectional Study setting: 1 hospital and 1 Community Health Center in Chicago Measurement period: 1999-2003 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA: Inadequate Health Literacy: 0-16 Marginal Health Literacy: 17-22 Adequate Health Literacy: 23-36	Eligibility criteria: Included: 65 and older Medicare recipient One or more outpatient visit between 1999-2003 Cognitively intact, good vision Good hearing English speaking Not living in a nursing home. Excluded: NR Sampling strategy: Convenience Sample size: 489 Age (mean and range): 77.8 Gender, %: Females: 79.6 Race/Ethnicity, %: AA: 54.4 Income: NR Insurance status, %: Medicare: 100 Education, %: <HS: 39.7 HS diploma: 26.8 Some college: 33.5 Other characteristics: NA Health literacy/numeracy levels, %: Low HL (inadequate + marginal): 51

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Health status Covariates used in multivariate analysis: Age Gender Race Education Marital status Income Social support level Description of outcome measures: General health, measured by: 5 point Likert scale Compared with your peers, how would you rate your health? Mental health and physical health measured through SF12 Data source(s) for outcomes: Interview Attempts for control for confounding: Multivariate analyses Blinding: NR Statistical measures used: OLS regression and stratified OLS	Describe results: Low HL was sig negatively associated with self-reported general health and not sig associated with physical and mental health status. Greater social support had a sig and pos association with general, physical, and mental health in high HL group but was only associated with a better mental health outcome in the low HL group. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Difference in low HL (adjusted), β (SE): General health: -0.259 (0.115), $P < 0.05$ Physical Health: -0.107 (0.112), P = NS Mental Health: -0.182 (0.111), P = NS HL and social support interaction (adjusted): General health, β (SE): Low HL x social support: 0.82 (0.071), P = NS High HL x social support: 0.280 (0.084), $P < 0.01$ Physical health, β (SE): Low HL x social support: 0.79 (0.066), P = NS High HL x social support: 0.308 (0.089), $P < 0.001$ Mental health, β (SE): Low HL x social support: 0.213 (0.074), $P < 0.01$ High HL x social support: 0.367 (0.073), $P < 0.001$

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: LeVine et al., 2004[40] Research objective: Explore whether literacy skills influence mothers' ability to understand health messages in text and radio and health narrative skills Study design: Cross-sectional study Study setting: Patan (urban) and Godavari (rural) Nepal Measurement period: October 1996 - June 1998 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: Literacy measured as continuous and a composite score of reading comprehension and noun definition. Reading comprehension: assessed in Nepali, using 6 health-related texts graded by difficulty of comprehension according to school grade levels 1, 3, 5, 7, 9 and first post-secondary year. Comprehension assessed through questions based on texts. Score was grade level at which able to answer 50% of questions. Scores were converted into a continuous scale of 0–6. Noun definitions: assessed by asking participant to define 10 nouns for common objects, such as ‘‘dog,’’ with the question, ‘‘What is a ?’’ Responses were scored for the presence of superordinate category membership (‘‘a dog is an animal’’). Scores were the mean number of objects for which a superordinate term like was given.	Eligibility criteria: Included: Mothers who have children in kindergarten or class 1 of primary school Excluded: NR Sampling strategy: Convenience sampling from a cluster of households in center of designated neighborhood in each community. Interviewers canvassed the neighborhood, from center outward, for women with designated characteristics until a sample of at least 80 women Sample size: 167 Age (mean and range) (SD): Patan: 30.8 (4.9) Range: 22-59 Godavari: 28 (3.9) Range: 20-38 Gender, %: Females: 100 Race/Ethnicity: NR Income: NR Insurance status: NR Education: NR Other characteristics: NR Health literacy/numeracy levels: NR

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Comprehension of printed health messages Comprehension of radio health messages Health narrative skills Covariates used in multivariate analysis: Maternal schooling Childhood SES Age Current SES Husband's schooling Urban/rural dummy Description of outcome measures: Comprehension of radio health messages: Tape recording played of 3 health messages that were broadcast regularly on the radio (use of oral rehydration salts, family planning, vaccinations). Content of each message was divided into idea units. Participant recall was evaluated. Responses were coded for idea units mentioned, total number of which constituted a score (scores 0-29). Comprehension of printed health messages: Participants presented with 3 radio messages to read and recall was evaluated. Responses were coded for idea units (scores 0 -27). Health narrative skills: This task was designed to simulate the response to questioning in a health clinic. Participants were asked to recount a health problem they, one of their children, or a relative, had. Interviewers were instructed to ask mostly general questions (e.g., and then what happened?) to move the narrative along. If a participant seemed to provide too short an account or was missing a lot of important information, interviewers asked more specific questions. A maximum of 10 specific questions was allowed. Narratives were dichotomized as organized or disorganized. Data source(s) for outcomes: Participant performance on assessments and self-report in interview Attempts for control for confounding: Multivariate logistic regression Blinding: NA Statistical measures used: Multinomial regression, logistic regression. Analysis of comprehension of visual print messages limited to sample with HS ed.	Describe results: Higher literacy composite score was predictor of better understanding of print and radio health messages and giving more organized health narrative. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Comprehension of audio radio health messages (adjusted), β (SE): 1.11 (0.18), $P < 0.001$ Comprehension of visual print health messages (adjusted), β (SE): 1.08 (0.21), $P < 0.001$ Probability of giving an organized health narrative: logic estimate: 0.73, $P < 0.01$

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Lincoln et al., 2006[41] Research objective: Examine relationship between low HL and addiction severity, depressive symptoms, and mental health functioning in adults with alcohol and drug dependence over 2-year period. Study design: Prospective cohort Study setting: 35-bed inner-city short-term inpatient detoxification unit Measurement period: June 1997 - March 1999 Follow-up duration: NR Completeness of follow-up: NR Measurement tools including cutpoints: REALM Low Literacy: 8th grade and below Higher Literacy: 9th grade and above	Eligibility criteria: Included: Inpatient detox admission Age greater than 17 Report of alcohol, heroin, or cocaine as substances of 1st or 2nd choice Excluded: Having a primary care provider and having seen provider on at least one occasion in past 2 years Pregnancy Mini-Mental State examination score less than 21 Lack of fluency in English Less than 3 contacts available to facilitate follow-up Specific plans to leave Boston in 2 years Sampling strategy: Convenience Sample size: 390 Age, mean (SD): 36 (7.64) Gender, %: Males: 76 Race/Ethnicity, %: Black: 53 White: 35 Hispanic: 6 Other: 6 Income, %: <$19,000: 58 $20,000-49,000: 34 >$50,000: 9 Insurance status: NR Education, mean (SD): Years formal education: 11.98 (1.98) Other characteristics, %: Primary Substance of Choice: Alcohol: 37 Cocaine: 36 Heroin: 27 Health literacy/numeracy levels, %: Low Literacy: 46 Higher Literacy: 54

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: CES-D, mean (SD): 33.03 (12.56) Addition Severity Index-alcohol scale (ASI-Aic), mean (SD): 0.47 (0.34) Addition Severity Index-drug scale (ASI-drug), mean (SD): 0.26 (0.14) Mental Component Summary of SF-36 (MCS), mean (SD): 31.18 (12.75) Covariates used in multivariate analysis: Time Sex Age Race Education Income Primary language Primary substance of choice Randomization group Mini-mental status exam Baseline outcomes variable Description of outcome measures: CES-D: measures depressive symptoms with higher scores indicating greater levels of distress. Range from 0 to 60 with a score ≥ 16 interpreted as a clinically significant level of distress. ASI-Drug: assesses addiction severity with composite scores ranging from 0 to 1. ASI-Alc: assesses addiction severity with composite scores ranging from 0 to 1. MCS: assesses mental health-related quality of life, scores ranging from 0 to 100 with higher scores indicating higher quality of life. Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Regression including controlling for time	Describe results: Lower literacy among alcohol and drug dependent individuals is not associated with any mental health outcomes in cross sectional analysis but is associated with higher degree of depressive symptoms in longitudinal models. Adding use of health care Effect in no exposure (i.e., adequate literacy) or control group, mean (SD): CES-D: 34.82 (13.32) ASI-Alc: 0.48 (0.34) ASI-Drug: 0.26 (0.15) MCS: 29.67 (12.39) Effect in exposure (i.e., low/moderate literacy) or intervention, mean (SD): CES-D: 30.91 (11.26) ASI-Alc: 0.46 (0.34) ASI-Drug: 0.26 (0.13) MCS: 33.02 (12.97) Difference: Difference in CES-D: (Adjusted-cross sectional): ($P = 0.09$) (Adjusted-longitudinal): ($P < 0.01$) ASI-Alc: (Adjusted-cross sectional): ($P = 0.88$) (Adjusted-longitudinal): ($P = 0.86$) ASI-Drug: (Adjusted-cross sectional): ($P = 0.11$) (Adjusted-longitudinal): ($P = 0.35$) MCS: (Adjusted-cross sectional): ($P = 0.42$) (Adjusted-longitudinal): ($P = 0.14$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Lindau et al., 2006[42] Research objective: Examine relationship between literacy and patient adherence to follow-up recommendations after abnormal pap smear. Study design: Prospective cohort Study setting: Clinics at Chicago area academic medical center Measurement period: January - December 1999 Follow-up duration: One year Completeness of follow-up: Patients that did not come back after enrollment were classified in the 'did not follow up' category Measurement tools including cutpoints: REALM: Adequate, ≥ 9th grade: ≥ 61	Eligibility criteria: Included: Self-identified English speaking Excluded: < 18 years old Missing data Sampling strategy: Convenience Sample size: 68 Age (range), %: Adequate Health Literacy: 18-24: 34 25-30: 25 31-39: 27 40-49: 14 Inadequate Health Literacy: 18-24: 46 25-30: 17 31-39: 20 40-49: 17 Gender, %: Females: 100 Race/Ethnicity, %: Adequate Health Literacy: AA: 52 Hispanic: 21 White: 18 Other: 9 Inadequate Health Literacy: AA: 67 Hispanic: 29 White: 4 Other: 0 Insurance status, %: Adequate Health Literacy: Medicaid: 64 Private: 27 Self pay/no insurance: 9 Inadequate Health Literacy: Medicaid: 92 Private: 8 Self pay/no insurance: 0 Education: NR

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: On-time patient follow-up Patient follow-up Duration of time to follow-up Covariates used in multivariate analysis: Age HIV status Cancer Race Unemployment Insurance status Description of outcome measures: On-time patient follow-up Patient follow-up Duration of time to follow-up Data source(s) for outcomes: Patient charts Attempts for control for confounding: Multivariate analysis Blinding: No Statistical measures used: Logistic regression Cox proportional hazards regression	Describe results: HL not statistically significant in predicting women's on-time follow-up after an abnormal Pap smear or follow-up within 1 year. Effect in no exposure (i.e., adequate literacy) or control group: Recommended days to follow-up, mean (SD): 89.3 (53.4) Patient followed up on time, %: 66 Patient followed up within one year, %: 80 Days to follow-up, %: 0-60: 26 61-120: 26 121-180: 20 181 - 365: 28 HIV Positive: 36 Effect in exposure (i.e., low/moderate literacy) or intervention: Recommended days to follow-up: mean (SD): 87.6 (62.0) Patient followed up on time, %: 33 Patient followed up within one year, %: 67 Days to follow-up, %: 0-60: 31 61-120: 7 121-180: 31 181 - 365: 31 HIV Positive: 25 Difference: Difference in recommended days to follow up (unadjusted): (P = 0.99) Difference in Patient followed up on time (adjusted), OR (CI): 2.05 (0.47-8.85) Difference in patient followed up within one year (adjusted), OR (CI): 3.75, 95% (0.81-17.4) Difference in HIV status (unadjusted): (P = 0.45)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Lindau et al., 2006[42] (continued)	Other characteristics: Adequate Health Literacy Unemployed: 50 Inadequate Health Literacy Unemployed: 63 Health literacy/numeracy levels, %: Adequate literacy: 65 Inadequate literacy: 35 Subjective health literacy: Adequate: 59 Inadequate: 41

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Mancuso and Rincon, 2006[43] (Companion: Mancuso and Rincon, 2006[44]) Research objective: Measure association between health literacy and asthma outcomes and to assess if effect of health literacy is mediated through covariates Study design: Prospective cohort Study setting: Cornell Internal Medicine Associates, a primary care practice serving patient of diverse socioeconomic groups from all areas of New York City. Measurement period: 1995-1999 Follow-up duration: 2 years Completeness of follow-up: NR Measurement tools including cutpoints: TOFHLA Adequate literacy: ≥75 Inadequate/Marginal literacy: <74	Eligibility criteria: Included: Adults enrolled in an observational study Require daily asthma medications Completed TOFHLA Excluded: NR Sampling strategy: Convenience Sample size: 175 Age (mean and range) (SD): 42 (10) Gender, %: Females: 83 Race/Ethnicity, %: White: 20 AA: 31 Latino: 41 Mixed/other: 8 Income: NR Insurance status, %: Medicaid: 45 Education, %: College graduate: 33 High school graduate: 42 Less than High School: 25 Other characteristics, % (SD): Duration Asthma: 21 years (14) Prior hospitalization asthma: 50 Daily corticosteroids inhaler: 78 Daily beta antagonist inhaler: 93 Daily beta antagonist oral: 6 Described access to care as very difficult: 8 Health literacy/numeracy levels, %: Adequate literacy: 82 Marginal literacy: 8 Inadequate literacy: 10

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: AQLQ SF-36 PCS Resource utilization for asthma Covariates used in multivariate analysis: Asthma severity Asthma self-efficacy Age Education Depressive symptoms Asthma knowledge Description of outcome measures: AQLQ - 32 item well established scale measuring asthma symptoms SF-36 PCS- physical component summary scores for functional status Resource utilization for Asthma - self report of ED visits, self-report Data source(s) for outcomes: AQLQ, SF-36, and ED visits: self report Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Bivariate analysis: t tests, analysis of variance, and chi-squared tests. Multivariate analysis for continuous and dichotomous outcomes. Mixed effects models with random subject effects were used for analysis of outcomes that were continuous. Forward stepwise regression.	Describe results: Health Literacy is not statistically significantly related to asthma and more general health outcomes variables after controlling for asthma knowledge and depressive symptoms. Effect in no exposure (i.e., adequate literacy) or control group, % (SD): Duration Asthma: 20 years (14) Prior hospitalization asthma: 48 Daily corticosteroids inhaler: 78 Daily beta antagonist inhaler: 93 Daily beta antagonist oral: 6 Access to care very difficult: 8 Effect in exposure (i.e., low/moderate literacy) or intervention, % (SD): Duration Asthma: 25 years (15) Prior hospitalization asthma: 59 Daily corticosteroids inhaler: 75 Daily beta antagonist inhaler: 93 Daily beta antagonist oral: 3 Access to care very difficult: 9 Difference: Difference in duration asthma (unadjusted): (P = 0.06) Difference in prior hospitalization asthma (unadjusted): (P = 0.23) Daily corticosteroids inhaler (unadjusted): (P = 0.68) Daily beta antagonist inhaler (unadjusted): (P = 0.88) Daily beta antagonist oral (unadjusted): (P = 0.46) Access to care very difficult (unadjusted): (P = 0.76) Difference in AQLQ (adjusted), β: Controlling for asthma severity: 0.69, P=0.005 Controlling for 1. and Asthma self-efficacy: 0.61, P = 0.003 Controlling for 2. and age, education: 0.52, P = 0.03 Controlling for 3. and depressive symptoms: 0.40, P = 0.07 Controlling for 4. and asthma knowledge: 0.20, P = 0.38 Difference in SF-36 PCS (adjusted), β: Controlling for asthma severity: 6.69, P = 0.0005 Controlling for 1. and Asthma self-efficacy: 6.29, P = 0.0003 Controlling for 2. and age, education: 3.00, P = 0.11 Controlling for 3. and depressive symptoms: 2.23, P = 0.22 Controlling for 4. and asthma knowledge: 1.21, P = 0.53 Difference in treated in ED (adjusted), β: Controlling for asthma severity: 0.93, P = 0.04 Controlling for 1. and Asthma self-efficacy: 0.94, P = 0.03 Controlling for 2. and age, education: 1.11, P = 0.02 Controlling for 3. and depressive symptoms: 1.01, P = 0.04 Controlling for 4. and asthma knowledge: 0.95, P = 0.07

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Mancuso and Rincon, 2006[44] (Companion: Mancuso and Rincon, 2006[43]) Research objective: Measure health literacy and its association with asthma patients' assessments of care and their desire to participate in making decisions about their treatment. Study design: Cross-sectional Study setting: Cornell Internal Medicine Associates, a primary care practice in New York City. Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: TOFHLA Adequate literacy: ≥75 Inadequate/Marginal literacy: <74	Eligibility criteria: Included: Require daily asthma medications, but not daily oral corticosteroids Completed TOFHLA Excluded: NR Sampling strategy: Convenience Sample size: 175 Age, mean (SD): 42 (10) Gender, %: Females: 83 Race/Ethnicity, %: White: 19 AA: 31 Latino: 41 Mixed/other: 9 Income, %: Per household member: ≤$12,000: 59 Insurance status, %: Medicaid: 45 Education, %: High school graduate: 73 Other characteristics, %: Prior hospitalization asthma: 50 Daily corticosteroids inhaler: 78 Asthma exacerbations more than once/month: 62 Medical conditions in addition to asthma: 28 Health literacy/numeracy levels, %: Adequate literacy: 82 Marginal literacy: 8 Inadequate literacy: 10

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Less satisfied with asthma status More difficult to access to asthma care Worse results from care for asthma More difficult access to medical care for other medical conditions Worse results from care for other medical conditions Does not want to part Covariates used in multivariate analysis: Covariates used in models predicting satisfaction with asthma status, difficulty of accessing asthma care, results from asthma care, decision making participation: Sex Race/ethnicity Language Asthma duration Asthma severity Asthma control Covariates used Description of outcome measures: Satisfaction with asthma status: "Overall, how satisfied are you with the status of your asthma?" Responses: very satisfied to very dissatisfied on a 5-point scale Access to asthma care:"How difficult is it for you to get care for your asthma?" Responses: Data source(s) for outcomes: Patient self-report Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Multivariate analysis	Describe results: Lower HL was associated with less satisfaction with asthma status, worse results from care for asthma, more difficult access to medical care for other medical conditions, and want to have less participation in treatment decision making. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Difference (effect of) marginal/inadequate HL on (adjusted): Less satisfied with asthma status: (P = 0.002) More difficult to access asthma care: (P = 0.58) Worse results from care for asthma: (P = 0.005) More difficult access to medical care for other medical conditions: (P = 0.005) Worse results from care for other medical conditions: (P = 0.001) Does not want to participate in making treatment decisions, OR (CI): 0.29 (0.13-0.65)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Mancuso, 2010[45] Research objective: To examine if health literacy and patient trust in one's health care provider impacts gylcemic control in an uninsured population diagnosed with diabetes. Study design: Cross-Sectional Study setting: 2 urban mid-western US primary care clinics Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: TOFHLA (0-100): Inadequate: 0-59 Marginal: 60-74 Adequate: 75-100	Eligibility criteria: Inclusion: ≥ 18 years Ability to speak fluent English Diagnosis of type 1 or 2 diabetes HbA1c test with a 6 month period Primary healthcare provider that had been following and had seen the participants at least twice in the past year. Exclusion: A diagnosis of end-stage renal disease, psychotic disorder, dementia, or blindness Sampling strategy: Convenience sample Sample size: N = 102 Age (mean and range), %: Mean (SD): 52.0 (9.10) Range: 26-67 Gender, %: Female: 61% Race/Ethnicity, %: Race, %: Non-Hispanic Caucasian: 13 Non-Hispanic Black/African American: 79 Hispanic/Latino American: 6 Other: 2 Income, %: NR Insurance status, %: Uninsured: 100% Education, %: Education: <7th grade:1.0 Junior hs (9th grade): 8.8 Partial hs (10th or 11th grade): 23.5 HS graduate: 37.3 Partial college/specialized traing (at least 1 year): 21.6 College or university graduate: 7.8 Other characteristics, %: Diabetes type: Type 1: 3.9 Type 2: 96.1 Duration of diabetes in years: < 1: 10.8 1-5: 50.0 6-10: 25.5 12-18: 8.8 20-23: 2.9

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: HbA1c Covariates used in multivariate analysis: Patient trust measured through Health Care Relationship Trust Scale), depression (measured through Center for Epidemiological Studies Depression Scale), diabetes knowledge (measured through Diabetes Knowledge Test), and performance of self-care activities (measured through Summary of Diabetes Self-Care Activities) Description of outcome measures: Diabetes outcome was assessed by HbA1c measured at one point in time over past 6 months. Adequate glycemic control was a HbA1c of ≤ 7%. Inadequate glycemic control was a HbA1c of > 7%. Data source(s) for outcomes: HbA1c obtained from provider Attempts for control for confounding: Multiple regression analysis Blinding: NR Statistical measures used: Cronbach's alpha was calculated and determine the reliabilityh of the TOFHLA, HCR Trust Scale, DKT, SDSCA, and CES-D Multiple regression analysis; correlation coefficients Pearson's r and Spearman rho	Describe results: HL was not a sig predictor of HbA1c. However, HL was sig correlated with other included variables including age, socioeconomic status, and diabetes knowledge. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Health literacy (measured as a continuous variable) (adjusted): B = -0.063 (0.080) (P = 0.436)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Mancuso, 2010[45] (continued)	Diabetes treatment: Oral medications: 63.7 Insulin: 19.6 Oral medications and insulin: 14.7 Diet: 2.0 Diabetes complications (comorbidities): Hypertension: 81.4 Depression: 27.5 HbA1c: ≤ 7.0 (controlled diabetes): 35.3 > 7.0 (uncontrolled diabetes): 64.7 Health literacy/numeracy levels, %: TOFHLA (0-100), %, mean (SD), range: Inadequate: 15.7; 31.3 (20.20); 0-56 Marginal: 20.6; 67.7 (4.00); 61-74 Adequate: 89.5 (6.50); 76-100

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Marteleto et al., 2008[46] Research objective: Study effects of literacy/numeracy on sexual debut and pregnancy. Study design: Longitudinal Study setting: Metropolitan Cape Town South Africa Measurement period: Wave 1: 2002 Wave 2: 2003-2004 Wave 3: 2005 Wave 4: 2006 Follow-up duration: 3-4 years Completeness of follow-up: Attrition: 18% Measurement tools including cutpoints: Cape Area Panel Study Literacy and Numeracy evaluation - scores standardized, enter probit regressions as continuous variables	Eligibility criteria: Included: Young people in Cape Town, 14-22 years old at time of Wave 1 Excluded: NR Sampling strategy: 2 stage probability sample of households; up to 3 youth per household Sample size: Age 14-22: Wave 1: 4,751 Wave 3 or 4: 3,916 Age 14-16: Wave 1: 1,591 Wave 3 or 4: 1,413 Age (mean and range): Separate analyses done in 14-22 and 14-16, means not provided Gender, %: Male: Wave 1: 46.6 (calculated) Wave 3: 46.2 (calculated) Race/Ethnicity, %: Weighted Percentage: Black/African: 28.2 Colored: 53.2 White: 18.6 Income: Wave 1: (South African rands/month) African: Male: 372 Female: 353 Colored: Male: 888 Female: 865 White: Male: 3,972 Female: 3,917 Wave 3: (South African rands/month) African: Male: 372 Female: 354 Colored: Male: 892 Female: 870 White: Male: 3,950 Female: 4,008

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Sexual debut Pregnancy Covariates used in multivariate analysis: Grades completed Enrolled in 2002 Age Age since 14 Race Income Household shock Mother's education Father's education Living with mother Living with father Description of outcome measures: Sexual debut: dichotomous Pregnancy: dichotomous Data source(s) for outcomes: Cape Area Panel Survey Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Probit regressions	Describe results: Higher literacy/numeracy scores significantly predict lower probability of sexual debut; Literacy/numeracy scores not statistically significant in predicting pregnancy. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: An increase in literacy/numeracy exam score by one standard deviation results in a 7% reduction in probability of sexual debut, $P < 0.05$. First pregnancy probit coefficient (adjusted): Females: 0.41 (not sig at 0.05 level or better) Males: -0.030 (not sig)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Marteleto et al., 2008[46] Research objective: Study effects of literacy/numeracy on sexual debut and pregnancy. Study design: Longitudinal Study setting: Metropolitan Cape Town South Africa Measurement period: Wave 1: 2002 Wave 2: 2003-2004 Wave 3: 2005 Wave 4: 2006 Follow-up duration: 3-4 years Completeness of follow-up: Attrition: 18%	Insurance status: NR Education: Wave 1: (number of grades completed) African: Male: 6.83 Female: 7.43 Colored: Male: 7.63 Female: 8.07 White: Male: 8.02 Female: 8.13 Wave 3: (number of grades completed) African: Male: 6.89 Female: 7.42 Colored: Male: 7.64 Female: 8.09 White: Male: 8.12 Female: 8.10 Other characteristics: NR Health literacy/numeracy levels: Wave 1: (standardized scores) African: Male: -0.68 Female: -0.52 Colored: Male: -0.03 Female: -0.05 White: Male: 1.17 Female: 1.07 Wave 3: (standardized scores) African: Male: -0.63 Female: -0.54 Colored: Male: -0.02 Female: -0.04 White: Male: 1.23 Female: 1.0

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Mayben et al., 2007[47] Research objective: Assess relationship between HL and CD4 cell counts at time of HIV diagnosis Study design: Cross-sectional Study setting: Patients receiving care at 4 publicly funded health care facilities in Houston, TX Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: TOFHLA Inadequate (combined inadequate and marginal): 0 - 74 Adequate: 75 - 100	Eligibility criteria: Included: Diagnosed with HIV in past 3 years Accessible med records Excluded: <18 years old Not able to communicate in English or Spanish Blind, too sick to participate Did not receive care at one of the four clinics Katrina evacuee Cognitively impaired Sampling strategy: Convenience sample Sample size: 119 Inadequate, n = 33 Adequate, n = 86 Age (range), %: 18-29: 22 30-39: 28 40-49: 34 >50: 16 Gender, %: Females: 36 Race/Ethnicity, %: Black: 53 White: 33 Other/mixed: 14 Hispanic: 28 Not Hispanic: 72 Income: NR Insurance status: NR Education, %: <HS: 28 HS/GED: 43 Some higher education: 29 Other characteristics, %: HIV Risk Factor Men who have sex with men: 28 Injection drug use: 13 Heterosexual intercourse: 60 Health literacy/numeracy levels: Inadequate: 28 Adequate: 72

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Delayed diagnosis of HIV (measured by CD4 count upon initial diagnosis) Covariates used in multivariate analysis: Gender Reason for getting tested Marijuana Description of outcome measures: Initial CD4 cell count was abstracted from medical records and was defined as first CD4 cell count recorded after diagnosis of HIV infection. Initial CD4 cell counts were stratified into 3 categories (0–200 cell/mm3, 201–350 cells/mm3, 350 cells/mm3) based on clinical parameters and cross-tabulated with health literacy. Data source(s) for outcomes: Medical record Attempts for control for confounding: Multivariable regression Blinding: NA Statistical measures used: Univariable and multivariable linear regression. CD4 cell counts were natural log transformed in regression analyses. Explanatory variables with a $P < 0.25$ in univariable regression analysis were placed into a multivariable regression model and then selectively removed at $P > 0.10$ to determine final model.	Describe results: Health literacy was not associated with CD4 cell count at diagnosis. Interaction terms of health literacy and reason tested, and health literacy and gender were also not significantly associated with initial CD4 cell count in separate analyses. Effect in no exposure (i.e., adequate literacy) or control group: Median CD4 cell count: 247 Interquartile range: 31, 517 Effect in exposure (i.e., low/moderate literacy) or intervention: Median CD4 cell count: 175 Interquartile range: 69, 272 Difference: Difference (adjusted): ($P = 0.35$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Miller et al., 2007[48] Research objective: Determine association between health literacy and colorectal cancer screening (CRC) screening behavior. Study design: Cross-sectional Study setting: Private setting associated with Wake Forest University community-based internal medicine clinic. Measurement period: 38,231 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM Limited: < 9th grade Adequate: 9th +	Eligibility criteria: Included: English-speaking 50+ years Excluded: Obvious cognitive or physical impairments that would interfere with ability to complete survey Sampling strategy: Convenience sample Sample size: 50 Limited, n = 24 Adequate, n = 26 Age, mean (SD): Total: 62.5 Limited: 62.9 (10.5) Adequate: 62.2 (9.2) Gender, %: Female: 72 Limited: 71 Adequate: 73 Race/Ethnicity, %: Total AA: 58 White: 42 Limited: AA:75 White: 25 Adequate: AA: 42 White: 58 Income, %: Total: <$25,000: 87 Limited: <$25,000: 79 $25,000 +: 8 Adequate: <$25,000: 81 $25,000 +: 15 Insurance status, %: Limited: Uninsured: 25 Medicare: 46 Medicaid: 38 Commercial/Military: 21

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Receipt of screening (according to CRC screening guidelines) Covariates used in multivariate analysis: Age Description of outcome measures: Self-report of last time received screening, if ever. Completed screening defined as: FOBT within last year flex sig within 5 years colonoscopy within 10 years. Data source(s) for outcomes: In-person survey administered by study staff Attempts for control for confounding: To construct logistic regression model, examined bivariate association of literacy level and receipt of CRC screening with each possible covariate. Variables sig at 5% level from bivariate analyses were included in final multivariable logistic regression model. Given that education is highly correlated with literacy, they did not include education in multivariable model. Blinding: Literacy and demographic data were collected at completion of survey to keep surveyor blinded to literacy level. Statistical measures used: Chi-square Fisher's Exact tests Logistic regression Exact logistic regression performed using network method described by Mehta et al. Estimates of adjusted RR for receipt of CRC screening obtained using Cochran-Mantel-Haenszel methods since multivariable modeling resulted in at most only one other covariate additional to literacy level.	Describe results: There was no significant difference in self-reported receipt of screening between limited literacy and high literacy patients. Effect in no exposure (i.e., adequate literacy) or control group: CRC Screening current, n (%): Yes: 15 (58) Effect in exposure (i.e., low/moderate literacy) or intervention: CRC Screening current, n (%): Yes: 13 (54) Difference: Difference (adjusted), RR (CI): 0.99 (0.64 -1.55)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Miller et al., 2007[48] (continued)	Adequate: Uninsured: 15 Medicare: 54 Medicaid: 54 Commercial/Military: 23 Education, %: Limited: <HS: 71 HS: 29 >HS: 0 Adequate: <HS: 31 HS: 23 >HS: 46 Other characteristics, %: Frequency of medical visits Limited < 4/yr: 33 4+/yr: 67 Adequate: < 4/yr: 20 4+/yr: 80 Health literacy/numeracy levels, %: Limited: 48 Adequate: 52

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Morris et al., 2006[49] Research objective: Explore whether low HL among diabetic adults is related to being less likely to achieve recommended goals for A1C, systolic blood pressure, diastolic blood pressure, and low density lipoprotein and having more complications related to their diabetes Study design: Cross-sectional Study setting: Patients in a region-wide sample of primary care practices in Vermont. Measurement period: July 2003 - March 2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA: Inadequate Literacy: 0-16 Marginal Literacy: 17-22 Adequate Literacy: 23-36	Eligibility criteria: Included: Diabetes diagnosis Adult Excluded: Major cognitive impairment Poor vision or other physical impairment that could affect HL assessment Sampling strategy: Randomized subsample from list of participants in Vermont Diabetes Information System until reached 15% participation across all member primary care practices. Sample size: 1,002 Age (range): 66 (56-79) Gender, %: Males: 46 Race/Ethnicity, %: White: 97 Income, %: Annual income >$30,000: 59 Insurance status, %: Private insurance: 58 Medicare: 60 Medicaid: 21 Military/VA: 5 No insurance: 2 Education, %: Some high school or less: 25 High school graduate: 36 College graduate/some college: 31 Graduate education: 9 Other characteristics, %: Married/living as married: 63 Alcohol intake: > 1 drink/week: 20 Years with diabetes, median (IQR): 6.8 (3-14) Attended diabetes class: 35 Treatments for diabetes: Diet alone: 24 Oral hypoglycemic alone: 57 Insulin alone: 9 Insulin and oral agent: 9 Hypertension medications: 83 Cholesterol medications: 59

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: A1C Systolic Blood Pressure Diastolic Blood Pressure LDL-cholesterol Diabetes Complications Retinopathy Nephropathy Gastroparesis Foot/leg problems Cerebrovascular disease Coronary artery disease Depression, Patient Health Questionnaire-9: >9, dictomous Depression Score-Patient Health Questionnaire(0-27), median (IQR): 2 (0-6) Covariates used in multivariate analysis: Age Sex Race Marital status Insurance Income Duration of diabetes Education Depression Alcohol use Medication use specific to each outcome Physician practice Description of outcome measures: Glycated hemoglobin (A1C) Systolic Blood Pressure Diastolic Blood Pressure LDL-cholesterol Diabetes Complications - self report of: Retinopathy, Nephropathy, Gastroparesis, Foot/leg problems, Cerebrovascular disease, Coronary artery disease Depression, Patient Health Questionnaire Depression Score-Patient Health Questionnaire Data source(s) for outcomes: A1C - lab values Systolic Blood Pressure - lab value; Diastolic Blood Pressure - lab value; LDL-cholesterol - lab values Diabetes Complications - self report of: Retinopathy Nephropathy Gastroparesis Foot/leg problems Cerebrovascular disease Coronary	Describe results: HL is not associated with glycated hemoglobin, blood pressure, lipid levels or self reported diabetes complications in a cross-sectional study of older adults with diabetes under relatively good glycemic control. Effect in no exposure (i.e., adequate literacy) or control group: A1C, median: 6.9 SBP, median: 138 DBP, median: 79 LDL-cholesterol, median: 99 Complications from Diabetes: Retinopathy, %: 18 Nephropathy, %: 9 Gastroparesis, %: 6 Foot/leg problems, %: 30 Cerebrovascular disease, %: 10 Coronary artery disease, %: 17 Depression, Patient Health Questionnaire > 5, %: 31 Depression, Patient Health Questionnaire Score, median (IQR): 2 (0-6) Effect in exposure (i.e., low/moderate literacy) or intervention: A1C Inadequate: median 6.9 Marginal: median 6.8 SBP Inadequate: median 137 Marginal: median 144 DBP Inadequate: median 76 Marginal: median 77 LDL-cholesterol Inadequate: median 99 Marginal): median 94 Complications from Diabetes (Inadequate), %: Retinopathy: 30 Nephropathy: 15 Gastroparesis: 9 Foot/leg problems: 30 Cerebrovascular disease: 21 Coronary artery disease: 30 Complications from Diabetes (Marginal), %: Retinopathy: 34 Nephropathy: 0 Gastroparesis: 10 Foot/leg problems: 44 Cerebrovascular disease: 17 Coronary artery disease: 27

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Morris et al., 2006[49] (continued)	Health literacy/numberacy levels: Inadequate Literacy: 10 Marginal Literacy: 7 Adequate Literacy: 83

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Regression analysis was used to measure association between HL and A1C, SBP, DBP, Low Density Lipoproteins. Multivariate logistic regression was used to measure association between HL and self-reported retinopathy, neuropathy, gastroperesis, foot and leg ulcerations, cerebrovascular disease, and coronary artery disease. Bivariate analysis examined relationship between HL and depression.	Depression, Patient Health Questionnaire >5: Inadequate: 40 Marginal: 54 Depression, Patient Health Questionnaire Score Inadequate, median: 3 Marginal, median: 5 Difference: Difference in DBP (adjusted, TOFHLA measured as continuous): (*P* = 0.39) Difference in LDL-cholesterol (adjusted, TOFHLA measured as continuous): (*P* = 0.59) Diabetes Complications (Adjusted) Difference in Retinopathy Adequate vs. Inadequate: (*P* = 0.09) Difference in Retinopathy Adequate vs. Marginal: (*P* = 0.21) Difference in Nephropathy Adequate vs. Inadequate: (*P* = 0.93) Difference in Nephropathy Adequate vs. Marginal: (*P* = 0.53) Difference in Gastroparesis Adequate vs. Inadequate: (*P* = 0.28) Difference in Gastroparesis Adequate vs. Marginal: (*P* = 0.55) Difference in Foot/leg problems Adequate vs. Inadequate: (*P* = 0.11) Difference in Foot/leg problems Adequate vs. Marginal: (*P* = 0.55) Difference in Cerebrovascular disease Adequate vs. Inadequate: (*P* = 0.72) Difference in Cerebrovascular disease Adequate vs. Marginal: (*P* = 0.54) Difference in Coronary artery disease Adequate vs. Inadequate: (*P* = 0.49) Difference in Coronary artery disease Adequate vs. Inadequate: (*P* = 0.85) Difference in Depression, Patient Health Questionnaire-9 Score > 5 across literacy categories (unadjusted): (*P* = 0.03) Difference in Depression Score-Patient Health Questionnaire across literacy categories (unadjusted): (*P* = 0.04)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Muir et al., 2008[50] Research objective: Assess relationship between health literacy and vision-related quality of life (VRQol), general HRQoL and mental HRQol Study design: Cross-sectional survey and medical chart review Study setting: Glaucoma patients at the Duke University Eye Center Measurement period: 1-time survey administered between July 2000 and June 2001 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: Low: ≤ 8th grade Adequate: ≥ 9th grade	Eligibility criteria: Included: ≥18 Glaucoma diagnosis Presence of visual field tests in the medical record Excluded: Refused to participate Low cognitive status Sampling strategy: All patients at clinic at time of study Sample size: 195 Multivariate analysis: N=110 Age (mean and range), %: ≤65: 28 66-73: 22 74-80: 26 >80: 23 Gender, %: Female: 59 Race/Ethnicity, %: White: 55 Black: 42 Income: NR Insurance status: NR Education, %: ≥HS: 75 <HS: 25 Other characteristics: Health literacy/numeracy levels, %: Low: 52 Adequate: 48

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: 1. VRQoL 2. General HRQol 3. Mental HRQol Covariates used in multivariate analysis: Age Race Visual acuity Visual fields SF-12 score (as a surrogate for co-morbid conditions) Description of outcome measures: VRQoL: 25-item Visual Function Questionnaire (VFQ-25) Total score based on following subscales: General health General vision Near vision Distance vision Driving Peripheral vision Color vision Ocular pain Role limitations Dependency Social Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis: controlled for agenrace, visual acuity, visual field, and education. A second model excluded education. Blinding: NA Statistical measures used: Relationship between VRQoL and HL was measured using bivariate analysis and linear regression for the multivariate analysis	Describe results: In bivariate analysis, low health literacy was associated with physical HRQoL but not mental HRQoL In multivariate analysis, health literacy was not related to total VRQoL (with and without education in model) but was related to subscale component "dependency". It was not significantly related to any other subscale components. Effect in no exposure (i.e., adequate literacy) or control group: 1. VRQoL (VFQ-25), mean (SD): 76 (18) 2. General HRQoL: NR 3. Mental HRQoL: NR Effect in exposure (i.e., low/moderate literacy) or intervention: 1. VRQoL (VFQ-25), mean (SD): 84 (18) 2. General HRQoL: NR 3. Mental HRQoL: NR Difference: Difference (unadjusted) 1. VRQoL: ($P < 0.001$) 2. General HRQoL: ($P = 0.0002$) 3. Mental HRQoL: ($P = 0.068$) Difference total VFQoL score (adjusted): ($P = 0.621$) Difference VFQoL subscale-dependency (adjusted): ($P = 0.040$) Difference Physical QoL (SF-12) (unadjusted): ($P = 0.002$) Difference Mental QoL (unadjusted): ($P = 0.068$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Murphy et al., 2010[51] Research objective: Investigates association between HL and adherence to antiretroviral medications among HIV positive adolescents. Study design: Cross-sectional Study setting: Five U.S. sites, primarily through the Adolescent Trials Network: FORT Lauderdale, FL; Philadelophia, PA; Baltimore, MD; and Los Angeles, CA; 1 non-network site was located in Detroit, MI Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: The S-TOFHLA: cut points not provided but inadequate and marginal combined for analyses. Four items from the numeracy section of the original TOFHLA were added to the S-TOFHLA for the study. Multivariate analysis included reading score only.	Eligibility criteria: Inclusion: HIV-positive Ages 16-24 English-speaking Engaged in 2 of the following: currently prescribed antiretroviral medications, or told by physician to be on antiretroviral medications (whether taking them or not); ever had sexual intercourse; ever tried alcohol/drugs At least one behavior had to be at problem level: adherence < 90% in the last month, unprotected intercourse within the last 3 months, or screening at problem level for alcohol and/or drug. Exclusion: NA Sampling strategy: Convenience sample Sample size: N = 186 (missing data for some analyses) Age (mean and range), %: Mean (SD): 20.5 (2.3) Range: 16-24 Gender, %: Male: 49.5% Female: 47.3% Transgender/transsexual: 3.2% Race/Ethnicity, %: African American/Black only: 78.0% European American only: 3.2% Hispanic only: 11.3% Mixed race/ethnicity: 7.5% Income, %: Monthly income ($): Mean (SD): 644.30 (626.50) Median: 506.00 Range: 5.00-4000 Insurance status, %: NR Education, %: <HS: 50.0 HS graduate/GED: 32.8% Attended school beyond HS: 17.2% Other characteristics, %: Perinatally HIV-infected, 16.7%: Hospital ER visits during th past 3 months: Number of participants visiting ER: 54 Mean (SD): 1.3 (0.7) Median: 1 Range: 1-4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Medication adherence, viral-load, self-efficacy to adherence to medication regimens and medical care received. Covariates used in multivariate analysis: Age and education level Description of outcome measures: Adherence: Participants completed the diabetic self-care practice instrument, adapted for HIV-positive adolescents, assessing illness management, and Module 1 of the pediatric adherence questionnaire for current HIV medications and number of missed doses over the last 3 days. Alcohol, smoking and substance abuse: Participants completed the alcohol, smoking and substance involvement screening test (ASSIST), which assessed drug and alcohol use for the past 3 mos. Mental status: Participants completed the brief symptom inventory measures mental status. Self-efficacy: Self-efficacy for health promotion and risk reduction assessed confidence in taking medications and keeping health care appointments. Lboratory evaluations: Included CD4+ measures and plasma HIV-1 RNA (viral load) Data source(s) for outcomes: Self-report (questionnaires), computer-assisted personal interviews, and Laboratory test (CD4+ measures and plasma HIV-1 RNA (viral load) Attempts for control for confounding: Regression modeling Blinding: NR Statistical measures used: Cronbach's alpha, the Fisher-Freeman-Halton exact test Wilcoxon rank sums test, logistic regression modeling	Describe results: Among HIV-positive adolescents health literacy was not sig associated with: medication adherence, viral load, self-efficacy for adherence; ER visits, or overnight hospital stays, adjusting for age and education but HL was positively associated with medical care received. Effect in no exposure (i.e., adequate literacy) or control group: Univariate Analysis: Average percentage adherence of all medications taken over past 3 days,n (%): ≥ 90%: 30 (35.7) > 0 to < 90%: 20 (23.7) 0%: 34 (40.5) Log10 viral load: N: 158 Mean (SD): 3.69 (1.19) Median: 3.93 Range: 1.40-5.88 Geometric mean: 4,855 Effect in exposure (i.e., low/moderate literacy) or intervention: Average percentage adherence of all medications taken over past 3 days, n(%): ≥ 90% (adherent): 4 (23.5) 7 (41.2) 6 (35.3) Log10 viral load: N: 27 Mean (SD): 3.82 (1.08) Median: 3.73 Range: 1.70-5.67 Geometric: 6572 Difference: Difference avg % adherence of all meds taken over past 3 days compared to 0% adherent (adjusted): >= 90% adherent: OR, 1.00; 95% CI, 0.96-1.05 >0% and < 90% adherent: OR, 1.00; 95% CI, 0.95-1.04 Log10 viral load (adjusted): B = -0.007 (*P* = 0.13) CD4 count (adjusted): B = 2.78 (*P* = 0.15) BSI GSI (adjusted): B = 0.186 (*P* = 0531) Total substance involvement (adjusted): B = 0.433 (*P* = 0181) Self efficacy adherence to HIV medication regimen score >= 4 (adjusted): OR, 0.99; 95% CI, 0.95-1.03 Self efficacy adherence to keep medical appointment score >= 4 (adjusted): OR, 1.01; 95% CI, 0.95-1.06 ER visits (adjusted): OR, 0.98; 95% CI, 0.96-1.01 Overnight hospital stay >= (adjusted):OR, 0.97; 95% CI, 0.93-1.01 Medical care received 3 or more times (adjusted): OR, 1.09; 95% CI, 1.04-1.15 Medical care received once or twice (adjusted): OR, 1.06; 95% CI, 1.02-1.09

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Murphy et al., 2010[51] (continued)	Overnight or longer hospital stay during the past 3 months: Number of participants with overnight stay: 17 Mean (SD): 1.1 (0.3) Median: 1 Range: 1-2 Health literacy/numeracy levels, %: TOFHLA-modified: Inadequate: 11.8 Marginal: 2.7 Adequate: 85.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Murray et al., 2009[52] Research objective: Determine factors independently Associated with clinical exacerbation of heart failure over 12 months as well as relative strengths of their associations Study design: Prospective cohort Study setting: University-based public clinic practice in Indianapolis, Indiana Measurement period: Feb 2001- Jun 2004 Follow-up duration: 1 yr Completeness of follow-up: NR Measurement tools including cutpoints: sTOFHLA: Inadequate Health Literacy: 0-16 Marginal Health Literacy: 17-22 Adequate Health Literacy: 23-36	Eligibility criteria: Included: 50 yo+ Congestive heart failure diagnosis Use Wishard pharmacy Prescribed an ACE, ARB, beta blocker, diuretic, digoxin, or aldosterone antagonist Not planning to use pill box Telephone access Able to hear normal conversation Excluded: Dementia Sampling strategy: Cohort obtained from usual care arm of an RCT Sample size: 192 Age, mean (SD): 63.2 (8.9) Gender, %: Females: 66.7 Race/Ethnicity, %: Black: 51.6 White 46.9 Other: 1.6 Income, %: Adequate income: 63.5 Insurance status, %: Medicare: 56.8 Medicaid: 36.5 Education, mean years (SD): 10.6 (2.7) Other characteristics: NA Health literacy/numeracy levels, % (SD): sTOFHLA adequate: 70.8 Prescription reading score: 1.5 (0.7) Comparison task score: 17.1 (5.5) Prescription label reading test: No correct responses: 0 Accurately read and interpret prescription instructions: 2 Cognitive test: Letter -comparison tests (max score 42) and pattern-comparison tests (max score 30)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: All cause ED visits Heart-failure specific ED visits All cause hospitalizations Heart failure specific hospitalizations Covariates used in multivariate analysis: Insurance NYHA class LVEF Refill adherence Prescription label reading score Hct Race Chronic Heart Failure questionnaire score Serum Na Income adequacy Serum K Kansas City cardiomyopathy questionnaire Age Comparison task score Depression Description of outcome measures: Clinical exacerbations (ED and hospitalizations) over 12 months Data source(s) for outcomes: Medical records, participant charts, verified by research assistants at participant visits and endpoints adjudicated by RN as abstractor using previously validated methodology Attempts for control for confounding: Multivariate analyses Blinding: NR Statistical measures used: Log-Linear Regression, step-wise inclusion of independent vars, chi-square	Describe results: Prescription label reading skills were associated with lower incidence of all cause and heart failure specific emergency care and all cause hospitalization. Participants with adequate health literacy had a lower risk of hospitalization for heart failure Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: All Cause ED visits (unadjusted), IRR (CI): Prescription label reading score, 1 pt increment: 0.76 (0.59-0.97) Heat failure specific ED visits (unadjusted): Prescription label reading score: 0.36 (0.19-0.69) All cause hospitalization (unadjusted): Prescription label reading score: 0.68 (0.54-0.86) Heart failure specific hospitalization (unadjusted): sTOFHLA 0.34 (0.15-0.76)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Nokes et al., 2007[53] Research objective: Determine influence of health literacy on depressive symptoms, HIV symptom intensity and distress over body changes attributed to HIV among persons with HIV/AIDS Study design: Cross-sectional Study setting: HIV positive patients receiving care at Infectious disease clinics or community-based organizations in 6 US cities (San Francisco, Fresno, Richmond, New York City, Corpus Christi) Measurement period: 6-month period from 2002-2003 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: Possible range: 0-66; measured as a continuous variable	Eligibility criteria: Included: ≥18 HIV positive Excluded: NR Sampling strategy: Convenience Sample size: 489 Age, mean (SD): 42.6 (8.77) Gender: NR Race/Ethnicity, %: AA: 50 Hispanic/Latino: 25 White/ Non-Hispanic: 20 Income, %: "Barely adequate": 54 Insurance status, %: Uninsured: 37 Education, %: Some HS: 40 >HS: 30 Other characteristics, %: HIV Positive: 59 Aids: 37 Health literacy/numeracy levels, mean (SD): 59.1 (12.9)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Physical health Depressive symptoms Distress over body changes HIV-symptom intensity Covariates used in multivariate analysis: Hispanic Description of outcome measures: Physical health: global health status rating scale developed by investigators Depressive symptoms: Center for Epidemiology Studies Depression Scale (CES-D) Distress over body changes: Assessment of Body Change Distress Scale (ABCD) HIV-symptom intensity: Revised Sign and Symptom Checklist for persons with HIV Disease (SSC-HIVrev) Data source(s) for outcomes: Self-report Attempts for control for confounding: Step-wise multiple regression Blinding: NR Statistical measures used: Bivariate correlation analysis Step-wise linear regression using list wise deletion on the predictor variables	Describe results: Higher HL was significantly related to greater body change distress, symptom intensity and depressive symptoms in step-wise regression analyses. Effect in no exposure (i.e., adequate literacy) or control group: Physical health, mean (SD): 6.68 (2.22) Data on other outcomes not provided Effect in exposure (i.e., low/moderate literacy) or intervention: Physical health, mean (SD): 7.21 (2.42) Data on other outcomes not provided Difference: Physical health (mean difference): 0.53 Correlation analysis: Depressive symptoms: .09, $P < 0.05$ Distress over body changes: .11, $P < 0.05$ HIV-symptom intensity: .16, $P = 0.01$ Step-wise regression (adjusted), β: Depressive symptoms: 4.26, $P < 0.05$ Distress over body changes: 2.91, $P < 0.05$ HIV-symptom intensity: 8.62, $P < 0.05$

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Osborn et al., 2007[54] (Companions: Wolf et al., 2007[55] and Waite et al., 2008[56]) Research objective: Examine mediating effect of limited HL on relationship between race and HIV-medication adherence. Study design: Cross-sectional Study setting: Outpatient infectious disease clinics at Northwestern Memorial Hospital, Chicago or Louisiana State University Health Sciences Center, Shreveport, LA Measurement period: June to September 2001 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM ≤ 6th grade: Low literacy (score of 0 to 44) 7th - 8th grade: Marginal literacy (score of 45 to 60) ≥ 9th grade: Adequate (score of 61 - 66)	Eligibility criteria: Included: HIV-infected patients on one or more antiretroviral medications Excluded: HIV patients on current ART regimen for < 2 weeks Diagnosis of dementia Blindness or severely impaired vision not correctable with eyeglasses Deafness or hearing problems uncorrectable with a hearing aid Too ill to participate in the survey Sampling strategy: Convenience Sample size: 204 Age, mean (SD): 40.1 (9.2) Gender, %: Females: 20.1 Race/Ethnicity, %: AA: Total: 45.1 Marginal/low HL: 52 Non-AA Marginal or low HL: 14.3 Income, %: Annual Income: < $10,000: 39.7 $10,000-$11,999: 23 $12,000-$17,999: 9.8 ≥ $18,000: 27.5 Insurance status, %: Private: 27.5 Medicare: 19.6 Medicaid or free care: 52.9 Education, %: < HS: 12.3 HS graduate: 26 > HS: 61.8 Number of HIV medications in regimen: 1-2 medicines: 29.9 ≥3 medicines: 70.1 ≥1 non-HIV comorbid conditions: 52.5 Adherence to HIV-medication in past 4 days: Non-AA: 76.8 AA: 60.1 Health literacy/numeracy levels, %: Low: 11.3 Marginal: 20.1 Adequate: 68.

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Medication Adherence Covariates used in multivariate analysis: Gender Age Income Number of medications in regimen Non-HIV comorbid condition Mental illness Description of outcome measures: Patients reported any missed doses in past 4 days through reviewing names and color photographs of common HIV medications included in a revised version of the PMAQ Patients rated as having proper adherence if no missed doses during time period were reported. Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate regression Blinding: NR Statistical measures used: Chi-square and t-tests to test bivariate associations. Multivariate regression: to analyze mediational effect of HL on racial differences in HIV-medication adherence. First, relationship between race and adherence established after adjusting for covariates and potential interaction effects (Model 1). Next, relationship between literacy and adherence tested, which was confirmed in a prior study using this same cohort. Finally, literacy was added to Model 1 as a mediator (Model 2).	Describe results: Low HL was a significant predictor of nonadherence but marginal HL was not. By adding HL to mediation adherence model, coefficient for black race changed from being statistically sig to not and coefficient decreased in size, from an odds of 2. Effect in no exposure (i.e., adequate literacy) or control group, %: Nonadherence to HIV-medication in past 4 days: Adequate literacy: 30 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Nonadherence to HIV-medication in past 4 days: Low literacy: 52.2 Difference: Model 1 - Nonadherence to HIV-medication without literacy level (adjusted), OR (CI): AA: 2.4 (1.14 5.08) Model 2 - Nonadherence to HIV-medication with literacy level (adjusted), OR (CI): AA: 1.8 (0.51-5.85) Marginal HL: 1.55 (0.93-2) Within Intervention Group (unadjusted) : +0.39

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Osborn et al., 2009[57] Research objective: To examine whether health literacy, numeracy and diabetes specific numeracy mediate the association between African American race and A1C level Study design: Cross-sectional Study setting: Two primary care and 2 diabetes specialty clinics located at 3 medical centers. Measurement period: March 2004 to November 2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: DNT: Q1, Q2, Q3, Q4 (cutpoints not explained but lower quartile indicates lower diabetes related numeracy) REALM < 9th grade ≥ 9th grade WRAT-3 < 9th grade ≥ 9th grade	Eligibility criteria: Included: Diagnosis or type I or II diabetes, age 18-85 years, English-speaking Excluded: Previous diagnosis of dementia, psychosis, or blindness Pts with a corrected visual acuity of 20/50 or worse using Rosenbaum Screener Sampling strategy: Convenience sampling Sample size: N = 383 Quartile (Q) by DNT Q1, n = 104 Q2, n = 97 Q3, n = 98 Q4, n = 84 Age (mean and range), %: Total, median (range) = 56 (47-64) By DNT quartile Q1 = 61 (51 - 67) Q2 = 57 (49 - 66) Q3 = 56 (47 - 62) Q4 = 50 (41 - 56) Gender, %: Female: 50% By DNT quartile Q1: 60% Q2: 44% Q3: 50% Q4: 45% Race/Ethnicity, %: Total White: 65% Nonwhite: 35% By DNT quartile Q1 White: 31% Nonwhite: 69% Q2 White: 67% Nonwhite: 33% Q3 White: 79% Nonwhite: 21%

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: A1C: most recent in medical record Covariates used in multivariate analysis: Covariates in Model 1: Age Sex Years of ed Annual income Insulin use Diabetes type Years of diagnosed diabetes Race Covariates in Models 2 and 3 (sig variables from Model 1): Age Year of diagnosed diabetes Insulin use African American race Description of outcome measures: Glycemic control was assessed by most recent A1C value in patient's medical record. 96% were obtained within 6 months of the participant evaluation and median time between A1C and evaluation was 15 days. Data source(s) for outcomes: Chart review Attempts for control for confounding: Structural equation modeling Blinding: NR Statistical measures used: Three structural equation models were estimated. Model 1 tested whether African American race predicted higher A1C levels after controlling for potential confounders. Model 2 tested whether African American race predicted low HL skills, low general numeracy skils, and low DNT, and whether these variables, in turn, predicted A1C levels. Model 3: Sig HL and numeracy predictors from Model 2 and potential confounders.	Describe results: Model 1: younger age, using insulin, having been diagnosed with diabetes for more years, and African American race were associated with sig higher A1C levels and accounted for 17% of the variability in A1C levels. Model 2: African American race was associated with limited literacy skills (r = -0.39, *P* < 0.001), limited general numeracy skills (r = -0.43, *P* < 0.001), and limited DNT skills (r = -0.46, *P* < 0.001). AA race did not have a sig direct effect on A1C (r = 0.10, *P* = NS). Of the skills measures, only DNT significantly directly predicted A1C levels. Higher DNT was associated with lower A1C levels (r = -0.15, *P* <0.01) Model 3--literacy and general numeracy removed from the model : AA race associated with lower DNT (r = -0.47, *P* < 0.001). Lower DNT associated with higher A1C level (r = -.17, *P* < 0.01). Direct effect of AA race on A1C not measured Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: AIC (%) Q1: 7.6 (6.5-9.0) Q2: 7.2: (6.3-8.3) Q3: 7.2 (6.5-8.0) Q4: 7.2 (6.4-8.2) (*P* = 0.24) Difference: Model 2 Overall model fit, X2 (12, n = 383) = 485.47, *P* < 0.001, CFI = 0.464, RMSEA = 0.32 (90% CI, 0.30–0.35). Test of significance of individual paths: REALM, *P* = NS General numeracy, *P* = NS DNT, *P* < 0.01 Model 3 Overall model fit, X2 (3, n = 383) = 6.91, *P* = 0.07, CFI = 0.99, RMSEA = 0.06 (90% CI, 0.00–0.12). Test of significance of individual paths: DNT, *P* < 0.001

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Osborn et al., 2009[57] (continued)	Q4 White: 89% Nonwhite: 11% Income, %: Total <$20,000: 44% By DNT quartile Q1: <$20,000: 80% Q2: <$20,000: 49% Q3: <$20,000: 23% Q4: <$20,000: 20% Insurance status, %: Has Private Insurance Total: 48% By DNT quartile Q1: 31% Q2: 40% Q3: 59% Q4: 67% Education, %: Total <HS= 43% HS/GED or more = 57% DNT quartile 1 <HS = 73% HS/GED or more = 27% DNT Quartile 2 <HS = 49% HS/GED or more = 51% DNT Quartile 3 <HS = 23% HS/GED or more = 77% DNT Quartile 4 <HS = 20% HS/GED or more = 80% Health literacy/numeracy levels, %: Diabetes Numeracy Test (DNT) Q1 = 27% Q2 = 25% Q3 = 26% Q4 = 22% REALM < 9th grade = 31% ≥ 9th grade = 69% WRAT-3 < 9th grade = 69% ≥ 9th grade = 31%

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Osborn et al., 2010[58] Research objective: To develop and validate a brief assessment of health knowledge and action in the context of HIV treatment, referred to as the Brief Estimate of Health Knowledge and Action-HIV version (BEHKA-HIV). The BEHKA-HIV and REALM were evaluated as predictors of medication adherence. Study design: Cross sectional Study setting: Outpatient infectious disease clinics at Northwestern Memorial Hospital in Chicago, Illinois and Louisiana State University Health Sciences Center in Shreveport, Louisiana Measurement period: NR; however, participants were recruited from June to September 2001. Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: REALM: 0-18 Correct words pronunciation: ≤ 3rd grade reading level (low literacy) 19-44 Correct words pronunciation: 4th-6th grade reading level (low literacy) 45-60 Correct word pronunciation: 7th or 8th grade reading level (marginal literacy) 61-66 Correct word pronunciation: ≥ 9th grade (adequate literacy)	Eligibility criteria: Inclusion: Prescribed 1 or more antiretroviral medications Receiving medical care through outpatient infectious disease clinics at Northwestern Memorial Hospital in Chicago, Illinois and Louisiana State University Health Sciences Center in Shreveport, Louisiana Exclusion: Had been on current regimen for less than 2 weeks Too ill to participate Had one or more of the following conditions, as noted in the medical recored: (1) dementia; (2) blindness or severely impaired vision not correctable with eyeglasses; (3) deafness or hearing problems uncorrectable with a hearing aid. Sampling strategy: Convenience sample Sample size: N = 204 Age (mean and range), %: Mean (SD): 40.1 (9.2) Gender, %: Female: 20.1 Race/Ethnicity, %: African-American: 45.1 Income, %: Household income ≤ $800/month: 39.7 Insurance status, %: Uninsured: 27.5 Education, %: At least some college education: 60 Other characteristics, %: Unemployed: 55.9 Receiving treatment for a non-HIV related chronic illness: 52.5 Receiving mental health serves: Nearly one-third Receiving treatment for alcohol or illicit drug use in the past 6 mos: 9.3 Taking 3 or more HIV medications: Over 70 Health literacy/numeracy levels, %: REALM: ≥ 9th grade (adequate): 68.6 7th-8th grade (marginal): 20.1 ≤ 6th grade (low): 11.3

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Adherence HIV knowledge and action Covariates used in multivariate analysis: Age Insurance coverage Employment status Number of medications in HIV regimen Number of non-HIV prescription meds currently taken Presence of a comorbid chronic condition Treatment for a mental health condition in the past 6 months Treatment for alcohol or drug use in past 6 months. Description of outcome measures: Patient Medication Adherence Questionnaire (PMAQ): Patients self-reported any recent missed doses of HIV medication using pages that contained names and color photographs of common HIV medications included in a revised version of the PMAQ; Patients were required to identify their medication and then report on a missed dose in the past 4 days for each antiretroviral agent. Brief Estimate Health Knowledge and Action-HIV Version (BEHKA-HIV): 8-item assessment of HIV treatment knowledge and action; 3 items were associated with knowledge and 5 with action. The BEHKA-HIV scores ranged from 0 to 8, and patients were classified as low, marginal, or adequate on the BEHKA-HIV. Higher scores corresponded with fewer missed doses of a regimen. Data source(s) for outcomes: Self-report, in-person interviews: Patient Medication Adherence Questionnaire (PMAQ) Brief Estimate Health Knowledge and Action-HIV Version (BEHKA-HIV) Attempts for control for confounding: Multivariate logistic regression models Blinding: NR Statistical measures used: Cronbach's alpha Stratum-specific likelihood ratios (SSLRs) Chi-square, logistic regression	Describe results: Low but not marginal HL was significantly associated with poor self-reported HIV medication non-adherence. Effect in no exposure (i.e., adequate literacy) or control group: Brief Estimate Health Knowledge and Action-HIV (BEHKA-HIV), %: 6-8 (adequate): 31.8 Adherence: 90.9% of patients scoring 6-8 on the BEHKA-HIV (adequate) were adherent to their current regimen Adherence in relation to REALM score: NR Effect in exposure (i.e., low/moderate literacy) or intervention: Brief Estimate Health Knowledge and Action-HIV (BEHKA-HIV), %: 4-5 (marginal): 34.1 0-3 (low): 34.1 Adherence: 51.0% of patients scoring 0-3 on the BEHKA-HIV (low) were adherent to their current regimen 82.3% of patients scoring 4-5 on the BEHKA-HIV (marginal) were adherent to their current regimen Adherence in relation to REALM score not reported Difference: Difference in non-adherence (adjusted): Marginal HL vs adequate: OR, 2.1; 95% CI, 0.8-5.5 Low HL vs adequate: OR, 3.3; 95% CI, 1.3-8.7

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Paasche-Orlow et al., 2005[59] Research objective: Identify educational factors (including literacy) associated with HIV risk behaviors among incarcerated women. Study design: Cross-sectional study Study setting: Rhode Island Adult Correctional Institute Measurement period: Within 4 days of arrival, February 4, 2004 to July 19, 2004 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM (score 0-66) Cut points: ≤ 6th Grade (0-44) 7th - 8th Grade (45-60) ≥ 9th Grade (61-66)	Eligibility criteria: Included: English speaking housed in general facility population Age 18+, not yet sentenced able to competently provide verbal consent Excluded: NR Sampling strategy: Consecutive request to enroll during a 2 week period Sample size: 423 Age, mean (range): Total: 34 (18-64) Gender, %: Females: 100 Race/Ethnicity, %: Caucasian: 63 AA: 25 Hispanic: 10 Income: NR Insurance status: NA Education, %: ≤ 8th grade: 9 9th - 11th grade: 46 HS graduate: 45 Other characteristics, %: Received special Education: 26 Had Individualized Educational Plan:15 History of problem drinking: 37 Health literacy/numeracy levels, %: ≤ 6th Grade: 10 7th - 8th Grade: 19 ≥ 9th Grade: 71

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: HIV Risk Behavior Covariates used in multivariate analysis: Age Race Problem drinking Description of outcome measures: HIV risk: dichotomous variable based on response to question, "During the last 3 months, have you had sex without using a condom OR have you shared any part of injection drug equipment (needle, syringe, cotton, cooker, or rinse water) at least once a month?" Data source(s) for outcomes: Self-report data from in-person interview. Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Fisher exact test Two-sample t tests ANOVA Bi-variate logistic regression related primary independent variables (health literacy and other education variables) and demographic variables to HIV risk behavior. Multivariate logistic regression added race, age, and problem drinking to the model.	Describe results: No significant association between literacy level and HIV risk behavior. Effect in no exposure (i.e., adequate literacy) or control group: HIV Risk Behavior, % (n): 7th - 8th Grade: 19 (42) ≥ 9th Grade: 72% (162) Effect in exposure (i.e., low/moderate literacy) or intervention: HIV Risk Behavior, % (n): ≤ 6th Grade: 9 (21) Difference: Difference in odds of reporting HIV Risk behavior (adjusted), OR (CI): 7th - 8th Grade: 1.89 (0.74 - 4.81) ≥ 9th Grade: 2.02 (0.83-4.92)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Paasche-Orlow et al., 2006[60] Research objective: Investigate relationship between health literacy and antiretroviral adherence and HIV-RNA Suppression in HIV patients with a history of alcohol problems. Study design: Longitudinal Study setting: Boston Measurement period: July 1997-August 2001 Follow-up duration: Up to 3 years Completeness of follow-up: NR Measurement tools including cutpoints: REALM <6th grade: 7th - 8th grade: >9th grade:	Eligibility criteria: Included: 2 or more positive responses to CAGE questionnaire or physician assessment of alcohol abuse or dependency Fluent in English or Spanish Mini-Mental State Examination score >21 No plans to move from Boston area within 2 years Excluded: Those that did not complete health literacy assessment Not on Antiretroviral therapy Conducted research interview in Spanish Sampling strategy: Convenience Sample size: 235 Age, mean (IQR): 42 (9) Gender, %: Males: 79 Race/Ethnicity, %: Black: 45 White: 38 Other: 17 Income: NR Insurance status: NR Education, %: High school graduate or equivalent degree: 63 Other characteristics: Homeless, %: 23 Nested adherence trial status: Not in nested trial, %: 42 Intervention subject in nested trial, %: 30 Control subject in nested trial, %: 28 Alcohol consumption, median drinks/day (IQR): 6 (9) Drank to intoxication in past 30 days, %: 33 Injected drugs past 6 months, %: 19 ASI alcohol score, median (IQR): 0.1 (0.3) ASI drug score, median (IQR): 0.1 (0.2) Health literacy/numeracy levels, %: <6th grade: 14 7th - 8th grade: 29 >9th grade: 57

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: 100% Adherence at baseline, %: 64 Viral load suppressed at baseline visit, %: 60 Covariates used in multivariate analysis: Gender Age Education Randomization group Ethnicity Homeless status Drank to intoxication past 30 days Injected drugs past 6 months Complexity of regimen Model predicting HIV-RNA Suppression also uses medication adherence as covariate Description of outcome measures: 100% Adherence: dictomous; 3-day ART adherence (100% adherent vs. <100% adherent) Viral load suppressed at baseline visit: measured using branched-chain DNA techniques; detection threshold 500 copies/mL; viral load suppression defined as having undetectable Data source(s) for outcomes: 100% Adherence at baseline: self-report questionnaire Viral load suppressed at baseline visit: lab values Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Bivariate analysis to assess the associations between characteristics and HL. Compared across HL groups using Chi-squared for categorical variables and Kruskall-Wallis test for continuous variables. Longitudinal logistic regression models used to examine association between HL and each main outcome over time. A GEE approach used an independence working correlation matrix to account for correlation due to analyzing repeated measure from the same subject over time.	Describe results: HL was not associated with a lower odds of adherence or virologic suppression in this longitudinal analysis of HIV-infected patients with a history of alcohol problems. Effect in no exposure (i.e., adequate literacy) or control group, %: 100% adherence: 64 Viral load suppressed: 61 Effect in exposure (i.e., low/moderate literacy) or intervention, %: 100% adherence (≤ 6th grade): 69 100% adherence (7th-8th grade): 63 Viral load suppressed (≤ 6th grade): 63 Viral load suppressed (7th-8th grade): 58 Difference: Difference in 100% Adherence (adjusted), OR (CI): ≤ 6th grade vs.≥ 9th grade: 1.93 (0.86-4.31) 7th-8th grade vs.≥ 9th grade: 1.29 (0.77-2.19) Difference in HIV-RNA Suppression (adjusted), OR (CI): ≤ 6th grade vs. ≥ 9th grade: 1.70 (0.79-3.65) 7th-8th grade vs. ≥9th grade: 1.29 (0.77-2.18)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Paasche-Orlow, 2005[61] Research objective: To assess whether inadequate health literacy is a barrier to learning and retaining discharge and medication instructions and appropriate metered-dose inhaler technique among asthmatics. Study design: Quasi-experimental (pre-post test) Study setting: Two inner-city hospitals Measurement period: April 2001 - October 2002 Follow-up duration: 2 weeks Completeness of follow-up: 77% Note: patients who did not f/u were more likely to be younger, female, AA, high school grad, be hospitalized in the last 12 months, and have lower Measurement tools including cutpoints: sTOFHLA: Inadequate: ≤ 16/36 Adequate: >16/36 asthma scores	Eligibility criteria: Included: Age 18 or older Admitted with a physician diagnosis of asthma exacerbation to 2 inner-city academic medical centers Excluded: Other chronic lung disease Contraindication to corticosteroids Patients or physicians who declined consent Investigators' patients Discharged to location other than home Sampling strategy: Convenience Sample size: 73 Note: adherence data only available on 46 (63%)--baseline characteristics not given for these individuals to compare to full sample Age, mean (SD): 40.9 (10.9) Gender, %: Female: 66 Race/Ethnicity, %: AA: 79 Income, %: Income ≥ $19,000: 65 Insurance status: NR Education, %: High School graduate or GED: 60 Other characteristics, %: Asthma-related health care use: Hospital visit past 12 mo: 58 ED visit past 12 mo: 77 Near-fatal asthma: 42 Cigarette smoking history: Never: 44 Past: 27 Current: 29 Asthma: Physician for asthma care, %: 51 Asthma knowledge score, mean (SD): 6.9 (2.0) Health literacy/numeracy levels: Inadequate: 22%

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Better (≥ mean) asthma medication knowledge Better (≥ mean) Metered Dose Inhaler technique Mastery of discharge regimen after one round Poor (< 50%) adherence to corticosteroid therapy Better (≥ mean) asthma symptom control Covariates used in multivariate analysis: Age Sex Ethnicity Education Income History of near fatal asthma Hospitalization in prior 12 mo. Having a physician for asthma care Prior ED visit for Asthma last 12 mo. Note: given sample size, model should hold only 4 covariates Description of outcome measures: Better asthma medication knowledge: Asthma Medication Knowledge Questionnaire, 10-item developed by investigators based upon existing asthma knowledge scales, professional opinion, and the desire for each item to be directly related to medication use; dichotomous (yes [≥mean score] vs. no]). Better Metered Dose Inhaler technique: score 0-6 based on assessed technique meeting 6 criteria (shaking, exhaling prior, lips around mouthpiece, full deep breath without triggering indicator, hold breathe 5 seconds); dichotomous (yes [≥mean score =4] vs. no]). Mastery of discharge regimen after 1 round: dichotomous (yes. vs. no) Poor adherence to corticosteroid therapy: using Doser CT which records the numeracy of actuations for inhaled steroid (poor adherence < 50%: dichotomous (yes vs. no)) and MEMS Caps which record the number of times the pill bottle opened for oral steroids (poor adherence <50%). Better asthma symptom control: using 6 symptom items in Asthma Control Questionnaire: dichotomous (yes [≥mean score] vs. no]). Data source(s) for outcomes: Better (≥mean) asthma medication knowledge Better (≥mean) Metered Dose Inhaler technique Mastery of discharge regimen after one round Poor (<50%) adherence to corticosteriod therapy Better (≥mean) asthma symptom control Attempts for control for confounding: Multivariate analysis	Describe results: Outcomes: Inadequate health literacy was associated with poor asthma medication knowledge, poor MDI technique, and hospitalization. Asthma knowledge appeared to mediate relationship between inadequate literacy and MDI technique. Intervention: Inadequate health literacy was not a barrier to learning key asthma management skills in a one-on-one 30 minute asthma education session. Note: power is a significant limitation to this conclusion, however. Effect in no exposure (i.e., adequate literacy) or control group: Asthma-related health care use, %: Hospital visit past 12 mo: 52 ED visit past 12 mo: 75 Near-fatal asthma: 37 Cigarette smoking history, %: Never: 46 Past: 30 Current: 25 Physician for asthma care, %: 53 Asthma knowledge score (at baseline), mean: 7.2 Mastery of Metered Dose Inhaler technique (at baseline), %: 63% (read from chart) Intervention: Mastery of Metered Dose Inhaler technique (at baseline), %: 32 (read from chart) Mastery of Discharge Regimen (at baseline), %: 75 (read from chart; average of 76 Inad Lit; 73 AdLit) Poor Adherence (baseline): NR Asthma Symptom control (baseline): NR Effect in exposure (i.e., low/moderate literacy) or intervention: Asthma-related health care use, %: Hospital visit past 12 mo: 81 ED visit past 12 mo: 88 Near-fatal asthma: 63 Cigarette smoking history, %: Never: 38 Past: 19 Current: 44 Physician for asthma care, %: 44 Asthma knowledge score (at baseline), mean: 5.2 Mastery of Metered Dose Inhaler technique (at baseline), %: 32 (read from chart)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Paasche-Orlow, 2005[61] (continued)	

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Blinding: Yes, to outcome assessors at 2 weeks No to patient Statistical measures used: Wilcoxon rank sum, matched pairs signed rank, and x2 for bivariate. Logistic regression models for adjusted analyses.	INTERVENTION: Mastery of Metered Dose Inhaler technique (after single round education), %: 64 (avg 59 Inad Lit; 73 AdLit) Better Metered Dose Inhaler technique (at 2-week follow-up), %: 88 (read from chart; avg 86 Inad Lit; 90 AdLit) Understanding of Discharge Regimen after single round education, %: 69 Mastery of Discharge Regimen (at 2 week follow-up), %: 95 (read from chart; average 92 Inad Lit; 98 AdLit) Poor Adherence (at 2 week follow-up, available on 46 participants), %: 48 Asthma Symptom Control (at 2 week follow-up): NR Difference: Difference in Cigarette smoking history (unadjusted): (P = 0.31) Difference in Physician for asthma care (unadjusted): (P = 0.53) Difference in Asthma knowledge score (at baseline) (unadjusted): -2.0, P < 0.01 OR (adjusted) (CI): 0.08 (0.02-0.38) Difference in Mastery of Metered Dose Inhaler technique (at baseline) (adjusted), %: -31 (read from chart), P = 0.03 OR (CI)l 0.29 (0.08-1.00) Intervention: Difference in Mastery of Metered Dose Inhaler technique (at 2-week follow-up): (unadjusted), %: 56, NR; p for interaction by literacy, P = 0.02 Difference in Understanding of Discharge Regimen (at 2-week follow-up) (unadjusted), %: + 20, NR; p for interaction by literacy, P = 0.40 Difference in Adherence (at 2 week follow-up, available on 46 participants) by literacy sub group (adjusted): NR, P for interaction, P = 0.45 Asthma Symptom Control (at 2 week follow-up) by literacy subgroup: NR, P for interaction, P = 0.84

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Pandit et al., 2009[62] Research objective: Determine whether there is an association between hypertension control and HL level. Study design: Cross-sectional Study setting: Patients receiving care from primary care safety net clinics in Grand Rapids, MI, Chicago, IL, or Shreveport, LA Measurement period: July 2006 and August 2007 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: S-TOFHLA (scores range from 0 to 100) Scores are typically placed in one of three literacy categories: inadequate, marginal,adequate. However, in this study, they divided scores into five categories to "provide a larger spectrum of literacy skills." They created the categories based on the S-TOFHLA frequency distribution: Category I: 0–30 Category II: 31–50 Category III: 51–70 Category IV: 71–90 Category V: 91–100	Eligibility criteria: Included: ≥ 18 yrs old Diagnosis of hypertension in their medical record Had a clinic appointment during study period Excluded: Did not speak English Clinic nurse determined they were too ill or cognitively impaired to participate Sampling strategy: Convenience Sample size: 330 Category I, n = 56 Category II, n = 37 Category III, n = 51 Category IV, n = 84 Category V, n = 102 Age (mean and range) (SD): Total : 53.6 (12) Category I: 60 (10.5) Category II: 55.9 (13.6) Category III: 54.6 (9.4) Category IV: 52.3 (11.8) Category V: 49.7 (12) Gender, %: Female Total: 67.9 Category I: 50 Category II: 75.7 Category III: 68 Category IV: 69.9 Category V: 74.5 Race/Ethnicity, %: AA Total: 78.5 Category I: 89.3 Category II: 83.3 Category III: 84.3 Category IV: 81.7 Category V: 67.6 Income: NR Insurance status, %: Total: Private: 10 Medicare: 18.8 Medicaid: 27.3 None/free care: 43.9

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Hypertension control Covariates used in multivariate analysis: Age Race Gender Marital status Employment status Insurance coverage Site location Number of comorbid conditions Years treated for hypertension Clinic site Education Description of outcome measures: Hypertension control was measured by blood pressure readings which were recorded from medical chart and considered controlled if less than 140 mmHg systolic and less than 90 mmHg diastolic (or < 130 mm Hg systolic and < 80 mm Hg diastolic for patients Data source(s) for outcomes: Medical chart review Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Chi-square Student's t-tests Multivariate logistic regression	Describe results: Lower HL level was sig associated with a lower probability of having controlled BP. Effect in no exposure (i.e., adequate literacy) or control group, %: Controlled Blood Pressure Category III: 45.1 Category IV: 60.7 Category V: 45.1 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Controlled Blood Pressure Category I: 33.9 Category II: 48.6 Difference: Difference hypertension control compared to Categrory V (adjusted), OR (CI): Category I: 2.68 (1.54-4.70) Category II: 1.47 (0.53-4.05) Category III: 1.69 (1.08-2.63) Category IV: 1.10 (0.40-3.01)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Pandit et al., 2009[62] (continued)	Category I: Private: 10.7 Medicare: 14.3 Medicaid: 32.1 None/free care: 42.9 Category II: Private: 13.5 Medicare: 24.3 Medicaid: 24.3 None/free care: 37.8 Category III: Private: 7.8 Medicare: 21.6 Medicaid: 33.3 None/free care: 37.3 Category IV: Private: 11.9 Medicare: 20.2 Medicaid: 19 None/free care: 48.8 Category V: Private: 7.8 Medicare: 16.7 Medicaid: 29.4 None/free care: 46.1 Education: Grades 1 - 8, n = 45 Grades 9-11, n = 45 HS, n = 103 >HS, n = 96 Other characteristics, %: Employment: Total: Full-time: 20.9 Part-time: 13.3 Unemployed/ retired: 65.8 Category I: Full-time: 8.9 Part-time: 14.3 Unemployed/ retired: 76.8 Category II: Full-time: 21.6 Part-time: 10.8 Unemployed/ retired: 67.6 Category III: Full-time: 9.8 Part-time: 19.6 Unemployed/ retired: 70.6

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Pandit et al., 2009[62] (continued)	Category V: Full-time: 27.5 Part-time: 9.8 Unemployed/ retired: 62.7 Site: Total: Chicago: 30.6 Grand Rapids: 36.1 Shreveport: 33.3 Category I: Chicago: 25 Grand Rapids: 30.4 Shreveport: 44.6 Category II: Chicago: 24.3 Grand Rapids: 45.9 Shreveport: 29.7 Category III: Chicago: 33.3 Grand Rapids: 35.3 Shreveport: 31.4 Category IV: Chicago: 35.7 Grand Rapids: 35.7 Shreveport: 28.6 Category V: Chicago: 30.4 Grand Rapids: 36.3 Shreveport: 33.3 Health literacy/numeracy levels, %: Category I: 17 Category II: 11 Category III: 15.5 Category IV: 25.5 Category V: 31

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Peterson et al., 2007[63] Research objective: Determine if health literacy is associated with reported self-efficacy for completing colorectal cancer screening and with receipt of colorectal cancer tests. Study design: Cross-sectional Study setting: Patients at a community health clinic in Nashville, TN, located in a medically underserved community adjacent to a public housing project Measurement period: 9/2004 - 6/2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: Limited HL: ≤8th (score of 0-60) Adequate HL: ≥9th (score of 61-66)	Eligibility criteria: Included: ≥50 years-old Receive primary care at clinic English-speaking Have TennCare (TN's Medicaid program) or Medicare Excluded: NR Sampling strategy: Convenience sample Sample size: 99 Limited HL, n = 29 Adequate HL, n = 70 Age, mean (SD): 59.5 (7.8) Limited HL: 60 (8.8) Adequate HL: 60 (7.5) Gender, %: Female: 56 Limited HL: 55 Adequate HL: 40 Race/Ethnicity, %: Total: White: 66 Black: 32 American IndiaNAlaskan native: 1 Asian: 1 Hispanic Ethnicity: 1 Limited HL: White: 48 Black: 52 Adequate HL: White: 73 Black: 24 American IndiaNAlaskan native: 1 Asian: 1 Hispanic Ethnicity: 1 Income, %: Total: ≤$15,000: 65 $15,000-30,000: 19 >$30,000-50,000: 9 >$50,000-75,000: 2 >$100,000-150,000: 1 Don't know/refused: 4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Colorectal cancer screening Self-efficacy (FOBT and colonoscopy) Appropriate receipt of CRC screening (FOBT, colonoscopy, sigmoidoscopy) Covariates used in multivariate analysis: Age Sex Race Insurance status Description of outcome measures: Perception of self-efficacy for obtaining and completing FOBT measured through 8 questions. Perception of self efficacy for obtaining and commpleting colonoscopy measured through 13 questions regarding a respondent's ability to schedule a colonoscopy, complete the preparation for colonoscopy and overcome Any concerns about the test. Responses to self-efficacy statements were on a five-point Likert scale ranging from 1=strongly disagree to 5=strongly agree. Perception scale was validated Up to date on CRC testing: either FOBT in last year, colonoscopy at any time or flexible sigmoidoscopy in the last 5 years. Data source(s) for outcomes: Structured interview (in person or telephone) Attempts for control for confounding: Multivariate regression to control for potential confounding from demographic characteristics Blinding: NA Statistical measures used: Bivariate analyses Multivariate linear regression to estimate the effect of HL on reported self-efficacy, controlling for sociodemographic variables. Logistic regression to estimate the effect of HL on receipt of CRC tests, controlling for sociodemograhics	Describe results: Literacy was not associated with reported self-efficacy or being up to date with CRC testing. Effect in no exposure (i.e., adequate literacy) or control group: Self-efficacy, mean (SD): FOBT: 3.93 (0.34) Colonoscopy: 3.99 (0.32) Up-to-date CRC screening, %: 65.7 Effect in exposure (i.e., low/moderate literacy) or intervention: Self-efficacy, mean (SD): FOBT: 3.87 (0.41) Colonoscopy: 3.92 (0.39) Up-to-date CRC screening, %: 51.7 Difference: Self-efficacy difference (adjusted): FOBT: (P = 0.44) Colonoscopy: (P = 0.52) Up-to-date CRC screening difference (adjusted), OR (CI): 0.67 (0.24-1.83)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Peterson et al., 2007[63] (continued)	Limited HL: ≤$15,000: 79 $15,000-30,000: 14 >$30,000-50,000: 3 Don't know/refused: 3 Adequate HL: ≤$15,000: 59 $15,000-30,000: 21 >$30,000-50,000:11 >$50,000-75,000: 3 >$100,000-150,000: 1 Don’t know/refused: 4 Insurance status, %: Total: Medicaid: 56 Medicare: 11 Both: 32 Limited HL: Medicaid: 34 Medicare: 14 Both: 52 Adequate HL: Medicaid: 64 Medicare: 10 Both: 24 Education, %: Total: ≤8th: 14 9th-12th: 44 > 12th: 41 Limited HL: ≤8th: 38 9th-12th: 48 >12th: 14 Adequate HL: ≤8th: 4 9th-12th: 43 >12th: 53 Other characteristics: Health literacy/numeracy levels, %: Limited HL: 29 Adequate HL: 71

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Powell et al., 2007[64] Research objective: Explore relationship among health literacy and patients' readiness to take health actions among individuals with type 2 diabetes. Study design: Cross-sectional Study setting: General internal medicine clinic that predominately serves a low-income, medically underserved population Measurement period: 1-month study period (specific month not specified) Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: <4th grade 4th-6th grade 7th-8th grade High school	Eligibility criteria: Included: Type 2 diabetes Excluded: Not able to complete study materials independently Sampling strategy: Convenience Sample size: 68 Age, median (IQR): 55 (51-60) Gender, %: Males: 21 Race/Ethnicity, %: AA: 66 Income: NR Insurance status: NR Education, %: <4th grade: 4 4th-6th grade: 10 7th-8th grade: 13 >9th grade: 72 Other characteristics, median (IQR): Years with diabetes: 7 (3 -15.5) Most recent A1C, %: 8.24 (7.6-10) Health literacy/numeracy levels, %: REALM: < 4th grade: 13.2 4th-6th grade: 25 7th-8th grade: 19.1 High school: 42.6

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Diabetes Health Belief Model scale score Most recent hemoglobin A1C level Covariates used in multivariate analysis: Education Age Race Diabetes knowledge Most recent A1C Description of outcome measures: Diabetes Health Belief Model scale score - 11-question health beliefs questionnaire that operationalizes the Health Belief Model for individuals with diabetes. Patients read questions and respond on Likert scale regarding their belief in a given statement regarding diabetes and its management. Most recent hemoglobin A1C level - an indicator of patient's current level of glycemic control Data source(s) for outcomes: Diabetes Health Belief Model: self-report A1C: medical record Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Relationship between Diabetes Health Belief Model and HL was measured using bivariate analysis and linear regression for the multivariate analysis. Relationship between A1C and HL was measure using bivariate analysis and linear regression for the mutlivariate analysis.	Describe results: No significant relationship between Diabetes Health Belief Model scale score and HL. Lower literacy was clinically and statistically significant in predicting H1C levels. Effect in no exposure (i.e., adequate literacy) or control group: Diabetes Health Belief Model Score, mean (SD): HS: 42.0 (4.5) 7th-8th grade: 41.2 (3.9) 4th-6th grade: 38.8 (3.9) Median HbA1C%: HS: 7.9 7th-8th grade: 9.6 4th-6th grade: 8.3 Effect in exposure (i.e., low/moderate literacy) or intervention: Diabetes Health Belief Model Score: <4th grade, mean (SD): 37.7 (4.8) Median HbA1C (IQR): <4th grade, %: 8.3 (7.7-9.3) Difference: Difference in Health Belief Model Scores across HL levels (adjusted): (*P* = 0.29) Difference in Hemoglobin A1C across HL levels (adjusted): (*P* = 0.02)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Powers et al., 2008[65] Research objective: Examine association between literacy and blood pressure in primary care patients with hypertension and to determine if relationship was consistent across 2 distinct healthcare delivery systems. Study design: Cross-sectional Study setting: Primary care clinics in VAHS and UHS in Durham, NC. Measurement period: VAHS: March 2002 to April 2003 UHC: May 2004 to December 2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM < 9th grade (score of 0 - 60): limited ≥ 9th grade (score of 61 - 66): adequate	Eligibility criteria: Included: Diagnosis of hypertension based on ICD-9 codes (401.0, 401.1, or 401.9) A filled prescription for hypertensive meds in previous year Excluded: Spouse participating in study Not living in 8 county catchments area Receiving kidney dialysis Recipient of an organ transplant Planning a pregnancy Hospitalization for stroke Myocardial infarction Coronary artery revascularization in prior 3 months Metastatic cancer Dementia Residence in nursing home or receiving home healthcare Difficulty speaking or understanding English Severe hearing or speech impairment Sampling strategy: Convenience Sample size: 1224 Age (range): 62.3 yrs (21-92) Gender, %: Female: 35 Race/Ethnicity, %: White: 52.5; Black: 47.2 Income, %: Adequate: 80; Inadequate: 20 Insurance status: NR Education, %: 0 - 9th grade:10.6 10th - 12th grade: 32.7 Some College/Vocational: 25 College graduate: 31.7 Other characteristics: Participatory decision-making score VAHS, mean (SD): 26.0 (5.6) UHS, mean (SD): 26.1 (5.0) Health literacy/numeracy levels: VAHS, %: Limited: 38.4; Adequate: 58.3 UHS, %: Limited: 27.5; Adequate: 72.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: SBP DBP Covariates used in multivariate analysis: Age Race Marital status Education Adequacy of income Diabetic status Medication Adherence Smoking Exercise Participatory decision-making score Description of outcome measures: Blood pressure readings were abstracted from individuals' medical record at the time of study entry. Clinic nurses using standard automated devices obtained the patient's resting seated BP prior to their visit with the primary care provider. Data source(s) for outcomes: Medical record abstraction Attempts for control for confounding: Multiple linear regression Blinding: NA Statistical measures used: Multiple linear regression: relationship between literacy and healthcare system with the primary outcome SBP after controlling for potential confounders. An interaction term of literacy and health system was included in the model to test whether association between literacy and SBP differed across healthcare systems. Logistic regression used to examine relationship between literacy and healthcare system on DBP and BP control outcome.	Describe results: Not sig difference between limited and adequate literacy in relation to SBP. However, interaction between literacy and healthcare system was sig suggesting larger differences in SBP according to literacy level for patients in UHS than VAHS. Similar interaction effects were not found in relation to DBP or BP control. Effect in no exposure (i.e., adequate literacy) or control group, mean (SD): VAHS – SBP: 138.4 (17.5) UHS – SBP: 133 (17.6) VAHS – DBP: 75.5 (11.1) UHS – DBP: 77.2 (10.6) VAHS - BP in control: 141 (41.1) UHS - BP in control: 237 (51.4) Effect in exposure (i.e., low/moderate literacy) or intervention, mean (SD): VAHS – SBP: 138.7 (17.8) UHS – SBP: 142 (24.9) VAHS – DBP: 75.5 (11.9) UHS – DBP: 79.7 (11.8) VAHS - BP in control: 99 (43.8) UHS - BP in control: 76 (43.4) Difference: Difference in systolic BP (adjusted), β (CI): -1.2 (-4.8-2.3), *P* = NS Difference in systolic BP (adjusted): Literacy by Healthcare system (interaction), (≥ 9th grade and VAHS, ref): 7.4 (2.5-12.3), *P* = 0.003

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Raehl et al., 2006[66] Research objective: To test whether the REALM and sTOFHLA are predictors of intended oral prescription medication adherence among older adults Study design: Cross-sectional Study setting: 3 Comprehensive retirement communities and an adult day care center, Amarillo TX Measurement period: 1-time assessment, date not reported Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: < 3rd grade (0-18) 4th-6th grade (19-44) 7th-8th grade (45-60) > 9th grade (61-66) sTOFHLA: Inadequate (0-16) Marginal (17-22) Adequate (23-36)	Eligibility criteria: Included: Conversational English Adequate hearing Age 65+ years Corrected vision of 20/200 or better Excluded: Non-English speaking Inadequate corrected vision or hearing Alexia Self-reported diagnosis of Alzheimer's disease or dementia Sampling strategy: NR Sample size: 57 Age (range) (SD): 79.49 (65-91) (7.26) Gender, %: Females: 72 Race/Ethnicity, %: White: 81 Hispanic: 9 AA: 5 Other: 5 Income: NR Insurance status, %: Received Medicaid in last 10 years: 25 Education, (range) (SD): 11.33 years(0-17) (3.88) Other characteristics: Geriatric Depression Scale (GDS), (SD), range: 10.39 (6.90), 0-26 MMSE: 25.14 (3.56), 16-30 Former occupation professional/technical, %: 42 Married, %: 26 Owned a car in last 10 years, %: 77 Received food assistance in last 10 years, %: 16 Lives alone, %: 66 Health literacy/numeracy levels, mean (SD) and range: REALM: 55.42 (18.25), 0-66 sTOFHLA: 17.32 (13.14), 0 36

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Medication adherence Covariates used in multivariate analysis: Age Gender Marital status Education MMSE GDS Number of drugs Owned a car in last 10 years Received Medicaid in last 10 years Received food assistance in last 10 years Manages medications independently Receives legal help Active DNR Description of outcome measures: Medication adherence measured by the MedTake Test: pharmacist observes subject opening prescription medication containers and demonstrating intended medication taking ability for their own drugs; pharmacist gives score of 0-100% based on accuracy of dose, indication, regimen, and coingestion with food or water; total score is a composite mean of individual drug scores Data source(s) for outcomes: Patient demonstration Attempts for control for confounding: Multivariate linear regression Blinding: NR Statistical measures used: Pearson's correlation, Cramer's V, Spearman rank correlation coefficient, multivariate linear regression	Describe results: In multivariate model, participants with higher REALM scores had sig higher scores on MedTake Test, measure of medication adherence (controlling for sTOFHLA score and educational achievement, among other variables). Relationship between MedTake and STOFHLA was not sig. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Composite MedTake Test (adjusted) REALM (continuous), β: 0.666, *P* <0.01 each point increase in REALM score, participants had a 0.666 higher MedTake Test score. sTOFHLA (continuous), β: <0.1, *P* = NS

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al., 2006[67] Research objective: Examine relationship between health literacy and the understanding of food labels. Study design: Cross-sectional Study setting: Academic primary care clinic Measurement period: June 2004 - April 2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM to measure literacy ≥HS level (9th grade or above) WRAT-3 to measure numeracy <HS: Below HS= level (9th grade or above)	Eligibility criteria: Included: Adult patients 18-80 Excluded: Poor vision Dementia Psychiatric illness Non-English speaking Sampling strategy: Convenience Sample size: 200 Age, mean (SD): 43 (14.6) Gender, %: Females: 72 Race/Ethnicity, %: White: 67 Black: 25 Other: 8 Income, %: <$20,000: 25 $20,000-39,999: 24 $40,000-59,999: 22 ≥60,000: 28 Insurance status, %: Private insurance: 73 Education, %: ≤High School: 33 Some college: 34 College or more: 34 Other characteristics, %: Reads Food Labels: 89 Health literacy/numeracy levels, %: Literacy: <HS: 23 ≥HS: 77 Numeracy: <HS: 63 ≥HS: 37

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Main Outcome of this study is comprehension of nutrition labels, which is not a relevant outcome for this review. However, descriptive analysis measure other outcomes by HL: Chronic illness Obesity Read food labels Covariates used in multivariate analysis: Age Gender Race/ethnicity Income Education Insurance status Presence of chronic disease Status of being on a specific diet Label reading frequency Description of outcome measures: Chronic illness: dichotomous variable indicating if patient had a chronic illness that required dietary restriction, includes hypertension, coronary artery disease, high cholesterol, diabetes, and heart failure. Obese: BMI ≥30, dichotomous Read food labels: dichotomous NLS: questions related to understanding real food labels, both literacy and numeracy evaluations Data source(s) for outcomes: Self report Attempts for control for confounding: Yes in relation to NLS Blinding: NR Statistical measures used: t-tests Wilcoxon rank-sum tests for continuous variables Fisher's exact test or Chi square test for categorical variables Multinomial logistic regression	Describe results: Lower literacy and numeracy skills sig associated with poorer performance on NLS, controlling for potential confounders. No statistically sig difference existed in presence of chronic disease, obesity or reading food levels between higher and lower literacy or numeracy. Effect in no exposure (i.e., adequate literacy) or control group, %: Literacy: Chronic illness: 38 Obese: 43 Read food labels: 89 Numeracy: Chronic illness: 35 Obese: 40 Read food labels: 93 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Literacy: Chronic illness: 52 Obese: 53 Read food labels: 87 Numeracy: Chronic illness: 44 Obese: 48 Read food labels: 86 Difference: Literacy: Difference in NLS score (adjusted): data NR, $P < 0.001$ Difference in percent with chronic illness (unadjusted): ($P = 0.08$) Difference in percent obese (unadjusted): ($P = 0.31$) Difference in percent reads food labels (unadjusted): ($P = 0.71$) Numeracy: Difference in NLS score (adjusted): data NR, $P < 0.001$ Difference in percent with chronic illness (unadjusted): ($P = 0.20$) Difference in percent obese (unadjusted): ($P = 0.30$) Difference in percent reads food labels (unadjusted): ($P = 0.11$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2006[68] Research objective: Determine whether literacy mediates relationship between education and glycemic control among diabetes patients. Study design: Cross sectional Study setting: Two primary care clinics at San Francisco General Hospital Measurement period: June - December 2000 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: s-TOFHLA no cut points, used as continuous variable	Eligibility criteria: Included: Visited 1 of 2 primary care clinics in prior 12 months At least 1 visit to primary care physician in prior 6 months Had recorded HbA1C in database > 30 years old Spoke English or Spanish Type 2 diabetes Excluded: End-stage renal disease Psychotic disorder Dementia Blindness Sampling strategy: Convenience Sample size: 395 Age (mean) (SD): 57.9 (11.4) Gender: NR Race/Ethnicity, %: Asian/Pacific Islander: 18.5 Black: 25.3 Hispanic: 42.3 White: 13.9 Income, %: Less than $5,000: 24.3 $5,000 - 9,999: 44.5 $10,000-<20,000: 21.8 $20,000-<30,000: 5.3 $30,000+: 4.1 Insurance status, %: None: 30.6 Medicare: 37.0 Medi-Cal: 23.3 Commercial: 9.1 Education, %: Some high school or less: 46.8 High school/GED: 24.1 College/technical school: 29.1 Other characteristics, %: Primary language other than English: 51.7% Health literacy/numeracy levels, mean (SD): 20.6 (12.1)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: HbA1C Covariates used in multivariate analysis: Ethnicity Primary language other that English Insurance Education Full mediation model: age, immigration status, type of health insurance Description of outcome measures: HbA1C - measure of patients' glycemic control over approximately 3 month period. Mean (SD): 8.5 (1.9) Log transformed to correct for non-normal distribution. Data source(s) for outcomes: HbA1C - Value obtained from San Francisco General Hospital database, which used ion-exchange chromatography to measure HbA1C. Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Path Analysis: Analyses compared 2 competing models—a direct effects model and a mediational model—to explain patients' glycemic control. Direct effects model: relationship between educational attainment and HbA1C (w/out literacy). Mediational model: estimated strength of the direct relationshop between educational attainment and HbA1C when HL added into model to allow expression of a relationship between HL scores and HbA1C.	Describe results: In low-income population with diabetes, literacy mediated relationship between education and HbA1C. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Effect of education partially mediated through HL: Difference (Effect) of Literacy Score on Log HbA1C: ($P < 0.05$) Higher literacy associated with greater glycemic control Effect of education fully mediated through HL: Difference (effect) of Literacy Score on Log HbA1C: ($P = 0.03$) Higher literacy associated with greater glycemic control Both specifications including HL improved model.

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Sentell and Halpin, 2006[69] Research objective: Understand effect of adult literacy on explanatory power of education and race in predicting health status among US adults Study design: Cross-sectional Study setting: NALS administered in-person Measurement period: 1992 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: Total NALS score combining prose, document, and numeracy domains Level 1: <224 Level 2: 225-274 Level 3: 275-324 Level 4: 326-374 Level 5: 375+	Eligibility criteria: Included: NA Excluded: Below 18 years old Blind Mentally retarded Sampling strategy: Random, nationally representative, with over sampling of AA and Hispanic Sample size: 23,889 Age (mean and range), %: >25: 15 25 to 34: 23 35 to 44: 22 45 to 54: 14 55 to 64: 11 65+: 15 Gender, %: Males: 48 Race/Ethnicity, %: White: 68 Black: 18 Hispanic: 7 Other: 7 Income, %: <$5,000: 19 $5,000-9,999: 16 $10,000-14,999: 14 $15,000-19,999: 11 $20,000-29,999: 16 $30,000-39,999: 10 $40,000-49,999: 6 $50,000-74,000: 5 $75,000-99,999: 1 $100,000+: 1 Income missing: 23 Insurance status: Education, %: None: 1 Elementary: 1 Middle School: 7 Some High School: 15 GED/High School Diploma: 58 BA/BS: 13 Postgraduate: 6

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Condition keeps from work Long-term illness Covariates used in multivariate analysis: Race Education Understand English Born in USA. Unemployed Family income Missing Sex Age Married Get food stamps Live in Metropolitan Statistical Area Region Description of outcome measures: Self-report: Condition keeps from work: "Do you have a physical, mental, or other health condition that stops your participation fully in work, school, housework, or other? Long-term illness: Do you have a long-term illness (6 months or more)? Data source(s) for outcomes: NALS - in person survey Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Multivariate logistic regression Odds ratios represent the effect of a 10-point increase on the original NALS literacy scale compared to the level below it.	Describe results: Higher HL is associated with lower odds of having condition that keeps you from work as well as having long-term illness. Adding HL to the models predicting these two health status measures partially mediates the effect of race and reduces the size Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference, OR (CI): Difference in having a condition that keeps you from work (adjusted): 0.90 (0.88-0.92) Difference in having a long-term illness (adjusted): 0.96 (0.94-0.98) Difference in being black on having a condition that keeps you from work (adjusted): Model without HL: 1.54 (1.29-1.84) Model with HL: 1.04 (0.85-1.26) Difference in being black on having long-term illness (adjusted) Model without HL: 1.24 (1.03-1.49) Model with HL: 1.07 (0.89-1.30)

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Sentell and Halpin, 2006[69] (continued)	Other characteristics, %: Born in USA: 89 Unemployed: 7 Married living with spouse: 49 Food Stamps: 9 Live in Metropolitan Statistical Area: 77 Census region: Northeast: 21 Midwest: 24 South: 34 West: 21 Health literacy/numeracy levels, %: Level 1: 20 Level 2: 27 Level 3: 34 Level 4: 18 Level 5: 2

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Sharif and Blank, 2010[70] Research objective: To test the relationship between child health literacy and BMI in overweight children Study design: Cross-sectional Study setting: Primary care pediatrics clinic in an inner city academiccommunity health center in the Bronx, NY Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: STOFHLA Adequate HL: >or=23	Eligibility criteria: Inclusion: Children ages 6-19 BMI >or= 85th percentile for age and sex Receiving primary care at study site Enrolled with one legal guardian Exclusion: Developmental impairment Hemodynamically siginificant heart disease Neuromuscular disorders Sampling strategy: Convenience Sample size: N = 78 Children from 69 families Age (mean and range), %: Median=11.5 (10-16) Gender, %: NR Race/Ethnicity, %: AA: 35 Latino: 62 White: 3 Income, %: NR Insurance status, %: Medicaid: 78 Non-medicaid: 22 Education, %: Median (range) Grade school: 6 (5-11) Other characteristics, % (SD): Child BMI: 30.9 (5.1) Child BMI Z-score: 2.3 (0.4) Parental BMI: 33.3 (8.5) Parental education: < 12th grade: 24 12th grade: 40 >12th grade: 36 Child eating self-efficacy: 3.4 (1.0) Parent eating self-effiicacy: 3.1 (1.1) Health literacy/numeracy levels, %: Child STOFHLA (mean , SD): 22.9 (9.0) (52% adequate HL) Parental STOFHLA (mean, SD): 29.1 (8.6) (77% adequate HL)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: BMI-Z score Covariates used in multivariate analysis: Age Parental BMI Child-eating self-efficacy Parental eating self-efficacy Parental STOFHLA Description of outcome measures: BMI Z-scores calculated using weight, height, age, gender Data source(s) for outcomes: Measured directly Attempts for control for confounding: Regression analysis Blinding: NR Statistical measures used: Descriptive statisitcs followed by bivariate analysis followed by a regression model	Describe results: Child health literacy was negatively and independently correlated with BMI-Z score in overweight children. Effect in no exposure (i.e., adequate literacy) or control group: NA Effect in exposure (i.e., low/moderate literacy) or intervention: Child STOFHLA accounted for 13% of the relationship between BMI Z-score and child age, parental BMI, child self-efficacy, and child STOFHLA Beta scores (*P* value) Child STOFHLA= -0.43 ($P < 0.0001$) Chld eating self-efficacy= -0.39 ($P < 0.0001$) Child age= -0.21 ($P = 0.055$) Parental BMI= 0.27 ($P = 0.006$) Difference: Child BMI Z-score For every one point increase in child's HL score (adjusted), the BMI Z-score decreased by 0.016 points (95% CL, -0.025 to -0.008)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Shone et al., 2009[71] Research objective: Determine relationship between numeracy levels and ability to correctly interpret treatment benefits Study design: Cross-sectional Study setting: Rochester City School District in New York, where over 40% of children live in poverty Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: Low HL: < 9th grade Adequate: ≥ 9th grade	Eligibility criteria: Included: Parents of children with persistent asthma, who began elementary school within school district in 2006, 2007, or 2008 Excluded: No health literacy data Parent conducted interview in Spanish Sampling strategy: Convenience Sample size: 499 Adequate HL: (n = 335) Low HL: (n = 164) Age (mean and range): Total: 7 years (3-10) Gender: NR Race/Ethnicity, %: Total: Black: 63.3 White: 12.4 Other: 24.4 Parent is: Hispanic: 21.9 Adequate HL Black: 67.2 White: 14.6 Other: 18.2 Low HL: Black: 55.5 White: 7.9 Other: 36.6 Income: NR Insurance status, %: Child has public insurance: Total: 87.4 Adequate HL: 85.3 Low HL: 91.9 Education: NR Other characteristics, %: Parent employed: Total: 65.8 Adequate HL: 72.7 Low HL: 51

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Number of symptom-free days over two weeks Use of any urgent care in past yr Unmet health care need in past yr Parent experiences with reading/ filling out medical forms Parent perception of child's overall health Parent perception of asthma control Covariates used in multivariate analysis: Child health insurance and parent Employment, ethnicity, and race Description of outcome measures: Self-report: # symptom-free days over 2 wks, use of any urgent care in past yr, unmet health care need in past yr (parent had to delay or not get health care for child when parent felt care was needed; or delay or not get prescriptions for child when parent felt they were needed), parent experiences with reading/ filling out medical forms Parent perception of child's overall health (excellent/good, fair/poor), parent perception of asthma control, and degree of parent worry about the child's health PACQLQ: parent-reported QoL, 13 items about impairment related to child's asthma during past wk (emotional function and activity Items are scored on a 7-point Likert scale. Other subscales used to measure dependent variables (previously validated): Perceived need for asthma meds (e.g., ''My child's life would be impossible without their controller medicines'') Parent beliefs about asthma meds (BMQ) (e.g., ''My child's controller medicines are a mystery to me'''). Higher scores greater need or concern. Treatment expectations, degree of parent optimism or pessimism about child's asthma treatment (e.g., ''I expect that my child can fully participate in gym and normal physical activity") Higher scores more positive expectations. Ten items that describe parent perception of interactions with providers regarding child's asthma. Higher scores represent greater worry or concern. Four items measuring parent beliefs about when to seek care for child's asthma. Higher scores indicate greater inclination to seek care Data source(s) for outcomes: In-person interviews during home visits Attempts for control for confounding: Multivariate regression	Describe results: In bivariate analyses, parent HL level was not related to different use of preventive asthma medicines or urgent care for the child, or BMQ concerns for the child. In adjusted analyses, low HL did significantly predict perception of child's health as more likely to be fair/poor, greater worry about child's health, lower PACQoL, greater perceived need for asthma medicines, lower expectations about asthma treatment, and perception of worse interactions with providers about the child's asthma. HL was not related to BMQ concerns. Effect in no exposure (i.e., adequate literacy) or control group, %: Used any preventive medicines: 66.9 Used any urgent care: 41.2 Any unmet health care need: 22.1 Child's health is fair/poor: 17.3 Worry more than other parents: 42.8 Asthma is not under good control: 82.4 Number of symptom free days, mean (SD): 8.02 (4.76) Parent quality of life, mean (SD): 5.41 (1.17) Treatment expectations, mean (SD): 3.06 (0.64) Interactions with provider, mean (SD): 4.14 (0.52) Parent beliefs about when to seek care, mean (SD): 3.83 (0.86) BMQ need for medicines, mean (SD): 16.56 (3.86) BMQ concerns, mean (SD): 14.17 (3.70) Effect in exposure (i.e., low/moderate literacy) or intervention, %: Used any preventive medicines: 71.3 Used any urgent care: 40.9 Any unmet health care need: 18.9 Child's health is fair/poor: 39 Worry more than other parents: 60.7 Asthma is not under good control: 75.6 Number of symptom free days, mean (SD): 8.01 (4.98) Parent quality of life (SD): 5.18 (1.36) Treatment expectations, mean (SD): 2.82 (0.62) Interactions with provider, mean (SD): 3.85 (0.5) Parent beliefs about when to seek care, mean (SD): 3.90 (0.84) BMQ need for medicines, mean (SD): 18.15 (3.89) BMQ concerns, mean (SD): 14.80 (4.11) Difference: Difference (unadjusted): Used any preventive medicines: (P = 0.357) Used any urgent care: (P > 0.999) Any unmet health care need: (P = 0.483) Asthma not under good control: (P = 0.094) Number of symptom free days: (P = 0.99) Parent beliefs about when to seek care: (P = 0.353) Difference in BMQ concerns, Std. β (CI): 0.69 (-0.21-1.35)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Shone et al., 2009[71] (continued)	Health literacy/numeracy levels, %: Adequate: 67 Low: 33 Health literacy/numeracy levels, %: Adequate: 67 Low: 33

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Blinding: NR Statistical measures used: Bivariate analyses (chi-square and t-test) to identify associations between parent HL and dependent measures. Multivariate logistic and linear regression analyses of dependent variables that were sig in bivariate analyses at a level of $P<0.10$.	Difference (adjusted): Child's health is fair/poor, OR (CI): 3.96 (2.4-6.4) Worry more than other parents, OR (CI): 1.85 (1.2-2.8) Parent quality of life, Std. β (CI): -0.097 (-0.51 - -0.004) Treatment expectations, Std. β (CI): -0.15 (-0.3 - -0.7) Interactions with provider, Std. β, (CI): -0.2 (-0.3 - -0.1) BMQ need for medicines, Std. β (CI): 0.15 (0.4-0.2) Difference in BMQ concerns, Std. β (CI): 0.69 (-0.21-1.35)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Smith and Haggerty, 2003[72] Research objective: Assess whether health literacy is associated with self-perceived health status Study design: Cross-sectional Study setting: University-affiliated family practice center in Montreal, Canada Measurement period: November 1997 - December 1997 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM Low: ≤ 6th (0 - 44) Adequate: > 6th grade (45+)	Eligibility criteria: Included: 18-85 years old Had clinical encounters in English Excluded: Too ill Poor vision Sampling strategy: Convenience sample Sample size: 229 Low, n = 15 Adequate, n = 214 Age: Mean: 47 Range: 18-85 Gender, %: Females: 61 Race/Ethnicity: NR Income: NR Insurance status: NR Education, mean: 13.5 years Other characteristics, %: Maternal language: English: 51 French: 12 Other: 37 Current smoker: 26.6 Health literacy/numeracy levels, %: Low: 6.5 Adequate: 93.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Perceived general health Covariates used in multivariate analysis: Age Smoking status Maternal language Description of outcome measures: COOP/WONCA Charts, based on Nelson's COOP Charts, measure primary care patients' perceptions of their overall health and well-being. Each category is illustrated with a pictogram and accompanying qualitative words. Patients are asked to rate each health dimension during the last two weeks on a scale from 1 (excellent) to 5 (poor). To differentiate between current and overall health, they also asked patients to rate their health "today." Has been validated against other measures. Perceived overall health measured on a scale from 1 excellent - 5 poor Data source(s) for outcomes: In person interview administered by study staff Attempts for control for confounding: Multivariable linear regression Blinding: No Statistical measures used: Correlation analysis and multivariable linear regression controlling for observed confounders. To profile low-literacy patients, multivariable modeling used to find the best explanatory model	Describe results: Perceived general health was not significantly different between literacy groups. Effect in no exposure (i.e., adequate literacy) or control group: Perceived overall health: (mean score): 3.0 Effect in exposure (i.e., low/moderate literacy) or intervention: Perceived overall health (mean score): 3.3 Difference: Perceived general health (adjusted), β (CI): -0.11 (-0.25-0.03) Not sig at $P < 0.05$

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Sudore et al., 2006[73] (companion: Sudore et al., 2006[74]) Research objective: Assess relationship between limited literacy and mortality in elders. Study design: Prospective cohort, retrospective analysis Study setting: Random sample of 70-79 year olds including white Medicare beneficiaries and black residents in designated ZIP code areas surrounding U of Pittsburgh and U of Tennessee, Memphis Measurement period: Baseline exam: May 1997-June 1998 Literacy assessment: 1999 Mortality data: July 1999-August 2004 Follow-up duration, mean, median: 5.1 years, 4.2 years Completeness of follow-up: NR Measurement tools including cutpoints: REALM: < 3rd grade (0-18) 4th-6th grade (19-44) 7th-8th grade (45-60) > 9th grade (61-66)	Eligibility criteria: Included: Medicare eligible Community dwelling Age 70-79 Residence in designated study zip codes Excluded: Difficulty walking one quarter of a mile Difficulty climbing a flight of stairs Difficulty performing basic activities of daily living Cinical dementia Inability to communicate with the interviewer Sampling strategy: Brochures mailed to random sample of residents in designated zip codes; then all eligible residents were contacted by phone to request participation. Recruited: 3,075, of these, 563 HL not assessed for various reasons Sample size: 2,512 Age, mean, range (SD): 75.6, 71-82 (2.8) Gender, %: Female: 52.0 Male: 48.0 Race/Ethnicity, %: Black: 38.1 Income, %: > $50,000: 17.5 $25,000-$50,000: 33.3 $10,000-$25,000: 37.4 <$10,000: 11.9 Insurance status, %: Lack insurance for medications: 36.0% Education, %: Postgraduate: 12.9 College: 13.1 Vocational/some college: 23.9 High school: 27.8 < High school: 22.1 Health literacy/numeracy levels, %: Limited literacy (<9th grade): 23.7 Adequate literacy (≥9th grade): 76.3

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: All-cause mortality Covariates used in multivariate analysis: Demographics: age, race, gender, income, ed. Health status: self-rated health, cardiac disease, stroke, cancer, hypertension, Diabetes, obesity. Health-related behaviors: Either former smoker (>100 cigarettes in lifetime) or current smoker Drinking >1 alcoholic beverage per day Poor health care access: lack of a regular doc or clinic, no flu shot within the past 12 months, no ins to cover meds Psychosocial status: high depressive symptoms, poor personal mastery Description of outcome measures: All-cause mortality Data source(s) for outcomes: All-cause mortality identified by: Notification of death during attempts to contact participants or by proxy, spouse, relative, or friend Hospital records Local obituaries Social Security Death Index data (all deaths subsequently confirmed by Attempts for control for confounding: Multivariable logistic regression Blinding: NR Statistical measures used: t-tests Chi-square Kaplan Meier survival curves Cox proportional hazard models Multivariable logistic regression Propensity scoring	Describe results: Compared to participants with adequate literacy, those with limited literacy had a higher risk of death in fully adjusted and partially adjusted models. Similar results were found in sub-populations identified by race, sex, and income. Effect in no exposure (i.e., adequate literacy) or control group, %: Adequate literacy, died: 10.6 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Limited literacy, died,: 19.7 Difference: Association between HL and mortality (adjusted): Partial adjustments, HR (CI): Demographics: 1.83 (1.34-2.50) Health status: 1.86 (1.47-2.35) Health-related behaviors: 2.12 (1.69-2.67) Poor health care access: 2.01 (1.59-2.55) Poor psychological status: 1.96 (1.56-2.47) Fully adjusted: 1.75 (1.27-2.41) Adjusted, after excluding participants with incident cognitive impairment, HR (CI): 1.94 (1.37-2.74) Sub-population analysis: association between HL (0-8th grade vs. higher) and mortality (unadjusted), HR (CI): White: 2.36 (1.63-3.42) Black: 1.66 (1.28-2.29) Men: 2.01 (1.51-2.67) Women: 1.77 (1.20-2.62) ≥HS: HR, 2.27 (1.67-3.09) <HS: 1.77 (1.10-2.81) ≥$10,000 annual income, HR (CI): 2.06 (1.60-2.64) <$10,000 annual income, HR (CI): 1.86 (0.96-3.60)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Sudore et al., 2006[74] (Companion: Sudore et al., 2006[73]) Research objective: Determine relationship between health literacy, demographics and access to health care Study design: Cross-sectional (participants part of larger prospective cohort study-Health ABC Study) Study setting: In-clinic assessment in Memphis (49%) and Pittsburgh (51%) areas Well-functioning, Medicare recipients living in the community with multiple sources of medical care Measurement period: One time (1999/2000) Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: 0-6th grade 7-8th grade ≥9th grade	Eligibility criteria: Included: Medicare eligible English-speaking Community-dwelling Part of health ABC Study Excluded: Self-reported difficulty walking 1/4 mile Climbing a flight of stairs Performing basic activities of daily living Clinical dementia Sampling strategy: All persons in ABC study who participated in the clinic interview Sample size: 2,512 Age (mean and range) (SD): 76 (2.8) Range: 71-82 Gender, %: Males: 48 Race/Ethnicity, %: Black: 38 White: 62 Income, %: <$10,000: 12 Insurance status, %: Medicare eligible: 100 Education, %: <HS: 22 Other characteristics: NR Health literacy/numeracy levels, %: Limited: 24 Memphis: 32 Pittsburgh: 16 0-6th grade: 8 7-8th grade: 15 ≥9th grade: 76

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Health status Poor health Hypertension Diabetes Obesity Depression Access to care including: No doctor/clinic No influenza shot in 12 months No insurance for medication Composite access measure is any of the 3 above Covariates used in multivariate analysis: Demographics (age, race, sex, income) Study site Self-rated health status Comorbidities (cardiac disease, stroke, cancer, hypertension, diabetes, obesity, high depressive symptoms) Description of outcome measures: Dichotomous for yes/no outcomes Data source(s) for outcomes: Health status measured through self-reported physician diagnosis, clinical data, and medication use. Obesity measured through BMI. Depression measured through CES-D Survey self report Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Analysis of variance for continuous variables Chi-square for dichotomous variables Logistic regression for multivariate analysis	Describe results: Those with lower HL had significantly worse health status in unadjusted analyses. including poor health, hypertension, diabetes, obesity, and depression In relation to access to health care measures, lowest literacy group had significantly less access than the highest literacy group on 3 out of 4 measures. 7th-8th grade literacy group did not differ significantly from higher literacy group in any access measures Outcomes for 0-6th grade versus ≥9th grade sig after education added to the models. Effect in no exposure (i.e., adequate literacy) or control group, %: >9th grade Health Status: Poor health: 13.9 Hypertension: 54.7 Diabetes: 14.6 Obesity: 23.0 Depression: 1.6 Access: No doctor/clinic: NR No influenza shot in 12 months: NR No insurance for medications: NR Composite access measure: NR Effect in exposure (i.e., low/moderate literacy) or intervention, %: 7th-8th grade Health Status: Poor health: 28.0 Hypertension: 63.2 Diabetes: 25.6 Obesity: 32.1 Depression: 2.9 Access: No doctor/clinic: NR No influenza shot in 12 months: NR No insurance for medications: NR Composite access measure: NR 0-6th grade Health Status: Poor health: 32.6 Hypertension: 61.8 Diabetes: 24.5 Obesity: 29.3 Depression:- 5.7 Access: No doctor/clinic: NR No influenza shot in 12 months: NR No insurance for medications: NR Composite access measure: NR

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Sudore et al., 2006[74] (Companion: Sudore et al., 2006[73]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Difference: Poor health (unadjusted): 0-6th and 7-8th grade versus ≥ 9th grade: OR, 2.60, 95% CI, 2.09- 3.23 Hypertension (unadjusted): 0-6th and 7-8th grade versus ≥ 9th grade, OR (CI): 1.39 (1.25-1.68) Diabetes Mellitus (unadjusted): 0-6th and 7-8th grade versus ≥ 9th grade, OR (CI): 1.98 (1.58-2.48) Obesity (unadjusted): 0-6th and 7-8th grade versus ≥ 9th grade, OR (CI): 1.51 (1.23-1.85) Depression (unadjusted): 0-6th and 7-8th grade versus ≥ 9th grade, OR (CI): 2.54 (1.47-4.42) Access: No doctor/clinic (adjusted), OR (CI): 0-6th grade versus ≥ 9th grade: 1.27 (0.69-2.33) 7-8th grade versus ≥ 9th grade: 1.11 (0.67-1.86) No influenza shot in 12 months (adjusted), OR (CI): 0-6th grade versus ≥ 9th grade: 1.70 (1.20-2.41) 7-8th grade versus ≥ 9th grade: 1.06 (0.80-1.41) No insurance for medication (adjusted), OR (CI): 0-6th grade versus ≥ 9th grade: 1.73 (1.23-2.43) 7-8th grade versus ≥ 9th grade: 1.03 (0.80-1.33) Composite access measure (adjusted), OR (CI): 0-6th grade versus ≥ 9th grade: 1.95 (1.33-2.85) 7-8th grade versus ≥ 9th grade: 0.95 (0.74-1.23)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Tang et al., 2008[75] Research objective: Determine if health literacy is associated with HbA1C levels Study design: Cross-sectional survey And medical chart review Study setting: Diabetes education management Center of a public hospital in Hong Kong Measurement period: 30 min interviews from Sept 2005 to Feb 2006 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: Chinese S-TOFHLA (validation part of the study) Inadequate: 0-58 Marginal: 59-66 Adequate: 67-100	Eligibility criteria: Included: Type 2 DM ≥18 Able to read and wrote Chinese Able to give informed consent Excluded: < 20/100 vision Unintelligible speech Overt psychiatric illness Sampling strategy: Convenience Sample size: 149 Age (range): 59.8 (27-90) Gender, %: Females: 45.6 Race/Ethnicity: NR (assumed 100% Chinese) Income: NR Insurance status, %: No insurance: 66.4 Education, %: No formal:12.8 Primary: 43 Junior secondary: 28.9 Senior secondary: 10.7 ≥ College: 4.7 Other characteristics, %: Receiving diabetes education: 63.1 Diabetes treatment: Diet only: 8.7 Diet and oral anti-diabetic drug (OAD): 85.2 Diet, OAD and insulin therapy: 2.7 Diet and insulin therapy: 3.4 Health literacy/numeracy levels: NR

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: HbA1C Covariates used in multivariate analysis: Gender Insurance Duration of diabetes Patient awareness score C-SDSCA (management of diabetes) Description of outcome measures: HbA1C Data source(s) for outcomes: Medical records Attempts for control for confounding: Univariate analysis of variables associated with HbA1C followed by step-wise multivariate regression analysis Blinding: NA Statistical measures used: Univariate: Spearman's coefficient (rs) was used to examine whether there was an association between health literacy, complication awareness factors and HbA1C level Multivariate: Stepwise regression analysis to examine factors predictive of patients' HbA	Describe results: Higher HL was significantly associated with lower HbA1C levels in adjusted model. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: HbA1C level (adjusted): B, -0.12, $P < 0.001$

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Torres and Marks, 2009[76] Research objective: Examine relationships among health literacy, self-efficacy, and behavioral intent concerning hormone therapy. Study design: Cross-sectional Study setting: Nagle Family Health Center, Washington Heights/Inwood section of New York City Measurement period: August to September, 2005 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: sTOFHLA: Inadequate: 0-16 Marginal: 17-22 Adequate: 23-26	Eligibility criteria: Included: NR Excluded: NR Sampling strategy: Convenience Sample size: 106 Age, mean (SD): 52.58 (5.35) Gender: Females: 100% Race/Ethnicity, %: Hispanic: 75 White: 23 Black: 2 Income: NR Insurance status: NR Education, %: Elementary school: 13 High School or GED: 60 Some college: 19 Bachelor's degree: 4 No response: 4 Other characteristics, %: Length of time with current providers: Less than one month: 1 1-6 months: 14 7-11 months: 44 1-2 years: 35 3-5 years: 4 More than 5 years: 1 No response: 1 Discussion about hormone therapy with provider: Yes: 9 No: 37 Don’t recall/No response: 54 Marital status: Married: 52 Single: 8 Widowed: 10 Divorced or separated: 30 Health literacy/numeracy levels, %: Mean (SD): 19.66 (7.15) Inadequate: 46 Marginal: 18 Adequate: 36

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Self-Efficacy (SD): 26.85 (7.81) Behavioral intent regarding hormone therapy Covariates used in multivariate analysis: Age Current knowledge of hormone therapy Education Marital status Race Description of outcome measures: Self-efficacy: 11 question scale rating self-confidence or belief in one's ability to make decisions Behavioral intent concerning hormone therapy: 0-10 scale rating certainty with which woman would choose hormone therapy Data source(s) for outcomes: Survey questionnaire Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Bivariate correlations Pearson's correlation tests Stepwise regression	Describe results: A statistically significant (unadjusted) positive correlation between health literacy and self-efficacy was observed. In adjusted model, self-efficacy and health literacy explain 75% of variance in behavioral intent, controlling for age, knowledge of hormone therapy, education, marital status, and race. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Self efficacy correlated with health literacy (unadjusted): 0.70, $P < 0.01$ Behavioral intent: Health literacy explains 9% of R2 variance when entered as step 2 of stepwise regression after self-efficacy explained 66% (adjusted): ($P < 0.05$). Direction of relationship not presented.

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: von Wagner, 2009[77] Research objective: Aimed to document association between health literacy and willingness and ability to seek information about new CRC screening program in UK. Aimed to assess self-efficacy for screening to determine impact of health lit Study design: Cross-sectional Study setting: Study sessions were conducted in a private room at the Department of Epidemiology, University College London Measurement period: Participants reported on key demographic characteristics (age, gender, education, employment, race and ethnicity) Information seeking: Participants read information about the UK CRC screening program and FOBT screening kit using an interactive com Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: UK-TOFHLA	Eligibility criteria: Included: Aged 50-69 years No prior participation in the screening Excluded: NR Sampling strategy: Investigators invited 144 members from Health Behavior Research Centre Participant Panel; 86 (60%) agreed to participate; 12 participants recruited by snowballing from primary recruits Sample size: Total Sample: 96 144 Recruited from Participant Panel, 86 agreed to participate 12 From snowball sample 2 Excluded (prior screening participation; over age 70) Age, mean (SD), range, median: 54.2 (4.3) - Table 59.8 (4.3)- In text Range: 52-69 Median: 59 Gender, %: Females: 66.7 Race/Ethnicity, %: Non-white: 19.8 Income: NR Insurance status: NR Education, %: <University: 33.3 Other characteristics, %: Retired or unemployed: 38.9 Health literacy/numeracy levels: Mean (SD): 92.19 (9.79) Range: 26-100 Median: 95

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Information seeking: number of times participants accessed information links in an interactive computer menu Effort (average reading time per information link): Divided the total amount of time participants spent in the information menu by the number of Covariates used in multivariate analysis: Demographics (age, gender, ethnicity and employment status) Description of outcome measures: Information seeking: numerical count Effort: numerical average Comprehension: composite scale (3 questions excluded from final analyses b/c >80% answered them correctly) Self-efficacy: 5-point ordinal scale (1=strong disagree 5=strong agree) Data source(s) for outcomes: Information seeking: computer clicks (clicking on links pops up new windows) Comprehension and self-efficacy: survey self-report Attempts for control for confounding: Multivariate linear regression Blinding: NA Statistical measures used: Bivariate analyses Multivariate linear regression Dichotomized race and ethnicity (white vs. non-white) and employment status (employed vs. retired or unemployed) in multivariate analyses Tested for impact of outliers (defined as standard residuals >2)	Describe results: Information-seeking (unadjusted): # links open (SD): 7.19 (3.25) Range: 0-11 Median: 7 Participants with lower health literacy scores opened fewer links, r = 0.18, *P* = 0.07 Processing Effort (unadjusted), mean (SD): Reading time per link: 00:34 (00:25) Range: 00:13-02:52 Median: 00:25 Health literacy scores were significantly associated with reading time; participants with lower health literacy scores took longer to read individual informational links, r= -0.57, *P* < 0.001 Comprehension (unadjusted), mean (SD): CRC screening knowledge 3.30 (1.64) Range: 0-7 Median: 3 No significant association between health literacy and CRC screening knowledge, r = -0.05, *P* = 0.64 Self-efficacy (unadjusted), mean (SD): Perceived ability to take part in BCSP 17.85 (2.03) Range: 9-15 Median: 18.5 [reported range and median seem questionable given median is larger than upper bound of range] Health Literacy is significantly associated with self-efficacy, r = 0.33, (*P* < 0.001) Information seeking (adjusted), β (CI): Participants with lower health literacy opened fewer links: 0.079 (0.001-0.157) Effort (adjusted), β (CI): Participants with lower health literacy take more time per link, β (CI): -0.965 (-1.457- -0.473) Self-efficacy for CRC screening participation (adjusted), β (CI): Performing well on the UK-TOFHLA was predictive of higher self-efficacy for participating in CRC screening: 0.041 (0.007-0.076) Effect in no exposure (i.e., adequate literacy) or control group: NA Effect in exposure (i.e., low/moderate literacy) or intervention: NA Difference: NA

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Waite et al., 2008[56] (companions: Osborn et al., 2007[54]; Wolf et al., 2007[55]) Research objective: Examine whether social stigma is possible mediator to relationship between literacy and self-reported HIV medication adherence. Study design: Cross-sectional Study setting: Infectious disease clinics in Shreveport, Louisiana and Chicago, Illinois Measurement period: June - September, 2001 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: low: 0 - 44 Marginal: 45 - 60 Adequate: 61 - 66	Eligibility criteria: Included: Receiving one or more antiretroviral medications Excluded: Patient on regimen for less than 2 weeks Patients with blindness or impaired vision not correctable with glasses, dementia, deafness or hearing problems not correctable with hearing aid, or too ill to participate in survey Sampling strategy: Consecutive series of HIV-infected patients receiving medical care at one of the infectious disease clinics Sample size: 204 Age, mean: 40.1 Gender, %: Males: 79.9 Race/Ethnicity, %: AA: 45.1 Income, %: <$800/month: 39.7 Insurance status, %: Uninsured: 27.5 Education, %: Some college education: 60 Other characteristics, %: Unemployed: 55.9 Also being treated for non-HIV related chronic illness: 52.5 Mental health services: nearly one-third Substance abuse: 9.3 Health literacy/numeracy levels, %: Low: 11.3 Marginal: 20.1 Adequate: 68.6

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Medication adherence Covariates used in multivariate analysis: Stigma concerns Age Gender Site Employment status Number of medications in HIV regimen Number of non-HIV prescription medications taken Comorbid chronic condition Treatment for mental health condition Treatment for substance abuse Description of outcome measures: Medication adherence - Administered Patient Medication Adherence Questionnaire, asked to identify the medications in their current regimen, as well as self-report any recent missed doses (in last four days) using pages that contained names and color photographs of common HIV medications Data source(s) for outcomes: Patient survey (self-report) Attempts for control for confounding: Multivariate analysis Blinding: No Statistical measures used: Logistic regression Mediation analysis	Describe results: Patients with low literacy were more likely to report medication nonadherence until stigma is entered into the model, then significance of literacy disappears, indicating that perceived social stigma mediates the relationship between health literacy and medication adherence. Effect in no exposure (i.e., adequate literacy) or control group: Non-adherence in past 4 days 1 or more missed doses, %: 30 Effect in exposure (i.e., low/moderate literacy) or intervention: Non-adherence in past 4 days Marginal: 1 or more missed doses: 19.5 Low: 1 or more missed doses: 52.2 Difference: Adjusted: Model 1: (Model does not include social stigma) Difference in Adherence (Low vs. Adequate), OR (CI): 3.3 (1.3-8.7) Difference in Adherence (Marginal vs. Adequate), OR (CI): 2.1 (0.8-5.5) Model 2: (Model does not include health literacy)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Waldrop-Valverde et al., 2009[78] Research objective: To test the relationship between health literacy and numeracy to medication management capacity among HIV positive men and women, and to test whether health literacy and/or numeracy mediated the effects of gender on the outcome Study design: Cross-sectional Study setting: HIV clinics or participants in AIDS drug assistance program in Miami, Florida Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: Health Literacy: TOFHLA, Range 0-50 and the % correct was calculated Numeracy: Applied problems subset of Woodcock Johnson III 63 items Cut point: when the participant responds incorrectly to the last 6 consecutively administered items or when the final item is administered. Scores convented to Z scores with a mean of 0 and a SD of 1	Eligibility criteria: HIV positive, > or = 18 yrs Receiving antiretorviral treatment (ART) or "in process" for first course of ART, no history of head injury or loss of conciousness lasting more than 30 mins, no presence of psychotic symptoms at time of enrollment, not used heroin, cocaine or marijuana in the past 12 mts Sampling strategy: Convenience Sample size: N=155 Male (n=90) Female (n=65) Age (mean and range), %: NR other than no sig difference between men and women Gender, %: Female: 58 Race/Ethnicity, %: Black: Among Men: 81 Among Women: 95 Income, %: NR Insurance status, %: NR Education, % (SD): Men: 11.7 yrs (2.6) Women: 11.3 yrs (1.8) Other characteristics, %: Regular place to stay: Men: 84 Women: 99 Yrs since HIV diagnosis, % (SD): Men: 8.6 (7.0) Women: 11.1 (6.2) Health literacy/numeracy levels, %: Health Literacy (% TOFHLA correct): Men: 78 Women: 73 Numeracy (Applied problems Z-score): Men: -0.81 Women: -1.32

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Medication Management Test (MMT): MMT % correct: Men: 65% Women: 58% (*P* = NS) Covariates used in multivariate analysis: Included only variables found to be sig related to MMT: Gender, education and time since HIV diagnosis Regression analysis includes health literacy and numeracy Path analysis includes numeracy and excludes health literacy. Description of outcome measures: Medication Management Test (MMT): Measures ability to understand ART medication instructions 8 items with a totoal of 16 points, There were 5 "mock" HIV medications with labels. Test score based on answers to questions about the medication labels, the loperamide insert, the ability to correctly count out and place a week's supply of pills in a medication organizer and to determine missed doses and refills. Total % correct used in the analysis Data source(s) for outcomes: Directly measured Attempts for control for confounding: Hierarchical multiple regression to examine whether health lit and numeracy are associated with the outcome. Path analysis to examine mediator analysis. Blinding: NR Statistical measures used: Hierarchical multiple regression testing the association of health literacy and numeracy with MMT scores. Mediation effects were tested using path analytic techniques	Describe results: MMT score outcome (hierarchical multiple regression model): Step 1 regressors: years of ed, time since HIV diagnosis and gender; explained 14% of variance in outcome (P < 0.001) Step 2 (adding TOFHLA to step 1 variables); adding health literacy accounted for additional 21% of variance (P < 0.001) Step 3 Final model (adding numeracy to step 2): accounted for an additional 12% of the variance. The final model explained a total of 48% of the variance in MMT scores Health literacy and numeracy were positively and significantly associated with MMT Women were less likely to understand medication instructions as assessed by the MMT and so path analysis conducted to determine if numeracy mediated differences between men and women in MMT performance. Found that the relationship between gender and MMT performance is mediated by numeracy Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Difference in MMT score Health literacy: $\beta = 0.210$ ($P < 0.05$) Numeracy (applied problems: $\beta = 0.538$ ($P < 0.01$) Mediator Path analysis: Difference in Medication Management Capacity Female: Indirect effect on numeracy: -0.428 ($P < 0.01$) Direct effect on Medication Management Capacity: 0.073 (*P* = NS) Numeracy: Direct effect on Medication Management Capacity: 0.644 ($P < 0.01$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Walker et al., 2007[79] Research objective: Intervention: Determine effectiveness of a pictorial 'mind map' together with ARC booklet for imparting knowledge to participants with rheumatoid arthritis, and to relate this to participant reading ability Study design: RCT Study setting: Participants recruited in three hospital Rheumatology departments in the UK. Measurement period: NR Follow-up duration: 1 week Completeness of follow-up: NR Measurement tools including cutpoints: For the intervention: REALM as a continuous variable	Eligibility criteria: Included: Patients diagnosed by their Rheumatologist as having rheumatoid arthritis and willing to take part in the study Excluded: NA Sampling strategy: Convenience sample Sample size: 363 Intervention, n = 175 Control, n = 188 Age, mean (SD): Intervention: 61.96 (12.23) Control: 61.57 (11.64) Gender, % F: Overall: 70.5 Intervention: 71.4 Control: 69.7 Race/Ethnicity: NR Income: NR Insurance status: NR Education, %: HS or equiv: 85 7th–8th: apprx.: 11 < 7th: < 4 Other characteristics: Disease duration, Mean (SD) Intervention: 13.7 (10.27) Control: 12.76 (10.85) English is 1st language: 97% Health literacy/numeracy levels: Overall REALM < 60, %: 15 REALM < 45, %: 4 REALM score, Mean (SD) Intervention: 62.26 (9.12) Control: 63.28 (7.96) For the health outcomes of Depression and Anxiety: REALM ≥60: good readers REALM < 60: poor readers

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: KSQ Anxiety Depression Covariates used in multivariate analysis: None Description of outcome measures: KSQ: The KSQ was adapted from an existing rheumatoid arthritis knowledge questionnaire for use in clinical settings. Eight sections comprised 40, true/false statements. Scoring system was +1 if correct, 0 if not completed or don't know, and -1 if incorrect. Possible scores ranged from -40 to +40. KSQ administered pre-intervention and post-intervention by telephone. Depression and Anxiety: Patients performed Hospital Anxiety and Depression scale (HAQ and HAD) See Zigmond Acta Psychiatric Scand 1983; 67: 361-70. See Fries. Arthritis Rheum 1980; 23: 137-45. Data source(s) for outcomes: KSQ: pre-intervention, not clear if administered as a written survey or interview; post-intervention, interviewed by telephone. HAQ/HAD: it isn't clear if administered as written survey or interview. Attempts for control for confounding: Randomization ANOVA Blinding: NR Statistical measures used: Mann-Whitney U test used to compare mean increases in knowledge between the intervention and control groups. Univariate analysis of variance with difference between KSQ scores as the dependent variable and REALM score, age,intervention group, depression	Describe results: No statistically significant difference in knowledge gained between participants who received mind map and booklet and those who received booklet only. People with higher REALM scores gained more knowledge, regardless of whether they were in intervention or control. Poor readers were significantly more anxious and more depressed than the good readers. Effect in no exposure (i.e., adequate literacy) or control group: KQ2 (Control group) Increase in knowledge, mean (CI): 6.56 (3.36-8.75) KQ1 (good reader)* Depression, mean (CI): 6.5 (5.9-7.0*) Anxiety, mean (CI): 7.7 (7.1-8.2*) *read from a figure Effect in exposure (i.e., low/moderate literacy) or intervention: KQ2 (Intervention group) Increase in knowledge, mean (CI): 6.45 (3.78-10) KQ1 (poor reader)* Depression, mean, (CI): 8.1 (6.8-9.5*) Anxiety, mean, (CI): 9.4 (7.9-10.8*) *read from a figure Difference: KQ2 Difference in increase in knowledge between intervention and control groups: Mann-Whitney U-statistic -0.11, (unadjusted $P > 0.3$) Note: REALM score predicts change in knowledge, (adjusted $P < 0.003$) KQ1 Anxiety: ($P = 0.03$) Depressed: ($P = 0.01$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Weiss and Palmer, 2004[80] Research objective: Determine effectiveness of a pictorial 'mind map' together with ARC booklet for imparting knowledge to participants with rheumatoid arthritis, and to relate this to participant reading ability Study design: Secondary analysis of cross-sectional survey, retrospective review of records Study setting: Medicaid subjects in Arizona Measurement period: 1992 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: IDR: scores 0-8, equivalent to grade reading level. Low literacy: ≤ 3rd grade Higher literacy: ≥ 4th grade	Eligibility criteria: Included: Enrolled in a Medicaid managed-care plan based on medical need or medical indigence, English or Spanish speaking, ≥ 18 years old Excluded: Enrolled due to pregnancy Sampling strategy: Computer-generated, random sample Sample size: 74 Age (mean and range): 49.9 (21-77) Gender, %: Females: 28.4 Race/Ethnicity, %: Hispanic: 52.1 White: 37 Other: 10.9 Income: NR Insurance status, %: Medicaid: 100 Education, mean (SD): 9.1 (4), (0-13) Other characteristics: Unemployed, %: 78.4 Self-Assessment of Health, %: Excellent: 6.8 Good: 23.3 Fair: 45.2 Poor: 24.7 Lang. of Best Reading Skill: English: 72.9 Spanish: 27 Health literacy/numeracy levels, %: Low: 24.32 Higher: 75.68

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Total medical care charges Covariates used in multivariate analysis: Age Ethnic group Health status (Education used in separate analysis and found not to be a significant predictor of costs) Description of outcome measures: Sum of health plan billing charges: hospital, ED, short-term nursing home, and physician care, outpatient and inpatient charges for laboratory, radiographs, pharmacy, and durable medical equipment. Data source(s) for outcomes: In person interviews, billing records Attempts for control for confounding: Multivariable analysis Blinding: NA Statistical measures used: t-tests measured differences in health care costs between low- and higher literacy groups. Multivariable analysis to control for potential confounders	Describe results: Participants in low literacy group generated higher charges for health care than those in higher literacy group, after controlling for potential confounders. A separate analysis predicting effect of education (not controlling for health lit) found education not significant. Effect in no exposure (i.e., adequate literacy) or control group: Total charges, mean (range): $2,890 ($0-$38,957) Inpatient charges, mean (range): $824 ($0-$18,135) Effect in exposure (i.e., low/moderate literacy) or intervention: Total charges, mean (range): $10,688 ($0-$95,002) Inpatient charges, mean (range) $7,038 ($0-$76,884) Difference: Difference between high and low literacy groups (adjusted): ($P = 0.037$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: White et al., 2008[12] (companion: Bennett et al., 2009[11]) Research objective: Assess relationship between health literacy and utilization of preventive health services among nationally representative US sample Study design: Cross-sectional survey Study setting: Nationally representative US sample living in households Measurement period: 90 minute interviews from March 2003 to January 2004 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: NAAL: measures functional health literacy (prose, quantitative, and document literacy) Grouped into below basic, basic, intermediate and proficient literacy level Oral Reading Fluency instrument: Reading aloud, in English 150-200 words measured as correct words read/minute	Eligibility criteria: Included: ≥ 16 Living in a US household Excluded: Inmates Unable to be interviewed because of a language barrier Unable to be interviewed because of a mental illness Sampling strategy: 4-stage stratified area design to select a nationally representative sample Sample size: 18,100 Age (mean and range), %: Mean age: 44 years 16-39 years: 44 40-64 years: 41% >65 years: 15 Gender, %: Females: 52 Race/Ethnicity, %: White: 71 Black: 11 Hispanic: 12 Other: 6 Income, %: Below poverty: 17 100-175% poverty: 18 >175% poverty: 64 Insurance status, %: Uninsured: >18 Education: NR Other characteristics, %: Reported poor health: 4 Reported fair health: 11 Reported good to excellent health: 86 Average oral reading fluency: 154 words read correctly/minute Health literacy/numeracy levels, %: Basic or below basic: 36 Intermediate: 53 Proficient: 12

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Preventive health care (dental check-up, vision check, osteoporosis screening, colon cancer screening, pneumonia shot, flu shot, pap smear, mammogram, prostate cancer screening) Covariates used in multivariate analysis: Age Gender Race Poverty level Insurance status Self-reported health status Oral reading fluency Description of outcome measures: Self-report Data source(s) for outcomes: Interview Attempts for control for confounding: Marginal maximum likelihood probit regression analyses Blinding: NA Statistical measures used: MML probit regression analyses: Represents each respondent's literacy proficiency as a probability distribution rather than assigning a literacy score	Describe results: Adults under 40: Low health literacy was related to decreased probability of having a pap smear and a vision check-up, and an increased probability of having a flu shot. It was not associated with dental check-ups, $P<0.05$ Effect in no exposure (i.e., adequate literacy) or control group: NA Effect in exposure (i.e., low/moderate literacy) or intervention: NA Difference: NA

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2005[7] (companions:Gazmararian, 2006;[3] Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Baker et al., 2008;[8] Howard et al., 2005;[9] Baker et al., 2004;[2]) Research objective: Investigate relationship between health literacy and functional health status among cohort of new Medicare managed care enrollees from 4 US cities Study design: Cross-sectional Study setting: In-person in-home interviews with and subsequent claims data for enrollees in Cleveland, Houston, Tampa, and south Florida (including Ft. Lauderdale and Miami) Measurement period: Interviews occurred May 1997-December 1997 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: S-TOFHLA: Adequate Marginal Inadequate	Eligibility criteria: Included: Medicare managed-care enrollee 65+ Enrolled in Prudential HealthCare 3 months or more Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Missed 1 or more screening questions for severe cognitive impairment (not able to correctly identify year, month, state, year of their birth, or home address) Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: 2,923 Age (mean and range): 71 By health literacy level: Adequate, %: 65-69 - 44.3 70-74 - 28.2 75-79 - 17.3 80-84 - 8.0 > 85 - 2.2 Marginal, %: 65-69 - 29.4 70-74 - 26.1 75-79 - 23.9 80-84 - 15.2 > 85 - 5.6 Inadequate, %: 65-69 - 24.5 70-74 - 25.6 75-79 - 22.5 80-84 - 16 Gender, %: Female by HL status: Adequate: 58.4 Marginal: 53.6 Inadequate: 59.0

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Self-rated physical and mental health functioning Self-reported chronic conditions Activity of daily living limitations Covariates used in multivariate analysis: Age Sex Race/ethnicity Income Education Tobacco Alcohol consumption Self-reported comorbid conditions Site Description of outcome measures: Self-rated physical and mental health functioning measured by Medical Outcomes Study 36-Item SF-36 subscales Chronic conditions (hypertension, diabetes, coronary artery disease, heart failure, bronchitis or emphysema, asthma, arthritis, cancer) self-reported in in-person interview Activity limitations measured by, instrumental activities of daily living, activities of daily living, limitations in activity because of physical health, fewer accomplishments because of physical health, and pain that "quite a bit" or "extremely" interfered with normal work activities Data source(s) for outcomes: In-person orally administered survey Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Chi-square, logistic regression, linear regression	Describe results: In adjusted models, in relation to chronic conditions, enrollees with inadequate HL were sig more likely to report having diabetes and heart failure, significantly lower self-reported physical funtion and mental health scores, and were more likely to have limitations in IADLs, ADLs, limitations because of physical health, fewer accomplishments because of physical health, and pain that interfered with work. Those with marginal HL did not report any increased prevalence of chronic diseases compared to those with adequate HL, showed reduced physical and mental health functioning only in models that did not adjust for eduction, and were more likely to have limitations in IADLs, ADLs, and limitations and fewer accomplishments due to physical health in fully adjusted models. Effect in no exposure (i.e., adequate literacy) or control group: Hypertension, %: 43.3 Diabetes, %: 12.8 Coronary artery disease, %: 7.6 Heart failure, %: 3.8 Bronchitis or emphysema, %: 13.5 Asthma, %: 7.3 Arthritis, %: 50.1 Cancer, %: 6.0 Physical function mean score: 78.0+24.6 Mental health mean score: 84.0+16.1 Smoking, %: Never: 38.6 Former: 49.0 Current: 12.4 Current alcohol use, %: None: 57.9 Light to moderate: 38.0 Heavy: 4.1 BMI, %: <18.5: 4.3 18.5-24.9: 56.8 25.0-29.9: 26.8 >30.0: 12.1 Effect in exposure (i.e., low/moderate literacy) or intervention: Inadequate -Prevalence of self-reported conditions, %: Hypertension: 49.9 Diabetes: 18.7 Coronary artery disease: 5.6 Heart failure: 6.1 Bronchitis or emphysema: 9.7 Asthma: 6.6 Arthritis: 57.3 Cancer: 4.2 Smoking, %: Never: 46.7 Former: 41.6 Current: 11.7

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2005[7] (companions:Gazmararian, 2006;[3] Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Baker et al., 2008;[8] Howard et al., 2005;[9] Baker et al., 2004;[2]) (continued)	Race/Ethnicity, %: By HL status: Adequate: White: 83.6 AA: 6.5 Hispanic English-speaking: 1.8 Hispanic Spanish-speaking: 7.0 Other: 1.1 Marginal: White: 66.1 AA: 13.0 Hispanic English-speaking: 2.7 Hispanic Spanish-speaking: 17.9 Other: 0.3 Inadequate : White: 57.1 AA: 25.6 Hispanic English-speaking: 2.6 Hispanic Spanish-speaking: 13.8 Other: 0.9 Income, %: Income <$15,000 by HL status: Adequate: 31.9 Marginal 46.8 Inadequate 54.8 Insurance status, %: Medicare: 100 Education, %: By HL status: >12 years of school completed: Adequate: 39.5 Marginal: 20.4 Inadequate: 22.1 0-8 years of school completed: Adequate: 7.3 Marginal: 24.7 Inadequate: 41.8 Other characteristics: Health literacy/numeracy levels, %: Adequate: 66.5 Marginal: 11.3 Inadequate: 22.2

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Current alcohol use, %: None: 75.6 Light to moderate: 22.9 Heavy: 1.5 BMI, %: <18.5: 7.5 18.5-24.9: 56.3 25.0-29.9: 25.0 >30.0: 11.2 Physical function mean score: 67.7+29.7 Mental health mean score: 76.2+20.9 Marginal - Prevalence of self-reported conditions, %: Hypertension: 46.2 Diabetes: 15.2 Coronary artery disease: 6.7 Heart failure: 3.7 Bronchitis or emphysema: 9.7 Asthma: 8.2 Arthritis: 56.5 Cancer: 7.0 Smoking, %: Never: 42.1 Former: 44.9 Current: 13.0 Current alcohol use, %: none: 64.2 Light to moderate: 33.9 Heavy: 1.8 BMI, %: <18.5: 4.0 18.5-24.9: 56.2 25.0-29.9: 25.5 >30.0: 14.3 Physical function mean score (unadjusted): 73.7+27.5 Mental health mean score (unadjusted): 81.8+18.6 Difference: Difference in prevalence of chronic disease (adjusted), OR (CI): Inadequate/Adequate: Hypertension: 1.20 (0.95-1.50) Diabetes: 1.48 (1.09-2.02) Coronary artery disease: 0.93 (0.59-1.47) Heart failure: 1.69 (1.02-2.80) Bronchitis or emphysema: 0.75 (0.53-1.08) Asthma: 0.96 (0.62-1.37) Arthritis: 0.98 (0.78-1.23) Cancer: 0.91 (0.54-1.52) Marginal/Adequate, OR (CI): Hypertension: 1.03 (0.80-1.34) Diabetes: 1.10 (0.75-1.59) Coronary artery disease: 0.85 (0.51-1.43) Heart failure: 0.97 (0.49-1.90)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2005[7] (companions:Gazmararian, 2006;[3] Wolf et al., 2007;[4] Baker et al., 2007;[5] Howard et al., 2006;[6] Baker et al., 2008;[8] Howard et al., 2005;[9] Baker et al., 2004;[2]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Bronchitis or emphysema: 0.81 (0.53-1.22) Asthma: 1.26 (0.79-2.01) Arthritis: 1.11 (0.85-1.44) Cancer: 1.38 (0.84-2.27) Differences in self-reported physical and mental health (adjusted including ed), β (CI): Inadequate/Adequate - Physical function: -6 (-8.4--3.5) Mental health: -4.9 (-6.7--3.1) Marginal/Adequate: Physical function: -1.1 (-3.9-1.8) Mental health: -0.9 (-2.9-1.2) Differences in self-reported activity limitations (adjusted including ed), OR (CI): Inadequate/Adequate: IADLS: 2.25 (1.74-2.92) ADLs: 2.83 (1.62-4.96) Limitations because of physical health: 1.79 (1.39-2.32) Fewer accomplishments: 1.90 (1.48-2.45) Pain interfering with activities: 2.01 (1.46-2.77) Marginal/Adequate: IADLS: 1.65 (1.22-2.24) ADLs: 2.05 (1.06-3.97) Limitations because of physical health: 1.35 (1.00-1.84) Fewer accomplishments: 1.46 (1.08-1.97) Pain interfering with activities: 1.23 (0.83-1.82)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2006[81] Research objective: Assess relationship between literacy and medication guide and patient information leaflet use. Study design: Cross-sectional Study setting: Patients at Primary Care Clinic at Louisiana State University Health Sciences Center Measurement period: July 2003 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: ≤ 6th grade: low 7th-8th grade: marginal ≥ 9th grade: adequate	Eligibility criteria: Included: ≥ 18 yrs old Excluded: Severe visual or hearing impairment Too ill to participate Non-English speaking Sampling strategy: Convenience Sample size: 251 ≤ 6th grade: 74 7th-8th grade: 78 ≥ 9th grade: 99 Age, (mean and range) (SD): ≤ 6th grade: 50.0 (15.5) 7th-8th grade: 47.6 (15) ≥ 9th grade: 44.9 (14.2) Gender, % : Female: ≤ 6th grade: 60.8 7th-8th grade: 70.5 ≥ 9th grade: 78.8 Race/Ethnicity, %: AA: ≤ 6th grade: 89.2 7th-8th grade: 76.9 ≥ 9th grade: 40.4 White: ≤ 6th grade: 9.5 7th-8th grade: 20.5 ≥ 9th grade: 56.6 Other: ≤ 6th grade: 1.3 7th-8th grade: 2.6 ≥ 9th grade: 4 Income: NR Insurance status, %: Payment source for medication: Private: ≤ 6th grade: 5.4 7th-8th grade: 6.4 ≥ 9th grade: 12.1 Medicaid: ≤ 6th grade: 5.4 7th-8th grade: 7.7 ≥ 9th grade: 9.1

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Use of Medication Guides Number of prescriptions taken Covariates used in multivariate analysis: Age Gender Race Education Number of prescriptions taken Description of outcome measures: Medication guide use was assessed by a single survey item, "Do you ever look at the written materials that come with your prescription medications?" Data source(s) for outcomes: In-person interview Attempts for control for confounding: Multiple logistic regression Blinding: NR Statistical measures used: Bivariate: Student's t test, chi-square test Multiple logistic regression:	Describe results: Patients with lower literacy were less likely to report having looked at Medication Guide or informational leaflet information included with their prescription medications. Effect in no exposure (i.e., adequate literacy) or control group: Read medication guides? ≥ 9th grade: 32.9% # Medication taken daily: ≥ 9th grade: mean (SD): 2.8 (0.21) Effect in exposure (i.e., low/moderate literacy) or intervention: Read medication guides? ≤ 6th grade, %: 16.7 7th-8th grade, %: 21.8 # Medication taken daily: ≤ 6th grade, mean (SD): 2.9 (0.62) 7th-8th grade, mean (SD): 3.5 (0.40) Difference: Difference in whether Read medication guides low vs reference (authors do not specify if reference is marginal/adequate or just adequate: (adjusted), OR (CI): 2.5 (1.2-5.2) Difference in # medications taken daily (unadjusted): (*P* = NS)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2006[81] (continued)	Out of Pocket: ≤ 6th grade: 58.1 7th-8th grade: 71.8 ≥ 9th grade: 63.6 Other: ≤ 6th grade: Education, %: Grades 1-8: ≤ 6th grade: 21.6 7th-8th grade: 6.4 ≥ 9th grade: 4 Grades 9-11: ≤ 6th grade: 42 7th-8th grade: 37.2 ≥ 9th grade: 20.2 HS/GED: ≤ 6th grade: 33.8 7th-8th grade: 43.6 ≥ 9th grade: 40.4 >HS: ≤ 6th grade: 2.7 7th-8th grade: 12.8 ≥ 9th grade: 35.4 Other characteristics: Health literacy/numeracy levels, %: ≤ 6th grade: 29.5 7th-8th grade: 31 ≥ 9th grade: 39.5

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2006[82] Research objective: Evaluate association between literacy and PSA level in men newly diagnosed with prostate cancer Study design: Cross-sectional Study setting: Four outpatient oncology and urology clinics in Chicago area hospitals Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: ≤ 6th grade: low 7th-8th grade: marginal ≥ 9th grade: functional	Eligibility criteria: Included: English-speaking Men newly diagnosed with prostate cancer who have not, or only recently, begun treatment Excluded: Blind or severely impaired vision not correctable with eyeglasses, deaf or hearing problems Uncorrectable with a hearing aid, too ill to participate, did not understand the questions. Sampling strategy: Convenience Sample size: 308 Functional, n = 153 Marginal, n = 101 Low, n = 54 Age, mean (SD): 66.5 (8.4) < 65 yrs: Functional, %: 56 Marginal, %: 28.6 Low, %: 15.4 65-74 yrs: Functional, %: 40.7 Marginal, %: 37.9 Low, %: 21.4 > 74 yrs: Functional, %: 56.5 Marginal, %: 30.4 Low, %: 13 Gender: Male: 100% Race/Ethnicity, %: AA: Total: 68.5 Functional: 35.7 Marginal: 41.4 Low: 22.9 White: Functional:80 Marginal: 12.9 Low: 7.1 Income, %: < $10,000: Functional: 53.2 Marginal: 27.4 Low: 19.4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: PSA level at diagnosis (20.0 ng/mL or less vs > 20.0 ng/mL) Covariates used in multivariate analysis: Age Race Annual income Marital status Description of outcome measures: PSA level at diagnosis was obtained from medical record reviews. Elevated PSA levels defined as > than 20 ng/mL according to clinical criteria for "high-risk" prostate cancer Data source(s) for outcomes: Medical records Attempts for control for confounding: Multiple logistic regression Blinding: NR Statistical measures used: Chi-square, median, and Student t tests Logistic regression analysis: Model fit was assessed with c-statistics from the receiver operating characteristic curves and Hosmer-Lemeshow goodness-of-fit chi-square tests. Models adjusted for clustering	Describe results: Low HL was found to be a significant predictor of having elevated PSA but marginal HL was not. Health literacy was found to be a confounder/mediator for association between race and PSA level and contributed to a 35% reduction in association between race and PSA level. Effect in no exposure (i.e., adequate literacy) or control group, %: PSA Level > 20 ng/mL Functional: 13.5 Effect in exposure (i.e., low/moderate literacy) or intervention, %: PSA Level > 20 ng/mL Marginal: 24.1 Low: 33.3 Difference: Difference in PSA Level > 20 ng/mL (adjusted), OR (CI): Marginal HL vs functional HL: 1.4 (0.9-2.2) Low HL vs function HL: 2.5 (1.5-4.2) Race mediator analysis, OR (CI): AA (adjusted): 3.0 (0.8- 9.1) AA (adjusted model without HL): 4.6 (2.0- 9.5)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2006[82] (continued)	$10,000-$19,999: Functional: 40.4 Marginal: 40.4 Low: 19.3 $20,000-$29,999: Functional: 45.5 Marginal: 39.4 Low: 15.2 ≥ $30,000: Functional: 54.6 Marginal: 29.5 Low: 15.9 Insurance status: NR Education: NR Other characteristics, %: Marital Status: Not currently married: Functional: 54.4 Marginal: 29.8 Low: 15.8 Married: Functional: 48.2 Marginal: 37.5 Low: 14.3 Health literacy/numeracy levels, %: Low: 17.53 Marginal: 32.79 Functional: 49.68

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2007[19] (Companion: Davis et al., 2006[18]) Research objective: Investigate how patients approached and interpreted prescription drug label instructions, and document nature of misunderstanding that may contribute to high prevalence of medication error. Study design: Qualitative/In-person cognitive interviews Study setting: 3 primary care clinics in Shreveport, Louisiana, Jackson, Michigan, and Chicago, IL Measurement period: Consecutive summers beginning July 2003 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM Low: 0-44 Marginal: 45-60 Adequate: 61-66	Eligibility criteria: Included: 18 or older Excluded: Blindness or severely impaired vision not correctable with eyeglasses Deafness or hearing impairment not correctable with hearing aid Too ill to participate Non-English speaking Sampling strategy: Convenience Sample size: 395 Age (mean and range) (SD): 45 (14) (19-85) Gender, %: Male: 32 Race/Ethnicity, %: AA: 47 White: 48 Income: NR Insurance status, %: Lacked prescription drug coverage: 71 Education, %: Grades 1-8: 4 Grades 9-11: 24 Completed High School/GED: 43 High School: 29 Other characteristics, %: Physician most likely source of medication information: 71 Shreveport: 57 Jackson: 25 Chicago: 18 Health literacy/numeracy levels, %: Low: 19 Marginal: 29 Adequate: 52

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Misunderstanding of 1 or more dosage instructions Correctly interpreted primary label instructions Amoxicillin Trimethoprim Guaifenesin Felodipine Furosemide Attendance to auxiliary warnings Amoxicillin Trimethoprim Guaifenesin Felodipine Furosemide Demonstrated understanding Guaifenesin Covariates used in multivariate analysis: None used Description of outcome measures: Misunderstanding of 1 or more dosage instructions and correctly interpreting primary label instructions Participants provided container primary labels of prescription med instructions and asked "how would you take this medication?" Short probes often followed. Responses documented verbatim and rated correct or incorrect by three physicians. Correct scores given only if responses included all aspects of label's instructions, including dosage, timing, and if applicable, duration. Expert panel ruled on discordant ratings. Assessed as overall understanding and separately for each of the five drugs used. Dichotomous - correct or not Attendance to auxiliary warnings Interviewer instructed to document whether patient attempted to interpret auxiliary label along with primary label, or physically inspected bottle's color stickers. Assessed separately for each of the five drugs. Demonstrated understanding Patients asked to demonstrate how many pills were to be taken on a daily basis from a sample label and candy pills for one drug, Guaifenesin. After questions mentioned above - interviewer asked "show me how many pills of this medicine you would take in one day". dichotomous - correct or not. Data source(s) for outcomes: In-person interviews Attempts for control for confounding: No	Describe results: Differences in health literacy are associated with patient understanding of prescription bottle medication instructions. Effect in no exposure (i.e., adequate literacy) or control group, %: Misunderstanding of 1 or more dosage instructions: Adequate: 38 Marginal: 51 Rates of understanding primary label instructions and attendance to auxiliary warnings: Amoxicillin: Adequate: Correctly interpreted primary label: 86 Attended to auxiliary label(s): 5 Marginal: Correctly interpreted primary label: 66 Attended to auxiliary label(s): 4 Trimethoprim: Adequate: Correctly interpreted primary label: 73 Attended to auxiliary label(s): 8 Marginal: Correctly interpreted primary label: 66 Attended to auxiliary label(s): 7 Guaifenesin: Adequate: Correctly interpreted primary label: 89 Demonstrated understanding: 80 Attended to auxiliary label(s): 14 Marginal: Correctly interpreted primary label: 84 Demonstrated understanding: 63 Attended to auxiliary label(s): 7 Felodipine: Adequate: Correctly interpreted primary label: 95 Attended to auxiliary label(s): 3 Marginal: Correctly interpreted primary label: 88 Attended to auxiliary label(s): 11 Furosemide: Adequate: Correctly interpreted primary label: 91 Attended to auxiliary label(s): 15 Marginal: Correctly interpreted primary label: 91 Attended to auxiliary label(s): 9

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2007[19] (Companion: Davis et al., 2006[18]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Blinding: General internal medicine physicians and expert panel were blinded to all patient information in evaluating outcomes. Statistical measures used: Bivariate analysis	Effect in exposure (i.e., low/moderate literacy) or intervention, %: Misunderstanding of 1 or more dosage instructions: 63%Rates of understanding primary label instructions and attendance to auxiliary warnings: Amoxicillin (inadequate): Correctly interpreted primary label: 59 Attended to auxiliary label(s): 0 Trimethoprim (inadequate): Correctly interpreted primary label: 52 Attended to auxiliary label(s): 1 Guaifenesin (inadequate): Correctly interpreted primary label: 70 Demonstrated understanding: 35 Attended to auxiliary label(s): 0 Felodipine (inadequate): Correctly interpreted primary label: 87 Attended to auxiliary label(s): 4 Furosemide (inadequate): Correctly interpreted primary label: 83 Attended to auxiliary label(s): 3 Difference: Difference in misunderstanding of 1 or more dosage instructions (unadjusted): across the 3 HL groups: $P < 0.001$ Rates of understanding primary label instructions and attendance to auxiliary warnings: Amoxicillin (unadjusted): Difference in correctly interpreting primary label: across the 3 HL groups: ($P < 0.001$) Difference in attending to auxiliary label(s): across the 3 HL groups: ($P = 0.13$) Trimethoprim (unadjusted): Difference in correctly interpreting primary label: across the 3 HL groups: ($P < 0.001$) Difference in attending to auxiliary label(s): across the 3 HL groups: ($P = 0.14$) Guaifenesin (unadjusted): Difference in correctly interpreting primary label: across the 3 HL groups: ($P < 0.001$) Difference in demonstrating understanding: ($P < 0.001$) Difference in attending to auxiliary label(s): ($P < 0.001$) Felodipine (unadjusted): Difference in correctly interpreting primary label: across the 3 HL groups: ($P = 0.03$) Difference in attending to auxiliary label(s): ($P = 0.11$) Furosemide (unadjusted): Difference in correctly interpreting primary label: across the 3 HL groups: ($P = 0.09$) Difference in attending to auxiliary label(s): ($P = 0.01$)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2007[4] (companions: Gazmararian, 2006;[3] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8]) Howard et al., 2005;[9] Baker et al., 2004;[2]) Research objective: Investigate relationship between anxiety/depression and HL Study design: Cross-sectional Study setting: In-person in-home interviews for enrollees in Cleveland, Houston, Tampa, and south Florida (including Ft. Lauderdale and Miami) Measurement period: Interviews occurred May 1997-December 1997 Follow-up duration: NA Completeness of follow-up: 3487 enrolled, 3260 completed interview and S-TOFHLA; in addition, excluded 282 for previous stroke and 55 for severe cog impairment Measurement tools including cutpoints: S-TOFHLA: Adequate: 67-100 Marginal: 56-66 Inadequate: 0-55	Eligibility criteria: Included: Medicare managed-care enrollee 65+ Enrolled in Prudential HealthCare 3 months or more Excluded: Not comfortable speaking English or Spanish Blind or severely impaired vision not correctable with eyeglasses Living in a nursing home Missed 1 or more screening questions for severe cog impairment (not able to correctly identify year, month, state, year of their birth, or home address) Previous stroke Sampling strategy: Convenience sample of consecutive new Medicare managed-care enrollees Sample size: 2,923 Age (mean and range): 71 Gender, %: Female by HL: Adequate: Female: 58.4 Marginal: Female: 53.6 Inadequate: Female: 59.0 Race/Ethnicity, %: By HL status: Adequate: White: 83.6 AA: 6.5 Hispanic English-speaking: 1.8 Hispanic Spanish-speaking: 7.0 Other: 1.1 Marginal: White: 66.1 AA: 13.0 Hispanic English-speaking: 2.7 Hispanic Spanish-speaking: 17.9 Other: 0.3 Inadequate: White: 57.1 AA: 25.6 Hispanic English-speaking: 2.6 Hispanic Spanish-speaking: 13.8 Other: 0.9

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Smoking status Current alcohol use Physical activity Body mass index Seat belt use Covariates used in multivariate analysis: Age Gender Race/ethnicity Language Site Education Annual income Occupation Description of outcome measures: Smoking status - self-reported as never, former, or current Current alcohol use - measured by CAGE questionnaire Physical activity - self-reported # of times per wk exercises > 20 minutes Body mass index - calculated from self-reported height and weight Seat belt use - self reported as always, nearly always, sometimes, seldom, or never Data source(s) for outcomes: One-hour in-person orally administered survey Attempts for control for confounding: Multinomial logistic regression Blinding: NR Statistical measures used: Chi-square, multinomial logistic regression	Describe results: In unadjusted analysis, seat belt use did not differ by HL level. In adjusted analyses, smoking status, alcohol consumption, physical activity level, and BMI did not sig differ by HL level. Effect in no exposure (i.e., adequate literacy) or control group: Adequate: Smoking: Never: 38.6% Former: 49.0% Current: 12.4% Current alcohol use: None: 57.9% Light to moderate: 38.0% Heavy: 4.1% Physical Activity (per week): < 1 time: 21.6% 1-2 times: 15.1% 3 times: 15.3% > 4 times: 48.0% BMI: <18.5: 4.3% 18.5-24.9: 56.8% 25.0-29.9: 26.8% >30.0: 12.1% Seat belt use: Always: 77.5% Nearly always: 9.1% Sometimes: 6.4% Seldom: 3.0% Never: 4.0% (all numbers represent unadjusted figures) Effect in exposure (i.e., low/moderate literacy) or intervention, %: Inadequate: Smoking: Never: 46.7 Former: 41.6 Current: 11.7 Current alcohol use: None: 75.6 Light to moderate: 22.9 Heavy: 1.5 Physical Activity (per week): < 1 time: 38.2 1-2 times: 14.6 3 times: 13.9 > 4 times: 33.3

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2007[4] (companions: Gazmararian, 2006;[3] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8]) Howard et al., 2005;[9] Baker et al., 2004;[2]) (continued)	Income, %: Income <$15,000 by HL status: Adequate: 31.9 Marginal 46.8 Inadequate 54.8 Insurance status, %: Medicare: 100 Education, %: By HL status: >12 years of school completed: Adequate: 39.5 Marginal: 20.4 Inadequate: 12.2 0-8 years of school completed: Adequate: 7.3 Marginal: 24.7 Inadequate: 41.8 Other characteristics, %: Occupation: Primary "white collar": Adequate HL: 26.7 Marginal HL: 14.4 Inadequate HL: 9.6 Secondary "white collar": Adequate HL: 32.2 Marginal HL: 20.3 Inadequate HL: 16.8 Primary "blue collar": Adequate HL: 9.7 Marginal HL: 19.1 Inadequate HL: 14.2 Secondary "blue collar": Adequate HL: 24.1 Marginal HL: 37.2 Inadequate HL: 50.0 Not classified: Adequate HL: 7.3 Marginal HL: 9.1 Inadequate HL: 9.4 Health literacy/numeracy levels, %: Adequate: 66.5 Marginal: 11.3 Inadequate: 22.2

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	BMI: <18.5: 7.5 18.5-24.9: 56.3 25.0-29.9: 25.0 >30.0: 11.2 Seat belt use: Always: 72.4 Nearly always: 10.0 Sometimes: 8.3 Seldom: 3.7 Never: 5.1 Marginal: Smoking: Never: 42.1 Former: 44.9 Current: 13.0 Current alcohol use: None: 64.2 Light to moderate: 33.9 Heavy: 1.8 Physical Activity (per week): < 1 time: 25.1 1-2 times: 16.5 3 times: 17.7 > 4 times: 40.7 BMI: <18.5: 4.0 18.5-24.9: 56.2 25.0-29.9: 25.5 >30.0: 14.3 Seat belt use: Always: 78.3 Nearly always: 10.9 Sometimes: 6.7 Seldom: 3.6 Never: 4.9 (All numbers represent unadjusted figures) Difference, OR (CI): Smoking Status (adjusted)- Ever Smoked (vs never): Marginal/Adequate: 0.9 (0.7-1.2) Inadequate/Adequate: 0.9 (0.7-1.1) Quit Smoking (vs ever): Marginal/Adequate: 0.7 (0.5-1.0) Inadequate/Adequate: 0.9 (0.6-1.3) Alcohol Consumption (adjusted): Light to Moderate (vs none): Marginal/Adequate: 1.4 (0.6-3.3) Inadequate/Adequate: 1.1 (0.5-2.5)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2007[4] (companions: Gazmararian, 2006;[3] Baker et al., 2007;[5] Howard et al., 2006;[6] Wolf et al., 2005;[7] Baker et al., 2008;[8]) Howard et al., 2005;[9] Baker et al., 2004;[2]) (continued)	

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
	Heavy (vs none): Marginal/Adequate: 1.2 (0.5-2.8) Inadequate/Adequate: 1.3 (0.6-3.0) Physical Activity (per week) (adjusted): 1-2 times (vs < 1): Marginal/Adequate: 1.3 (0.9-1.8) Inadequate/Adequate: 1.0 (0.7-1.4) 3 times (vs < 1): Marginal/Adequate: 1.0 (0.7-1.5) Inadequate/Adequate: 0.9 (0.7-1.3) > 4 times (vs < 1): Marginal/Adequate: 1.0 (0.7-1.4) Inadequate/Adequate: 1.3 (0.9-1.7) BMI (adjusted): < 18.5 (underweight vs normal weight): Marginal/Adequate: 1.2 (0.6-2.3) Inadequate/Adequate: 0.8 (0.5-1.3) 25-29.9 (overweight vs normal weight): Marginal/Adequate: 1.1 (0.4-1.1) Inadequate/Adequate: 0.6 (0.4-1.1) 30 or greater (obese vs normal weight): Marginal/Adequate: 1.4 (0.3-1.1) Inadequate/Adequate: 0.6 (0.4-1.1) Comparisons across 3 HL groups (unadjusted): Seat belt use: (*P* = 0.13)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Wolf et al., 2007[55] (Companions: Osborn et al., 2007[54] and Waite et al., 2008[56]) Research objective: Examine relationship between patient literacy level and self-reported HIV medication adherence, while estimating mediating roles of treatment knowledge and self-efficacy on this relationship Study design: Cross-sectional Study setting: Outpatient infectious disease clinics at Northwestern Memorial Hospital (Chicago) and the Louisiana State University Health Sciences Center at Shreveport. Measurement period: June to September 2001 Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints: REALM: Low: < 6th grade Marginal: 7th - 8th grade Adequate: 9th grade and above	Eligibility criteria: Included: HIV-infected patients receiving medical care Prescribed one or more antiretroviral medications Excluded: On current regimen for less than 2 weeks Dementia Blindness or severely impaired vision not correctable with glasses Deafness or severely impaired hearing not correctable with hearing aid Too ill to participate in survey Sampling strategy: Consecutive HIV patients Sample size: 204 Age, mean (SD): 40.1 (9.2) Gender, %: Male: 79.9 Race/Ethnicity, %: AA: 45.1 Income, %: Household income less than $800/month: 39.7 Insurance status, %: Uninsured: 27.5 Education, %: Some college: 60 Other characteristics, %: Receiving treatment for a non-HIV related chronic illness: 52.5 Receiving mental health services: nearly 1/3 Alcohol/substance abuse treatment: 9.3 Health literacy/numeracy levels, %: Low literacy: 11.3 Marginal literacy: 20.1 Adequate: 68.6

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Medication adherence Covariates used in multivariate analysis: Age Insurance coerage Employment status Number of medications in HIV regimen Number of non-HIV prescription medications currently taking Presence of comobid chronic conditions Treatment for mental health condition past 6 months Treatment alcohol or drug use past 6 months Description of outcome measures: Medication adherence Patients self-reported any missed doses using pages that contained names and color photographs of common HIV medications included in a revised version of the PMAQ. PMAQ requires patients to identify their medication and then report on a missed dose in past 4 days for each antiretroviral agent in their regimen. Patients with any missed doses over last 4 days classified as non-adherent. Dictomous. Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Multivariate logistic regression Mediational analysis used to assess mediation effects of knowledge and self-efficacy on medication adherence.	Describe results: Low HL, but not marginal HL, was a significant predictor of medication non-adherence in the past 4 days. Low HL, not not marginal HL, was a significant predictor of low medication self-efficacy. Low HL is no longer significant in a model predicting adherence controlling for mediational effects of knowledge and self-efficacy. Moderator analysis testing interaction between HL with knowledge and self-efficacy was not significant. Effect in no exposure (i.e., adequate literacy) or control group, %: Poor HIV medication adherence: 70 Low HIV self-efficacy: 24.3 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Poor HIV medication adherence Marginal: 80.5 Low: 47.8 Low HIV self-efficacy: Marginal: 19.5 Low: 60.9 Difference, OR (CI): Difference in Poor HIV medication adherence (Adjusted): Adequate vs. Marginal: 2.1 (0.8-5.5) Adequate vs. Low: 3.3 (1.3-8.7) Difference in low medication self-efficacy (adjusted): Adequate vs. Marginal: 1.6 (0.3-3.2) Adequate vs. Low: 5.8 (2.0-15.7) Difference in Poor HIV medication adherence (Adjusted for HIV treatment knowledge and HIV medication self-efficacy Mediational Analysis): Adequate vs. Marginal: 1.6 (0.6-4.7) Adequate vs. Low: 0.8 (0.8-5.3) Difference in Poor HIV medication adherence (Adjusted for interaction of HIV treatment knowledge and HIV medication self-efficacy to test whether moderator relationship): (*P* = NS) (data not shown)

Evidence Table 1: Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Yin et al., 2010[83] Research objective: To assess parents' liquid medication administration errors by dosing instrument type and to examine the degree to which parents' health literacy influences dosing accuracy Study design: Cross-sectional survey Study setting: Public hospital (Bellevue) pediatric clinic in New York, NY Measurement period: October 2008 - December 2008 Follow-up duration: Immediately Completeness of follow-up: 1 Measurement tools including cutpoints, %: Newest Vital Sign 0-1: high likelihood of limited literacy 2-3: possible limited literacy 4-6: adequate literacy	Eligibility criteria: Inclusion: English- and Spanish-speaking parents or legal guardians presenting with a child to the Bellevue pediatric clinic Exclusion: NA Sampling strategy: Convenience sample Sample size: N = 302 Age (mean and range), % (SD): 31.1 (8.6) Gender, %: Female: 95 Male: 2.6 Unspecified: 2.3 (gender was listed only in regards to the relationship to the child seeking care; 95% were mothers, 2.6% were fathers, and 2.3% were legal guardians, whose genders were not further specified) Race/Ethnicity, %: Hispanic: 80.1 White, non-Hispanic: 3.0 Black, non-Hispanic: 9.9 Asian, non-Hispanic: 5.0 Native American, Hawaiian, or Pacific Islander: 0.3 Other: 1.3 Income, %: Hollingshead SES level 4 or 5: 81.1 Insurance status, %: NR Education, %: High school graduate or equivalent: 51.0% Other characteristics, %: Spanish-speaking: 56.4 Non-US born: 76.4 Marital status of single: 30.1 Child in house <8: 86.4 # of children in house (mean): 1.2 Presence of child with chronic medical problem: 32.1 Health literacy/numeracy levels, %: high likelihood of limited literacy: 40.5 possible limited literacy: 37.5 adequate literacy: 22.1

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Dosing accuracy Covariates used in multivariate analysis: Parent's age Relationship to child Marital status Language Ethnicity US birth SES Presence of a child in the house < 8 years old Presence of a child in the house with a chronic medical condition (education was excluded from the model) Description of outcome measures: Measured by asking participants to measure out a standard 5ml dose using six different dosing instruments Accuracy was analyzed as both a continuous and a categorical variable; Categories were as follows: No error - within 20% of recommended dose Small error - >20%-40% deviatrion from recommended dose Large error - >40% deviation from recommended dose Data source(s) for outcomes: Accuracy was determined by measuring the weight of each participant's 5mL dose and comparing it to a standardized weight (the average weight of 5mL as measured by 5 pediatricians). Attempts for control for confounding: Multiple logistic regression Blinding: N/A Statistical measures used: Chi-square, multiple logistic regression	Describe results: Participants with a high likelihood of limited literacy were significantly more likely to make any dosing error than individuals who had possible limited literacy and individuals with adequate literacy; in addition, participants with a high likelihood of limited literacy were significantly more likely to make a large error than individuals who had adequate literacy, though there was no significant difference in large errors between those with high likelihood of limited literacy and possible limited literacy. Effect in no exposure (i.e., adequate literacy) or control group: Any dosing error: Adequate literacy: AOR = 1 (reference) Large dosing error: Adequate literacy: AOR = 1 (reference) Effect in exposure (i.e., low/moderate literacy) or intervention: Any dosing error: High likelihood of limited literacy: 1.7 (95%CI, 1.1-2.8) Possible limited literacy: 1.6 (95%CI, 1.02-2.6) Large dosing error: High likelihood of limited literacy: 2.3 (95%CI, 1.2-4.6) Possible limited literacy: 1.9 (95%CI, 0.95-3.7) Difference: Any dosing error (adjusted): High likelihood of limited literacy: AOR, 1.7; 95% CI, 1.1-2.8; P = 0.02 Possible limited literacy: AOR, 1.6; 95% CI, 1.02-2.6; P = 0.04 Large dosing error (adjusted): High likelihood of limited literacy: AOR, 2.3; 95% CI 1.2-4.6; P = 0.01 Possible limited literacy: AOR 1.9; 95% CI, 0.95-3.7); P = 0.07

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Yin et al., 2009[84] Research objective: To assess whether health literacy of US parents is related to their children having health care coverage and understanding of OTC medication labels Study design: Cross-Sectional Study Study setting: Household data collection of nationally representative sample of U.S. population Measurement period: sample of the 2003 NAAL Follow-up duration: NA Completeness of follow-up: NA Measurement tools including cutpoints, %: National Assessment of Adult Literacy (NAAL): measures functional health literacy (prose, quantitative, and document literacy) Scores categorized into 4 levels: below basic, basic, intermediate, and proficient.	Eligibility criteria: Inclusion: ≥ 16 years old Living in a US household Exclusion: Inmates Unable to be interviewed because of a language barrier Unable to be interviewed because of a mental illness Sampling strategy: Representative of the US population Sample size: N = 6100 parents Age (mean and range), % (SD): Parent's age: 37.9 (9.0) Gender, %: Female: 54.9 Race/Ethnicity, %: White, non-Hispanic: 66.1 Black, non-Hispanic: 12.1 Hispanic: 16.1 Other: 5.7 Income, %: Below poverty threshold: 18.2 100%-175% of proverty threshold: 16.2 > 175% of poverty threshold: 58.0 Missing: 7.6 Insurance status, %: At least 1 child without health insurance: 8.1 Education, %: In school: 0.5 < HS: 13.7 HS/equivalent: 29.5 > HS: 56.3 Other characteristics, %: English proficiency, % Understands very well: 83.1 Understands well: 10.8 Understands not well/not at all: 6.1 Country of birth: US: 81.9 Outside of US: 18.1 Health literacy/numeracy levels, %: Health literacy: Below basic: 11.2 Basic: 17.5 Intermediate: 56.3 Proficient: 15.1 Health literacy, mean (SD): 253.8 (51.1)

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Parent's self report of children's health insurance status and difficulty understanding OTC Medication labels Covariates used in multivariate analysis: Age Gender Number of children living in the home Educational attainment Race/ethnicity Country of birth English proficiency Income Region Metropolitan statistical area (MSA) Description of outcome measures: Self-report Data source(s) for outcomes: Face-to-face interview for NAAL Attempts for control for confounding: Multivariate analyses Blinding: NA Statistical measures used: 2-way contingency table analyses Logistic regression analyses	Describe results: Parents with below-basic health literacy were more likely to have a child without health insurance in their household and report having difficulty understanding over-the-counter medication labels. Effect in no exposure (i.e., adequate literacy) or control group, %: Food-label use (unadjusted): Parents with intermediate/proficient health literacy report of difficulty: 38.3 At least 1 child without health insurance: Intermediate: 5.5 Proficient: 2.7 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Food-label use reported difficulty: Parents with below basic HL: 73.6 Parents with basic HL: 42.7 At least 1 child without health insurance: Below basic: 24.5 Basic: 10.5 Difference: At least 1 child without health insurance compared to proficient (adjusted): Below basic: OR = 2.4; 95% CI, 1.1-4.9 Basic: OR = 1.7; 95% CI, 0.5-5.7 Intermediate: OR = 1.4; 95% CI, 0.4-4.2 Mediator analysis: after HL was added to the model, education and race/ethnicity were no longer sig Difficulty understanding OTC medication labels compared to intermediate/proficient (adjusted): Below basic: OR, 3.4; 95% CI, 1.6-7.4 Basic: OR, 1.1; 95% CI, 0.4-2.5 Mediator analysis: after HL was added to the model, education, income, and MSA were no longer sig

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Study Description	Participant Characteristics
Author, year: Yin et al., 2007[85] Research objective: Assess whether caregiver HL was associated with risk factors for liquid medication dosing errors Study design: Cross-sectional Study setting: Pediatric emergency department at urban public hospital in New York City (Bellevue Hospital) Measurement period: July 2006 - October 2006 Follow-up duration: NA Completeness of follow-up: 292 completed of 307 enrolled (95%) Measurement tools including cutpoints: TOFHLA Inadequate: 0-59 Marginal: 60-74 Adequate: 75-100	Eligibility criteria: Included: Parent or caregiver with child aged between 30 days and 8 years Non-urgent visit Presence of primary caregiver responsible for giving medications Caregiver's language English or Spanish Child's medication generally given in liquid form Visit not involving Excluded: NR Sampling strategy: Convenience sample of parents and caregivers presenting to the ED Sample size: N = 292 Age (mean and range): NR Gender: NR Race/Ethnicity, %: Latino: 72.9 Black or African-American: 12.7 Asian: 5.5 White: 4.8 Other: 4.1 Income: NR Insurance status: NR Education, %: < HS: 39.7 Other characteristics, %: Born outside US: 57.9 English-speaking: 62.4 Spanish-speaking: 37.6 Hollingshead Socioeconomic Status: 1.4 level 1: 1.4, level 2: 7.5, level 3: 15.8, level 4: 25.0 level 5: 50.3 Child has regular MD: 72.9 Ever received a dosing tool: 57.2 Child ≥ 1year old: 81.5 Health literacy/numeracy levels, %: Inadequate: 9.6 Marginal: 15.9 Adequate: 74.4

Evidence Table 1. Key Question 1: Health literacy outcome studies (continued)

Outcomes	Results
Main outcomes: Caregiver use of a non-standardized measurement tool as a primary dosing instrument Covariates used in multivariate analysis: Caregiver education Caregiver country of origin Caregiver language Caregiver SES Age of child Regular child health-care provider Experience of ever having received a dosing instrument in a health-care setting Description of outcome measures: Caregiver self-report of a nonstandardized liquid measurement tool, offering choices of kitchen teaspoon, kitchen tablespoon, dosing spoon, measuring spoon, dosing cup, dropper, and syringe. Answers dichotomized as incorrect (kitchen spoons) or correct (other standardized instruments). Data source(s) for outcomes: Interview with child's primary caregiver Attempts for control for confounding: Multiple logistic regressions Blinding: NR Statistical measures used: Fisher exact test Chi square Multiple logistic regression	Describe results: Caregivers with lower HL literacy scores (marginal/inadequate, reading comprehension below the median, numeracy score below the median) were significantly more likely to use a non-standardized measurement tool (after adjusting for caregiver and child characteristics not confounded with HL). Effect in no exposure (i.e., adequate literacy) or control group, %: Poor knowledge of weight dosing: Numerate: 62 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Poor knowledge of weight based dosing: Innumerate: 76 Difference AOR (CI): Difference in reported use of non-standardized dosing instrument (adjusted for all control variables) Marginal/inadequate vs. adequate: 1.5 (0.8-2.8) Reading comprehension score below median: 2.4 (1.3-4.7) Numeracy score below median: AOR, 1.4 (0.8-2.7) Difference in reported use of non-standardized dosing instrument (adjusted for child's age, regular health care provider for child, history of receiving dosing instructions in clinic or ED--not controlling for confounders with HL) Marginal/inadequate vs. adequate: 1.9 (1.0-3.5) Reading comprehension score below median: 3.1 (1.7-5.7) Numeracy score below median: 1.9 (1.1-3.4)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies

Study Description	Participant Characteristics
Author, year: Aggarwal et al., 2007[86] Research objective: Determine whether numeracy skills affect cancer screening knowledge and practices Study design: Cross-sectional survey 85-item written survey in the exam room with research assistant available to answer participant questions. Study setting: 4 ambulatory care sites of urban academic medical center in US: 2 hospital based and 2 community based Measurement period: August 2004 -July 2005 Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: Women ≥40 Read and speak English, Spanish or Haitian Creole (Note: 6% non-English) No history of non-melanoma cancer or cognitive impairment Excluded: NR Sampling strategy: Consecutive women presenting for primary care Sample size: 264 *Note: sample for actual colon screening 152 (b/c excluded women <age 50 who would not be eligible for screening) Age, mean (SD): Mean: 55 (10.4) (Range 40-84) 40-49: 44 50-59: 29 60-69: 18 70+ : 9 Different by literacy group Note: numbers by literacy group not appropriately calculated in article for any baseline characteristic (i.e., give proportion adequate/inadequate literacy for all in each subgroup) Gender, %: Female: 100 Race/Ethnicity, %: AA: 39 White: 25 Caribbean Black: 17 Hispanic: 12 Other: 6 Different by literacy group Income, %: <$20,000: 29 $20-50,000: 29 >$50,000: 13 NR: 29 Different by literacy group Insurance status, %: Private: 36 Other: 64

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: A) Knowledge of breast cancer screening guidelines B) Up-to-date on breast and colorectal cancer screening Covariates used in multivariate analysis: A) Age, race, education, primary care provider and family history of the disease B) Age, race, insurance, primary care provider, and family history of the disease. NOTE: education, insurance, and SES collinear; so only 1 from each of these 3 included in each model Description of outcome measures: A) Correctly answering questions about the recommended age for an average-risk woman, to start screening (i.e., 40-49 years for breast cancer and 50-59 years for colorectal cancer) B) Having routine mammogram within last 2 years. Those age 50 years and older, having fecal occult blood test in past year or ever having lower endoscopy (flexible sigmoidoscopy or colonoscopy). Data source(s) for outcomes: Self-report Attempts for control for confounding: Age, race, education, insurance, income, and site of care were controlled for sensitivity analysis was performed by excluding subjects who failed to answer all 3 numeracy questions. Breast and colorectal cancer screening models were also run after excluding subjects who failed to answer questions which determined being up-to-date. Blinding: NA Statistical measures used: Bivariate analysis: chi-square and Fisher-exact tests Multivariate analyses: Logistic regression Sensitivity analysis: looked at effect excluding those with missing responses	Describe results: Bivariate Analysis (unadjusted) A) Knowledge of screening guidelines: Adequate numeracy was significantly associated with breast and colon cancer B) Up-to-date with cancer screening : Numeracy was not associated with being up-to-date with breast or colon cancer Multivariate analysis (Adjusted) Only knowledge of breast cancer screening guidelines was associated with numeracy status. Effect in no exposure (i.e., adequate literacy) or control group, %: A) breast CA: 48 colon CA: 35 B) breast CA: 77 colon CA: 51 Effect in exposure (i.e., low/moderate literacy) or intervention, %: A) breast CA: 25 colon CA: 17 B) breast CA: 71 colon CA: 46 Difference, mean (CI): Knowledge of breast CA guidelines (inadeq. vs. adeq, adjusted): 0.37 (0.19-0.71) Knowledge of Colon Cancer guideline (inadeq. vs. adeq., adjusted): 0.63 (0.2–1.25) OR for Up-to-date breast cancer screening (inadeq. vs. adeq.): OR, 1.43 (0.62-3.33) OR for up-to-date colon cancer screening (inadeq. vs. adeq): OR, 0.91 (0.3-2.0)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Aggarwal et al., 2007[86] (continued)	Different by literacy group Education, %: <High School: 18 High School: 24 >High School: 49 NR (N=21): 9 Different by literacy group Other characteristics, %: Primary care provider Yes: 78 No: 22 Family history of breast cancer Yes: 15 No: 70 NR: 15 Family history of colon cancer Yes: 8 No: 84 NR: N=20 (8) wrong % in table Perceived Risk for Breast Cancer <Average: 36 Average: 41 >Average: 8 Missing (N=40): 15 Perceived Risk for Colorectal Cancer <Average: 36 Average: 40 > Average: 7 Missing (N=46): 17 No appreciable difference by literacy group Health literacy/numeracy levels, %: Numeracy: Inadequate: 73.9 Adequate: 26.1 Measurement tools including cutpoints: Numeracy only: 3 criteria adapted from Black et al. (J Natl Cancer Inst, 1995; 87(10): 720-31). 1) basic familiarity with probability: heads on coin flip 2) comfort with using probability: likelihood of breast and colon CA 3) basic familiarity with proportions: compared estimates of lifetime and 5-yr CA risk Dichotomous - numerate if they met all 3 criteria. The specific questions for 2 and 3 differed from that used by Black but the concepts were the same.

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Cavanaugh et al., 2008[87] Research objective: Examine association between diabetes-related numeracy and glycemic control and other diabetes measurements Study design: Cross-sectional Study setting: 2 primary care clinics 2 endocrinology clinics located in 3 medical centers Measurement period: March 2004 - November 2005 Follow-up duration: NA Completeness of follow-up: 398/406 (98%)	Eligibility criteria: Included: Type I or type II diabetes 18 to 85 years of age English speaking Excluded: Previous diagnosis of dementia, psychosis or blindness Corrected visual acuity of 20/50 or worse by Rosenbaum screener Sampling strategy: NR Sample size: 398 Age (mean and range): 55 (median), IQR, 46-64 Gender, %: Female: 51 Race/Ethnicity, %: White: 63 Income, %: <$20,000: 44 Insurance status, %: Private insurance: 49 Education, %: High-school, GED, or less: 43 Other characteristics, %: Type II diabetes: 86 Median duration of diabetes (yrs): 9 Past diabetes education: 83 Insulin use: 61 Median BMI: 32 Median HbA1C: 7.2 Health literacy/numeracy levels, %: WRAT-3, numeracy: < 9th grade: 69 > 9th grade: 31 DNT (median % correct): Overall : 65 Quartile 1: 27 Quartile 2: 25 Quartile 3: 26 Quartile 4: 23 Measurement tools including cutpoints: Literacy: REALM General numeracy: WRAT-3 Diabetes-related numeracy: DNT

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Primary outcome: most recent HbA1C Secondary outcomes: Diabetes knowledge Self-efficacy of diabetes self-management behaviors Covariates used in multivariate analysis: Age Sex Race Annual income Type of diabetes Years since diabetes diagnosis Clinic site Description of outcome measures: Primary outcome: Most recent HbA1C: electronic medical record Secondary outcomes: Diabetes knowledge: Diabetes Knowledge Test (score range 0-100) Self-efficacy of diabetes self-management: PDSMS (score range 8-40) Self-management behaviors: self report and Summary of Diabetes Self-Care Activities scale (score range 0-7) General diet Specific diet Exercise Blood glucose level testing Foot care Data source(s) for outcomes: HbA1C: electronic medical record Diabetes knowledge: self-report Self-efficacy of diabetes self-management: Self report Self-management behaviors: self report Attempts for control for confounding: Multivariate regression Blinding: NR Statistical measures used: Cuzick nonparametric test Chi-square Wilcoxon rank-sum Generalized least-squares methods	Describe results: Adjusted regression analysis found lower numeracy scores on DNT modestly associated with HbA1Cs. 10% point decrease in DNT was associated with an increase of 0.09% (CI, 0.01%, 0.16%) in HbA1C. Unadjusted results showed DNT to be associated with lower perceived self-efficacy and some self-management behaviors. Effect in no exposure (i.e., adequate literacy) or control group, %: Primary outcome (n = 90) (unadjusted) Median HbA1C in highest DNT quartile (unadjusted) = 7.1% (IQR, 6.3-8.1) Secondary outcomes n = 90) (unadjusted) ((highest IQR) Diabetes knowledge (median, range 0-100) = 86 (78-93) Self-efficacy of diabetes self-management (median, range 8-40) = 32 (26-35) Self-management behaviors (median, range 0-7): General diet = 5 (4-6) Specific diet = 3.5 (3-4) Exercise = 2.75 (1-4.5) Blood glucose level testing = 6.5 (5-7) Foot care = 3.25 (1.5-5.5) Effect in exposure (i.e., low/moderate literacy) or intervention: Primary outcome (n=107) (unadjusted) Median HbA1C in lowest DNT quartile (unadjusted)= 7.6% (IQR, 6.5-9.0) Secondary outcomes (n=107) (unadjusted) (lowest IQR) Diabetes knowledge (median, range 0-100)= 52 (43-81) Self-efficacy of diabetes self-management (median, range 8-40)= 28 (24-33) Self-management behaviors (median, range 0-7): General diet= 5 (3.5-6.0) Specific diet= 3.5 (2.5-4.0) Exercise= 3.5 (1-4.5) Blood glucose level testing= 7 (5-7) Foot care= 5.5 (3.5-7.0)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Cavanaugh et al., 2008[87] (continued)	

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
	Difference: Absolute difference in Median HgbA1c (quartile 1 vs. 4: +0.5%, *P* = 0.119 In adjusted analysis, every 10% decrease in % correct DNT questions resulted in an increase in HgbA1c of 0.09% (95% CI 0.01% to 0.16%) Median diabetes knowledge: DNT Quartile 1 vs. 4 (unadjusted): -34, *P* for trend < 0.001 Median Self-efficacy: DNT Quartile 1 vs. 4: -4, *P* for trend = 0.003 Absolute difference in General diet behaviors (Quartile 1 vs. 4): 0, *P* = 0.21 Absolute difference in Specific diet behaviors (Quartile 1 vs. 4): 0, *P* = 0.82 Absolute difference in Exercise behavior (Quartile 1 vs. 4): +0.75, *P* = 0.25 Absolute difference in Blood glucose level testing (Quartile 1 vs. 4): 1.5, *P* = 0.44 Absolute difference in Foot care behavior (Quartile 1 vs. 4): 2.25 *P* < 0.001

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Davids et al., 2004[88] Research objective: Identify sociodemographic characteristics, numeracy levels, and breast cancer risk factors that are independently associated with accuracy of lifetime and 5-year breast cancer risk perceptions. Study design: Cross-sectional Study setting: 2 primary care internal medicine practices associated with the Medical College of Wisconsin Measurement period: June 1999 to June 2000 Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: Female gender Ages 40-85 years Ability to speak English Excluded: Personal history of breast cancer Dementia Co morbid condition leading to a life expectancy of less than 2 years as judged by their PCP Sampling strategy: Convenience (invitation sent to 25% of clinic population, not otherwise specified) Sample size: 254 (18% of clinic population invited) Age, years (SD): 57.6 (10-10.6) Range: 40 to 84 Gender, %: Female: 100 Race/Ethnicity, %: White: 68 Black: 30 Hispanic: 1.6 Native American: 0.7 Income, %: <$20,000: 50 Insurance status: NR Education, %: HS graduates: 81 Other characteristics, %: No family history of breast cancer: 82 No prior breast biopsies: 77 Health literacy/numeracy levels, %: 0 correct: 38 (14.96) 1 correct: 42 (16.54) 2 correct: 69 (27.17) 3 correct: 105 (41.34) Measurement tools including cutpoints: 3-item scale, adapted from previously validated numeracy scale (alpha 0.63): a) imagine that you flipped a coin 100 times. About how many times will the coin come up heads in 100 flips? b) 100 people have entered the Spring City Run. 70% of the runners

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Gail model risk (lifetime and 5-year); perceived risk (lifetime and 5-year); estimation error Covariates used in multivariate analysis: Age Race Years of education Income level Numeracy score Family history of breast cancer Age at menses Age at first live birth Number of prior breast biopsies. Description of outcome measures: Gail model risk: model includes information on age, race, number of first-degree relatives with breast cancer, age at menarche, age at first live birth, number of breast biopsies, and history of atypical hyperplasia. Perceived breast cancer risk: survey; measured lifetime and 5-year risk on percent scale ranging from 0% to 100%. Asked participants "what do you think your personal risk or chance is of getting breast cancer (in your lifetime) (in the next 5-years)?" Estimation error: absolute difference of the perceived risk and the Gail model risk Data source(s) for outcomes: Gail model risk: patient history self reported Perceived breast cancer risk: self-report Estimation error: mathematical calculation Attempts for control for confounding: Multivariate analysis Blinding: NA Statistical measures used: Bivariate association with nonparametric statistics (Spearman correlation, Kruskal Wallis) Multivariate linear regression models with dependent variable transformed using a log transformation [Log [1 + estimation error]] to improve the normality of the distribution.	Describe results: NR Effect in no exposure (i.e., adequate literacy) or control group (SD): Lifetime Risk Estimation Error: Numeracy Score: 3 correct: 25.8 (21.7) 5-year Risk Estimation Error Numeracy Score: 3 correct: 20.5 (20.8) Effect in exposure (i.e., low/moderate literacy) or intervention: Lifetime Risk Estimation Error: Numeracy Score (SD): 0 correct: 40.1 (25.3) 1 correct: 28.3 (24.2) 2 correct: 30.1 (21.1) 5-Year Estimation Error: Numeracy Score (SD): 0 correct: 32.2 (28.6) 1 correct: 24.0 (26.7) 2 correct: 27.8 (22.7) Difference: Lifetime Risk Estimation Error (adjusted): Beta-coefficient for every additional numeracy question incorrect: 0.18; 95% CI, 0.05-0.30 5-year Risk Estimation Error (adjusted): NR Note: unadjusted correlation NS

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Estrada et al., 2004[21] Research objective: Examine association between low literacy and numeracy in patients taking warfarin with anticoagulation control and other processes of care Study design: Prospective cohort Study setting: Anticoagulation management units: 1 based at a university and 1 based at a VA hospital Measurement period: November 1998-May 1999 Follow-up duration: Mean: 91 days (SD 18.9) Completeness of follow-up: 100%	Eligibility criteria: Included: > 50 years old Been on warfarin ≥ 1 month Excluded: Unable to speak Non-English speaking Did not consent to participate Sampling strategy: Convenience Sample size: N=143 Participants were 3.9 years younger than eligible patients who refused or were excluded, $P = 0.03$ Age, mean (SD): 65.3 (9.8) Gender, %: Female: 37.8 Race/Ethnicity, %: Nonwhite: 29.4 Income: NR Insurance status: VA patients: 36 University-based clinic: 4 patients said they could not afford medication, so it was provided to them. Education, %: ≤ 3rd grade: 3.5 4-6th grad: 7.0 7-8th grade: 10.5 >8th grade: 79.0 Other characteristics, %: Indications for anticoagulation therapy: Atrial fibrillation: 39.2 Valvular heart disease: 16.8 Venous thrombosis: 16.8 Neurologic condition: 11.2 Length of time on wafarin: < 6 months: 19.6 6 - 12 months: 14 > 1 yr: 66.4 INR goal: 2-3: 79.7 of patients 2.5-3.5 or other: 20.3 of patients

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Primary outcomes: Variability of the INR Optimal intensity of anticoagulation Secondary outcomes: % INR tests within patients therapeutic range Maximum INR value # dose changes Dose change # missed visits Covariates used in multivariate analysis: Age Description of outcome measures: INR variability: measured by computing the deviation in the patient's INR from his/her therapeutic range over time. A wider INR range indicates poorer anticoagulation and is one of the strongest predictors of bleeding risk. Optimal intensity of anticoagulation (time in range): estimates the amount of time a patients INR is within his/her therapeutic range Data source(s) for outcomes: Self-report and medical record review Attempts for control for confounding: Multiple linear regression Blinding: Provider's making adjustments to warfarin dosage were not informed of patients' literacy or numeracy assessments Statistical measures used: Relationship between literacy or numeracy levels and INR variability, time in range, and secondary outcomes was measured with the Spearman rank test. Multiple linear regression	Describe results: After adjusting for age, low numeracy skills were associated with greater INR variability, while the optimal intensity of anticoagulation (time in range) was similar among patients at different literacy or numeracy levels Numeracy skills were associated with the time spent above the patients therapeutic INR range (unadjusted). Neither low literacy nor numeracy were associated with any other secondary outcomes examined. Effect in no exposure (i.e., adequate literacy) or control group: % INR tests within range: 5-6 correct: 56% INR variability using mean sigma score: 5-6 correct: 0.45 Effect in exposure (i.e., low/moderate literacy) or intervention: % INR tests within range: 0 correct: 56% INR variability using mean sigma score: 0 correct:0.80 Difference: Difference in INR variability: Higher among patients at lower literacy levels (adjusted): $P = 0.06$ Higher among patients with lower numeracy skills (adjusted): $P = 0.03$ Optimal intensity of anticoagulation (time in range): The optimal intensity of anticoagulation (time in range) (adjusted) was similar among patients at different literacy, $P = 0.71$ or numeracy levels, $P = 0.35$

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Estrada et al., 2004[21] (continued)	Health literacy/numeracy levels, %: 6-items (including 3 adapted from Schwarz and Woloshin): 0 correct: 13.3 1-2 correct: 35 3-4 correct: 34.3 5-6 correct: 17.5 Measurement tools including cutpoints: Literacy: REALM Numeracy: 6 item test; Schwartz 3-item (1997) and 3 items developed by study researches specific to anticoagulation therapy

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Haggstrom and Schapira, 2006[89] Research objective: Evaluate black-white differences in risk perceptions of Breast Cancer Survival and Screening Mammography benefit. Study design: Cross sectional Study setting: Patients attending 2 general internal medicine clinics at academic medical center in Milwaukee, WI. Measurement period: June 1999- July 2000 Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: Female Age 40 to 85 English-speaking Excluded: Personal history of breast cancer Dementia Life expectancy < 2 years Race other than Black, White Age 70-85 Sampling strategy: Random sample Sample size: 207 Note: this is 18% of those invited Age (mean and range): 55 (40-69) Note: none of baseline characteristics provided by literacy group Gender, %: Female: 100 Race/Ethnicity, %: Black: 31 Income, %: Family Income Black <$20,000: 80 >=$20,000: 20 White <$20,000: 35 >=$20,000: 65 Insurance status, %: Black Private fee-for-service: 6 HMO: 5 Medicare: 34 Medicaid or Milwaukee County: 44 None or other: 11 White Private fee-for-service: 42 HMO: 12 Medicare: 23 Medicaid or Milwaukee County: 18 None or other: 5

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Perceptions of Breast Cancer Survival Perceptions of Screening Mammography Benefit Covariates used in multivariate analysis: Race Age Family history Family income Insurance Education Numeracy Description of outcome measures: Perceptions of Breast Cancer Survival Survey item "On average, when women get breast cancer what are their chances of living for 5 years or longer?" Response scale included options: 0-25%, 26-50%, 51-75%, 76-100%. Dichotomous Accuracy variable created by whether response was in agreement for average 5-years survival rates for individual's race (71% for blacks, 86% for whites). Dichotomous Pessimism variable created by a response between 0 and 50% survival. Perceptions of Screening Mammography Benefit Survey item "For women your age, how much do you think regular mammograms decreast the risk of dying from breast cancer?" Response scale included options: Not at all, 5-25%, 26-50%, 51-75%, 76-100%. Dichotomous Accuracy variable created by whether response was in agreement (including within confidence intervals) with results of metaanalysis on mammography screening benefits (mammography reduced chance of death of breast cancer by 26% (95% CI, 17%-34%) in women 50-69; by 7% (CI, -13%-24% for women 40-49). Dichotomous Pessimism variable created by a response between 0 and 50% reduction in the risk of dying. Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Pearson chiX Multivariate logistic regression	Describe results: Numeracy was not related to patients accurate or pessimistic perception of 5-year breast cancer survival rate in either unadjusted or adjusted analysis. Numeracy was related to patients accuracy and pessimistic perception of benefits of mammography screening in unadjusted analysis, but no in adjusted analysis. Black women more accurately perceived 5-year breast cancer survival rates and screening mammography benefit as compared to white women. The magnitude of effect decreased with adjustment; there was no analysis adjusting for numeracy alone. Black women were not more likely to have a pessimistic perception of 5-year breast cancer survival rate as compared to white women. However, they were more likely to have a pessimistic perception of screening mammography benefit as compared to white women. The magnitude of the latter effect decreased with adjustment for multiple covariates; there was no analysis adjusting for numeracy alone. Effect in no exposure (i.e., adequate literacy) or control group: KQ1b: NR KQ1D: Accurate Perception of Breast Cancer Survival: White: 26% Accurate Perception of Screening Mammography Benefit: White: 15% Effect in exposure (i.e., low/moderate literacy) or intervention: KQ1b: NR KQ1D: Accurate Perception of Breast Cancer Survival: Black: 48% Accurate Perception of Screening Mammography Benefit: Black: 39% Difference OR (CI): Adjusted KQ1b Accurate perception of Breast Cancer Survival (Numerate vs not; adjusted): OR = 0.84; 95% CI, 0.38-1.85 Pessimistic perception of Breast Cancer Survival (Numerate vs not; adjusted): OR = 0.60; 95% CI, 0.26-1.38 Accurate perception of Screening Mammography Benefit (Numerate vs not): OR = 0.75; 95% CI, 0.28-2.02 Pessimistic perception of Screening Mammography Benefit (Numerate vs not): OR = 0.86; 95% CI, 0.33-2.26 KQ1d Accurate perception of Breast Cancer Survival (Black vs white, unadjusted): OR 2.69, 95% CI 1.45 to 4.99

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Haggstrom and Schapira, 2006[89] (continued)	Accurate perception of Breast Cancer Survival (Black vs white, adjusted): OR = 3.58; 95% CI, 1.56-8.21 Pessimistic perception of Breast Cancer Survival (Black vs white, unadjusted): OR 2.17, 95% CI 1.14 -4.13 Pessimistic perception of Breast Cancer Survival (Black vs white, adjusted): OR = 1.49; 95% CI, 0.67-3.32 Accurate perception of Screening Mammography Benefit (Black vs white, unadjusted): OR 3.53, 95% CI 1.79 to 6.94 Accurate perception of Screening Mammography Benefit (Black vs white, adjusted): OR = 2.70; 95% CI, 1.09-6.69 Pessimistic perception of Screening Mammography Benefit (Black vs white, unadjusted): OR = 4.85, 95% CI 2.49 to 9.47 Pessimistic perception of Screening Mammography Benefit (Black vs white, adjusted): OR = 3.94; 95% CI, 1.62-9.56 Education, %: Black Less than high school: 33 High school graduate: 61 College graduate: 6 Post-graduate: 0 White Less than high school: 8 High school graduate: 62 College graduate: 13 Post-graduate: 16 Other characteristics, %: Black >=1 first-degree relative with breast cancer: 17 White >=1 first-degree relative with breast cancer: 19 Health literacy/numeracy levels: NR Note: need to query investigators Measurement tools including cutpoints: 3-item instrument developed from Schwartz, designed to measure a patient's facility with basic probability and numerical concepts. Numeracy values based on the instrument ranged from 0 to 3. Patient numeracy was dichotomized into 2 categories Numerate/Not numerate

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Hibbard et al., 2007[30] Research objective: Examine contribution of health literacy, numeracy, and patient activation to comprehension of comparative health care performance reports and use in making informed choice Study design: Cross-sectional Study setting: Community Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Adults (18-64 years of age) Excluded: NR Sampling strategy: Convenience Sample size: N=303 Age (mean and range): Mean: 37 Range: (18-64) Gender, %: Female: 48 Race/Ethnicity: NR Income, %: Income <25,000: 74 Insurance status, %: Health Insurance: 45 Education, %: High school or less: 45 Some college or more: 55 Other characteristics, %: Good to excellent health: 40 Fair to poor health: 24 Health literacy/numeracy levels, %: (Calculated) TOFHLA Low Health Literacy: 45% High Health Literacy: 55 Low Numeracy: 43 High Numeracy: 57 Measurement tools including cutpoints: TOFHLA (passage B only) Numeracy: 11 item measure from Lipkus, Samsa and Rimer, plus 4 items on interpreting risk magnitude

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Choosing high performing hospital Covariates used in multivariate analysis: Age Gender Education Comprehension Activation Description of outcome measures: Quality Choice: Experiment of choosing a higher quality hospital based on performance measures Comprehension: how well a patient understood information in the data display Data source(s) for outcomes: Interview Attempts for control for confounding: Multivariate analyses Blinding: NA Statistical measures used: Multivariate logistic regression Path analysis	Describe results: Numeracy and literacy predict comprehension but do not predict quality choice. In a path analysis, higher numeracy and literacy predict better comprehension, which in turn predicts a better quality choice. Making a better quality hospital choices is related to activation level, separate from comprehension. Effect in no exposure (i.e., adequate literacy) or control group, %: Choice of Higher Quality Hospital: High numeracy: 71.7% Note: interaction by patient activation (ie. motivation to engage with material: High numeracy: Low activation: 66.3% High activation: 77% *P* for interaction: $P < 0.001$ Effect in exposure (i.e., low/moderate literacy) or intervention, %: Choice of Higher Quality Hospital: Low numeracy: 59.9 Note: interaction by patient activation (ie. motivation to engage with material: Low numeracy: Low activation: 53 High activation: 66.8 *P* for interaction: $P < 0.05$ Difference: Absolute difference in choice of high quality hospital (high vs. low, unadjusted): -11.8%, $P < 0.01$ Quality Choice (adjusted): Literacy: -0.023 (P = NS) Numeracy: 0.032 (P = NS) Activation X Numeracy: (P = NS) Activation X HL: (P = NS) Path analysis (adjusted): HL predicts comprehension: ($P < 0.001$) Numeracy predicts comprehension: ($P < 0.001$) Comprehension predicts Quality Choice: ($P < 0.001$)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Huizinga et al., 2008[33] Research objective: Examine association between numeracy skills and weight status as measured by BMI Study design: Cross-sectional Study setting: Academic primary care clinic at Vanderbilt University Medical Center Measurement period: July 2006 - August 2007 Follow-up duration: NA Completeness of follow-up: 160/169 (95%)	Eligibility criteria: Included: NR Excluded: Age < 18 years Non-English speaking Dementia Corrected visual acuity equal to or worse than 20/50 by Rosenbaum Pocket Vision Screener Sampling strategy: Convenience sample (referred by clinic staff) Sample size: 169, no comparisons Age (mean and range): 46 (SD 16) Low Num 45.1 High Num 47.6 Gender, %: Female: 70 Low Num: 70 High Num: 70 Race/Ethnicity, %: White: 66 Low Num: 52 High Num: 93 Income, %: <$20,000: 16 Low Num: 23 High Num: 4 Insurance status: NR Education, %: High-school or GED: 91 Low Num: 87 High Num: 98 Other characteristics, %: Dyslipidemia: 26 Hypertension: 38 CAD: 8 Diabetes: 17 NR by numeracy subgroup Health literacy/numeracy levels (SD): Numeracy: All participants - mean: 89.1 (16) < 9th grade (66% of participants) - mean: 80.9 (11) > 9th grade (34% of participants) - mean: 105 (9.1)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: BMI Covariates used in multivariate analysis: Age Sex Race Income Years of education REALM score Description of outcome measures: BMI calculated from height and weight Data source(s) for outcomes: Self-report by patient after measurement by clinic staff Attempts for control for confounding: Linear regression Blinding: NR Statistical measures used: Spearman's rank correlation Wilcoxon rank sum Linear regression	Describe results: Lower numeracy was significantly associated with higher BMI. Literacy was not significantly associated with BMI Effect in no exposure (i.e., adequate literacy) or control group (SD): Numeracy > 9th grade: BMI: 27.9 (6.0) Literacy > 9th grade: BMI: 30.2 (7.8) Effect in exposure (i.e., low/moderate literacy) or intervention (SD): Numeracy < 9th grade: BMI: 31.8 (9.0) Literacy < 9th grade: BMI: 31.7 (9.9) Difference: BMI (low versus high Num) (unadjusted): +3.9, $P = 0.008$ Beta coefficient for effect of Numeracy on BMI: (adjusted for age, sex, race, income, and years of education): -0.14, $P = 0.01$ BMI (low versus high Lit) (unadjusted): +1.5, $P = 0.50$

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Huizinga et al., 2008[33] (continued)	Eligibility criteria: Literacy: All participants - mean: 61.0 (8.7) < 9th grade (22.5% > 9th grade (77.5%) Measurement tools including cutpoints: Numeracy: WRAT-3 Literacy: REALM

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Osborn et al., 2009[57] Research objective: To examine whether health literacy, numeracy and diabetes specific numeracy mediate the association between African American race and A1C level Study design: Cross-sectional Study setting: Two primary care and two diabetes specialty clinics located at three medical centers. Measurement period: March 2004 to November 2005 Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Diagnosis or type I or II diabetes Age 18-85 years English-speaking Excluded: Previous diagnosis of dementia, psychosis, or blindness Patients with a corrected visual acuity of 20/50 or worse using Rosenbaum Screener Sampling strategy: Convenience sampling Sample size: N = 383 Quartile (Q) by DNT" Q1, n: 104 Q2, n: 97 Q3, n: 98 Q4, n: 84 Age (mean and range), % (SD): Total, median (range): 56 (47-64) By DNT quartile Q1: 61 (51 - 67) Q2: 57 (49 - 66) Q3: 56 (47 - 62) Q4: 50 (41 - 56) Gender, %: Female: 50% By DNT quartile, %: Q1: 60 Q2: 44 Q3: 50 Q4: 45 Race/Ethnicity, %: Total, %: White: 65 Nonwhite: 35 By DNT quartile, %: Q1 White: 31 Nonwhite: 69 Q2 White: 67 Nonwhite: 33 Q3 White: 79 Nonwhite: 21 Q4 White: 89 Nonwhite: 11

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Glycemic control was assessed by most recent A1C value in patient's medical record. 96% were obtained within 6 months of the participant evaluation and median time between A1C and evaluation was 15 days. Covariates used in multivariate analysis: Covariates in Model 1: Age, sex, years of education, annual income, insulin use, diabetes type, years of diagnosed diabetes, race Covariates in Models 2 and 3 (sig variables from Model 1): Age Year of diagnosed diabetes Insulin use African American race Description of outcomes measures: Glycemic control was assessed by most recent A1C value in patient's medical record. 96% were obtained within 6 months of the participant evaluation and median time between A1C and evaluation was 15 days. Data source(s) for outcomes: Chart review Attempts for control for confounding: Structural equation modeling Blinding: NR Statistical measures used: Three structural equation models were estimated. Model 1 tested whether African American race predicted higher A1C levels after controlling for potential confounders. Model 2 tested whether African American race predicted low HL skills, low general numeracy skills, and low DNT, and whether these variables, in turn, predicted A1C levels. Model 3: Sig HL and numeracy predictors from Model 2 and potential confounders.	Describe results: Model 1: Younger age, using insulin, having been diagnosed with diabetes for more years, and African American race were associated with sig higher A1C levels and accounted for 17% of the variability in A1C levels. Model 2: African American race was associated with limited literacy skills (r = -0.39, *P* < 0.001), limited general numeracy skills (r = -0.43, *P* < 0.001), and limited DNT skills (r = -0.46, *P* < 0.001). AA race did not have a sig direct effect on A1C (r = 0.10, *P* = NS). Of the skills measures, only DNT significantly directly predicted A1C levels. Higher DNT was associated with lower A1C levels (r = -0.15, *P* <0.01) Model 3--literacy and general numeracy removed from the model : AA race associated with lower DNT (r = -0.47, *P* < 0.001). Lower DNT associated with higher A1C level (r = -.17, *P* < 0.01). Direct effect of AA race on A1C not measured Effect in no exposure (i.e., adequate literacy) or control group, %: Effect in exposure (i.e., low/moderate literacy) or intervention: AIC (%) Q1: 7.6 (6.5-9.0) Q2: 7.2: (6.3-8.3) Q3: 7.2 (6.5-8.0) Q4: 7.2 (6.4-8.2) (*P* = 0.24) Difference, %: Model 2 Overall model fit, X2 (12, n = 383) = 485.47, (*P* < 0.001), CFI = 0.464, RMSEA = 0.32 (90% CI 0.30–0.35). Test of significance of individual paths: REALM, (*P* = NS) General numeracy, (*P* = NS) DNT, (*P* < 0.01) Model 3 Overall model fit, X2 (3, n = 383) = 6.91, (*P* = 0.07), CFI = 0.99, RMSEA = 0.06 (90% CI 0.00–0.12). Test of significance of individual paths: DNT, (*P* < 0.001) Structural Equation Model Results: Correlation between African-American Race and Numeracy: -0.46, (*P* < 0.001) Correlation between Numeracy and HgbA1c: -0.15, (*P* < 0.01) Correlation between African-American Race and HgbA1c: Without moderator: 0.12, (*P* < 0.01) With moderator: 0.10, NS

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Osborn et al., 2009[57] (continued)	Income, %: Total <$20,000: 44 By DNT quartile, %: Q1, < $20,000: 80 Q2, < $20,000: 49 Q3, < $20,000: 23 Q4, < $20,000: 20 Insurance status, %: Has Private Insurance Total: 48 By DNT quartile, %: Q1: 31 Q2: 40 Q3: 59 Q4: 67 Education, %: Total, %: < HS: 43 HS/GED or more: 57 By DNT quartile, %: Q1 < HS: 73 HS/GED or more: 27 Q2 <HS: 49 HS/GED or more: 51 Q3 < HS: 23 HS/GED or more: 77 Q4 < HS: 20 HS/GED or more: 80 Other Characteristics NR

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al., 2006[67] Research objective: Examine relationship between health literacy and understanding food labels. Study design: Cross sectional Study setting: Academic primary care clinic Measurement period: June 2004 - April 2005 Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Adult patients 18-80 Excluded: Poor vision Dementia Psychiatric illness Non-English speaking Sampling strategy: Convenience Sample size: N = 200 Age (mean and range) (SD): 43 (14.6) Gender, %: Female: 72 Race/Ethnicity, %: White: 67 Black: 25 Other: 8 Income, %: <$20,000: 25 $20,000-39,999: 24 $40,000-59,999: 22 >=60,000: 28 Insurance status, %: Private insurance: 73 Education, %: <=High School: 33 Some college: 34 College or more: 34 Other characteristics, %: Reads food labels: 89 Health literacy/numeracy levels, %: Literacy: <HS: 23 >=HS: 77 Numeracy: <HS: 63 >=HS: 37 Measurement tools including cutpoints: REALM to measure literacy: >=HS level (9th grade or above) WRAT-3 to measure numeracy <HS: Below HS: level (9th grade or above)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Main Outcome of this study is comprehension of nutrition labels, which is not a relevant outcome for this review. However, descriptive analysis measure other outcomes by HL: Chronic illness Obesity Read food labels Covariates used in multivariate analysis: Age Gender Race/ethnicity Income Education Insurance status Presence of chronic disease Status of being on a specific diet Label reading frequency Description of outcome measures: Chronic illness: dichotomous variable indicating if patient had a chronic illness that required dietary restriction, includes hypertension, coronary artery disease, high cholesterol, diabetes, and heart failure. Obese: BMI >=30, dichotomous Read food labels: dichotomous NLS: questions related to understanding real food labels, both literacy and numeracy evaluations Data source(s) for outcomes: Self report Attempts for control for confounding: Yes in relation to NLS Blinding: NR Statistical measures used: t-tests Wilcoxon rank-sum tests for continuous variables Fisher's exact test or Chi square test for categorical variables Multinomial logistic regression	Describe results: Lower literacy and numeracy skills sig associated with poorer performance on NLS, controlling for potential confounders. No statistically sig difference existed in presence of chronic disease, obesity or reading food levels between higher and lower literacy or numeracy. Effect in no exposure (i.e., adequate literacy) or control group, %: Literacy Chronic illness: 38 Obese: 43 Read food labels: 89 Numeracy Chronic illness: 35 Obese: 40 Read food labels: 93 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Literacy: Chronic illness: 52 Obese: 53 Read food labels: 87 Numeracy: Chronic illness: 44 Obese: 48 Read food labels: 86 Difference: Literacy Difference in NLS score (adjusted): data NR, $P < 0.001$ Difference in percent with chronic illness (unadjusted): $P = 0.08$ Difference in percent obese (unadjusted): $P = 0.31$ Difference in percent reads food labels (unadjusted): $P = 0.71$ Numeracy Difference in NLS score (adjusted): data NR, $P < 0.001$ Difference in percent with chronic illness (unadjusted): $P = 0.20$ Difference in percent obese (unadjusted): $P = 0.30$ Difference in percent reads food labels (unadjusted): $P = 0.11$

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Schwartz et al., 1997[90] Research objective: Assess relation between numeracy and accuracy of breast cancer risk perception Study design: Randomized Trial Study setting: Mailed survey, completed at home Measurement period: 12/1995 - 2/1996 Follow-up duration: NA Completeness of follow-up: Response rate 302/474 (64%) 15 did not complete 4/5 questions final survey page Total sample 287/474 (61%)	Eligibility criteria: Included: Women from a registry of female Veterans maintained at Dept. of Veterans Affairs Medical Center in Vermont Excluded: NR Sampling strategy: Simple random sample Sample size: N = 287 Age (range): 68 (48-74) Gender, %: Female: 100 Race/Ethnicity, %: White: 96 Income, %: < $10,000: 26 $10,000 - 24,999: 42 ≥ $25,000: 32 Insurance status: NR Education, %: < HS: 4 HS grad: 60 Some college or greater: 36 Other characteristics, %: Employed: 24 Unemployed: 6 Homemaker or Retired: 70 History of breast cancer: 9 Health literacy/numeracy levels, %: Numeracy scores: 0 correct answers: 30 1 correct answer: 28 2 correct answers: 26 3 correct answers: 16 Correct answers to numeracy measures: Likely number of heads in 1,000 coin flips: 54 Convert 1% to 10 in 1000: 54 Convert 1 to 1000 to 0.1%: 20 Measurement tools including cutpoints: Schwarz and Woloshin measure: 3 questions designed for purpose of this study Aggregated answers into aggregate numeracy score: 0,1,2, 3 correct answers

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Accuracy in applying risk reduction information Covariates used in multivariate analysis: Age Income Education Framing of the information (RRR +/-baseline risk; ARR +/-baseline risk) Description of outcome measures: Comparison of participants' perceived risk for death from breast cancer with mammography and perceived risk for death without mammography. Accuracy was judged by ability to adjust perceived risk in accordance with risk reduction data presented Risk reduction was calculated from responses to these 2 questions. Data source(s) for outcomes: Mailed, written questionnaire Attempts for control for confounding: Multiple logistic regression Blinding: NA Statistical measures used: Chi-square tests and Kruskal-Wallis tests. Multivariate logistic regression. All comparisons were 2-sided and were considered statistically significant at a $P < 0.05$.	Describe results: Higher numeracy scores were associated with greater accuracy in applying risk reduction information. As the number of correct responses to the three numeracy questions increased, the percentage of women who accurately gauged the risk reduction of mammography increased linearly. ARR with baseline risk results in more accuracy than ARR without baseline risk. Adding baseline risk to RRR doesn't result in improvements. Effect in no exposure (i.e., adequate literacy) or control group, %: KQ1: Accuracy rate 1 correct: 8.9% 2 correct: 23.7% 3 correct: 40% Effect in exposure (i.e., low/moderate literacy) or intervention, %: KQ1: Accuracy rate 0 correct: 5.8% Difference: KQ1: Accuracy, Adjusted and compared to a score of 0 1 correct: OR, 1.3; 95% CI 0.3 - 4.7 2 correct: OR, 7.1; 95% CI 2.2 - 23.4 3 correct: OR, 13.1; 95% CI 3.6 - 48

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Sheridan and Pignone, 2002[91] Research objective: Test medical students' numeracy and how it relates to ability to interpret risk-reduction information. Study design: Randomized, cross-sectional survey Study setting: UNC-Chapel Hill Medical School Measurement period: 1-day Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: First year male and female medical students Attendance of required seminar on risk communication. Excluded: NR Sampling strategy: Sampled students who attended a required seminar on risk communication, which discussed only qualitative dimensions of risk, such as the timing of risk, permanence of risk, and differing preferences for risk. No formal quantitative instruction was given. Sample size: N=62 Age (mean and range): Median: 24 years Gender, %: Female: 48 Race/Ethnicity, %: White: 76 Income: NR Insurance status: NR Education, %: First year medical students: 100 Other characteristics, %: Reportedly had pastime requiring use of risk concepts: 24 Health literacy/numeracy levels, %: All three questions correct: 77 2 questions correct: 18 0-1 question correct: 5 Measurement tools including cutpoints: 3-question numeracy scale adapted from Schwartz and colleagues. Blank lines (ie. ____ out of 1000 persons) were provided for responses. 3 question assessment: 1) imagine that we flip a coin 1000 times. What is your best guess about how many times the coin would come up heads? 2) in the lottery, the chance of winning a prize is 1%. what is your best guess about how many people would win a prize if 1000 people each buy a single ticket to the lottery? 3) in the publishing sweepstakes the chance of winning a car is 1 in 1000. what percentage of tickets to the publishing sweepstakes win a car?

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Ability to correctly interpret treatment benefit Covariates used in multivariate analysis: NA Description of outcome measures: Ability to interpret treatment benefit: for comparative task, students were asked to circle correct answer. Response choices include "A is more effective than B," "B is more effective than A," "A and B are equally effective" and "Don't know." For quantitative task, the students were asked to fill in their answer on a blank line. Data source(s) for outcomes: Survey self-report Attempts for control for confounding: NR Blinding: NA Statistical measures used: Relationship b/w numeracy and data interpretation was analyzed using chi-square tests for categorical variables and t-tests for continuous variables Fisher exact tests were used when comparison involved a small number of participants (< 5) Similar bivariate analyses were used Determine relationships b/w risk-reduced formats and ability to provide correct comparative and quantitative data interpretations.	Describe results: Numeracy and interpreting treatment benefit: 90% of students correctly stated which drug worked better, but only 61% correctly interpreted quantitative data. Students' numeracy was associated with correctly interpreting data both comparatively and quantitatively. Of students who considered themselves good with numbers, 91% had correct comparative interpretations compared with 75% students who considered themselves to be poor with numbers, *P* > 0.2. Effect in no exposure (i.e., adequate literacy) or control group: Correctly stated which treatment provided more benefit: 2 correct: 91% 3 correct: 94% Correctly calculated treatment benefit: 2 correct: 36% 3 correct: 71% Effect in exposure (i.e., low/moderate literacy) or intervention: Correctly stated which treatment provided more benefit: 0-1 correct: 33% Correctly calculated treatment benefit: 0-1 correct: 0% Difference: Correctly stated which treatment provided more benefit: 0-1 vs. 3 correct (unadjusted): - 61%, *P* = 0.03 Correctly calculated treatment benefit (unadjusted): 0-1 vs. 3 correct: -71%, *P* < 0.01

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Sheridan et al., 2003[92] Research objective: Determine whether numbers NNT helps patients interpret treatment benefits better than ARR, RRR, or a COMBO. Study design: Randomized cross-sectional survey Study setting: University internal medicine clinic Measurement period: June and November 2000 Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Men and women ages 50-80 presenting for care at a university internal medicine clinic Excluded: First visit to clinic Unable to understand, speak, or read English Previously participated in the survey Sampling strategy: Convenience, identified from daily clinical schedules and approached in the clinic Sample size: N=357 Age (mean and range), yrs: 63 Gender, %: Female: Overall: 65 COMBO: 68F RRR: 65 ARR: 73 NNT: 52 (*P* = 0.03) Race/Ethnicity, %: White: Overall: 69% white COMBO: 60 RRR: 76 ARR: 62 NNT: 79 (*P* = 0.01) Income: NR Insurance status: NR Education, %: Some college: 58 Other characteristics, %: Fair/poor health: 51 Discussion of medical decision with doctor: 62 Receiving some quantitative information from a doctor: 13 Health literacy/numeracy levels: Answering 3 numeracy questions correctly: 2 Answering 2 numeracy questions correctly: 27 Answering 1 numeracy questions correctly:30 Answering no numeracy questions correctly: 41 Measurement tools including cutpoints: Three-question numeracy scale by Schwartz, Woloshin et al.

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Relationship between numeracy and ability to: Correctly compare treatment benefit Correctly calculate treatment benefit Covariates used in multivariate analysis: NA Description of outcome measures: Subjects were given information about baseline risk of a hypothetical disease Y and were asked to: state which of 2 drug treatments for disease Y provided more benefit, and calculate the effect of one of these drug treatments on given baseline risk of disease Data source(s) for outcomes: Self-recorded responses to assessment Attempts for control for confounding: NA Blinding: No Statistical measures used: Chi-square tests were used Examine relationship b/w numeracy and the subjects ability to correctly perceive treatment benefit Fisher's exact tests were used when comparisons involved small numbers of subjects	Describe results: Patient's with better numeracy skills correctly compared and calculated treatment benefits more often Interpreting treatment benefit: 30% NNT compared with 60% of RRR, 42% ARR and 43% COMBO correctly statement which treatment was more beneficial $P = 0.001$ when calculating the effect of treatment on a given baseline risk of disease 6% NNT compared with 21% RRR, 17% ARR, 7% COMBO correctly stated which treatment provided more benefit, $P = 0.004$ No answer submitted when calculating the exact effect of treatment on a given baseline risk of disease, 39% NNT compared with 266% RRR, 32% ARR, 42% COMBO, $P = 0.12$ of those whole calculated the exact effect of treatment on the given baseline risk of disease 15% were off by an order of magnitude (25% NNT, 11% RRR, 17% ARR, 8% COMBO), $P = 0.08$ Substantial portion of each group (25% NNT, 19% RRR, 38% ARR, 45% COMBO) reported that the correct answer was 10 per 1000 (the magnitude of treatment benefit, not risk of disease after treatment, $P = 0.008$ Numeracy & the ability to interpret treatment benefit: Correctly stating which treatment provided more benefit: 88% of 3 correct answers, 69% of 2 correct answers, 35% of 1 or no correct answer $P < 0.001$ 50% of subjects who gave 3 correct answers to numeracy questions correctly calculate the effect of treatment on a given baseline risk of disease compared with 30% with 2 correct answers, 5% with 1 or no correct answers $P < 0.001$ Effect in no exposure (i.e., adequate literacy) or control group, %: Correctly stated which treatment provided more benefit: Those with 3 numeracy questions correct: 88% Correctly calculated treatment benefit: Those with 3 numeracy questions correct: 50% Effect in exposure (i.e., low/moderate literacy) or intervention, %: Correctly stated which treatment provided more benefit: Those with 2 numeracy questions correct: 63% Those with 1 or no numeracy questions correct: 35% Correctly calculated treatment benefit: Those with 2 numeracy questions correct: 30% Those with 1 or no numeracy questions correct: 5% Difference: Correctly stated which treatment provided more benefit: 0-1 vs. 3 correct: - 53%, $P < 0.001$ Correctly calculated treatment benefit: -45%, $P < 0.001$

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Vavrus, 2006[93] Research objective: Explore gender differences in general skills (e.g., numeracy and literacy) students acquire in primary schools and knowledge of HIV/AIDS prevention in United Republic of Tanzania. Study design: Cross sectional Study setting: Four schools in Moshi District of Kilimanjaro Region in United Republic of Tanzania Measurement period: 2000-2002 Follow-up duration: NA Note: there was follow-up survey work conducted, but it is not relevant to our question and is not reported in paper Completeness of follow-up: NA	Eligibility criteria: Included: Standard Six and Seven students at Bonde, Mbali, Miti, and Sokoni villages' primary schools Excluded: NR Sampling strategy: NR, assumed to be total population of the grades/schools (11 total schools) Sample size: 277 Age (mean and range): 14 Gender: NR Race/Ethnicity: NR Income: NR Insurance status: NR Education: All participants in Standard Six or Seven (primary school) Other characteristics, %: High Literacy Sokoni: Boys: 36 Girls: 45 Miti: Boys: 40 Girls: 67 Bonde: Boys: 31 Girls: 51 Mbali: Boys: 37 Girls: 38 Note: average life expectancy in Tanzania: 48 in 2002; prevalence of HIV/Aids in adult population 8% in 2001; school attendance: 30% enrolled in secondary school Health literacy/numeracy levels: Low Numeracy 57% (correctly completed 0-1 of 3 calculations on numeracy test NOS) Measurement tools including cutpoints: Participant asked 3 numeracy questions, "calculations" but not otherwise specified: Low Knowledge: 0 or 1 questions answered correctly High Knowledge: 2 or 3 questions answered correctly

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Knowledge about general health Knowledge about HIV/AIDS Covariates used in multivariate analysis: Gender Literacy Household education spending Parent's education Television in the home Siblings Electricity Piped water Description of outcome measures: Knowledge about general health - Participants answered five questions about general health; dichotomous; Low Knowledge: 0, 1, or 2 questions answered correctly High Knowledge: 3,4, or 5 questions answered correctly Knowledge about HIV/AIDS - Participants answered four questions about general health; dichotomous; Low Knowledge: 0, 1, or 2 questions answered correctly High Knowledge: 3 or 4 questions answered correctly Data source(s) for outcomes: Self-report Attempts for control for confounding: Multivariate analysis Blinding: NR Statistical measures used: Logistic regression	Describe results: High numeracy raised the odds of having high AIDS knowledge by a factor of 2.7. High numeracy was not significantly related to having a higher general health knowledge. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference: Difference in odds of having high HIV/AIDS knowledge (high vs low numeracy): OR = 2.75, $P < 0.001$ Difference in odds of having high general health knowledge (high vs. low numeracy): OR = 1.52, $P > 0.05$

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Waldrop-Valverde et al., 2009[78] Research objective: To test the relationship between health literacy and numeracy to medication management capacity among HIV positive men and women, and to test whether health literacy and/or numeracy mediated the effects of gender on the outcome Study design: Cross-sectional Study setting: HIV clinics or participants in AIDS drug assistance program in Miami, Florida Measurement period: NR Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: HIV positive ≥ 18 yrs Receiving antiretroviral treatment (ART) or "in process" for first course of ART No history of head injury or loss of consciousness lasting more than 30 mins No presence of psychotic symptoms at time of enrollment Not used heroin, cocaine or marijuana in the past 12 mos Excluded: NR Sampling strategy: Convenience Sample size: N = 155 Male, n: 90 Female, n: 65 Age (mean and range), % (SD): NR other than no sig difference between men and women Gender, %: Female: 58% Race/Ethnicity, %: Among Men: Black: 81% Among Women: Black: 95% Income, %: NR Insurance status, %: NR Education, %: Men (mean and SD): 11.7 yrs (2.6) Women (mean and SD): 11.3 yrs (1.8) Other Characteristics Regular place to stay, %: Men: 84 Women: 99 Yrs since HIV diagnosis (SD): Men: 8.6 (7.0) Women: 11.1 (6.2)

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Medication Management Test (MMT): Measures ability to understand ART medication instructions 8 items with a total of 16 points, There were 5 "mock" HIV medications with labels. Test score based on answers to questions about the medication labels, the loperamide insert, the ability to correctly count out and place a week's supply of pills in a medication organizer and to determine missed doses and refills. Total % correct used in the analysis. Covariates used in multivariate analysis: Included only variables found to be sig related to MMT: Gender, education and time since HIV diagnosis Regression analysis includes health literacy and numeracy Path analysis includes numeracy and excludes health literacy Description of outcomes measures: Medication Management Test (MMT): Measures ability to understand ART medication instructions 8 items with a total of 16 points, There were 5 "mock" HIV medications with labels. Test score based on answers to questions about the medication labels, the loperamide insert, the ability to correctly count out and place a week's supply of pills in a medication organizer and to determine missed doses and refills. Total % correct used in the analysis. Data source(s) for outcomes: Directly measured Attempts for control for confounding: Hierarchical multiple regression to examine whether health lit and numeracy are associated with the outcome. Path analysis to examine mediator analysis. Blinding: NR Statistical measures used: Hierarchical multiple regression testing the association of health literacy and numeracy with MMT scores. Mediation effects were tested using path analytic techniques.	Describe results: MMT score outcome (hierarchical multiple regression model): Step 1 regressors: years of education, time since HIV diagnosis and gender; explained 14% of variance in outcome ($P < 0.001$) Step 2 (adding TOFHLA to step 1 variables); adding health literacy accounted for additional 21% of variance ($P < 0.001$) Step 3 Final model (adding numeracy to step 2): accounted for an additional 12% of the variance. The final model explained a total of 48% of the variance in MMT scores Health literacy and numeracy were positively and significantly associated with MMT Women were less likely to understand medication instructions as assessed by the MMT and so path analysis conducted to determine if numeracy mediated differences between men and women in MMT performance. Found that the relationship between gender and MMT performance is mediated by numeracy Effect in no exposure (i.e., adequate literacy) or control group, %: NR Effect in exposure (i.e., low/moderate literacy) or intervention: NR Difference, %: Difference in MMT score Health literacy: $\beta = 0.210$ ($P < 0.05$) Numeracy (applied problems: $\beta = 0.538$ ($P < 0.01$) Path Analysis Results: Correlation between female gender and Numeracy: -0.428, ($P < 0.01$) Correlation between numeracy and Medication Management Capacity: 0.644, ($P < 0.01$) Correlation between female gender and Medication Management Capacity: Without moderator: NR, sig With moderator: 0.073, NS

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Study Description	Participant Characteristics
Author, year: Yin et al., 2007[85] Research objective: Assess whether caregiver HL was associated with risk factors for liquid medication dosing errors Study design: Cross-sectional Study setting: Pediatric emergency department at urban public hospital in New York City (Bellevue Hospital) Measurement period: July 2006 - October 2006 Follow-up duration: NA Completeness of follow-up: 292 completed of 307 enrolled (95%)	Eligibility criteria: Included: Parent or caregiver with child aged between 30 days and 8 years Non-urgent visit Presence of primary caregiver responsible for giving medications Caregiver's language English or Spanish Child's medication generally given in liquid form Visit not involving Excluded: NR Sampling strategy: Convenience sample of parents and caregivers presenting to the ED Sample size: N = 292 Age (mean and range): NR Gender: NR Race/Ethnicity, %: Latino: 72.9 Black or African-American: 12.7 Asian: 5.5 White: 4.8 Other: 4.1 Income: NR Insurance status: NR Education, %: < HS: 39.7 Other characteristics, %: Born outside US: 57.9 English-speaking: 62.4 Spanish-speaking: 37.6 Hollingshead Socioeconomic Status: 1.4 level 1: 1.4, level 2: 7.5, level 3: 15.8, level 4: 25.0 level 5: 50.3 Child has regular MD: 72.9 Ever received a dosing tool: 57.2 Child ≥ 1year old: 81.5 Health literacy/numeracy levels, %: Inadequate: 9.6 Marginal: 15.9 Adequate: 74.4 Measurement tools including cutpoints: TOFHLA Inadequate: 0-59 Marginal: 60-74 Adequate: 75-100

Evidence Table 2. Key Question 1: Numeracy Outcome Studies (continued)

Outcomes	Results
Main outcomes: Caregiver use of a non-standardized measurement tool as a primary dosing instrument Covariates used in multivariate analysis: Caregiver education Caregiver country of origin Caregiver language Caregiver SES Age of child Regular child health-care provider Experience of ever having received a dosing instrument in a health-care setting Description of outcome measures: Caregiver self-report of a nonstandardized liquid measurement tool, offering choices of kitchen teaspoon, kitchen tablespoon, dosing spoon, measuring spoon, dosing cup, dropper, and syringe. Answers dichotomized as incorrect (kitchen spoons) or correct (other standardized instruments). Data source(s) for outcomes: Interview with child's primary caregiver Attempts for control for confounding: Multiple logistic regressions Blinding: NR Statistical measures used: Fisher exact test Chi square Multiple logistic regression	Describe results: Caregivers with lower HL literacy scores (marginal/inadequate, reading comprehension below the median, numeracy score below the median) were significantly more likely to use a non-standardized measurement tool (after adjusting for caregiver and child characteristics not confounded with HL). Effect in no exposure (i.e., adequate literacy) or control group, %: Poor knowledge of weight dosing: Numerate: 62 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Poor knowledge of weight based dosing: Innumerate: 76 Difference AOR (CI): Difference in reported use of non-standardized dosing instrument (adjusted for all control variables) Marginal/inadequate vs. adequate: 1.5 (0.8-2.8) Reading comprehension score below median: 2.4 (1.3-4.7) Numeracy score below median: AOR, 1.4 (0.8-2.7) Difference in reported use of non-standardized dosing instrument (adjusted for child's age, regular health care provider for child, history of receiving dosing instructions in clinic or ED--not controlling for confounders with HL) Marginal/inadequate vs. adequate: 1.9 (1.0-3.5) Reading comprehension score below median: 3.1 (1.7-5.7) Numeracy score below median: 1.9 (1.1-3.4)

Evidence Table 3. Key Question 2: Intervention studies

Study Description	Participant Characteristics
Author, year: Bosworth et al., 2005[94] Research objective: Determine if nurse administered patient-tailored intervention can improve blood pressure control Study design: Randomized-controlled trial Study setting: Primary care clinic at Veterans Affairs Medical Center in Durham, NC Measurement period: NR Follow-up duration: 24 months (this article reports 6 month outcomes; final results not available) Completeness of follow-up: 97% retention rate for first 13 months (95% response rate at 6 months)	Eligibility criteria: Included: Outpatients who had a diagnosis of hypertension Enrolled in Durham VAMC primary care clinic Had a prescription for hypertensive medication (ACE inhibitors, beta blockers, calcium channel blockers, diuretics, alpha-1 blockers, and/or central alpha-2 agonists) in previous year Excluded: NR Sampling strategy: Random sample mailed intro letter, convenience sample approached Sample size: 588 Age, mean (SD): Intervention: 63 (11.24) Control: 64 (11.48) Gender, %: Female: 2 Race/Ethnicity, %: Intervention: White: 56 African-American: 41 Control: White: 58 African-American: 39 Income, %: Intervention: "inadequate income" (self-reported, not defined further): 23 Control: "inadequate income:" 21 Insurance status, %: 100 insured (VA sample) Education, %: Intervention: "high school or less:" 50 Control: "high school or less:" 51 Other characteristics, %: Taking BP meds > 5 years: Intervention: 62 Control: 61 BP Intervention: 138/75 Control: 139/76 BP Control Intervention: 43 Control: 44

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Primary outcome: BP control Secondary outcomes: confidence with treatment (similar to locus of control), hypertension knowledge, self-reported adherence Covariates used in multivariate analysis: NR Description of outcome measures: Hypertension knowledge was measured by 10-item questionnaire (score range 0-10) Confidence (more like locus of control; not self-efficacy) was measured with a 4-item questionnaire (score range 4-16): "the main thing which affects my bp is what I do" " Data source(s) for outcomes: Interview; NR how they obtained BP info Attempts for control for confounding: Randomization Blinding: NR Statistical measures used: NR	Describe results: After first 6 months of study, patients receiving nurse intervention had non-significant increase in hypertension knowledge, and non-significant increase in medication adherence. Effect in no exposure (i.e., adequate literacy) or control group: Change in hypertension knowledge score: +1.0 Change in medication adherence among initially adherent patients: -15% Medication adherence among initially non-adherent patients: +34% Effect in exposure (i.e., low/moderate literacy) or intervention: Change in hypertension knowledge score: +1.0 Medication adherence among initially adherent patients: -17% Medication adherence among initially non-adherent patients: +46% Difference, % (CI): Overall: 0, (unadjusted P = 0.49) Change among those initially adherent: -2, P = 0.68 Change among those initially non-adherent: +12, P = 0.08

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Bosworth et al., 2005[94] (continued)	Health literacy/numeracy levels: NR (although at least 8% b/c low literacy intervention activated in 8% of low literacy patients whose meds changed) Measurement tools including cutpoints: REALM, cut points not specified

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Brock and Smith, 2007[95] Research objective: Evaluate effects of using audiovisual animation displayed on PDA for patient education in clinical setting Study design: Quasi-experimental (pre-post test) Study setting: Outpatient infectious disease clinic at University of North Carolina Measurement period: NR Follow-up duration: 4-6 weeks (coincident with next study visit) Completeness of follow-up: 27/51 (53%)	Eligibility criteria: Included: ≥18 years-old Confirmed HIV diagnosis Initiating or continuing HIV medication at first visit English-speaking Willing to give informed consent Excluded: NR Sampling strategy: Convenience (clinical referral) Sample size: 51 Age (range): 42.1 (25-70) Gender, %: Female: 49 Race/Ethnicity, %: Black: 77 Income: 65% "did not have enough money to make ends meet at the end of the month" Insurance status: NR Education, %: 12th grade or GED: 60 Other characteristics, %: Reported easier to learn from videos rather than books: 94 Have used some computerized device: 96 Health literacy/numeracy levels, %: <8th grade: 55 Measurement tools including cutpoints: REALM

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Knowledge of HIV disease, medications and adherence behaviors Secondary: attitudes toward video and device, self-reported adherence to medication regime and practicality of the intervention Covariates used in multivariate analysis: NA Description of outcome measures: Knowledge of HIV disease and medications: 9 questions, not otherwise specified Adherence: 9-item Morisky scale, alpha 0.89 See also J. Am. Pharm. Assoc. 45 (2005): 625-28; Qual Life Res 14(2005): 935-44. Data source(s) for outcomes: Knowledge of HIV disease, medications: self report Adherence: self-report Attempts for control for confounding: None Blinding: NR Statistical measures used: Paired sample t-tests	Describe results: Intervention increased knowledge of HIV and medications immediately. At f/u appointment (4-6 weeks), increased self-reported adherence to medication regimen, although result significantly confounded by high loss to follow-up. Effect in no exposure (i.e., adequate literacy) or control group: Knowledge: NR Adherence: NR Effect in exposure (i.e., low/moderate literacy) or intervention, %: Knowledge: NR Adherence: NR Self-efficacy to take medications (post-test only): 96 Difference: Overall: NR, (unadjusted $P < 0.005$) Knowledge: NR, $P < 0.005$ Adherence: NR, $P < 0.005$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Bryant et al., 2009[96] Research objective: To determine whether a novel multimedia computer version of the AUA-SS would be better understood by patients than the original form, and to see whether improvement in understanding varied by literacy level Study design: RCT Study setting: Urology clinic at Grady Memorial Hospital and Emory University Hospital, two large, university-based, urban tertiary care hospitals in Atlanta, GA. Measurement period: NR Follow-up duration: Immediately Completeness of follow-up: 96%* Control (%): 112/122 (91.8) Intervention (%): 110/110 (100) *Calculated by research team	Eligibility criteria: Included: NR Excluded: Untreated psychiatric disorders Age < 18 years old Blindness Inability to speak English Major lower urinary tract surgery Chronic catheterization Sampling strategy: Convenience sample Sample size: N: 232 Control, n: 122 Intervention, n: 110 Age (mean and range), % (SD): Overall mean: 58.6 Control: 60.3 Intervention: 56.8 Gender, %: NR Race/Ethnicity, %: Overall, %: White: 46 Black: 51 Other: NR, 3* Control (%): White: 46/122 (38) Black: 63/122 (52) Intervention (%): White: 56/110 (51) Black: 50/110 (45) *Calculated by research team Income, %: NR Insurance status, %: NR Education, %: NR Other Characteristics Location (from which of the two hospitals they were recruited)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Measured in mean number of errors, or the difference in AUA-SS (a 35 point scale) between self-administered AUA-SS (experimental condition) and health-professional-administered AUA-SS (reference standard) Also measured as what % of questions patients understood (defined as less than 2 pt difference b/t experimental derived and interviewer derived score): all (7), some (4-6), some (1-3), none (0) Accuracy of classification as mild/moderate/severe symptoms on AUA-SS Covariates used in multivariate analysis: NR Description of outcomes measures: Measured in mean number of errors, or the difference in AUA-SS (a 35 point scale) between self-administered AUA-SS (experimental condition) and health-professional-administered AUA-SS (reference standard) Also measured as what % of questions patients understood (defined as less than 2 pt difference b/t experimental derived and interviewer derived score): all (7), some (4-6), some (1-3), none (0) Accuracy of classification as mild/moderate/severe symptoms on AUA-SS Data source(s) for outcomes: Self-administered AUA-SS and AUA-SS administered by a health professional Attempts for control for confounding: Multivariate regression Blinding: None Statistical measures used: Multivariate regression (although don't report what confounders adjusted for or whether presented P values are actually adjusted)	Describe results: Individuals who self-administered the multimedia computer-based AUA-SS made fewer errors than individuals using the traditional written form. In addition, the multimedia format reduced errors across all literacy levels, but reduced errors more in individuals with low health literacy. Effect in no exposure (i.e., adequate literacy) or control group, %: Mean symptom score error: Overall written: 3.48 ≥ HS: 3.10 < HS: 4.55 % Understanding all questions: Overall written: 34 ≥ HS: 37 < HS: 24 Accuracy of classification, %: Overall: 71 Effect in exposure (i.e., low/moderate literacy) or intervention: Mean symptom score error: Overall multimedia: 1.97 ≥ HS: 1.86 < HS: 2.24 % Understanding all questions: Overall multimedia: 53 ≥ HS: 55 < HS: 49 Accuracy of classification, %: Overall: 84 Difference, %: Mean symptom score error: Overall (multimedia-written): -1.51, $P < 0.001$ ≥ HS: -1.24, $P < 0.001$ < HS: -2.31, $P < 0.03$ % Understanding of questions Overall (multimedia-written): +19, P NR ≥ HS: +18, P NR < HS: +25, P NR Accuracy of classification: +13%, $P = 0.04$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Campbell et al., 2004[97] Research objective: Compare comprehension of consent information (for a hypothetical research study) as function of medium of presentation, mostly among low-literacy population Study design: RCT Study setting: University-based medical complex; but not in clinics Measurement period: 1999-2000 Follow-up duration: Immediate Completeness of follow-up, %: 233/238 (98)	Eligibility criteria: Included: Parents or Primary caretaker with a child less than age 10 in 1 of 2 Head Start programs Excluded: NR Sampling strategy: Convenience Sample size: 233 usable cases Age, (SD): 32.1 (9.7) Gender, %: Female: 85 (198/233) Race/Ethnicity, %: African-American: 84 White: 13 Other: 3 Income: NR Insurance status: NR Education, %: Less than HS: 24 HS grad: 26 Some college: 40 College grad: 10 Other characteristics: NR Health literacy/numeracy levels, % (SD): Average REALM: 56.3 (11.8) Average Woodcock-Johnson: 28.1 (5.1) Equivalent to average 8th grade-level: 50 Measurement tools including cutpoints, range: REALM: 0-66 Woodcock Johnson: cloze passages: 0-43 Low-literacy group was at or below 8th grade level by Woodcock Johnson

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Free recall Prompted recall Enrollment decision Covariates used in multivariate analysis: Woodcock Johnson score Description of outcome measures: Free recall assessed as % of total "bits" (irreducible bit of information) when participant asked to pretend she was telling friend about study Prompted recall assessed by open-ended questions with answers coded as 0 (no answer or poor attempt) to 3 (excellent response); % correct Based on participant's response to whether she would enroll her child in hypothetical study Data source(s) for outcomes: All based on respondents' answers; some potential for coding discrepancies with recall items - resolved by discussion/consensus of coders Attempts for control for confounding: Randomization Blinding: Investigators coding recall blinded Statistical measures used: General linear models	Describe results: Among entire sample, no differences in recall were noted according to format (although trends toward laptop > original), and more information was recalled about the low-risk study. However, among the 124 individuals with low-literacy, there were trend Effect in no exposure (i.e., adequate literacy) or control group, %: Standard consent: Free Recall: 4.3 (avg high/low risk) Prompted Recall: 47 (avg high/low risk) Effect in exposure (i.e., low/moderate literacy) or intervention, %: Enhanced print: Free Recall: 4.4 (avg high/low risk) Prompted Recall: 53 (avg high/low risk) Video: Free Recall: 4.2 (avg high/low risk) Prompted Recall: 50 (avg high/low risk) Computerized, %: Free Recall: 4.2 (avg high/low risk) Difference: % of total information remembered on free recall (adjusted): Simplified vs. standard: +0.1, NS Video vs. standard: 0.1 < NS Computer vs. standard: -0.1, NS Note: no interaction by literacy level % correct of correct answers on prompted recall: Simplified vs. standard: +6, NS Video vs. standard: +3, NS Computer vs. standard: +4, $P = 0.08$ Note: trend toward improvement in low literacy group

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Coyne et al., 2003[98] Research objective: Test effect of easy to read informed consent statement with participants in cancer treatment trial. Study design: RCT Study setting: Member institutions and affiliates of 3 cooperative oncology groups (eastern onc group; north central cancer treatment group; cancer and leukemia group b) Measurement period: 1998-2000 Follow-up duration: 2 weeks Completeness of follow-up, %: Int: 78/89 (88) Control: 129/137 (94)	Eligibility criteria: Included: Affiliated cooperative oncology groups Patients participating in one of 3 cancer treatment trials (1 NSCLC, 2 breast CA) at affiliated cooperative oncology groups Excluded: NR Sampling strategy: NOS Sample size: 44 oncology groups (24 control, 20 intervention) 226 patients (137 control, 89 intervention) Note: 1-38 patients/group Age, mean (range): Control: 53 (NR) Intervention: 53 (NR) Gender, %: Female: Control: 91 Intervention: 92 Race/Ethnicity, %: White: Control: 92 Intervention: 94 Income: NR Insurance status: NR Education, %: Control: <HS: 9 HS: 23 < college 23 ≥ college: 24 Intervention: <HS: 4 HS: 28 <college 30 >=college: 31 Possibly important difference by group that would bias toward bigger effect in intervention group Other characteristics, %: Type of Institution: Main: Control: 5 Intervention: 14

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Comprehension Note: Also measured anxiety, satisfaction, decision to participate, accrual Covariates used in multivariate analysis: None Description of outcome measures: % correct from 23 multiple choice or true false questions on privacy (3), treatment protocol (5), side effects (4), personal benefit (4), randomization (1), choice (5), benefit to others (3), reasons to be taken off study (2), financial (2) Content validity assessed by experts; no other validation Data source(s) for outcomes: Survey Attempts for control for confounding: No Blinding: NR Statistical measures used: Random effects models with randomization unit as random effect (continuous outcomes) GEE (binary outcomes) Accounted for clustering in sample size calculation and statistics	Describe results: No difference in comprehension b/t groups Of note, there was lower consent anxiety and higher satisfaction in intervention group Effect in no exposure (i.e., adequate literacy) or control group, %: 69 Effect in exposure (i.e., low/moderate literacy) or intervention, %: 72 Overall Difference (unadjusted), %: 3, $P = 0.21$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Coyne et al., 2003[98] (continued)	Health literacy/numeracy levels: Mean REALM: Control: 64 Intervention: 65 Measurement tools including cutpoints: REALM: ≤ 3 grade (0-18); 4-6th grade (19-44); 7th-8th grade (45-60); ≥9th grade (61-66)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Davis et al., 2008[99] Research objective: Assess efficacy of literacy-appropriate weight loss intervention targeting providers and patients in improving physicians' weight loss counseling and patients' self-reported beliefs, and self-efficacy Study design: Pre-post intervention study Study setting: Louisiana State University Health Sciences Center-Shreveport (LSUHSC-S) Nephrology Clinic (public health clinic) Measurement period: April to October 2003 Follow-up duration: Subsequent visit following group intervention, interval unclear Completeness of follow-up, %: 64/101 patients (64)	Eligibility criteria: Included: NR Excluded: BMI < 27 Legally blind Wheelchair bound In residential care Prisoners Sampling strategy: Consecutive sample Sample size: 101 Note: 111 invited Age, mean(SD): 57 (12) Gender, %: Female: 52 Race/Ethnicity, %: African American: 75 White: 23 Income: "Predominantly low income" not otherwise reported Insurance status, %: Medicaid: 46 Free care: 46 Medicare: 4 Private: 4 Education: NR Other characteristics: Mean BMI: 35 Health literacy/numeracy levels, %: <6th grade (low): 49 7-8th grade (marginal): 22 =>9th grade (adequate): 29 Measurement tools including cutpoints: REALM: 0-44 = 6th grade and below, low literacy; 45-60 = 7th-8th grade literacy, marginal literacy; 61 and above = 9th grade and above, adequate literacy

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Physician communication skills: Makes eye contact Established rapport Invites questions Uses facilitation Holds for answers Redirects patient as appropriate Explains medical terms/concepts Summarizes/repeats instructions Uses teach back technique Patient satisfaction: Doctor supportive of weight loss Patient recall of recommendations: Lose weight Increase physical activity Referral to dietician Patient perception of weight problem Patient motivation to lose weight Patient confidence in ability to lose weight (self efficacy) Covariates used in multivariate analysis: None Description of outcome measures: Validated checklist for communication behavior Unvalidated checklist for weight loss communication Unvalidated patient recall/motivation items, but based on prior surveys % of physicians and patients reporting a given behavior reported magnitude on a scale out of ten for "severity" and "motivation Data source(s) for outcomes: Checklists (communication) Structured interviews (patient factors) Attempts for control for confounding: NR Blinding: Physicians and patients were aware of being observed at baseline, but unaware of content of study Statistical measures used: Descriptive statistics including mean, standard deviation, median, and range for continuous variables, and percentage for categorical variables Student's t-test to compare groups for continuous variables Chi square, and Fisher's exact test for categorical data	Describe results: Some physician communication skills improved, while others did not Physician weight-loss counseling skills improved Patients were more likely to recall weight loss recommendation, to increase physical activity, to see dietician, and to report their physician was supportive of their weight loss efforts Patients were more motivated, more confident, and had higher self efficacy after intervention Effect in no exposure (i.e., adequate literacy) or control group, %: Physician communication skills: Makes eye contact: 82 Established rapport: 65 Invites questions: 32 Uses facilitation :82 Holds for answers: 65 Redirects patient as appropriate: 21 Explains medical terms/concepts: 77 Summarizes/repeats instructions 71 Uses teach back technique 29 Patient satisfaction: Doctor supportive of weight loss: 70 Patient recall of recommendations: Lose weight: 23 Increase physical activity: 28 Referral to dietician: 44 Patient recognizes weight is problem: 59 Perceived severity of weight problem: 6.3 (SD 2.2) out of ten Patient motivation: 5.8 (SD 2.6) out of ten Patient confidence: 52 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Physician communication skills: Makes eye contact: 98 Established rapport: 95 Invites questions :52 Uses facilitation :95 Holds for answers: 95 Redirects patient as appropriate: 96 Explains medical terms/concepts: 89 Summarizes/repeats instructions: 75 Uses teach back technique: 35 Patient satisfaction: Doctor supportive of weight loss: 81

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Davis et al., 2008[99] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Patient recall of recommendations: Lose weight: 66 Increase physical activity: 69 Referral to dietician: 83 Patient recognizes weight is problem: 62 Perceived severity of weight problem: 7.0 (SD 2.1) out of ten Patient motivation: 7.1 (SD 2.7) out of ten Patient confidence: 79 Difference, %: Overall self-efficacy (unadjusted): +27%, *P* = 0.01 Physician communication skills: Makes eye contact +16, *P* = 0.16 Established rapport +30, *P* = 0.01 Invites questions +20, *P* = 0.09 Uses facilitation +13, *P* = 0.39 Holds for answers +30, *P* = 0.01 Redirects patient as appropriate +75 Patient recall recommendations: Lose weight (unadjusted): +43%, *P* = 0.02 Increase physical activity (unadjusted): +41%, *P* = 0.01 Go to dietician (unadjusted): +39%, *P* = 0.002

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: DeWalt et al., 2006[100] Research objective: Compare efficacy of heart failure self-management program designed for patients with low literacy versus usual care. Study design: RCT Study setting: General internal medicine and cardiology clinic Measurement period: November 2001 to April 2003 Follow-up duration: 12 months Completeness of follow-up: Control: 59/65 Intervention 52/62	Eligibility criteria: Included: Clinical diagnosis of HF confirmed by provider and clinical indicators New York HearT Association class II-IV symptoms in past 3 months 30-80 years old Excluded: Moderate to severe dementia Terminal illness with life expectancy less than 6 months Severe hearing impairment Blindness Current substance abuse Serum creatinine <4 mg/dl or on dialysis Supplemental oxygen at home No telephone Scheduled to undergo cardiac surgery Awaiting a heart transplant or planned cardiac surgery Sampling strategy: All consenting eligible patients Sample size: N=127 Control: n= 64 Intervention: 59 Age, mean (SD): Control: 62 (11) Intervention: 63 (9) Gender, %: Female: Control: 59 Intervention: 42 Race/Ethnicity, %: Control: African American: 55 Other: 45 Intervention: African American: 54 Other: 46 Income, %: <$15,000/yr Control: 67 Intervention: 69 Insurance status: Control: Medicaid: 33 Medicare: 72 Intervention: Medicaid: 34 Medicare: 71

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Primary: Death or all-cause hospitalization HF related quality of life at 12 months Secondary: HF self efficacy HF Knowledge Self-management behavior Covariates used in multivariate analysis: For sub-group analysis: Age Gender Hypertension Minnesota Living with Heart Failure questionnaire (MLHF) Use of b-blockers Use of ACE inhibitors or ARBs Description of outcome measures: Hospitalization: patient reported and confirmed by chart review HF-related quality of life: assessed using a modified version of the MLHF; 21 question instrument with a 4-point Likert (responses 0, 1, 3, 5) scale response option and scores ranging from 0 Data source(s) for outcomes: Hospitalization: self-report confirmed by chart review HF-related quality of life: self-report HF self-efficacy: self-report Heart failure knowledge: self-report Heart failure self-management behavior: self-report Attempts for control for confounding: Primary outcomes: ANCOVA Secondary outcomes: multivariate analysis Blinding: No Statistical measures used: Two-sample t-tests for MLHF, HF self-efficacy, and heart failure knowledge. Parametric and Non-parametric tests performed for all comparisons. Negative binomial regression used for hospitalization or death. Analysis of covariance with negative binomial	Describe results: Patients in intervention group had lower rate of hospitalization or death. This difference was larger for patients with low literacy but the interaction was not statistically significant. Effect in no exposure (i.e., adequate literacy) or control group, %: Hospitalization or death: 61 Heart failure-related quality of life (Unadjusted): improved 5 points Secondary outcomes: HF Knowledge: NR HF self-efficacy: NR HF self-management (daily weighing at 12 months): 29 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Hospitalization or death: 42 Heart failure-related quality of life (unadjusted): improved 1 point Secondary outcomes: HF Knowledge: NR HF self-efficacy: NR HF self-management (daily weighing at 12 months): 79 Difference, IRR (CI): Hospitalization or death (incidence rate ratio unadjusted): 0.69 (0.40-1.19) Heart failure-related quality of life (unadjusted): 3.5 points difference: (11- -4) Heart failure-related quality of life (adjusted): 2 point difference: (9- -5) Secondary outcomes: HF Knowledge (adjusted): mean difference = 12% higher in intervention group: 95% CI, 6-18, $P < 0.001$ HF self-efficacy (adjusted): mean difference = 2 points improvement in intervention group: 95% CI, 0.7-3.1, $P = 0.003$ HF self-management (daily weighing at 12 months): $P < 0.001$ Sub-group analysis (low literacy n=24) Hospitalization or death (incidence rate ratio adjusted): 0.39; (0.16-0.91) Sub-group analysis (marginal/adequate literacy n=75) Hospitalization or death (incidence rate ratio adjusted): 0.56 (0.30-1.04) Effect on behavior, Overall (adjusted): NR, ($P < 0.001$)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: DeWalt et al., 2006[100] (continued)	Education, years (SD): Control: 9.9 (2.6) Intervention: 9.1 (3.2) Other characteristics, % (SD): Control: Diabetes: 52 Hypertension: 89 HF years: 7 (8) HF knowledge: 57 Self efficacy (mean score): 22 Daily wt measurement: 15% HFQOL (mean score range 0-10 Health literacy/numeracy levels, %: Inadequate: Control: 39 Intervention: 42 Measurement tools including cutpoints: s-TOFHLA Inadequate HL ≈ 4th grade reading level

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Ferreira et al., 2005[101] Research objective: To test whether health-care provider directed intervention increased colorectal cancer screening rates. Study design: Cluster RCT Study setting: Two general medicine clinics/firms at a VA medical center in Chicago Measurement period: May 2001 - June 2003 Follow-up duration: 18 months Completeness of follow-up: 100%	Eligibility criteria: Included: Providers: all in included firms Patients: Male 50 or older Scheduled to be see participating physician (new or ongoing problem) Excluded: Personal of family history of colorectal cancer or polyps Personal history of inflammatory bowel disease Sampling strategy: Providers: All Patients: All Sample size: Providers: Intervention: 60 Control: 53. Patient: Intervention: 1015 (1-40/provider; mean 19) Control: 963 (1-46/provider; mean 20) Patients completing health literacy assessment: Intervention: 197 Controls: 185 Age (mean and range): Provider: NR Patient: Total: 67.8 Intervention: 67.9 Control: 67.8 Gender, %: Provider: NR Patient: Male: 100 Race/Ethnicity, %: Provider: NR Patient: Total: White: 45 AA: 50 Intervention: White: 45.4 AA: 50.1 Control: White: 44.7 AA: 50.5

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Colorectal Cancer Screening Recommendation Fecal Occult Blood Testing only Flexible Sigmiodoscopy/Colonoscopy only Both Fecal Occult Blood Testing and Flexible Sigmiodoscopy/Colonoscopy Any screening test Completion of Colorectal Cancer Screening Test Covariates used in multivariate analysis: Random effects of clustering within provider Description of outcome measures: Colorectal Cancer Screening Recommendation Fecal Occult Blood Testing only: dichotomous (yes/no) Flexible Sigmiodoscopy/Colonoscopy only: dichotomous (yes/no) Both Fecal Occult Blood Testing and Flexible Sigmiodoscopy/Colonoscopy: dichotomous (yes/no) Data source(s) for outcomes: Patient chart, no details provided about fidelity of chart review Attempts for control for confounding: Adjustment for clustering of patients by provider Blinding: NR Statistical measures used: z test for comparing two independent proportions, with adjustment made for clustering of patients by provider	Describe results: Intervention improved rates of any colorectal screening recommendation by providers and any screening completion in patients overall, especially for patients with lower literacy skills. Effect in no exposure (i.e., adequate literacy) or control group, %: Entire Sample Recommendation: FOBT only: 2.8 Flex Sig/Colo only: 44.4 Both FOBT and Flex Sigm/Colo: 22.1 Any screening test: 69.4 Completion of Tests: FOBT only: 14.3 Flex Sig/Colo only: 15.3 Both FOB and Flex Sig/Colo: 2.8 Any screening test: 32.4 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Entire Sample Recommendation: FOBT only: 6.3 Flex Sig/Colo only: 19.2 Both FOBT and Flex Sig/Colo: 50.4 Any screening test: 76.0 Completion of Tests FOBT only: 22.6 Flex Sig/Colo only: 12.2 Both FOB and Flex Sig/Colo: 6.5 Any screening test: 41.3 Difference, %: Entire Sample Difference in Any Recommendations: 6.6, $P = 0.02$ Difference in Completion of Any Tests: 8.9, $P = 0.003$ Literacy subgroup results NR Low Literacy Subgroup Difference in Completion of Any Tests: 25.7, $P = 0.002$ High Literacy Subgroup Difference in Completion of Any Tests: 3, 0.65

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Ferreira et al., 2005[101] (continued)	Income: Patient: NR Insurance status: Patient: NR, but VA clinics Education: Patient: NR Other characteristics (SD): Patient, n clinic visits (SD): Total: 2.84 (1.64) Health literacy/numeracy levels: In 369/1978 patients in whom measured: Lower than 9th grade: 31% (note: text says ~1/3) >=9th grade: 79% Measurement tools including cutpoints: REALM Limited Literacy: lower than 9th grade (scores 60 or below)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Galesic et al., 2009[102] Research objective: Experiment 1: To investigate whether icon arrays increase accuracy of understanding medical risks (either ARR or RRR) Experiment 2: To investigate whether icon arrays and alternate denominators affect perceived seriousness of risks and helpfulness of treatments; this experiment is not of interest to SER Study design: Factorial RCT Study setting: Lab at the Max Planck Institute for Human Development in Berlin, Germany Measurement period: NR Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: NR Excluded: NR Sampling strategy: NR Sample size: Overall, N: 171 Group 1 (older adults), n: 59 Group 2 (students), n: 112 Age (mean and range), % (SD): Group 1 (older adults): 62-69: 49% 70-77: 51% Group 2 (students): 18-25: 63% 26-35: 57% Gender, %: Group 1 (older adults): 49% F Group 2 (students): 57% F Race/Ethnicity, %: NR Income, %: NR Insurance status, %: NR Education, %: Group 1 (older adults): High school or lower education: 57% College or university: 43% Group 2 (students): University students: 100% Other Characteristics NR

Evidence Table. KQ2 Update search

Outcomes	Results
Main outcomes: Accuracy of risk understanding was assessed with two questions, following the procedure used by Schwartz et al. with estimation of risk with and without treatment and subtraction/division of these numbers to define ARR/RRR Covariates used in multivariate analysis: Age Gender Education Description of outcomes measures: Accuracy of risk understanding was assessed with two questions, following the procedure used by Schwartz et al. with estimation of risk with and without treatment and subtraction/division of these numbers to define ARR/RRR Data source(s) for outcomes: Computerized Questionnaire: Participants' responses Attempts for control for confounding: ANOVA Blinding: Probably, b/c of computerized delivery Statistical measures used: ANOVA, mixed linear models	Describe results: Experiment 1: Icon arrays increased accuracy of both low- and high-numeracy people, even when transparent numerical representations were used. NOTE: In experiment 2, Risks presented via icon arrays were perceived as less serious than those present numerically. With larger icon arrays, risks were perceived more serious, and risk reduction larger. Effect in no exposure (i.e., adequate literacy) or control group, %: Experiment 1 Older adults, high numeracy: Numerical RRR only: 45% Numerical ARR only: 83% Older adults, low numeracy: Numerical RRR only: 0% Numerical ARR only: 56% Students, high numeracy: Numerical RRR only: 42% Numerical ARR only: 95% Students, low numeracy: Numerical RRR only: 20% Numerical ARR only: 70% Effect in exposure (i.e., low/moderate literacy) or intervention: Experiment 1 Older adults, high numeracy: Icons + Numerical RRR: 56% Icons + Numerical ARR: 88% Older adults, low numeracy: Icons + Numerical RRR: 75% Icons + Numerical ARR: 86% Students, high numeracy: Icons + Numerical RRR: 65% Icons+ Numerical ARR: 94% Students, low numeracy: Icons + Numerical RRR: 44% Icons + Numerical ARR: 91% Difference, %: Experiment 1 Older adults, high numeracy: Icons vs Numerical RRR (unadjusted): +11%, NS* Icons vs Numerical ARR (unadjusted): +5%, NS* Older adults, low numeracy: Icons vs Numerical RRR (unadjusted): +75%, S* Icons vs Numerical ARR (unadjusted): +30%, S* Students, high numeracy: Icons vs Numerical RRR (unadjusted): +23%,S* Icons vs Numerical ARR (unadjusted): -1%, NS*

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Galesic et al., 2009[102] (continued)	

Evidence Table 3. KQ2 Update search

Outcomes	Results
	Students, low numeracy: Icons vs Numerical RRR (unadjusted): +24%, NS* Icons vs Numerical ARR (unadjusted): +21%, NS* Overall *P* for numerical format (ARR vs RRR): +49%**, *P* = 0.001 Overall *P* for icon array (yes/no): +23%**, *P* = 0.002 *Difference calculated by research team, significance read from figure **Calculated by research team

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Galesic et al., 2009[103] Research objective: To examine whether natural frequencies can improve posterior probability judgments of older adults and of people with lower numeracy skills. Study design: RCT Study setting: The Max Planck Institute for Human Development in Berlin, Germany Measurement period: NR Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: NR Excluded: NR Sampling strategy: Convenience Sample size: Overall N: 162 Group 1 (older adults), n: 47 Group 2 (younger adults), n: 115 Age (mean and range), % (SD): Group 1 (older adults): 62-69 yrs.: 49% 70-77: 51% Group 2 (younger adults): 18-25 yrs.: 63% 26-35 yrs.: 37% Gender, %: Group 1 (older adults): 49% F Group 2 (younger adults): 57% F Race/Ethnicity, %: NR Income, %: NR Insurance status, %: NR Education, %: Group 1 (older adults): High school or lower education: 57% College or university education: 43% Group 2 (younger adults): University students: 100% Other Characteristics NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Participants were required to estimate the procedures' positive predictive value: probability of disease with a positive test Note: questions querying about answer different For conditional probability: "estimate the probability that a person has diabetes if he or she has a positive test" For natural frequencies: "estimate how many of these people actually have insulin dependent diabetes" Correct answer +~1% (counted < 5%) as accurate Based on answers to diabetes and trisomy problems participants were assigned a score from 0-2, indicating number of accurate answers Covariates used in multivariate analysis: NR Description of outcomes measures: Participants were required to estimate the procedures' positive predictive value: probability of disease with a positive test Note: questions querying about answer different For conditional probability: "estimate the probability that a person has diabetes if he or she has a positive test" For natural frequencies: "estimate how many of these people actually have insulin dependent diabetes" Correct answer +~1% (counted < 5%) as accurate Based on answers to diabetes and trisomy problems participants were assigned a score from 0-2, indicating number of accurate answers Data source(s) for outcomes: Computerized Questionnnaire - Participants' responses to the screening information Attempts for control for confounding: Randomization Blinding: NR (possibly, Computerized questionnaire) Statistical measures used: NR	Describe results: Natural frequencies helped elderly and younger adult patients, including those with lower numeracy skills, to understand positive values of medical screening tests. Effect in no exposure (i.e., adequate literacy) or control group, %: Older adults + low numeracy, 1 task correct: 8% Older adults + low numeracy, 2 tasks correct: 0% Older adults + high numeracy, 1 task correct: 10% Older adults + high numeracy, 2 tasks correct: 22% Younger adults + low numeracy, 1 task correct: 7% Younger adults + low numeracy, 2 tasks correct: 0% Younger adults + high numeracy, 1 task correct: 8% Young adults + high numeracy, 2 tasks correct: 10% *Data presented in figure; values determined by reviewer Effect in exposure (i.e., low/moderate literacy) or intervention: Older adults + low numeracy, 1 task correct: 35% Older adults + low numeracy, 2 tasks correct: 19% Older adults + high numeracy, 1 task correct: 39% Older adults + high numeracy, 2 tasks correct: 22% Younger adults + low numeracy, 1 task correct: 22% Younger adults + low numeracy, 2 tasks correct:8% Younger adults + high numeracy, 1 task correct: 28% Younger adult + high numeracy, 2 tasks correct: 34% *Data presented in figure; values determined by reviewer Difference, %: Natural frequency vs. conditional probability overall (unadjusted): NR, (*P* = 0.001) High numeracy vs. low numeracy, overall (unadjusted): NR, (*P* +0.01) Absolute difference in accurate answers (% all correct) by numeracy (unadjusted): High numeracy (natural frequency vs. conditional probability): + 24%, NR Low numeracy (natural frequency vs. conditional probability): +27%, NR Absolute difference (younger vs. older, overall): NR, (*P* = 0.31) *Calculated by research team

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Garcia-Retamero and Galesic, 2009[104] Research objective: (1) To determine whether participants show denominator neglect in their estimates of risk reduction and whether those with low numeracy show more denominator neglect than those with high numeracy (2) To evaluate whether icon array presentation helps reduce misunderstanding of risk reduction information due to denominator neglect (3) To determine whether US participants show more denominator neglect than German participants Study design: Factorial RCT Study setting: Households in US and Germany Measurement period: July to August 2008 Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: Age 25 to 69 yrs Living in households in Germany or US who are registered with 2 survey firms (Forsa in Germany and Knowledge Networks in US) Excluded: NA Sampling strategy: Probabilistic national samples Note: ~83% of Germans and 66% of US participants invited participated in study Sample size: 534 from German, 513 from US Age (mean and range), % (SD): Germany Low numeracy, %: 25-39 yrs: 21* 40-54 yrs: 39* 55-69 yrs: 40* High numeracy, %: 25-39 yrs: 40* 40-54 yrs: 37* 55-69 yrs: 23* US Low numeracy, %: 25-39 yrs: 33* 40-54 yrs: 39* 55-69 yrs: 28* High numeracy, %: 25-39 yrs: 40* 40-54 yrs: 44* 55-69 yrs: 16* *All estimates weighted Note: not reported by study group Gender, %: Germany, Male Low numeracy: 39* High numeracy:62* US, Male Low numeracy: 38* High numeracy: 52* * Weighted percents Note: not reported by study group Race/Ethnicity, %: NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Mean % accurate Covariates used in multivariate analysis: None Description of outcomes measures: Mean % accurate Data source(s) for outcomes: Attempts for control for confounding: None Blinding: NR Statistical measures used: ANOVA Tukey's honest significant difference test (post-hoc)	Describe results: Icon arrays help reduce inaccurate estimates of risk reduction when denominators vary, especially among those with low numeracy. Effect in no exposure (i.e., adequate literacy) or control group, %: Numbers only (when size of denominators unequal), %: Low numeracy Incorrect: 74 Correct: 26* High numeracy Incorrect: 26 Correct: 74* Numbers only (when size of denominators same), %: Low numeracy Incorrect: 56 Correct: 44 High numeracy Incorrect: 6 Correct: 94 Effect in exposure (i.e., low/moderate literacy) or intervention: Icon array added (when size of denominators unequal), %: Low numeracy Incorrect: 42 Correct: 58* High numeracy Incorrect: 15 Correct: 85* Numbers only (when size of denominators same), %: Low numeracy Incorrect: 45** Correct: 55* High numeracy Incorrect: 22** Correct: 78* *Calculated by research team **Reported backwards in text, see Figure 2 Difference, %: % accurate, same versus different denominators (with or without icon arrays): Low numeracy: +25%*, *P* not reported High numeracy: +16%*, *P* not reported Overall effect of denominator: not reported, adjusted (*P* = 0.001) Overall effect of numeracy: adjusted (*P* = 0.001) *calculated by research team

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Garcia-Retamero and Galesic, 2009[104] Research objective: (1) To determine whether participants show denominator neglect in their estimates of risk reduction and whether those with low numeracy show more denominator neglect than those with high numeracy (2) To evaluate whether icon array presentation helps reduce misunderstanding of risk reduction information due to denominator neglect (3) To determine whether US participants show more denominator neglect than German participants Study design: Factorial RCT Study setting: Households in US and Germany Measurement period: July to August 2008 Follow-up duration: Immediate Completeness of follow-up: 100%	Eligibility criteria: Included: Age 25 to 69 yrs Living in households in Germany or US who are registered with 2 survey firms (Forsa in Germany and Knowledge Networks in US) Excluded: NA Sampling strategy: Probabilistic national samples Note: ~83% of Germans and 66% of US participants invited participated in study Sample size: 534 from German, 513 from US Age (mean and range), % (SD): Germany Low numeracy, %: 25-39 yrs: 21* 40-54 yrs: 39* 55-69 yrs: 40* High numeracy, %: 25-39 yrs: 40* 40-54 yrs: 37* 55-69 yrs: 23* US Low numeracy, %: 25-39 yrs: 33* 40-54 yrs: 39* 55-69 yrs: 28* High numeracy, %: 25-39 yrs: 40* 40-54 yrs: 44* 55-69 yrs: 16* *All estimates weighted Note: not reported by study group Gender, %: Germany, Male Low numeracy: 39* High numeracy:62* US, Male Low numeracy: 38* High numeracy: 52* * Weighted percents Note: not reported by study group Race/Ethnicity, %: NR

Evidence Table 3. KQ2 Update search

Outcomes	Results
	Accurate estimates difference (when size of denominators different; unadjusted) : Low numeracy: +32%[c], *P* NR High numeracy: +11%[c], *P* NR Accurate estimates difference (when size of denominator same; unadjusted) : Low numeracy: +11%[c], *P* NR High numeracy: -16%[c], *P* NR Interactions between numeracy and icon arrays (*P* = 0.008) and size of denominators and icon arrays (*P* = 0.001)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Gerber et al., 2005[105] Research objective: Evaluate multimedia intervention for diabetes education targeting low literacy individuals from diverse population. Study design: RCT Study setting: Five urban outpatient clinics in Chicago Illinois Measurement period: June 2002 - October 2003 Follow-up duration: 12 months Completeness of follow-up: 75% Subjects who dropped out had lower self-reported medical care and were more likely to be uninsured	Eligibility criteria: Included: Diabetes diagnosis 18 years or older Self-reported history of type 1 or type 2 diabetes verbal fluency in English or Spanish Excluded: Individuals not directly included in their diabetes care Never used study computer Sampling strategy: Convenience Sample size: Baseline Intervention: 122 Controls: 122 One year follow-up: Intervention: 94 Controls: 89 Age, mean (SD): Intervention: Low Literacy: 57.7 (11.7) High Literacy: 49.4 (12.0) Controls: Low Literacy: 60.4 (10.8) High Literacy: 51.8 (11.3) Gender, %: Female Intervention: Low Literacy: 64.7 High Literacy: 75.9 Controls: Low Literacy: 59.7 High Literacy: 65.5 Race/Ethnicity, %: Intervention AA: Low Literacy: 19.1 High Literacy: 33.3 Latino: Low Literacy: 77.9 High Literacy: 55.6 Controls AA: Low Literacy: 26.9 High Literacy: 40.0 Latino: Low Literacy: 71.6 High Literacy: 54.5

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Mean Change in Hemoglobin A1C Mean Change in Systolic and Diastolic Blood Pressure (mmHg) Mean Change in Body Mass Index (kg/m2) Covariates used in multivariate analysis: Age Sex Latino race Insurance Clinical site Highest educational level Previous attendance at diabetes class Description of outcome measures: A1C - finger stick testing; Bayer DCA 2000 Analyzer Systolic Blood Pressure - measured at concurrent visit Diastolic Blood Pressure - measured at concurrent visit BMI - calculated from weight and height recorded at concurrent visit Knowledge - adapted knowledge previously developed and validated; see J Appl Meas 2002; 3: 243-71 Self-efficacy - adapted from Insulin Management Diabetes Self Efficacy Scale, a 12-item self-efficacy scale developed based on prior model for Spanish-speaking Latino population Medical Care - items based upon American Diabetes Association standards of medical care. Perceived Susceptibility - assessed by subjects evaluating their risk of developing complications on a scale from 1 to 10 (with 10 having the greatest risk) Data source(s) for outcomes: HgbA1c- finger stick Other Physiologic Outcomes - patient record Survey Outcomes - patient self-report Attempts for control for confounding: Randomization Multivariate analysis Blinding: No Statistical measures used: Compared patients by group assignment and literacy subgroup using t tests or Mann-Whitney U tests for continuous variables and Chi-squared or Fisher's exact tests for categorical variables. Repeated measures generalized estimating equation with adjustment	Describe results: Multimedia diabetes education intervention was related to an increase in the perceived susceptibility to diabetes complications, particularly among those with lower health literacy. Intervention had no effect on other outcomes (A1C, Blood Pressure, BMI, Effect in no exposure (i.e., adequate literacy) or control group: Lower Literacy: Change A1C: -0.1 Change Systolic Blood Pressure: 2 Change Diastolic Blood Pressure: 1 Change BMI: 0.0 Change Knowledge: 0.44 Change Self-efficacy: 0.99 Change Medical Care: 0.87 Change Perceived Susceptibility: 0.19 Higher Literacy: Change A1C: 0.3 Change Systolic Blood Pressure: -2 Change Diastolic Blood Pressure: -4 Change BMI: -0.4 Change Knowledge: 0.10 Change Self-efficacy: 0.59 Change Medical Care: 0.45 Change Perceived Susceptibility: 0.76 Effect in exposure (i.e., low/moderate literacy) or intervention: Lower Literacy Change A1C: -0.2 Change Systolic Blood Pressure: 1 Change Diastolic Blood Pressure: 4 Change BMI: 0.8 Change Knowledge: 0.32 Change Self-efficacy: 1.51 Change Medical Care: 0.58 Change Perceived Susceptibility: 1.48 Higher Literacy: Change A1C: 0.3 Change Systolic Blood Pressure: -2 Change Diastolic Blood Pressure: -4 Change BMI: -0.4 Change Knowledge: 0.10 Change Self-efficacy: 0.59 Change Medical Care: 0.45 Change Perceived Susceptibility: 0.76

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Gerber et al., 2005[105] Research objective: Evaluate multimedia intervention for diabetes education targeting low literacy individuals from diverse population. Study design: RCT Study setting: Five urban outpatient clinics in Chicago Illinois Measurement period: June 2002 - October 2003 Follow-up duration: 12 months Completeness of follow-up: 75% Subjects who dropped out had lower self-reported medical care and were more likely to be uninsured	Income, %: Intervention: Income <$15,000 Low Literacy: 64.7 High Literacy: 50.0 Controls: Income <$15,000 Low Literacy: 68.7 High Literacy: 40.0 Insurance status, %: Intervention No Insurance: Low Literacy: 41.2 High Literacy: 38.9 Medicaid: Low Literacy: 20.6 High Literacy: 29.9 Medicare: Low Literacy: 23.5 High Literacy: 7.4 Controls No Insurance: Low Literacy: 49.3 High Literacy: 30.9 Medicaid Low Literacy: Education, %: Intervention Less than High School Education: Low Literacy: 70.6 High Literacy: 16.7 Controls Less than High School Education: Low Literacy: 67.2 High Literacy: 16.4 Other characteristics: Intervention Use of Insulin: Low Literacy: 25 High Literacy: 14.8 Had diabetes class: Low Literacy: 30.9 High Literacy: 22.2 Used a computer: Low Literacy: 4.9 High Literacy: 48.1

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Difference: Low Literacy Subgroup: Change in HgbA1C: -0.1, NS Change in SBP: -1 mmHg, NS Change in DBP: 3 mmHg, NS Change in BMI: NR, NS Change Medical Care:-0.29, NS Change Knowledge (adjusted): -0.12, NS Change Self-efficacy (adjusted): +0.52, 0.113 High Literacy Subgroup: Change in HgbA1C: 0.0, NS Change in SBP: +1 mmHg, NS Change in DBP: -7 mmHg, NS Change in BMI: -1 kg/m2, NS Change Medical Care: -0.07, NS Change Knowledge (adjusted): +0.3, NS Change Self-efficacy (adjusted): -0.20, NS Note: In exploratory subgroup analyses of Hgba1c>9 (n=26), intervention more effective than control for low literacy (but not high literacy) group

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Gerber et al., 2005[105] (continued)	Baseline A1C: Low Literacy 8.1 High Literacy 8.3 Baseline Systolic/Diastolic Blood Pressure Low Literacy: 130 / 74 High Literacy: 128/77 Baseline BMI: Low Literacy: 31.0 High Literacy 32.9 Control Use of Insulin Low Literacy: 40.3 High Literacy: 21.8 Had diabetes class Low Literacy: 44.8 High Literacy: 32.7 Used a computer Low Literacy: 4.5 High Literacy: 49.1 Baseline A1C: Low Literacy 8.1 High Literacy 8.3 Baseline Systolic/Diastolic Blood Pressure Low Literacy: 136/75 High Literacy: 127/74 Baseline BMI: Low Literacy: 29.8 High Literacy 33.5 Health literacy/numeracy levels: Intervention Low Literacy: 55.7 High Literacy: 44.3 Controls Low Literacy: 54.9 High Literacy: 45.1 Measurement tools including cutpoints: sTOFHLA Lower Literacy: 0-22 Higher Literacy: >=23

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Greene and Peters, 2009[106] Research objective: To test whether simplifying official Medicaid comparison chart improved comprehension and to examine how important literacy and numeracy skills were for comprehension Study design: Experimental with alternating assignment to one of two formats Study setting: Duval County, Florida Measurement period: NA Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Age 18 or older Medicaid recipient (themselves or their children) Excluded: NR Sampling strategy: Convenience Sample size: 122 Age (mean and range), % (SD): 18-34: 57 35-44: 19 45-64: 64 Gender, %: Female: 78 Race/Ethnicity, %: African American: 90 White: 5 Other: 5 Income, %: Insurance status, %: All Medicaid recipients: Children: 20 Self: 18 Children and self: 62 Education, %: < High school: 26 High school/GED: 41 Some college/trade: 31 College graduate: 2.5 Other Characteristics

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Comprehension index based on number of correct answers to 9 questions written by authors. Identifying subindex assessed ability to identify specific information from chart while the synthesizing subindex assessed ability to make comparisons. Covariates used in multivariate analysis: Numeracy, literacy, chart version Description of outcomes measures: Comprehension index based on number of correct answers to 9 questions written by authors. Identifying subindex assessed ability to identify specific information from chart while the synthesizing subindex assessed ability to make comparisons. Data source(s) for outcomes: Participant responses Attempts for control for confounding: Pseudo-randomization Blinding: No Statistical measures used: Factorial ANOVA, multivariate regression	Describe results: Revised chart did not result in greater comprehension overall. However, for the synthesizing subindex, revised chart improved comprehension for the higher numerate. Effect in no exposure (i.e., adequate literacy) or control group, %: Lower literacy average 2.6 out of 6 on identifying subindex. Lower numerate 0.9 average out of 3 items on synthesizing subindex. Effect in exposure (i.e., low/moderate literacy) or intervention: Higher literacy average 4.5 out of 6 on identifying subindex. Higher numerate 1.5 (although figure 3 says 1.4) average out of 3 items on synthesizing subindex. Difference, %: Full index (out of 9): Overall: NR Low Lit: +0.1*, NS High Lit: +0.7*, NS Indentifying subindex (out of 6): Overall: NR Low Lit: -0.2*, NS High Lit: +0.5*, NS Synthesizing Subindex (out of 3): Overall: NR Low Lit: +0.3*, NS High Lit: +0.1*, NS *p for interaction for full and sub-indices < 0.05 Absolute difference 1.9 (out of 6) on identifying subindex (NS). Absolute difference of 0.6 (or is it 0.5 based on figure 3?) among higher numerate on synthesizing subindex ($P < 0.05$). In multivariate analysis, both literacy and numeracy independent predictors of the identifying subindex.

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Greene et al., 2008[107] Research objective: Test whether comprehension could be improved by varying the way information was presented Examine effect of numeracy on comprehension of CDHP design and informed decision making (i.e. is numeracy of moderator) Study design: Randomized trial Study setting: Oregon, not otherwise specified Measurement period: NA Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Adult population Excluded: NR Sampling strategy: Convenience Sample size: 303 Age, range in years, %: 18-34: 46 35-44: 22 45-64: 32 Gender, %: Female: 52 Race/Ethnicity, %: White: 74 Hispanic: 7 Other" 19 Income, %: < $20K: 75 20-40K: 15 >$40K: 10 Insurance status: NR Education, %: HS or less: 45 Some college: 37 college graduate: 19 Other characteristics, %: Unemployed: 36 Out of work force (student/retired): 20 Employed: 44 Health literacy/numeracy levels, %: Numeracy <10: 50 10-15: 50 Measurement tools including cutpoints: Lipkus for numeracy + 4 additional questions from Peters, dichotomized at median (0-9, 10-15) TOFHLA for literacy (cutoffs not provided) [paper states they focused on numeracy]

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: (1) Comprehension (2) Plan choice (3) Ease of understanding Covariates used in multivariate analysis: Sex Race Education Work status Income Age Health status Number of chronic conditions Description of outcome measures: Comprehension measured by number of correct responses on 6 multiple-choice questions comparing 2 plans Plan choice: which plan respondents would choose for themselves Self-reported ease of understanding measured on a 7-point Likert Data source(s) for outcomes: Self-report Attempts for control for confounding: Randomization Multivariate analyses Blinding: No Statistical measures used: ANOVA Multivariate regression	Describe results: Common unique presentations provided no advantage over side-by-side presentations. For low literacy individuals, frameworks reduced comprehension and ease of understanding; for higher numeracy individuals they resulted in no change. Effect in no exposure (i.e., adequate literacy) or control group: Side-by-side High numeracy: (1) 4.6 (2) 0.9 (3) 0.4 Low numeracy: (1) 3.2 (2) 0.8 (3) 0.5 No-framework High numeracy: (1) 4.1 (2) 1.5 (3) 0.4 Low numeracy: (1) 3.3 (2) 1.2 (3) 0.5 Effect in exposure (i.e., low/moderate literacy) or intervention: Common/unique: High literacy: (1) 4.3 (2) 1.5 (3) 0.4 Low literacy: (1) 2.9 (2) 0.8 (3) 0.6 Short framework High numeracy: (1) 4.8 (2) 1.0 (3) 0.4 Low numeracy: (1) 3.0 (2) 0.8 (3) 0.6 Long framework High numeracy: (1) 4.6 (2) 1.0 (3) 0.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Greene et al., 2008[107] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Low numeracy: (1) 2. Difference, comprehension: Common vs. Side to Side (unadjusted) High Numeracy Subgroup: -0.3, NS Low Numeracy Subgroup: -0.3, NS Short framework vs. No (unadjusted) High Numeracy Subgroup: +0.7, $P < 0.05$ Low Numeracy Subgroup: +0.3, $P < 0.05$ Long framework vs. No (unadjusted) High Numeracy Subgroup: +0.5, $P < 0.05$ Low Numeracy Subgroup: -0.5, $P < 0.05$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Hwang et al., 2005[108] Research objective: Determine whether addition of illustrations to these prescription labels affects patient comprehension Study design: Quasi-experiment (post/post) Study setting: Three family practice clinics affiliated with an urban academic teaching hospital in Toronto, Ontario Measurement period: January 2001 to September 2001 Follow-up duration: Immediate Completeness of follow-up, %: 100	Eligibility criteria: Included: Patients presenting to clinic during regular office hours on selected weekdays Excluded: Too ill to participate Unable to communicate in English Sampling strategy: Convenience sample Sample size: 130 Age, range in years, %: < 25: 19 25 - 39: 31 40 - 64: 39 ≥ 65: 11 Gender, %: Female: 56 Race/Ethnicity: NR Income: NR Insurance status: NR Education, %: Highest educational attainment: < HS: 4 Some HS: 6 HS graduate: 27 Some post-secondary: 63 Other characteristics, %: Native language English: 71 Other native language: 29 Health literacy/numeracy levels, %: ≤ 6th grade: 5 7 -8 grade: 22 ≥ 9th grade: 73 Measurement tools including cutpoints: REALM ≤ 6th grade 7 -8 grade ≥ 9th grade

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Comprehension of prescription label Covariates used in multivariate analysis: None Description of outcome measures: Comprehension:" If this label were on your pill bottle, how would you take this medication?" Unlimited time to reply. Answers coded by 2 independent coders as incorrect, partially correct, or completely correct. Disagreements resolved by consensus. Data source(s) for outcomes: Self-report Attempts for control for confounding: None Blinding: Investigators blinded at time of coding Patients not blinded Statistical measures used: Sign test for improvement/worsening	Describe results: Participants across all literacy levels correctly interpreted labels with instructions to take medication with water, with food, or not in conjunction with alcohol, regardless of whether they were accompanied by illustrations (data not provided). Illustrations for drowsiness and taking medication on an empty stomach did not significantly improve interpretation. Effect in no exposure (i.e., adequate literacy) or control group, %: Without illustration Interpretation of Label B (may cause drowsiness): Incorrect: 18 Partially correct: 49 Completely correct: 34 Interpretation of Label E (take on an empty stomach): Incorrect: 10 Partially correct: 35 Completely correct: 55 Note: interpretation of Labels A (take with water), C (take with food), and D (no alcohol) 100% correct Effect in exposure (i.e., low/moderate literacy) or intervention: With Illustration Interpretation of Label B (may cause drowsiness): Incorrect: 22% Partially Correct: 44% Completely Correct: 34% Interpretation of Label E (take on an empty stomach): Incorrect: 11% Partially Correct: 34% Completely Correct: 55% Note: interpretation of Labels A (take with water), C (take with food), and D (no alcohol) 100% correct Difference, %: Change in Interpretation of Label B: Improved: 5 No Change: 87% Worse: 9% *P* (unadjusted) = 0.33 Change in Interpretation of Label E: Improved: 7 No Change: 86 Worse: 7 *P* (unadjusted) = 1.00 Note: change in interpretation of labels A, C, D = 0

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Jay et al., 2009[109] Research objective: To determine whether a multimedia intervention can improve food label comprehension in a sample of low-income patients Study design: RCT Study setting: Gouvernour Healthcare Services in New York City Measurement period: November 2005 - November 2007 Follow-up duration: Immediately Completeness of follow-up: 61 recruited/56 randomized (5 poor vision), 2 didn't finish study, 12 were excluded after recruitment since they were employees of the hospital	Eligibility criteria: Included: English-speaking individuals who approached a community outreach table promoting BMI screening Excluded: Poor vision (< 20/50 by Rosenbaum card) Did not speak English Indicated that they could not read English Sampling strategy: Convenience sample Sample size: N = 56 Control: 27 Intervention: 29 Age (mean and range), % (SD): Mean (SD): Intervention: 52 (13) Control: 49 (15) Gender, %: Female: Intervention: 74 Control: 89 Race/Ethnicity, %: Intervention African American: 30 Caucasian: 13 Hispanic: 43 Asian: 4 Other: 0 Control African American: 21 Caucasian: 16 Hispanic: 32 Asian: 21 Other: 10 Income, %: Intervention $0-$20,000: 56 $20,001-$30,000: 22 $30,001-$40,000: 4 $40,001 and above: 4 Control $0-$20,000: 58 $20,001-$30,000: 16 $30,001-$40,000: 5 $40,001 and above: 16 Insurance status, %: NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: 12-item food label quiz developed by the authors in order to test participants' ability to accurately interpret and compare food labels; scored as % correct (cronbach's alpha 0.79-0.85) Covariates used in multivariate analysis: Demographic variables that were statistically different between the intervention and treatment groups (self-reported hypertension, weight, and BMI) Didn't adjust for appreciable differences in gender, educational status, use of food labels Description of outcomes measures: 12-item food label quiz developed by the authors in order to test participants' ability to accurately interpret and compare food labels; scored as % correct (cronbach's alpha 0.79-0.85) Data source(s) for outcomes: Food label quiz Attempts for control for confounding: ANOVA with and without covariates Blinding: None Statistical measures used: Chi-square, t-test, ANOVA	Describe results: Participants who received the intervention materials had significantly greater improvement on comprehension scores than those who received materials; when analyzed by literacy group, only the participants with adequate literacy who received the intervention improved. All others (adequate literacy in control group, and limited literacy in intervention or control group) showed no improvement Effect in no exposure (i.e., adequate literacy) or control group, %: (Adjusted results) Control, % correct: Pre-quiz: 55.5 Post-quiz: 55.4 Difference: -0.1* Adequate literacy (control): Pre-quiz: 38* Post-quiz: 38* Difference: 0* Inadequate literacy (control): Pre-quiz: 74* Post-quiz: 74* Difference: 0* *Read from graph Effect in exposure (i.e., low/moderate literacy) or intervention: (Adjusted results) Intervention, % correct: Pre-quiz: 52.2 Post-quiz: 63.9 Difference: 11.7* Adequate literacy (intervention): Pre-quiz: 66* Post-quiz: 89* Difference: +23* Limited literacy (intervention): Pre-quiz: 38* Post-quiz: 39* Difference: +1* *Read from graph Difference, %: Intervention-control (adjusted): + 11.8%*, $P < 0.05$ Adequate literacy, int-control (adjusted): +23%*, $P < 0.05$ Inadequate literacy, int-control (adjusted): +1%*, $P < 0.05$ *Calculated by research team

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Jay et al., 2009[109] (continued)	Education, %: Intervention Grades 1-5: 4 Grades 6-9: 4 Grades 10-12: 35 College: 56 Control Grades 1-5: 16 Grades 6-9: 10 Grades 10-12: 42 College: 32 Other Characteristics Self-reported chronic conditions, weight and BMI, exposure to food labels Note: Mean BMI and % hypertension higher in intervention group

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Kang et al., 2009[110] Research objective: 1) To investigate the recall and comprehension of orthodontic informed consent among patients and their parents with the traditional AAO informed consent form and other methods with improved readability and processability 2) To investigate the association between reading ability, anxiety, and sociodemographic variables, and recall and comprehension 3) To determine how different domains of information are affected by varying degrees of readability and processability Study design: RCT Study setting: University-based graduate orthodontic clinics in Columbus Ohio and Seattle Washington (Note: Authors aren't explicit about proportion recruited at these sites) Measurement period: NR Follow-up duration: Immediately Completeness of follow-up: 100%	Eligibility criteria: Included: (Patients): 12 to 18 years of age Able to communicate in English No developmental or learning disabilities No emergent conditions No previous orthodontic treatment No siblings or other family members who had undergone treatment at the university-based graduate orthodontic clinic Currently planning comprehensive orthodontic treatment (Parents): Legal guardianship of the patient for at least one year Could communicate in English Excluded: NR Sampling strategy: Convenience sample Sample size: Control: 31 MIC: 29 MIC + SS: 30 Age (mean and range), % (SD): Patient: Control: 14.3 MIC: 14.5 MIC + SS: 14.6 Parent: Control: 43 MIC: 41 MIC + SS: 42 Gender, %: Patient: Control, % Female: 71 MIC, % Female: 58.6 MIC + SS, % Female: 43.3 Parent: control, % Female:74.2 MIC, % Female: 75.9 MIC + SS, % Female: 80.0 Race/Ethnicity, %: Patient: Control, %: White Non-Hispanic: 62.1 White Hispanic: 13.8 Black Non-Hispanic: 13.8 Mixed: 10.3

Evidence Table 3. KQ2 Update search

Outcomes	Results
Main outcomes: Interviewer-assessment of informed consent understanding, measuring 18 aspects of orthodontic informed consent using open ended questions. Questions assessed both recall of information (assessed through recitation of info) and comprehension (assess through application of info to clinical scenarios). Reported as % correct. Self-assessment of informed consent understanding, measuring same 18 aspects of orthodontic informed consent State-Trait Anxiety Inventory (6-item) Covariates used in multivariate analysis: None Description of outcomes measures: Interviewer-assessment of informed consent understanding, measuring 18 aspects of orthodontic informed consent using open ended questions. Questions assessed both recall of information (assessed through recitation of info) and comprehension (assess through application of info to clinical scenarios). Reported as % correct. Self-assessment of informed consent understanding, measuring same 18 aspects of orthodontic informed consent State-Trait Anxiety Inventory (6-item) Data source(s) for outcomes: Interviewer-assessment of informed consent understanding (interview) Self-assessment of informed consent understanding (survey) State-Trait Anxiety Inventory (survey) Attempts for control for confounding: None Blinding: None Statistical measures used: Reliability: kappa statistic Associative data: chi-square, Fisher exact, Wilxcoxon rank sum, Spearman correlation coefficient, ANOVA	Describe results: In some cases, the REALM and WRAT-3 scores were significantly correlated with understanding of informed consent (for control and MIC + SS, not for MIC) Authors report: "Reducing grade level and making formatting changes alone (MIC) made no significant differences in recall or comprehension. This confirms early studies that found that consent forms modified for lower reading levels were more acceptable to patients than the standard written form but did not necessarily improve comprehension." Effect in no exposure (i.e., adequate literacy) or control group, %: Correlation between interviewer assessed combined recall + comprehension and measures of literacy Patient: Control: REALM: 0.62 ($P \leq 0.001$) WRAT-3: 0.55 ($P \leq 0.01$) Parent: Control - REALM: 0.22 (P = NS) WRAT-3: 0.24 (P = NS) % Combined recall and comprehension Patients: Control: 40.3 Parents: Control: 56.8 Effect in exposure (i.e., low/moderate literacy) or intervention: Correlation between interviewer assessed combined recall + comprehension and measures of literacy Patient: MIC : REALM: 0.35 (P = NS) WRAT-3: 0.39 ($P \leq 0.05$) MIC + SS: REALM: 0.58 ($P \leq 0.001$) WRAT-3: 0.43 ($P \leq 0.05$) Parent: MIC: REALM: 0.19 (P = NS) WRAT-3: 0.57 ($P \leq 0.01$) MIC + SS: REALM: 0.47 ($P \leq 0.01$) WRAT-3: 0.50 ($P \leq 0.01$) % Combined recall and comprehension Patients: MIC: 46.8 MIC + SS: 39.1

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Kang et al., 2009[110] Research objective: 1) To investigate the recall and comprehension of orthodontic informed consent among patients and their parents with the traditional AAO informed consent form and other methods with improved readability and processability 2) To investigate the association between reading ability, anxiety, and sociodemographic variables, and recall and comprehension 3) To determine how different domains of information are affected by varying degrees of readability and processability Study design: RCT Study setting: University-based graduate orthodontic clinics in Columbus Ohio and Seattle Washington (Note: Authors aren't explicit about proportion recruited at these sites) Measurement period: NR Follow-up duration: Immediately Completeness of follow-up: 100%	MIC: White Non-Hispanic: 77.8 South Asian: 7.4 Black Hispanic: 3.7 Black Non-Hispanic: 3.7 White Hispanic: 3.7 Mixed: 3.7 MIC + SS, %: White Non-Hispanic: 73.3 black Non-Hispanic: 20.0 White Hispanic: 3.3 Mixed: 3.3 Parent: Control, %: White Non-Hispanic: 79.3 White Hispanic: 6.9 Black Non-Hispanic: 13.8 MIC, %: White Non-Hispanic: 77.8 South Asian: 7.4 Black Hispanic: 3.7 Black Non-Hispanic: 3.7 White Hispanic: 3.7 Mixed: 3.7 MIC + SS, %: White Non-Hispanic: 73.3 Black Non-Hispanic: 20.0 White Hispanic: 3.3 Mixed: 3.3 Income, %: (Parents' income) Median for all groups: \$25,000-\$49,999 Insurance status, %: NR Education, %: Patient: Median for all groups: 8th grade Parent: Control: < 4 years college MIC: college graduate MIC + SS: < 4 years college Other Characteristics NR

Evidence Table 3. KQ2 Update search

Outcomes	Results
	Parents: MIC: 58.2 MIC + SS: 66.8 Difference, %: Differences in correlation: NR Differences in combined recall and comprehension among treatment arms Intervention-control (adjusted): Overall: +11.8*, *P* < 0.05 Adequate literacy: +23%* Inadequate literacy: +1% p for interaction: < 0.05 Combined recall and comprehension (unadjusted): Patient: MIC-control: +6.5%*, NS MIC +SS vs control: -1.2%*, NS Note: Recall improves with MIC + SS (+l0.5%, *P* < 0.05), comprehension doesn't (+6.3%, NS) Parent: MIC-control: 1.4%*, NS MIC + SS vs. control: +10.0*, *P* < 0.05 Note: Recall improves with MIC + SS (+8.9*, *P* < 0.05), so does comprehension (+11.6%*, *P* < 0.001) *Calculated by research team

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kim et al., 2004[111] Research objective: Examine association between health literacy and self management behaviors in patients with diabetes and to determine whether diabetes education improves self-management behaviors in patients with limited compared with adequate health literacy Study design: Uncontrolled intervention study (pre-post test) Study setting: Diabetes education class at the Hospital of the University of Pennsylvania Measurement period: NR Follow-up duration: 3 months Completeness of follow-up, %: 84 (77 of 92) Differential attrition in adequate (14) versus inadequate (24) HL groups	Eligibility criteria: Included: ≥ 18 yrs Attending a diabetes education class Excluded: English speaking Sampling strategy: All Note: only 58% invited participated Sample size, n = 92: Adequate HL: 71 Limited HL: 21 Age, years: Adequate HL: 58.2 Limited HL: 67.2 Gender, %: Female: Adequate HL: 6 Limited HL: 81 Race/Ethnicity, %: Adequate HL White: 36.2 Black: 60 Other: 2.9 Limited HL: White: 20 Black: 75 Other: 5 Income, %: Income <$20,000: Adequate HL: 36.5 Limited HL: 78.9 Insurance status, %: Commercial insurance Adequate HL: 57.8 Limited HL: 10.5 *P* = 0.002 Education, years: Adequate HL: 14 Limited HL: 10.2 Other characteristics: Diabetes Duration, years: Adequate HL: 7.8 Inadequate HL: 9.3 Prior Diabetes Education, %: Adequate HL: 17.6 Inadequate HL: 28.6

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes:	Describe results:
Diabetes Knowledge	AT baseline there was no association between HL and HbA1c
HbA1c	or diabetes self-management
Self-management behaviors:	Adjusted 3-month outcomes showed no significant differences
Diet	between adequate and limited literacy groups in relation to
Exercise	HbA1c results. Both literacy groups showed improvement in
Foot care	self management. Patients with adequate health literacy
Medication adherence	exercised more, but patients with lower literacy report better
Self-glucose monitoring	adherence to diet, self glucose monitoring, and foot care.
Covariates used in multivariate analysis:	Effect in no exposure (i.e., adequate literacy) or control group:
Baseline values, age, years of education, and	Diabetes Knowledge Score:
income	Adequate HL: 17.2
Importantly don't adjust for many important baseline	Inadequate HL: 13.9
differences (ie. prior diabetes education, years with	Baseline HbA1c:
diabetes, etc.)	Adequate HL: 8.4
Description of outcome measures:	Limited HL: 8.2
Diabetes Knowledge Questionnaire, validated scale	Baseline Self-management behaviors:
(% correct out of 24 questions)	Diet:
HbA1c levels	Adequate HL: 4.3
Summary of Diabetes Self-Care Activities Measure	Limited HL: 4.7
(SDSCA) (# days adherent during the past 7 days)	Baseline exercise:
Data source(s) for outcomes:	Adequate HL: 2.7
Diabetes Knowledge: self-report	Limited HL: 2.3
HbA1c: medical record	Baseline foot care:
Self-management behaviors: self-report	Adequate HL: 4.0
Attempts for control for confounding:	Limited HL: 4.7
ANCOVA	Baseline medication adherence:
Blinding:	Adequate HL: 6.0
NA for patients	Limited HL: 6.6
No blinding for outcome assessors doing medical	Baseline self-glucose monitoring:
record review	Adequate HL: 4.1
Statistical measures used:	Limited HL: 5.1
3-month analysis: paired t-tests and non-parametric	Effect in exposure (i.e., low/moderate literacy) or intervention:
tests, ANCOVA	3-month Diabetes Knowledge:
Magnitude of difference:	Adequate HL: 19.9
0.20: small effect size	Inadequate HL: 18.0
0.50: moderate effect size	3-month HbA1c:
0.80: large effect size	Adequate HL: 7.1
	Limited HL: 7.0
	3-month self-management behaviors:
	Diet :
	Adequate HL: 5.2
	Limited HL: 6.0
	3-month exercise:
	Adequate HL: 2.8
	Limited HL: 2.1

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kim et al., 2004[111] (continued)	Health literacy/numeracy levels, %: Adequate HL: 77 Limited HL: 23 (8 marginal, 15 inadequate) Measurement tools including cutpoints: S-TOFHLA Adequate HL score: ? 22 Limited HL score: < 22 Self-reported diabetes complications, %: Adequate HL: 32.4 Limited HL: 47.6 HgbA1C, %: Adequate HL 8.4 Limited HL: 8.2 Diabetes knowledge score: Adequate HL: 17.2 Inadequate HL: 13.9 Glucose monitoring: Adequate HL: 4.1 of 7 days Inadequate HL: 5.1 of 7 days.

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	3-month foot care: Adequate HL: 5.0 Limited HL: 5.1 3-month medication adherence: Adequate HL: 6.9 Limited HL: 6.4 3-month self-glucose monitoring: Adequate HL: 5.4 Limited HL: 6.6 Difference: Overall (adjusted): NR, sig Adeq vs. Inadeq HL (adjusted): Diet: NR, (*P* < 0.001; Inadeq. better) Exercise: NR, (*P* = 0.022; Adeq. better) Footcare: NR, (*P* = 0.001; Inadeq. better) Medication adherence: NR, (*P* = 0.751) Self-glucose monitoring: NR, (*P* = 0.002; Inadeq. better) Knowledge: Overall (adjusted): NR, sig Adeq. Vs. Inadeq. HL (adjusted): NR (+), (*P* < 0.001) Adherence: Overall: + 0.7, NR Adeq. Vs. Inadeq. HL (adjusted): NR, (*P* = 0.751) Disease prevalence and severity: Overall (unadjusted): -1.3, Sig Adeq vs. Inadeq HL (adjusted): NR, *P* = 0.086

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kripalani et al., 2008[112] Research objective: Determine whether simplified written documents, short verbal description of study, and visual aid to describe randomization process improved participant comprehension of informed consent and HIPAA Privacy Rule requirements regarding authorization for use and disclosure of protected health information Study design: Nested cross-sectional study within a larger randomized controlled trial Study setting: Primary care clinics at Grady Memorial Hospital, a public hospital in Atlanta, GA that serves as a teaching facility for Emory University School of Medicine Measurement period: March 2004-March 2005 Follow-up duration: Immediate Completeness of follow-up: 373/408 (91%) Note full RCT 435 participants; authors state that 408 enrolled "during period of scoring consent comprehension" No difference in baseline characteristics in those with versus without complete f/u	Eligibility criteria: Included: "History of CHD as determined by documentation in their medical chart of previous myocardial infarction, percutaneous transluminal coronary angioplasty, coronary artery bypass surgery, or greater than 30% stenosis on prior cardiac catheterization" Excluded: "Too ill to complete the study interviews" "Helped by a caregiver who managed their medications" "Lacked a mailing address or telephone number" "Already used an illustrated medication schedule that depicted their medical regimen" "Did not fill their prescriptions in the health system pharmacies" "Were in police custody" "Had a visual acuity H14 than 20/60" "Were unable to communicate in English" "Had a diagnosis of schizophrenia or bipolar disorder" "Patients with overt delirium or dementia who could not answer several screening questions for orientation to person, place, and time" Sampling strategy: Consecutive sample of all patients recruited for larger randomized controlled trial on CHD Sample size: 408 cases, no comparisons Age (SD): 64.0 (10.4) Gender, %: Female: 54.7 Race/Ethnicity, %: African-American: 90.3 Income: NR Insurance status: NR Education, years (SD): Mean: 10.9 (3.2) Other characteristics (SD): Mean score on MMSE was 24.6 (3.2) Health literacy/numeracy levels, %: <3rd grade: 20.9 4th-6th grade: 24.7 7th-8th grade: 30.6 >9th grade: 23.9 Measurement tools including cutpoints: REALM: <3rd grade, 4th-6th grade, 7th-8th grade, >9th grade

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Comprehension of informed consent and HIPAA Privacy Rule requirements regarding authorization for use and disclosure of protected health information, as measured by ability to teach-back information to interviewer Covariates used in multivariate analysis: For models looking at predictors of comprehension: age, years of education, race, gender, martial status, and employment status Description of outcome measures: Comprehension was measured by teach-back scores on eight items: Consent: Purpose Timing of follow-up interview Randomization (treatment in 4 groups) Risks Benefits HIPAA: Information collected Confidentiality Withdrawal options Data source(s) for outcomes: Scoring of teach-back answers using standardized method Attempts for control for confounding: Yes: multivariable logistic regression Blinding: Authors report that interviewer was "effectively blinded" to participants literacy level and patient characteristics, which had not yet been collected at the time of the intervention Statistical measures used: Descriptive statistics: (frequency, mean, median, SD) Univariate logistic regression to calculate odds ratios and 95% confidence intervals Multivariable logistic regression model	Describe results: Adjusted analyses, age and literacy level remained significant independent predictors of comprehension of consent and HIPAA content; older participants and those with lowest literacy were less likely to successfully comprehend consent process. Effect in no exposure (i.e., adequate literacy) or control group: NR Effect in exposure (i.e., low/moderate literacy) or intervention, %: Comprehension of all components: <3 grade: 16.7 4th-6th grade: 37* 7th-8th grade: 40* >9th grade: 60.7 *Read from graph (figure 2) Difference: Ability to correctly teach-back all consent and HIPAA information on first attempt: Age (per year) - 0.974 (0.951-0.997) Correctly teach-back 1st attempt by literacy subgroup (adjusted): 4th-6th grade: 2.259 (1.048-4.869) 7th-8th grade: 2.275 (1.049-4.935) ≥9th grade: 4.344 (1.814-10.404)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kripalani et al., 2007[113] Research objective: Design and evaluate illustrated medication schedule (pill card) that depicts patient's daily medication regimen using pill images and icons Study design: Nested uncontrolled intervention study Most measures post-test only Study setting: Primary care clinics at Grady Memorial Hospital, a public hospital in Atlanta, GA that serves as a teaching facility for Emory University School of Medicine Measurement period: March 2004-March 2005 IRB: Ethics and Human Research 30(2): 13-19. Follow-up duration: 3 months Completeness of follow-up: 209/242 (86%)	Eligibility criteria: Included: "History of CHD as determined by documentation in their medical chart of previous myocardial infarction, percutaneous transluminal coronary angioplasty, coronary artery bypass surgery, or greater than 30% stenosis on prior cardiac catheterization" Excluded: "Too ill to complete the study interviews" "Helped by a caregiver who managed their medications" "Lacked a mailing address or telephone number" "Already used an illustrated medication schedule that depicted their medical regimen" "Did not fill their prescriptions in the health system pharmacies" "Were in police custody" "Had a visual acuity lower than 20/60" "Were unable to communicate in english" "Had a diagnosis of schizophrenia or bipolar disorder" "Patients with overt delirium or dementia who could not answer several screening questions for orientation to person, place, and time" See JGIM 2006; 21: 852-6. Sampling strategy: All participants in the intervention arm of a randomized controlled trial Sample size: 242 patients randomized to receive pill card Age (SD): 63.7 (10.3) Gender, %: Female: 58.4 Race/Ethnicity, %: African-American: 91.4 White: 7.2 Hispanic/Latino: 1 Asian: 0.4 Income: NR Insurance status: NR Education, %: <12 years: 47.4 >12 years: 52.6 Other characteristics: Cognitive function as measured by MMSE Health literacy/numeracy levels, %: Inadequate (<6th grade): 41.6 Marginal (7th-8th grade): 36.9 Adequate (>9th grade): 21.5

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Frequency of pill-card use at baseline and at 3 months Perceived helpfulness and ease of use of pill card Self-efficacy Qualitative process evaluation Covariates used in multivariate analysis: None; no multivariate analysis Description of outcome measures: Self-reported frequency of pill-card use and helpfulness/ease of pill-care use Self efficacy measured by Self Efficacy for Appropriate Medication Use Scale (SEAMS) Data source(s) for outcomes: Survey instrument with open-ended and fixed-choice questions; SEAMS Attempts for control for confounding: None Blinding: NR Statistical measures used: Descriptive statistics Bivariate analysis using chi-square and Fisher's Exact Test to evaluate association between patient characteristics and usefulness and frequency of use of pill-card Mann-Whitney evaluated association between frequency of use and self-efficacy ANOVA used to evaluate changes in self-efficacy from baseline to 3 months	Describe results: Patients with inadequate or marginal literacy were more likely to refer to their pill-card on a regular basis, both initially and at 3 months. Patients reported the pillcard was easy to understand. There was little change in self efficacy with the pillcard. Effect in no exposure (i.e., adequate literacy) or control group (SD): Pill card use: NA Ease of understanding: NA Self efficacy at baseline: 30.8/39 (6.1) Effect in exposure (i.e., low/moderate literacy) or intervention, %: Frequency of pill-card use, immediate - Adequate literacy: Every day: 22.2 > once a week: 31.1 < once a week: 17.8 Never: 28.9 Inadequate literacy: Every day: 52.9 > once a week: 23.0 < once a week: 14.9 Never: 9.2 Difference: Correct teach back 1st attempt by literacy subgroup: 4th - 6th grade - 2.259 (1.048-4.869) 7th - 8th grade - 2.275 (1.049-4.935) ≥ 9th grade - 4.344 (1.814-10.404) Frequency of pill-card use, immediate: p for interaction by literacy $P = 0.017$ Frequency of pill-card use at 3 months: p for interaction by literacy $P = 0.001$ Ease of understanding: p for interaction by literacy, NS Self Efficacy, baseline to 3 mo f/u (unadjusted): +2.5, NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kripalani et al., 2007[113] (continued)	Measurement tools including cutpoints: REALM: inadequate (0–44, signifying <6th grade reading level), marginal (45–60, 7–8th grade reading level), and adequate (61–66, >9th grade level)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kripalani et al., 2007[114] Research objective: Determine effects of 2 low-literacy educational handouts on frequency of subsequent prostate cancer discussion and screening Study design: RCT Study setting: Primary care clinics at Grady Memorial Hospital, a public hospital in Atlanta, GA that serves as a teaching facility for Emory University School of Medicine Measurement period: June and July 2003 Follow-up duration: None Completeness of follow-up: 250/303=85% Patient Ed: 86/101 Cue: 81/101 Control: 83/101 Unclear if differential characteristics	Eligibility criteria: Included: All men age 45 -70 who presented for scheduled appointment with an Emory resident, faculty member, or nurse practitioner Excluded: Patients who were enrolled previously Who were in police custody Had arrived ill on a stretcher Who were not scheduled to see a primary care provider for a full visit Who could not converse fluently in English Who had a corrected visual acuity worse than 20/60 as assessed by a pocket vision screening card, Who had a history of prostate cancer as determined by review of EMR Sampling strategy: Consecutive (based on availability of student researcher) Sample size: 303 101 to each of three groups Age (SD): 56.5 (6.8) Pt Ed: 56.3 Cue: 58.1 Control: 55 Gender, %: Male: 100 Race/Ethnicity, %: African-American: 90.4 Pt Ed: 84 Cue: 91 Control: 96 Income: NR Insurance status: NR Education: 10.9 years (SD 2.5) Pt Ed: 11.3 Cue: 10.4 Control: 10.9 Other characteristics: NA Health literacy/numeracy levels, %: <3rd grade: 38 4-6th grade: 18 7th-8th grade: 23 >=9th grade 21

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Primary outcome: Discussion about PSA Secondary outcomes: whether or not a PSA test was ordered, whether or not DRE was documented Covariates used in multivariate analysis: Age Race Education level Literacy level Health care provider Description of outcome measures: Primary outcome: self-report answer to the question, "Did you and your doctor talk about prostate cancer today?"; response was dichotomous "yes" or "no" answer Secondary outcomes: chart review for whether or not a PSA test was ordered, whether or not DRE was documented; response was dichotomous (presence or absence) Data source(s) for outcomes: Primary outcome: self report Secondary outcomes: chart review Attempts for control for confounding: Logistic regression Blinding: Patient: no blinding Providers: no blinding, 26% patient gave them handouts interviewers: blinded Statistical measures used: Descriptive statistics, chi-square, t-test, Fisher's exact test, logistic regression, adjusted Ors, generalized estimating equations	Describe results: Compared to control group, both intervention groups were more likely to discuss prostate cancer and more likely to receive PSA testing. Effect in no exposure (i.e., adequate literacy) or control group, %: Discussion of prostate CA: 37.3 PSA test ordered: 2.4 DRE documented: 6.0 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Pt Ed: Discussion of prostate CA: 50 PSA test ordered: 14.1 DRE documented: 4.7 Cue: Discussion of prostate CA: 58.0 PSA test ordered: 12. 3 DRE documented: 6.2 Difference, OR (CI): Pt Ed (adjusted for literacy): Discussion of prostate CA: 1.92 (1.01-3.65) PSA test ordered: 7.62 (1.62-35.83) DRE documented: 0.85 (0.21-3.37) Cue (adjusted for literacy): Discussion of prostate CA: 2.39 (1.26-4.52) PSA test ordered: 5.86 (1.24-27.81) DRE documented: 1.04 (0.29-3.76)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Kripalani et al., 2007[114] (continued)	Pt Ed: <3rd grade: 34.9 4th-6th grade: 10.5 7th-8th grade: 20.9 >9th grade: 33.7 Cue: <3rd grade: 38.3 4th-6th grade: 22.2 7th-8th grade: 24.7 >9th grade: 14.8 Control: <3rd grade: 39.8 4th-6th grade: 22.9 7th-8th grade: 22.9 >9th grade: 14.5 Measurement tools including cutpoints: REALM: <3rd grade, 4th-6th grade, 7th-8th grade, >9th grade

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Mayhorn and Goldsworthy, 2007[115] Research objective: Refine teratogen warning symbols and evaluate them among an ethnically, geographically, [and otherwise] diverse sample [including those with low health literacy] Study design: Quasi (post only) Study setting: Public places Measurement period: Immediate Follow-up duration: NA Completeness of follow-up: NA	Eligibility criteria: Included: Efforts made to recruit diverse sample using stratification quota for adolescents, males, Hispanics. Inclusion targets for other groups mirrored 2000 US census levels Excluded: NR Sampling strategy: Convenience, 10 diverse cities across US Sample size: 700 Age: Mean: NR Range: 12-44 years Adolescents: 20% Gender, %: Female: 73 Race/Ethnicity, %: White: 48.3 AA: 24.3 Hispanic: 24.1 Asian: 1 Income: NR Insurance status: NR Education: NR Other characteristics, %: Reported taking Accutane at some point (a teratogenic drug): 2.3 Health literacy/numeracy levels, %: Low literacy: 42.9 Measurement tools including cutpoints: REALM, not otherwise specified

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Coded (as correct) responses to four qualitative questions: (1) What do you think this symbol means? (2) Who do you think this symbol is meant to reach? (3) What do you think a person should do if they saw this symbol? (4) What do you think the consequences of not paying attention to this symbol might be? Covariates used in multivariate analysis: NA Description of outcome measures: All responses coded according to coding scheme outlined by Goldsworthy (Birth Defects Res A Clin Mol Teratol 76; 453-460) Mean "correct," "correct, but insufficient" (if only partial info), "incorrect" Data source(s) for outcomes: Interviews of participants whose responses were coded by two trained research assistants; inter-rater reliability (2 raters): 86 to 98% Attempts for control for confounding: None Blinding: No Statistical measures used: ANOVA, t-tests, omnibus analyses Nonparametric statistics also done and produced same results	Describe results: Two tested symbols were better at conveying message that labeled medication should not be taken while pregnant and that medicine could cause birth defects. No symbol was understood correctly by > 85% of participants (currently accepted standard for warning labels) Effect in no exposure (i.e., adequate literacy) or control group: NA Effect in exposure (i.e., low/moderate literacy) or intervention, %: "Don't take if pregnant" Symbol 1: 70 Symbol 2: 58 Symbol 3: 66 Symbol 4: 69 Symbol 5: 74 Symbol 6: 37 Symbol 7: 59 "Causes birth defects: Symbol 1: 4 Symbol 2: 19 Symbol 3: 5 Symbol 4: 24 Symbol 5: 19 Symbol 6: 9 Symbol 7: 20 Not provided by literacy level Difference: "Don't take if pregnant" (x versus original symbol 3): Symbol 1: +4, NR Symbol 2: -8, NR Symbol 4: +3, NR Symbol 5: +8, NR Symbol 6: -29, NR Symbol 7: -10, NR "Causes birth defects" (x versus original symbol 3): Symbol 1: -1, NR Symbol 2: +14, NR Symbol 4: +19, NR Symbol 5: +14, NR Symbol 6: +4, NR Symbol 7: +15, NR *Note: addition of text that says “causes birt defects” increase understanding for all

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Murray et al., 2007[116] Research objective: Determine whether a pharmacist intervention improves medication adherence and health outcomes compared with usual care for low-income patients with heart failure. Study design: RCT Study setting: 4 Internal medicine outpatient clinics, 1 cardiology clinic, inpatient discharges at Wishard Hospital in Indiana Measurement period: February 2001 to June 2004 Follow-up duration: 12-months 9-month multilevel intervention 3-month f/u after completion intervention Completeness of follow-up (%): Overall: 270/314 (86) Usual Care: 164/192 (85) Intervention: 106/122 (87)	Eligibility criteria: Included: ≥50 years-old Receive care and meds at Wishard Health Services Confirmed HF diagnosis Regularly use at least 1 CV medication for HF Not using or planning to use a medication adherence aid Telephone and normal hearing range NOTE: all patients receiving prescription medications through state and local assistance plans at no cost Excluded: Patients with dementia Sampling strategy: Consecutive Sample size: 314 assigned (192 usual care, 122 intervention) Age (SD): Usual care: 62.6 (8.8) Intervention: 61.4 (7.7) Gender, %: Female: Usual care: 66.1 Intervention: 68 Race/Ethnicity, %: Usual Care: Black: 52.1 White: 46.9 Other: 1% Intervention: Black: 45.1 White: 54.1 Income, %: Sufficient (=comfortable) income Usual care: 64 Intervention: 62 Insurance status, %: Usual care: Medicare: 56.3 Medicaid: 36.5 Intervention: Medicare: 54.1 Medicaid: 30.3 Education, mean in years (SD): Usual care: 11 (3) Intervention: 11 (2)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Medication adherence, ED visits and hospitalizations , health-related quality of life, patient satisfaction with pharmacy services, total direct costs Covariates used in multivariate analysis: Only multivariate model looked at adherence as a predictor for ed visits/hospitalizations: controlled for functional class, counts of prescribed drugs, ejection fraction, and co morbid conditions when analyzing the exacerbations Description of outcome measures: Medication adherence via MEMS caps: Taking adherence (% of prescribed medication taken) Scheduling adherence (deviation in the timing of administration). Refill adherence (medication possession ratio) using prescription records. Self-reported adherence (Morisky scale and Inui Measure, NOS) ED visit or hospitalization: medical record using previously validated methods Health-related quality of life: average score on the validated Chronic Heart Failure Questionnaire with 4 dimensions: fatigue, dyspnea, emotion, and mastery (range from 1 worst functioning to 7 best functioning). Patient satisfaction with service: internally developed and validated 12-item instrument (a-level = 0.91) Total direct costs: measured using fixed (training of intervention pharmacist, material development, programming, equipment) and variable intervention costs (time spent delivering intervention, time spent by MD speaking with pharmacist and patients, cost of written materials) Data source(s) for outcomes: Medication adherence: MEMS caps, prescription records Self-report ED visits and hospitalizations: medical record. Health-related quality of life: Self report Patient satisfaction with pharmacy services: Self report Total direct costs: cost data Attempts for control for confounding: Randomization	Describe results: Taking and refill Adherence were greater in intervention group during intervention period, but effect dissipated to last f/u. Fewer ED visits and hospitalizations in intervention group. Disease related quality of life and satisfaction improved from baseline to f/u. The intervention was cost saving. Effect in no exposure (i.e., adequate literacy) or control group, %: Taking adherence: During intervention: 67.9 Post Intervention: 66.7 ED visits: Post Intervention: 2.68 visits Hospitalizations: Post Intervention: 0.97 hospitalizations Effect in exposure (i.e., low/moderate literacy) or intervention: Taking Adherence: During intervention: 78.8% Post Intervention: 70.6% ED visits: Post Intervention: 2.16 visits Hospitalizations: Post Intervention: 0.78 hospitalizations Difference: Within Intervention Group (unadjusted): +0.39 ED visits: Absolute difference (unadjusted): -0.52, NR Incidence rate ratio (unadjusted): 0.82 (95% CI, 0.70-0.95) Hospitalizations: Absolute difference (unadjusted): -0.21, NR Incidence rate ratio (unadjusted): 0.81 (95% CI, 0.64-1.04)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Murray et al., 2007[116] (continued)	Other characteristics, %: By New York Heart Failure Class: Usual Care: I: 19.8 II: 40.6 III: 34.9 IV: 4.7 Intervention: I 18.9% II 41.8% III 35.3% IV 4.1% Ejection Fraction: Usual Care: 50 Intervention: 49 Mean Cr: Usual care: 1.2 mg/dL Intervention: 1.2 mg/dL # Long-term meds: Usual care: 11 Intervention: 10 ACEi use: Usual care: 71.4% Intervention: 61.5% Beta-blocker: Usual care: 62.5% Intervention 58.2% Spironolactone: Usual care: 16% Intervention 11.5% Loop diuretic: Usual care: 61.5% Intervention: 56.6% Health literacy/numeracy levels, %: Health literate (NOS): Usual care: 71 Intervention: 72 Measurement tools including cutpoints: s-TOFHLA (cutoffs not defined)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Blinding: Interviewers were blinded to patients' study status and played no role in the delivery of the intervention Statistical measures used: t-tests, 2-sample Wilcoxon test, chi-square tests for ER visits and hospital admissions: log-linear regression models based on Poisson or negative binomial distributions. Incorporated log duration of follow-up into the log-linear model as an offset parameter to accommodate unequal durations of follow-up. Chi2 with accelerated bootstrap approach for 95% CI around the difference in cost. Sensitivity analyses assess the robustness of findings in the presence of missing MEMS adherence measures Krishnamoorthy and Thomson method to directly compare rates of adverse events.	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Paasche-Orlow et al., 2005[61] Research objective: Assess whether inadequate health literacy is barrier to learning and retaining discharge and medication instructions and appropriate metered-dose inhaler technique among asthmatics. Study design: Quasi-experimental (pre-post test) Study setting: Two inner-city hospitals Measurement period: April 2001 - October 2002 Follow-up duration: 2 weeks Completeness of follow-up: 77% Note: patients who did not f/u were more likely to be younger, female, African American, high school grad, be hospitalized in last 12 months, and have lower asthma scores	Eligibility criteria: Included: Age 18 or older Admitted with a physician diagnosis of asthma exacerbation to 2 inner-city academic medical centers Excluded: Other chronic lung disease Contraindication to corticosteroids Patients or physicians who declined consent Investigators' patients Discharged to location other than home Sampling strategy: Convenience Sample size: 73 Note: adherence data only available on 46 (63%)--baseline characteristics not given for these individuals to compare to full sample Age (SD): 40.9 (10.9) Gender, %: Female: 66 Race/Ethnicity, %: AA: 79 Income, %: Income ≥$19,000: 65 Insurance status: NR Education, %: High School graduate or GED: 60 Other characteristics: Asthma-related health care use, %: Hospital visit past 12 mo: 58 ED visit past 12 mo: 77 Near-fatal asthma: 42 Cigarette smoking history: Never: 44% Past: 27% Current: 29 Physician for asthma care: 51 Asthma knowledge score: mean 6.9 (SD=2.0) Health literacy/numeracy levels, %: Inadequate: 22 Measurement tools including cutpoints: sTOFHLA Inadequate: <=16/36 Adequate: >16/36

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Better (>=mean) asthma medication knowledge Better (>=mean) Metered Dose Inhaler technique Mastery of discharge regimen after one round Poor (<50%) adherence to corticosteroid therapy Better (>=mean) asthma symptom control Covariates used in multivariate analysis: Age Sex Ethnicity Education Income History of near fatal asthma Hospitalization in prior 12 mo. Having a physician for asthma care Prior emergency department visit for Asthma last 12 mo. Note: given sample size, model should hold only 4 covariates Description of outcome measures: Better asthma medication knowledge: Asthma Medication Knowledge Questionnaire, 10-item developed by investigators based upon existing asthma knowledge scales, professional opinion, and the desire for each item to be directly related to medication use; dichotomous (yes [>=mean score] vs. no]). Better Metered Dose Inhaler technique: score 0-6 based on assessed technique meeting 6 criteria (shaking, exhaling prior, lips around mouthpiece, full deep breath without triggering indicator, hold breathe 5 seconds); dichotomous (yes [>=mean score =4] vs. no]). Mastery of discharge regimen after one round: dichotomous (yes. vs. no) Poor adherence to corticosteroid therapy: using Doser CT which records the number of actuations for inhaled steroid (poor adherence < 50%: dichotomous (yes vs. no)) and MEMS Caps which record the number of times the pill bottle opened for oral steroids (poor adherence <50%). Better asthma symptom control: using 6 symptom items in Asthma Control Questionnaire: dichotomous (yes [>=mean score] vs. no]). Data source(s) for outcomes: Better asthma medication knowledge - self-report Better Metered Dose Inhaler technique - research assistant assessed Mastery of discharge regimen after one round - research assistant assessed Poor adherence to corticosteroid therapy - doser CT/MEMS ca	Describe results: Outcomes: Inadequate health literacy was associated with poor asthma medication knowledge, poor MDI technique, and hospitalization. Asthma knowledge appeared to mediate relationship between inadequate literacy and MDI technique. Intervention: Inadequate health literacy was not a barrier to learning key asthma management skills in a one-on-one 30 minute asthma education session. Note: power is a significant limitation to this conclusion, however. Effect in no exposure (i.e., adequate literacy) or control group, %: Hospital visit past 12 mo.: 52 ED visit past 12 mo.: 75 Near-fatal asthma: 37 Cigarette smoking history: Never: 46 Past: 30 Current: 25 Physician for asthma care: 53 Asthma knowledge score (at baseline): mean 7.2 Mastery of Metered Dose Inhaler technique (at baseline): 63 (read from chart) Intervention: Mastery of Metered Dose Inhaler technique (at baseline): 32 (read from chart) Mastery of Discharge Regimen (at baseline): 75 (read from chart; average of 76 In adLit; 73 Ad Lit) Poor Adherence (baseline): NR Asthma Symptom control (baseline): NR Effect in exposure (i.e., low/moderate literacy) or intervention, %: Outcomes: Hospital visit past 12 mo.: 52 ED visit past 12 mo.: 75 Near-fatal asthma: 37 Cigarette smoking history: Never: 46 Past: 30 Current: 25 Physician for asthma care: 53 Asthma knowledge score (at baseline): mean 7.2 Mastery of Metered Dose Inhaler technique (at baseline): 63 (read from chart) Intervention: Mastery of Metered Dose Inhaler technique (at baseline): 32 (read from chart) Mastery of Discharge Regimen (at baseline): 75 (read from chart; average of 76 Invalid; 73 Ad Lit) Poor Adherence (baseline): NR Asthma Symptom control (baseline): NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Paasche-Orlow et al., 2005[61] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Attempts for control for confounding: Multivariate analysis Blinding: Yes, to outcome assessors at 2 weeks No to patient Statistical measures used: Wilcoxon rank sum, matched pairs signed rank, and x2 for bivariate. Logistic regression models for adjusted analyses.	Difference: Outcomes: Asthma Knowledge: NR Difference in Asthma-related health care use (unadjusted): Hospital visit past 12 mo.: + 29%, P = 0.04 ED visit past 12 mo.: +13%, P =0.28 Near-fatal asthma: +26%, P = 0.07 Difference in Cigarette smoking history (unadjusted): P = 0.31 Difference in Physician for asthma care (unadjusted): P = 0.53 Difference in Asthma knowledge score (at baseline) (unadjusted): -2.0, P < 0.01; OR (adjusted), 0.08; 95% CI, 0.02-0.38) Difference in Mastery of Metered Dose Inhaler technique (at baseline) (adjusted): -31% (read from chart), P = 0.03; OR, 0.29, 95% CI, 0.08-1.00 Intervention: Overall (unadjusted): +20%, NR; p for interaction by literacy (P = 0.40) Difference in Mastery of Metered Dose Inhaler technique (at 2-week follow-up): (unadjusted): 56%, NR; P for interaction by literacy P = 0.02 % Mastering discharge medication regimen (baselinge- 2 weeks, unadjusted): + 20%, NR; P for interaction by literacy P = 0.40 Difference in Adherence (at 2 week follow-up, available on 46 participants) by literacy sub group (adjusted): NR, P for interaction P = 0.45 Asthma Symptom Control (at 2 week follow-up) by literacy subgroup: NR, P for interaction P = 0.69

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Peters et al., 2007[117] Research objective: Examine whether simpler presentations of quantitative information have larger influence on (on comprehension) among consumers with low numeracy compared to those higher in numeracy Study design: 3 separate RCTs Study setting: Community Measurement period: NR Follow-up duration: Immediate Completeness of follow-up: NR	Eligibility criteria: Included: 18-64 yrs Excluded: NR Sampling strategy: Convenience Sample size: 303 Age, years: 37 Gender, %: Female: 48 Race/Ethnicity, %: White: 76 Income, %: < $20K annual income: 74 Insurance status, %: Uninsured: 55 Education, %: High school or less: 50 Other characteristics: NA Health literacy/numeracy levels, %: (Score < 10 on DR Numeracy Test): 50 Measurement tools including cutpoints: DR Numeracy Test (split at median; 0-9, 10-15) Modified from Lipkus MDM 21: 37-44

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Mean # of correct comprehension questions (range 0-3) % choosing higher quality hospital Covariates used in multivariate analysis: NR Description of outcome measures: Comprehension questions varied. Study 1: What hospital most expensive? Which least likely to follow guidelines? Which has least registered nurses? Study 2: Highest death rate? Lowest patient satisfaction? Low or high death rate better? Low or high satisfaction better? Study 3: Greatest # patients/registered nurse? If cost less important, which hospital would you chose? If cost were extremely important, which would you choose? Which is better: greater or fewer registered nurses? Participants were also asked which hospital they would choose if they needed care (presumably based on quality). Data source(s) for outcomes: Self report (written) Attempts for control for confounding: Randomization Blinding: No Statistical measures used: ANOVA	Describe results: Participants were better able to comprehend cost and quality information and also more likely to choose a higher quality hospital (in hypothetical scenarios) when pertinent quantitative information was presented in an ordered manner, when the more important information was made easier to evaluate (e.g., highlighted), and when numerical information was presented to maintain a "higher is better" relationship. In general, these effects were more pronounced among those with low numeracy. Effect in no exposure (i.e., adequate literacy) or control group: Study 1 Ia. Comprehension (out of 3) 1. Unordered: High 2.7; Low 1.8 Ib. Hospital choice (% choosing highest quality) 1. Unordered: High 38%; Low 44% Effect in exposure (i.e., low/moderate literacy) or intervention: Study 1 1a. Comprehension (out of 3 items) 2. Ordered: High 2.8; low 2.4 3. Ordered, essential info only: High 3.0; Low 2.5 Ib. Hospital c Difference: Higher is better vs. Lower is better (unadjusted): Comprehension: Overall: +0.4, $P < 0.001$ High literacy Subgroup:+0.2, NS Low literacy Subgroup: +0.7, $P < 0.01$* Choice: Overall: +13%, $P < 0.01$ High Literacy Subgroup: NR (interaction by symbols) Low Numeracy Subgroup: +20%, $P < 0.05$* Symbols vs. No Symbols: Comprehension (unadjusted): Overall: NR, $P < 0.10$ High Literacy Subgroup: -0.3*, $P < 0.05$ Low Literacy Subgroup: -0.1, NR* Choice: Higher Literacy Subgroup: -7%, NR* Lower Literacy Subgroup: +5%, NR* Higher # better, no symbols vs. Control: High Literacy Subgroup: Comprehension: +0.3, NR Choice: -4% Low Literacy Subgroup: Comprehension: +0.3, NR Choice: +26%, $P < 0.05$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Peters et al., 2007[117] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Lower # better + symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: -0.2, NR Choice: -19% Low Literacy Subgroup: Comprehension: -0.2, NR Choice: +12%, NR Higher # better + symbols vs. Control (unadjusted): High Literacy Subgroup: Comprehension: -0.1, NR Choice: +1% Low Literacy Subgroup: Comprehension: +0.5, NR Choice: +25%, $P < 0.05$ Ordered, all vs. Control (unadjusted): High Literacy Subgroup: Comprehension: +0.1, NS Choice: +5%, NS Low Literacy Subgroup: Comprehension: +0.6, $P < 0.01$ Plan Choice: +9%, NS P for literacy interaction: comprehension: $P < 0.05$ Choice: NS Ordered, essential only, vs. control (unadjusted): Overall: Comprehension: +0.4, $P < 0.01$ Choice: +21%, $P < 0.01$ High Numeracy Subgroup: Comprehension: +0.3, $P < 0.01$ Choice: +19%, NR Low Numeracy Subgroup: Comprehension: +0.7, $P < 0.01$ Choice: +23%, NR P for interaction: comprehension: $P <0.05$ Choice: NS Symbols vs. Numbers: Overall: Comprehension: NR, NS Choice: +14%, $P < 0.05$ High Numeracy Subgroup: Comprehension: NR Choice: +18%, NR* Low Numeracy Subgroup: Comprehension: NR Choice: -5%, NR* P for interaction by numeracy: Comprehension: $P < 0.001$ Choice: NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Peters et al., 2007[117] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Colored vs. B & W symbols: Overall: Comprehension: NR Choice: +3%*, NS High Literacy Subgroup: Comprehension: NR Choice: =16%*, *P* < 0.05 Low Literacy Subgroup: Comprehension: NR Choice: -11%*, NS Effect of Symbol Choice: Essential info with B&W symbols (unadjusted): High Literacy Subgroup: +12%, NR Low Literacy Subgroup: +11%, NR Essential info with traffic light symbols (unadjusted): High Literacy Subgroup: +29%, NR Low Literacy Subgroup: +6%, NR Essential and non-essential info with B&W symbols (unadjusted): High Literacy Subgroup: +7%, NR Low Literacy Subgroup: -9%, NR Essential and non-essential info with traffic light symbols (unadjusted): High Literacy Subgroup: +22%, NR Low Literacy Subgroup: -26%, NR p for interaction (essential vs. non-essential): choice: *P* < 0.05 p for interaction (literacy level): *P* < 0.05

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Robinson et al., 2008[118] Research objective: Determine effects of literacy classes given to asthmatic pediatric patients in urban area on reading level, asthma treatment self-efficacy, ED visits and hospitalizations Study design: Uncontrolled intervention study (pre-post test) Study setting: South Los Angeles pediatric allergy clinic that serves an impoverished area Measurement period: NR Follow-up duration: 6 months Completeness of follow-up: 94/110 (86%)	Eligibility criteria: Included: Ages 6-14 Met criteria for moderate to severe persistent asthma Treated at pediatric clinic at King/Harbor MAC in south Los Angeles Excluded: NR Sampling strategy: NR Sample size: 110 However, data provided only for 94 who completed 6 month f/u. Age, range (%): 6-10: 57 11-14: 43 Gender, %: Female: 47 Race/Ethnicity, %: Hispanic American: 20 African American: 80 Income: NR Insurance status: NR Education: NR Other characteristics, %: Live with parents: 77 Live with foster parents: 23 Moderate persistent asthma: 80 Hospitalized >1 time in 6 months: 37 Asthma related ED visit in 6 months: 63 Health literacy/numeracy levels: Mean 3.2 Measurement tools including cutpoints: Gilmore Oral Reading Test (scale of 1-11) See Oscar KB. The 8th mental measurements yearbook. Highland Park, N; Gryphon Press; 1978.

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Self-efficacy, asthma ED visits and admissions Covariates used in multivariate analysis: Age Gender Ethnicity Changes in reading levels in baseline and 6-month f/u assessment Changes in asthma-related self-efficacy Description of outcome measures: Self-efficacy: Asthma Self Efficacy Scale (scale 40-100) Asthma ED visits and admission: info from chart review Data source(s) for outcomes: Self-efficacy: children self-report Asthma ED visits and admission: info abstracted from chart review Attempts for control for confounding: Multivariate logistic regression Blinding: NR Statistical measures used: Descriptive statistics Paired t-test Analysis of variance tests Multivariate logistic regression	Describe results: Hospitalization & ED admissions: ED admissions and hospitalizations dropped Self-efficacy (adjusted): Self efficacy improved and was directly related to hospitalizations and ER visits Effect in no exposure (i.e., adequate literacy) or control group, %: ED visits: 62.8% Hospitalizations: 37.2 Self Efficacy: 65.8 out of 100 Effect in exposure (i.e., low/moderate literacy) or intervention, %: ED visits: 33.2 Hospitalizations: 22.3 Self Efficacy: 76.2 out of 100 Difference, % (CI): ED visits (unadjusted): - 29.6, $P < 0.01$ Hospitalizations: -14.9, $P < 0.001$; no interaction Self Efficacy (unadjusted): +10.4 out of 100, $P < 0.001$ Interaction by literacy subgroup: adjusted OR for Effect of reading level on ER visits: 0.34 (0.22-0.52) OR for effect of reading level on hospitalization: 1.31 (0.82-2.10)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al, 2004[119] Research objective: To examine the role of literacy in glycemic control in a cohort of patients with type 2 diabetes Study design: Pre-post analysis Study setting: Academic center general internal medicine practice Measurement period: September 1999 to December 2000 Follow-up duration: 6 months Completeness of follow-up: 70% (111/159)	Eligibility criteria: Included: Patients who were aged 18 years or older and who participated in a pharmacist-led diabetes program between September 1999 and December 2000. Poor glucose control as indicated by an A1c of >8% Patients primary care physician had to be physician in clinic where program was being offered. Excluded: NR Sampling strategy: Convenience Sample size: 159 enrolled 111 had complete enrollment and follow up data Age (mean and range): Lower literacy group (N=61): 60 (no range provided) Higher literacy group (N=50): 55 (no range provided) $P < 0.01$ Gender, %: Female: Lower Literacy Group: 56 Higher literacy Group: 66 $P = 0.27$ Race/Ethnicity, %: AA: Lower Literacy Group: 85 Higher Literacy Group: 52 $P < 0.001$ Income: NR Insurance status, %: Receiving medication assistance Lower Literacy Group: 70 Higher Literacy Group: 47 $P < 0.05$ Education, high school or above, %: Lower Literacy Group: 18 Higher literacy group: 62 $P < 0.001$ Other characteristics, %: Lower Literacy Group: Duration of Diabetes (y): 11.3 Recent diagnosis of diabetes (within 3 mos): 8% Baseline A1c: 10.7 Higher Literacy Group, %: Duration of Diabetes (y): 10.8 Recent diagnosis of diabetes (within 3 mos): 14% Baseline A1c: 10.6%

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: A1c levels at baseline and follow-up Covariates used in multivariate analysis: Baseline A1c value Time between A1c data collection and study enrollment or conclusion Age Race Gender Education status New onset diabetes Body mass index Use of insulin Primary provider was a resident or an attending physician Description of outcome measures: Change in A1c level from baseline to follow up Data source(s) for outcomes: Medical records Attempts for control for confounding: Multiple linear regression analysis Blinding: NR Statistical measures used: 2-sample t-tests and Wilcoxon rank-sum tests paired and 2-sample t-tests with stratification by literacy status. Multiple linear regression analysis	Describe results: Both lower-literacy and higher-literacy groups had improvements in their A1C. However, there was no significant difference in improvement of A1c between the 2 groups Effect in no exposure (i.e., adequate literacy) or control group: Mean HgbA1C in Low literacy Subgroup at baseline: 10.7 Mean HgbA1c in High Literacy Subgroup at baseline: 10.6 Effect in exposure (i.e., low/moderate literacy) or intervention: Mean HgbA1C in Low literacy Subgroup at follow-up: 8.8* Mean HgbA1c in High Literacy Subgroup at follow-up: 8.8* *Read from graph/calculated by research team Difference, points (CI): Lower Literacy Subgroup (unadjusted): -1.9% points (95% CI, -2.5 to -1.2) Higher Literacy Subgroup (unadjusted): -1.8% points (95% CI,-2.5 to -1.0)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al, 2004[119] (continued)	Health literacy/numeracy levels, %: REALM Score 0 – 18: 32 REALM Score 19-44: 23 REALM Score 45-60: 21 REALM Score 61-66: 24 Lower Literacy: 55 Higher Literacy: 45 Measurement tools including cutpoints: REALM (Score 0 - 66) Lower Literacy: <45 Higher Literacy: >45

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al., 2004[120] Rothman et al., 2006[121] Research objective: Examine role of literacy on effectiveness of comprehensive disease management program for patients with diabetes. Study design: Randomized Controlled Trial Study setting: General internal medicine practice at academic medical center Measurement period: February 2001 to April 2003 Follow-up duration: 12 months Completeness of follow-up, %: Overall: 89 (193/217) Intervention Group: 87 (98/112) Control Group: 90 (95/105)	Eligibility criteria: Included: Aged 18 years Diagnosed with type 2 diabetes who were followed up for diabetes care in general internal medicine Practice had poor glucose control (i.e., glycosylated hemoglobin [HbA1c] levels 8.0%), spoke English, and had a life expectancy greater than 6 months Excluded: NR Sampling strategy: Convenience Sample size, n: Control group: 105 Intervention group: 112 Age (mean and range): Control Group: Low literacy: 59 y (no range provided) Higher literacy: 56 y (no range) Intervention Group Low literacy: 57 y (no range) Higher literacy: 51 y ($P < 0.05$ in intervention group) Gender, %: Female: Control Group: Low literacy: 53 Higher literacy: 58 Intervention Group: Low literacy: 55 Higher literacy: 65 ($P < 0.05$ in intervention group) Race/Ethnicity, %: AA: Control Group: Low literacy: 68 Higher literacy: 55 Intervention Group: Low literacy: 94 Higher literacy: 51 ($P < 0$ .05 in intervention group) Income, %: Control Group Household Income < $20,000 Low Literacy: 85 Higher Literacy: 71 Intervention Group: Low Literacy: 82 Higher Literacy: 59 ($P < 0.05$ in intervention group)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Improvement in HbA1c levels and systolic blood pressure from baseline to 12 months Obtain goal HbA1c levels (7.0%) Labor and Total Costs Covariates used in multivariate analysis: Age Race Sex Income Insulin status at enrollment Duration of disease Description of outcome measures: HbA1c levels - blood test Systolic blood pressure - performed with automated monitor Labor costs, not specified Total costs (labor costs + indirect costs) Data source(s) for outcomes: Medical records Attempts for control for confounding: Randomization Multivariate linear regression Logistic regression Intent to treat analysis Blinding: Pharmacists not blinded to literacy status of patients in intervention group Laboratory and nursing staff who tested HbA1c and blood pressure were blinded to patients' study status. Statistical measures used: t-tests Wilcoxon rank-sum test Chi-squared and Fisher exact tests Multivariate linear models adjusted for baseline covariates Logistic regression Intent-to-treat analysis	Describe results: Among low literacy patients, those in intervention group had more improvement in HbA1c levels than did control patients. Among patients with low literacy, intervention patients were more likely than control patients to achieve goal HbA1c levels. Effect in no exposure (i.e., adequate literacy) or control group, %: SBP in control group: Overall: NR Low literacy: 6 mo: 141* 12 mo: 141* High Literacy: 6 mo: 141* 12 mo: 139* Mean Hgba1c in Control Group: Overall: NR Low Literacy Group: 6 mo: 9.5* 12 mo: 9.5* High Literacy: 6 mo: 8.4* 12 mo: 8.5* Percentage attaining goal HbA1c level at 12 months in Control group: Overall: 20% Low Literacy: 15% Higher Literacy: 23% * Read from Graph Effect in exposure (i.e., low/moderate literacy) or intervention, %: Overall: NR Low literacy: 6 mo: 139* 12 mo: 135* High Literacy: 6 mo: 130* 12 mo: 131* Mean Hgba1c in intervention group: Overall: NR Low literacy: 6 mo: 7.2* 12 mo: 7.3* High Literacy: 6 mo: 8* 12 mo: 7.9*

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al., 2004[120] Rothman et al., 2006[121] (continued)	Insurance status, %: Control Group Low Literacy: Private Insurance: 9 Medicare: 47 Medicaid: 32 Higher Literacy: Private Insurance: 35 Medicare: 34 Medicaid: 20 Intervention Group Low Literacy: Private Insurance: 39 Medicare: 41 Medicaid: 18 Higher Literacy: Private Insurance: 43 Medicare: 22 Medicaid: 14 (P < 0.05 for intervention group) Education, %: Control Group Less than a high school education Low Literacy: 82% Higher Literacy: 26% (P < 0.05) Intervention Group: Low Literacy: 82% Higher Literacy: 59% (P < 0.05) Other characteristics (CI): Baseline HbAc1 (reported as median and IQR): Control Group: Low Literacy: 10.6 (9.1-11.3) Higher Literacy: 9.9 (9.0-11.6) Intervention Group: Low Literacy: 10.4 (8.8-12.1) Higher Literacy: 10.5 (9.4-12.2) Diabetes Knowledge Score (reported as median and IQR) Control Group: Low Literacy: 40 (20-50) Higher Literacy: 60 (40-70) (P < 0.05) Intervention Group: Low Literacy: 40 (30-50) Higher Literacy: 60 (40-80) (P < 0.05)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Percentage attaining goal HbA1c level at 12 months in Intervention Group: Overall: 32% Low Literacy: 42% Higher Literacy: 24% * Read from graph Difference: Mean change in SBP at 12 months (adjusted): Overall: -7.6 mmHg (-13 to -2.2 mmHg) Low literacy: -7.9 (95% CI -17.7 to 1.9) High literacy: -7.1 (95% CI -14.3 to 0.004) Mean change in Hgba1c (adjusted): Overall: -1 (95% CI-1.5 to-0.4) Low literacy: -1.4 (95% CI -2.3- -0.6) High literacy: -0.5 (95% CI -1.4 to 0.3) High literacy subgroup): HgbA1c (adjusted): -0.5%; 95% CI, -1.4%-0.3% Labor costs: $25.50 per patient per month (Sens. analysis $12.01 to $55.35 per patient per month) Total costs: $36.97 per patient per month (Sens. Analysis $16.22 to $88.56 per patient per month)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rothman et al., 2004[120] Rothman et al., 2006[121] (continued)	Health literacy/numeracy levels, %: Low Literacy (< sixth grade): 38 Higher Literacy: 62 Measurement tools including cutpoints: REALM Low literacy defined as < 6th grade level

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rudd et al., 2009[122] Research objective: Test efficacy of educational interventions to reduce literacy barriers and enhance health outcomes among patients with inflammatory arthritis. Study design: Randomized controlled trial Single blind Study setting: Urban teaching hospital Measurement period: 2003-2006 Follow-up duration: Data collected at baseline, 6, and 12 months post Completeness of follow-up: 100%	Eligibility criteria: Included: Participants with rheumatoid arthritis, psoriatic arthritis and inflammatory poly-arthritis ICD-9 codes - 714.0, 696.0, 714.9) Participants had at least one visit with a rheumatologist who gave permission to recruit his/her patients and who also agreed to have study visits tape recorded if the patient consented to the study Excluded: >18 years Medical professionals Those with a post graduate degree Those with a visual impairment affecting reading ability Those who reported not being comfortable with spoken and written English Sampling strategy: Participants were initially selected based on an enrollment ratio of 3 participants with ≤ HS education to 1 with a grade 13 or higher education Recruitment letter, signed by PI and patient's rheumatologist was sent approx 6 weeks before next appointmen Sample size: Identified in Clinical Database: 2,559 Approved by rheumatologist: 1,480 Received letter: 1,145 Screened by phone: 679 (Refused: 193, Ineligible: 271, Interested: 215) No questionnaire administered: 57 Completed questionnaire: 158 Not enrolled: 24 Consented Age, mean (SE): Standard Care: 59.5 (13.9) Individualized Care and Plain English: 57.6 (13.8) Gender, %: Female: Standard Care:78 Care and Plain English: 81 Race/Ethnicity, %: Caucasian: Standard Care: 94 Care and Plain English: 91 Income, %: <30K: Standard Care: 39 Care and Plain English: 20 Insurance status: NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: (1) Adherence to treatments (2) Self-efficacy scale (3) Satisfaction with medical care (4) Appointment keeping (5) Self-reported health status (6) Mental health Covariates used in multivariate analysis: Age Work status Literacy level Annual family income Baseline value of outcome measure Description of outcome measures: Adherence to treatments: 4-item measure based on a questionnaire byLevine (range 0-3, 0 best) Self-efficacy: Lorig's scale (range 1-4; 4 best) satisfaction with medical care: base don the 8-item subscale of the Medical Interview Satisfaction Scale (range 1-4; 4 best) Self-reported health status: assessed with the Health Assessment Questionnaire (HAQ) (range 0-3; 3 best) Mental Health: assessed with the 5-item Mental Health Index from the SF-36 (range 0-100; 100 best) Data source(s) for outcomes: Survey self-report Attempts for control for confounding: Randomization; Multivariate linear regression; adjustments for covariates that differed at baseline between the groups Blinding: The study staff members were blinded to participant's group assignment. The recruitment logs and tracking system were kept separate from the Study Educator's logs and appointment schedule. Statistical measures used: Independent sample t-tests for continuous variables Proportions were compared using the Chi-square test of independence or Fisher's exact test for all categorical variables Longitudinal data were analyzed as percent change between baseline and 6 months	Describe results: Intervention had no effect on primary outcomes of adherence to treatments, self-efficacy, satisfaction with care, and appointment keeping. There was an improvement in mental health score (secondary outcome) in the intervention group. Effect in no exposure (i.e., adequate literacy) or control group: Mean Change (percent change) in Mental Health Subscale of sF36 in Standard Care group: 6 months: -3.7 (-4.32%) 12 months: -2 (-0.78%) Mean change (percent change) in HAQ score in standard care group: 6 month: +0.1 (3.30%) 12 months: -0.2 (1.33%) Mean Change (Percent change) in Self-efficacy in standard care group: 6 months: -0.14 (-3.18%) 12 months: -0.09 (-2.04%) Mean change (percent change) in medication adherence in standard care group: 6 months: -0.06 (0.25%) 12 months: -0.12 (-3.12%) Effect in exposure (i.e., low/moderate literacy) or intervention: Mean Change (percent change) in Mental Health Subscale of sF36 in Individualized group: 6 months: +2.9 (4.56%) 12 months: +3.8 (4.79%) Mean change (percent change) in HAQ score in individualized care group: 6 month: -0.07 (-0.30%) 12 months: -0.08 (-0.79%) Mean Change (percent change) in Self-efficacy in individualized care group: 6 months: +0.05 (1.53%) 12 months: +0.13 (3.57%) Mean change in medication adherence in individualized care group: 6 months: -0.17 (-4.76%) 12 months: -0.23 (-12.21%) Difference: Mean percent change in Mental Health subscale of SF36 (unadjusted): 6 months: +8.8%*, *P* 0.04 12 months: +5.57%*, *P* 0.11

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Rudd et al., 2009[122] (continued)	Education, %: ≤ HS: Standard Care: 52 Care and Plain English: 48 Other characteristics, %: Working full/part-time: Standard care: 36 Care and plain English: 50 Disease Duration <5 years: Standard care: 25 Care and Plain English: 27 Health literacy/numeracy levels, %: A-REALM <h = high school level: Standard care: 21 Care and Plain English: 16 Measurement tools including cutpoints: A-REALM; arthritis modification to the REALM

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Mean change in Mental Subscale of SF36 (adjusted): 6 mo: 7.5, *P* 0.003 12 mo: NR Mean percent change in HAQ scores (unadjusted): 6 months: -3.60%*, *P* 0.45 12 months: -2.12%*, *P* 0.64 Mean percent change in self-efficacy 6 mo (unadjusted): +4.71%*, *P* 0.05 12 mo. (unadjusted) : +5.61%, *P* 0.04 12 mo (adjusted): NR, *P* = 0.12 Mean percent change in medication adherence (unadjusted): 6 mo: -5.01%, *P* 0.33 12 mo: -9.09%, *P* 0.10

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2008[123] Schillinger et al., 2009[124] Research objective: Schillinger (2009; main results): Eamine effects of 2 SMS (automated telephone self-management support (ATSM) and group medical visits (GMV)) across outcomes corresponding to Chronic Care Model Schillinger (2008; secondary paper): Primary objective: Describe reach of self management strategies across 3 dimensions (participation, representativeness of pts, uptake of programs) Secondary objective: Explore relationship of patient literacy level with engagement in 2 diabetes self-management support (SMS) programs (not compared statistically) Study design: RCT Sub-analysis of 2 intervention arms to examine secondary objectives of reach/intervention use Study setting: Clinics in a community health network in San Francisco (part of UCSF PBRN) Measurement period: June 2003 to December 2004 Follow-up duration: 1 year Completeness of follow-up, %: 305/339 (90)	Eligibility criteria: Included: Patient at participating clinic, > 17 yrs; diabetes by ICD9; spoke English, Spanish, or Cantonese; ≥ 1 primary care visit in past year; A1C > 8 Excluded: Moved away or died Had moderate to severe dementia Were not expected to live through the year Anticipated travel of more than 3 months in upcoming year Too ill or unable to travel to a GMV No phone access Self-reported hearing impairment Visual acuity of greater than or equal to 20|100 Inability to follow instructions on a telephone keypad Sampling strategy: Convenience sample of patients meeting criteria at 4 (of 9) participating clinics in network. Created a registry to identify adult patients in Community Health Network of San Francisco. Approached 557 (note 2008 article says 499) patients in their created database of 1307 potentially eligible patients Note: those who participated slightly different in language and insurance than total group; age, sex, hgba1c similar Sample size: 339 total ATDM: 112 GMV: 113 (2008 says 112) Usual care: 114 Note: there are minor discrepancies in exact numbers between this article and background article; reason is not clear b/c report on same number of total participants Age (mean and range): Schillinger (2008): 55.4 (11.9) Schillinger (2009): All: 56.1 (12) ATSM: 55.9 (12.7) GMV: 56.5 (11.4) Usual: 55.8 (11.8) Gender, %: Female: Schillinger (2008): 59 Schillinger (2009): All: 59% ATSM: 58 GMV: 63.7 Usual: 55.3

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Schillinger (2008): Engagement index Proportion action plans created # action plans achieved Schillinger (2009): Diabetes self-efficacy Self-management behavior (primary outcome) Functional status Metabolic outcomes Note: also measure degree to which structure/process of care aligned with Chronic Care Model Covariates used in multivariate analysis: Schillinger (2008) Analysis of language and literacy interactions): Age, sex, insurance, baseline A1C; stratified by language and literacy level Schillinger (2009) Main intervention analysis): baseline variable for main outcome only Description of outcome measures: Of interest to our review*: *Engagement index (proportion ever engaged in SMS X mean # sessions attended X proportion created action plan X mean # action plans achieved); range not reported * Diabetes self-efficacy: measured using Diabetes Quality Improvement Program measure. Self efficacy over the prior year using a 0-100 scale. See Diabetes Care 26; 738-43. *Self-management behavior (primary outcome): 1) validated instrument that asks on how many of previous 7 days individual performed recommended activities: eating healthy foods, following a diabetic diet, exercising, self-monitoring of blood glucose, caring for one's feet. Composite weekly self-care scores ranging from 0 to 7 with higher number scores corresponding to greater number of days carrying out recommended behaviors. See Diabetes Care 23: 943-50. 2) For exercise, subjects estimated minutes of moderate and vigorous physical activity on each of the days. *Functional status: Self-reported days in the prior month where participant "spent most of the day in bed due to health problems"	Describe results: Engagement Engagement in a diabetes self-management support automated telephone program was better among patients with limited health literacy. In contrast, engagement in a diabetes self-management support group medical visit program was better among patients with adequate literacy. Results were consistent across languages studied. Effects on structure and processes of care: ATSM & GMV participants showed improvement, relative to usual care, in PACIC and diabetes self-efficacy. There were no significant differences between ATSM & GMV on PACIC or diabetes self-efficacy change. Only ATSM improved in interpersonal communication relative to usual care and GMV. Effects on behavior: ATSM & GMV significanty increased in self-management behavior compared to usual care. ATSM reported signficiant increase in moderate physical activity relative to usual care and a greater percentage of ATSM achieved weekly minimum recommendations for physical activity in comparision to baseline and follow-up. There was little change for GMV and a reduction for those receiving usual care. Effects on functional outcomes: ATSM significantly decreased days restricted to bed compared to usual care. ATSM reported less activity restriction from baseline to follow-up versus GMV and usual care. SF-12 mental health improved for ATSM relative to GMV and usual care; neither one was appreciably different than usual care. Effects on metabolic outcomes: There were no significant differences in metabolic outcomes change bewteen ATSM, GMV and usual care. Effect in no exposure (i.e., adequate literacy) or control group: Schillinger (2009): PACIC Usual Care Baseline: 41.0 12 mo: 48.2 Diabetes Self Efficacy: Usual Care Baseline: 73.5 12 mo: 71.7 Interpersonal processes of care: Usual Care Baseline 62.9 12 mo: 65.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2008[123] Schillinger et al., 2009[124] (continued)	Race/Ethnicity, %: Schillinger (2008): Asian: 22.4 AA: 19.5 Hispanic: 47.2 White: 8.0 Other/unknown: 3 Schillinger (2009): Asian: 23.3 AA: 20.6 White/Latino: 46.9 White/non-Latino: 7.7 Other/unknown: 1.5 ATSM: Asian: 26.8 AA: 14.3 White/Latino: 46.4 White/non-Latino: 9.8% Other/unknown: 2.7 GMV: Asian 21.2% AA: 23.9 White/Latino: 46.0 White/non-Latino: 8 Other/unknown: 0.9 Usual: Asian: 21.9 AA: 23.7 White/Latino: 48.3 White/non-Latino: 5.3 Other/unknown: 0.9 Income, %: Schillinger (2008): NR Schillinger (2009): All: 28.6% ≤5K, 31.8% 5-10K 23.7% 10-20K 9.2% 20-30K 6.7% ≥ 30K ATSM: ≤5K: 26.9 5-10K: 31.5 10-20K: 18.0 20-30K: 14.6 ≥ 30K: 9.0

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Self-reported extent to which diabets prevented them from carrying out normal daily activities (diabetes interference), using a 5-point Likert-type scale ranging from "not at all" to "completely". Short Form (SF)-12 validated quality of life instrument, transforming physical and mental health to 0-100 scales. *Metabolic outcomes: Measured A1C (high-performance liquid chromatography method) Systolic (SBP) and diastolic blood pressure (DBP) using calibrated automated cuffs. Calculated BMI by measuring weight and height w/o shoes and with light clothing and empty bladder. Other measures: Degree to which structure of care was aligned with the CCM: Patient Assessment of Chronic Illness Care (PACIC) instrument; transformed summary scores to a 100-point scale with higher scores representing greater CCM alignment Degree to which processes of care were aligned with CCM: Used Interpersonal Care for Diverse Populations (IPC) instrument to capture patient reports of providers' communication over the prior year and generated a total IPC score on a 100 point scale. Data source(s) for outcomes: Engagement Index: Self report; not clear whether by patient or by nurse/ physician/ health educator Diabetes self efficacy: self-report Self-management behavior: self-report Functional status: self report and questionnaire Metabolic outcomes: measure Attempts for control for confounding: Randomization, Multivariate models, stratification Blinding: No Statistical measures used: Schillinger (2008): For subgroup analysis: Multivariate models (GEE) accounting for clustering of action plans within patients Schillinger (2009): Calculated standardized effect sizes for scales, used linear regression for continuous variables, logistic	Self-management, weekly: Usual care Baseline: 3.9 12 mo: 3.8 Moderate physical activity (min) Usual care Baseline: 195 12 mo: 193.5 Vigorous exercise (min) Usual care Baseline: 67 12 mo: 23.0 Bed days in prior month Usual care Baseline: 3.9 12 mo: 3.1 Restricted Activity (% >= 0ften/always) Usual care Baseline: 17.1 12 mo: 21.0 SF-12 mental health Usual care Baseline: 58.8 12 mo: 64.2 SF-12 physical health Usual care Baseline: 50.0 12 mo: 56.7 A1C (%) Usual care Baseline: 9.8 12 mo: 9.0 SBP (mmHg) Usual care Baseline: 139.6 12 mo: 141.5 DBP (mmHg) Usual care Baseline: 78.1 12 mo: 78.5 BMI (kg/m2) Usual care Baseline: 31.2 12 mo: 31.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2008[123] Schillinger et al., 2009[124] (continued)	GMV: ≤5K: 31.6 5-10K: 33.7 10-20K: 23.2 20-30K: 6.3 ≥ 30K: 5.2 Usual: ≤5K: 27.3 5-10K: 30.3 10-20K: 29.3 20-30K: 7.1 ≥ 30K: 6.0 Insurance status, %: All: Medicaid: 19.8 Medicare: 21.5 Uninsured: 50.2 Other: 8.6 ATSM: Medicaid: 20.5 Medicare: 19.6 Uninsured: 50.0 Other: 9.8 GMV: Medicaid: 22.1 Medicare: 23.0 Uninsured: 46.0 Other: 8.9 Usual: Medicaid: 16.7 Medicare: 21.9 Uninsured: 54.4 Other: 7.0 Education, %: All: Up to some HS: 54.3 HS/GED: 17.1 ≥ some college: 28.6 ATSM: Up to some HS: 51.8 HS/GED: 14.3 ≥ some college: 33.9 GMV: Up to some HS: 55.8 HS/GED: 17.7 ≥ some college: 26.6

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Effect in exposure (i.e., low/moderate literacy) or intervention: Schillinger (2009) PACIC ATSM: Baseline: 36.8 12 mo: 58.9 GMV: Baseline: 39.3 12 mo: 60.2 Diabetes Self Efficacy ATSM: Baseline: 71.7 12 mo: 77.2 GMV: Baseline: 73.3 12 mo: 77.2 Interpersonal processes of care ATSM: Baseline: 59.2 12 mo: 72.9 GMV: Baseline: 63.4 12 mo: 68.9 Self-management, weekly ATSM: Baseline: 3.7 12 Mo: 4.4 GMV: Baseline: 3.9 12 mo: 4.1 Moderate physical activity (min) ATSM: Baseline: 206 12 mo: 325.0 GMV: Baseline: 285 12 mo: 320.5 Vigorous exercise (min) ATSM: Baseline: 55 12 mo: 54.8 GMV: Baseline: 41 12 mo: 45.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2008[123] Schillinger et al., 2009[124] (continued)	Usual: Up to some HS: 55.3 HS/GED: 19.3 ≥ some college: 25.4 Other characteristics: Schillinger (2008): English language: 53.4 Spanish 35.7 Cantonese: 10.9% Schillinger (2009): ALL: English: 45.4 Spanish: 43.1 Cantonese: 11.5 Diabetes duration: 9.5 years Diabetes regimen: Diet only: 1.2 Oral agents only: 60.8 Insulin only: 10.1 Health literacy/numeracy levels, %: Schillinger (2008): ADTM: Limited literacy: 50/112 (45) Adequate literacy: 48/112 (43) 14/112 no TOFHLA? GMV: Limited literacy: 56/112 (50) Adequate literacy: 42/112 (38) 14/112 no TOFHLA? Schillinger (2009): All*: limited literacy 58.8, adequate Measurement tools including cutpoints: s-TOFHLA (English and Spanish) Limited: 0-22 Adequate: 23-36

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Bed days in prior month ATSM: Baseline: 3.8 12 mo: 1.4 GMV: Baseline: 3.6 12 mo: 3.6 Restricted activity (%>= often/always) ATSM: Baseline: 14.9 12 mo: 6.0 GMV: Baseline: 16.3 12 mo: 16.2 SF-12 mental health ATSM: Baseline: 57.2 12 mo: 67.0 GMV: Baseline: 61.7 12 mo: 63.0 SF-12 physical health ATSM: Baseline: 51.3 12 mo: 60.2 GMV: Baseline: 50.9 12 mo: 57.1 A1C (%) ATSM: Baseline: 9.3 12 mo: 8.7 GMV: Baseline: 9.3 12 mo: 9.0 SBP (mmHg) ATSM: Baseline: 136.9 12 mo: 136.9 GMV Baseline: 142.4 12 mo: 138.9 DBP (mmHg) ATSM: Baseline: 75.0 12 mo: 75.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2008[123] Schillinger et al., 2009[124] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	GMV: Baseline: 78.1 12 mo: 75.5 BMI (kg/m2) ATSM: Baseline: 30.3 12 mo: 30.7 GMV Baseline: 32.1 12 mo: 32.4 Schillinger (2008): Engagement Index: Overall ATDM: 22.1 GMV: 4.8 Low Lit ATDM: 28.0 GMV: 3.6 Adeq Lit ATDM: 15.6 GMV: 7.6 Action plans created: Overall ATDM: 5.2 GMV: 3.2 Low Lit: ATDM: 5.9 GMV: 2.8 Adeq Lit ATDM: 4.6 GMV: 3.7 Action plans completed: Overall ATDM: 42.3 GMV: 45.3 Low Lit ATDM: 43.5 GMV: 42.2 Adeq Lit ATDM: 39 GMV: 57.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Schillinger et al., 2008[123] Schillinger et al., 2009[124] (continued)	

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
	Difference: SF-12 mental health: ATSM-Usual Care (adjusted): 3.7 (-2 to 9.4) GMV-Usual Care (adjusted): -2.9 (-8.6 to 2.9) ATSM-GMV (adjusted): -6.5 (0.7 to 12.4) SF-12 physical health: ATSM-Usual Care (adjusted): 2.7 (-4.0 to 9.5) GMV-Usual Care (adjusted): -0.1 (-6.9 to 6.7) ATSM-GMV(adjusted): 2.9 (-4 to 9.7) # Bed Days over prior month: ATSM-Usual Care (adjusted): -1.7 (-3.3 to -0.1) GMV-Usual Care(adjusted): 0.6 (-1.0 to 2.2) ATSM-GMV (adjusted): -2.3 (-3.9 to -0.4) Extent limited activity: ATSM-Usual Care: NR, $P < 0.02$ GMV-Usual Care: NR, NS ATSM-GMV: NR, NS

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Seligman et al., 2005[125] Research objective: Determine if notifying physicians of patients' limited health literacy affects physician behavior, physician satisfaction, or patient self-efficacy. Study design: Cluster RCT Study setting: Urban, academic, public hospital Measurement period: May - December, 2000 Follow-up duration: Most data: 1 week; HgbA1c: 2-9 months Completeness of follow-up, %: F/U for most outcomes: 86 F/U for hgba1c: 86 No physicians lost to follow-up after randomization	Eligibility criteria: Included: Type 2 diabetes Older than 30 years old Spoke English or Spanish Assigned physician in database for at least 12 months with at least 1 visit to physician in last 6 months Limited health literacy Excluded: Psychotic disorders Dementia, acute intoxication, end-stage renal disease Corrected visual acuity worse than 20/50 Sampling strategy: Convenience Sample size: 63 physicians: Intervention: 31 Control: 32 182 patients: Intervention: 95 Controls: 87 Age (SD): Intervention: Patient age: 62.3 (11.3) Control: Patient age: 63.4 (9.5) Gender, %: Female Intervention: Physicians: 58 Patients: 56 Control Physicians: 66 Patients: 67 Race/Ethnicity, %: Intervention Patients Caucasian: 7 AA: 19 Hispanic: 58 Asian: 15 Other: 1 Control Patients Caucasian: 12 AA: 21 Hispanic: 48 Asian: 17 Other: 2

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Physician Outcomes Management Intensive* Physician strategies employed: Involved family members or friends Referred to a nutritionist Used pictures of diagrams Referred to a diabetes educator Reviewed understanding of medications Spent time teaching about diabetes Satisfied with Visit Felt effective during visit Patient Outcomes Self-efficacy* Feeling health literacy screening is useful HgbA1c* *outcomes of interest to our review Covariates used in multivariate analysis: Physician Outcomes patient language gender years with primary care provider health literacy score clustering of patients within provider Patient Outcomes (except perception screening is useful) gender language discordance HL Description of outcome measures: Physician Outcomes Management Intensive - dichotomous variable (yes/no) if physician employed >3 of the 6 (below) recommended management strategies during patient visit Physician strategies employed Involved family members or friends - Referred to a nutritionist Used pictures of diagrams Referred to a diabetes educator Reviewed understanding of medications Spent time teaching about diabetes Satisfied with Visit - 6-item scale developed from 2 previous scales measuring physician satisfaction and frustration; 5-point Likert scale responses. alpha 0.8 Felt effective during visit - 10-item effectiveness scale that asked physicians to rate the extent to which they impacted their patient's diabetes management in specific areas; 5-point Likert scale responses. alpha 0.8	Describe results: Health literacy screening increases the intensity of communication management by physician. However, physicians feel less satisfied with patient visits when health literacy status is presented. Additionally, intervention resulted in no difference in patient self-efficacy or hgba1c. Effect in no exposure (i.e., adequate literacy) or control group, %: Physician Outcomes (adjusted): Management Intensive: 7 Physician strategies employed: Involved family members or friends: 17 Referred to a nutritionist: 3 Used pictures of diagrams: 1 Referred to a diabetes educator: 31 Reviewed understanding of medications: 90 Spent time teaching about diabetes:63 Satisfied with Visit: 96 Felt effective during visit: 50 Patient Outcomes: Self-efficacy score: 12.9 Feeling health literacy screening is useful (unadjusted): 97 Change in HbA1c: 0.17 Effect in exposure (i.e., low/moderate literacy) or intervention: Physician Outcomes (adjusted): Management Intensive: 20 Physician strategies employed: Involved family members or friends: 27 Referred to a nutritionist: 11 Used pictures of diagrams: 8 Referred to a diabetes educator: 28 Reviewed understanding of medications: 92 Spent time teaching about diabetes: 69 Satisfied with Visit: 82 Felt effective during visit: 34 Patient Outcomes: Self-efficacy score: 12.6 Feeling health literacy screening is useful (unadjusted): 96 Change in HbA1c: -0.10 Difference, OR (CI): Physician Outcomes (adjusted): Difference in Management Intensive: 4.7 (1.4-16.0) Note: trends toward differences for individual communication strategies involving family/friends and refferent to a nutritionist Difference in Physician strategies employed: Involved family members or friends: 1.9 (1.0-3.5) Referred to a nutritionist: 4.0 (1.0-15.6) Used pictures of diagrams: 7.9 (0.9-74.7) Referred to a diabetes educator: 0.9 (0.4-1.9) Reviewed understanding of medications: 1.3 (0.5-3.5) Spent time teaching about diabetes: 1.3 (0.6-2.8)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Seligman et al., 2005[125] (continued)	Income: NR Insurance status: NR Education: NR Other characteristics: Intervention Physicians: Spanish speaking: 45% Attending (vs. resident): 35% Patients: Spanish speaking: 48% <3 years with primary care provider: 45% HbA1c: mean 8.70 (SD=1.72) Control Physicians: Spanish speaking: 53% Attending (vs. resident): 31% Patients: Spanish speaking: 39% <3 years with primary care provider: 69% HbA1c: mean 8.54 (SD=1.62) Health literacy/numeracy levels: Intervention Marginal: 21% Inadequate: 79% Control: Marginal: 31% Inadequate: 69% Measurement tools including cutpoints: s-TOFHLA Inadequate: ≤ 16 Marginal: 17-22 Adequate: ≥ 23

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Patient Outcomes Self-efficacy - previously validated Patient-Enablement Instrument (Fam Pract 1998; 15:165-71), which measures extent to which the physician visit affects patients' confidence in their ability to successfully manage their chronic disease. Scores range from 0-12. Feeling health literacy screening is useful - yes/no response, nonvalidated measure HbA1c - calculated change from baseline(most recent value in hospital database prior to study enrollment) to follow-up Data source(s) for outcomes: Physician self-report Patient self-report Except HbA1c - lab values Attempts for control for confounding: Randomization, multivariate analysis Blinding: Patients were blinded, Unable to blind physicians. NR if outcomes assessors blinded Statistical measures used: GEE linear or logistic models, except patient self-efficacy = standard linear regression b/c no intra physician correlation.	Difference in Satisfied with Visit: 0.2 (0.1-0.5) Difference in Felt effective during visit: 0.5 (0.2-1.2) Patient Outcomes: Difference in Self-efficacy (adjusted): -0.3, *P* = 0.61 Difference in Feeling health literacy screening is useful (unadjusted): -1%, *P* = 0.77 Difference in Change in HbA1c (adjusted): -0.27 (-0.80-0.27)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Sobel et al., 2009[126] Research objective: To determine whether a low-literacy multimedia tool can improve asthma knowledge in African-American adults Study design: Single group pre-test/post-test Study setting: "Three diverse settings in the Chicago area: a faith-based organization, an adult basic education center, and a general internal medicine ambulatory care clinic" Measurement period: August 2007 - January 2008 Follow-up duration: Immediately Completeness of follow-up: 100%	Eligibility criteria: Included: African American adults Excluded: Blindness or severely impaired vision, not correctable by glasses Deafness or hearing problems, not correctable by hearing aid Too ill to participate Non-English speaking Sampling strategy: Convenience sample Sample size: Control: none Intervention: 130 Age (mean and range), % (SD): 50.2 (SD 15.3) Gender, %: Female: 76.2 Race/Ethnicity, %: African-American: 100 Income, %: NR Insurance status, %: NR Education, %: < High school: 22.5 High school graduate: 22.3 > High school: 53.9 Other Characteristics Asthma diagnosis: 22.3 Family member with asthma: 63.8

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Knowledge: questions addressing understanding of asthma as a disease, body parts affected, identification of asthma symptoms, recognition of the link between symptoms and disease control, comprehension of the pathophysiology of asthma symptoms, and perception of the seriousness of the disease Score range was 0-12, nonvalidated measure Covariates used in multivariate analysis: For stratified analysis (by literacy level): pretest knowledge score, age, gender, education, asthma diagnosis (self or relative) Description of outcomes measures: Knowledge: questions addressing understanding of asthma as a disease, body parts affected, identification of asthma symptoms, recognition of the link between symptoms and disease control, comprehension of the pathophysiology of asthma symptoms, and perception of the seriousness of the disease Score range was 0-12, nonvalidated measure Data source(s) for outcomes: Structured interview Attempts for control for confounding: Multivariate linear regression Blinding: NA Statistical measures used: McNemar's test, paired t-test, multivariate linear regression	Describe results: Participants' understanding of basic asthma concepts significantly improved after the intervention; however, individuals with low literacy had smaller knowledge gains than those with marginal and adequate literacy Effect in no exposure (i.e., adequate literacy) or control group, %: Total knowledge score: Pre-intervention (SD): 4.2 (1.6) Effect in exposure (i.e., low/moderate literacy) or intervention: Total knowledge score: Post-intervention (SD): 6.8 (2.0) Post-intervention knowledge scores by literacy level (SD): Adequate: 7.8 (1.7) Marginal: 6.6 (1.9) Low: 5.6 (1.8) Difference, %: Difference in total knowledge score (unadjusted): +2.6*, $P < 0.001$ Mean knowledge score (post-pre adjusted) compared to adequate literacy score: Adequate reference Marginal: -0.8; 95% CI, -1.5 to -0.1 Low: -1.5; 95%CI, -2.3 to -0.6 *Calculated by research team

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Sudore et al., 2007[127] Sudore et al., 2008[128] Research objective: Determine whether advance directive redesigned to meet most adults' literacy needs was more useful for advance care planning than a standard form Study design: RCT Study setting: General Medicine Clinic at San Francisco General Hospital (SFGH), a public hospital affiliated with the University of California San Francisco (UCSF) Measurement period: February and July 2005 Follow-up duration: 6 months Completeness of follow-up, %: Same day: 100 6 month: 173/205 (84) Intervention group: 82/103 (80) Control Group: 91/102 (88)	Eligibility criteria: Included: Patients who were 50 years or older Reporting fluency in English or Spanish Having a telephone Having a primary care physician Excluded: Patients who were deaf Acutely ill, had dementia Had corrected visual acuity worse than 20/1 Sampling strategy: Convenience sample Sample size: 205 Intervention group: 103 Control group: 102 Age (SD): Intervention: 59.4 (8.1) Control: 61.9 (9.0) Gender, %: Female Intervention: 49.5 Control: 55.9 Race/Ethnicity, %: Intervention: White: 29.1 Hispanic: 33.0 Black: 20.4 Control: White: 21.6 Hispanic: 29.4 Black: 27.5 Income, %: Intervention: < $10,000: 43.4 Control: <$10,000: 53.5 Insurance status: NR Education, %: Intervention: College or graduate degree: 18.6 Some college: 32.4 High school: 19.6 < high school: 29.4

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Primary outcome: Acceptability of form Secondary outcomes: Knowledge of advance directive topics Proportion of advance directive completion during baseline interview Preference for form Advance directive completion at 6 months Tertiary outcomes (reported in ref #2776) Engagement in the four ACP steps: Contemplation Discussion with family or friends Discussion with physicians Documentation of plan Covariates used in multivariate analysis: For usability, age, prior history of helping another person fill out an advance directive form For knowledge: baseline knowledge For advance direction completion: cluster of parts within whole form. For DM outcomes: age, race or ethnicity, years of education Note: literacy not included as a covariate b/c education and literacy highly correlated and education more highly correlated with outcomes Description of outcome measures: Primary outcome: Acceptability: 3 domains, - 9 items scale, 8-item scale, 6-item scale Secondary outcomes: Knowledge: 12 item scale (% correct) Proportion of advance directive completion: proportion of each of 6 sections filled out Data source(s) for outcomes: Self report and review of completed forms Attempts for control for confounding: Regression models Blinding: Participants: not blinded Researchers: not blinded Statistical measures used: Bivariate analysis using x2, Fishers Exact test and t test Kuder-Richardson reliability coefficients ANCOVA Multiple linear regression Sensitivity analysis, GEE accounting for clustering (for completion of 6 parts of form)	Describe results: Intervention increased proportion of advanced directive completed and proportion completed at 6 months. It had no effect on knowledge. DM outcomes examined only post test. Effect in no exposure (i.e., adequate literacy) or control group, %: Knowledge: 71 Proportion advance directive completed: 47 Advance directive completed at 6 months: 8 DM outcomes: NR Effect in exposure (i.e., low/moderate literacy) or intervention, %: Knowledge: 72 Proportion advance directive completed: 61 Advance directive completed at 6 months: 19 Contemplation: Total 61% Limited Literacy 57% Adequate Literacy: 63% $P = 0.51$ Discussed with Family/friends: Total: 56 Limited literacy: 52 Adequate literacy: 58 $P = 0.42$ Discussed with MD: Total: 22 Limited literacy: 31 Adequate literacy: 17 $P = 0.03$ Documented Plan: Total: 13 Limited literacy: 8 Adequate ;iteracy: 15 $P = 0.20$ Difference: Knowledge (adjusted for baseline knowledge): +1%, $P = 0.30$ Proportion Advance directive completed (adjusted for clustering of parts within whole form): +11%; 95% CI, 1-21% Advance directive completed at 6 months (unadjusted): +11%, $P = 0.03$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Sudore et al., 2007[127] Sudore et al., 2008[128] Research objective: Determine whether advance directive redesigned to meet most adults' literacy needs was more useful for advance care planning than a standard form Study design: RCT Study setting: General Medicine Clinic at San Francisco General Hospital (SFGH), a public hospital affiliated with the University of California San Francisco (UCSF) Measurement period: February and July 2005 Follow-up duration: 6 months Completeness of follow-up, %: Same day: 100 6 month: 173/205 (84) Intervention group: 82/103 (80) Control Group: 91/102 (88)	Control: College or graduate degree: 14.7 Some college: 32.4 High school: 18.6 < high school: 34.3 Other characteristics, %: Religious: Intervention: 43 Control: 48 Fair/Poor Health status: Intervention: 69 Control: 69 Ever filled out an advanced directive: Intervention: 113.6 Control: 11.8 Ever helped fill out advanced directive: Intervention: 10.7 Control: 20.6 Knowledge of advanced directive (% correct): Intervention: 58.5 Control: 62.2 Health literacy/numeracy levels: Intervention: Limited literacy: 39.8 Control: limited literacy: 40.2% Measurement tools including cutpoints: s-TOFHLA: Limited literacy: <22 Adequate literacy: >22

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Sudore et al., 2006[129] Research objective: Describe modified consent process and determine whether literacy and other demographic characteristics are associated with consent information Study design: Cross-sectional descriptive study nested within a larger RCT Study setting: General Medicine Clinic at San Francisco General Hospital (public hospital) Measurement period: August 2004-December 2004 Follow-up duration: NA Completeness of follow-up: 204/208 participants (98%)	Eligibility criteria: Included: Primary care physician 50 years or older Reported speaking English or Spanish "well" or "very well" Excluded: Dementia Deaf Delirious Not well enough to complete the interview Sampling strategy: Convenience sample Sample size: 204 Age (SD): 61 (8.6) Gender: Female: 53 Race/Ethnicity, %: White/Non-Hispanic: 26 White/Hispanic: 31 Black: 24 Asian/Pacific Islander: 9 Multiethnic/Other: 10 Income, %: < $10,000: 48 Insurance status: NR Education, %: < High School: 32 High School graduate: 19 some college to graduate degree: 49 Other characteristics, %: Language most comfortable speaking: English: 62 Spanish: 29 Other: 9 US born 60 Health literacy/numeracy levels, %: Inadequate: 22 Marginal: 18 Adequate: 60 Measurement tools including cutpoints: s-TOFHLA: Inadequate: 0-16 Marginal: 17-22 Adequate: 23-36

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Primary - # of passes through the teach-to-goal consent process required to obtain consent Secondary - # of comprehension statements missed on first pass of questioning Covariates used in multivariate analysis: Literacy level Language Age Race/ethnicity Gender Income Educational attainment Place of birth (inside or outside of us) Foreign born participants # of years lived inside US Description of outcome measures: Primary - # of passes through consent process before participant answered all statements correctly (categorized as 1 pass, 2 passes, or 3 or more passes) Secondary - # of statements answered correctly on the first pass (categorized as all statements answered correctly on 1st pass, 1 statement answered incorrectly on 1st pass, or 2 or more statements answered incorrectly on 1st pass) Data source(s) for outcomes: Self-reported comprehension during consent interview Attempts for control for confounding: Yes: multivariable logistic regression models, stratified analyses by Mantel-Haenszel method Blinding: No Statistical measures used: Chi-square Fisher's exact test Multivariable ordinal logistic regression Mantel-Haenszel analysis	Describe results: Participants who had lower literacy required more passes through consent process before they demonstrated comprehension Effect in no exposure (i.e., adequate literacy) or control group, %: Adequate Literacy: 1 pass: 36.1 2 passes: 45.1 > 3 passes: 18.8 Effect in exposure (i.e., low/moderate literacy) or intervention, %: Marginal Literacy: 1 pass: 21.6 2 passes: 62.2 > 3 passes: 16.2 Inadequate Literacy: 1 pass: 11.1 2 passes: 62.2 > 3 passes: 26.7 Difference: Overall # of passes through teach to goal: 1: 28% 2: 53% 3: 20% Unadjusted *P* for literacy interaction: 0.02; 11% of those with inadequate literacy required only 1 pass whereas 36% of individuals of with adequate literacy required only 1 pass Adjusted OR for requiring more than 1 pass (for each 1-pt decrease in s-TOFHLA): 1.04 (95% CI 1.00 to 1.07) 25% more likely to require >1 pass Adjusted OR for requiring more than 1 pass (for each 1-pt decrease in s-TOFHLA): 1.04 (95% CI, 1.00-1.07) # of comprehension statements missed on first pass questioning: 0: 28% 1: 30% 2 or more: 42% Adjusted OR for missing comprehension (for each 1-pt decrease in s-TOFHLA): 1.04 (95% CI, 1.00-1.07)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Volandes et al., 2009[130] Research objective: To evaluate the effect of a video decision support tool on preferences for future medical care in older people if they develop advanced dementia, and stability of preferences after 6 weeks. Study design: RCT Study setting: Four primary care clinics affiliated with academic medical centers in Boston Measurement period: September 2007 to May 2008 Follow-up duration: 6 weeks Completeness of follow-up: 100% post intervention; 89% at 6 weeks	Eligibility criteria: Included: ≥ 65 years old English-speaking No moderate or severe dementia Excluded: NR Sampling strategy: Convenience Sample size: 200 randomized, 106 to control, 94 to intervention Age (mean and range), % (SD): 75 (8) both groups Gender, %: Female: Control: 56 Intervention: 61 Race/Ethnicity, %: Control: Black: 33 White: 67 Intervention: Black: 26 White: 74 Income, %: NR Insurance status, %: NR Education, %: Control: Elementary: 5 Some high school: 16 HS grad: 18 Some college: 18 College grad: 15 Post-grad/prof: 27 Intervention: Elementary: 6 Some high school: 17 HS grad: 18 Some college: 18 College grad: 15 Post-grad/prof: 26 Other Characteristics Diagnosis of dementia: Control: 11 Intervention: 6

Evidence Table 3. KQ2 Update search

Outcomes	Results
Main outcomes: Proportions indicating preference for comfort care Knowledge of whether advance dementia is curable, and associated with difficulty communicating, ambulating, and feeding oneself, recognize family; 0-5 scale, higher scores better Covariates used in multivariate analysis: Health literacy level, race in final model (Age, sex, education, marital status, diagnosis of dementia, previous relationship with person with advanced dementia were all place in initial model but no significant) Description of outcomes measures: Proportions indicating preference for comfort care Knowledge of whether advance dementia is curable, and associated with difficulty communicating, ambulating, and feeding oneself, recognize family; 0-5 scale, higher scores better Data source(s) for outcomes: Participant interview. Those unable to select a goal of care were considered "uncertain." Attempts for control for confounding: Randomization, adjustment for residual confounders Blinding: No Statistical measures used: Chi-square, t-test, kappa (for stability of preferences), logistic regression No accounting for natural clustering of participants in practice sites	Describe results: Participants in the video group were more likely to choose comfort care as their goal if they were to develop advanced dementia. For those with lower health literacy, intervention did not seem to affect choice, however (but those in higher health literacy group chose more comfort care). Intervention group had greater stability of preferences and knowledge. Effect in no exposure (i.e., adequate literacy) or control group, %: Chose comfort care: 64% Mean increase in knowledge score: 1.5 Effect in exposure (i.e., low/moderate literacy) or intervention: Chose comfort care: 86% Mean increase in knowledge score: 2.4 Difference, %: Overall unadjusted difference in comfort care: 22% (95% CI 11% to 34%) Overall adjusted OR for comfort care: aOR 3.9 (1.8-8.6) By HL group: Unadjusted differences in preferences for comfort care: ≤ 6th grade HL: ref 7th-8th grade HL: 13% (-13 to 38%) ≥ 9th grade HL: 39% (21% to 56%) Adjusted OR for preference for comfort care: ≤ 6th grade HL: ref 7th-8th grade HL: aOR 1.7 (0.54-5.3) ≥ 9th grade HL: aOR 4.1 (1.6-10.8) Difference in mean knowledge increases: +0.9, $P < 0.001$

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Characteristics	Participant Characteristics
Author, year: Volandes et al., 2009[130] (continued)	Previous relationship with person with advanced dementia: Control: 10 Intervention: 19

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Walker et al., 2007[79] Research objective: Intervention: Determine effectiveness of pictorial 'mind map' together with Arthritis Research Campaign (ARC) booklet for imparting knowledge to participants with rheumatoid arthritis, and relate this to participant reading ability Health outcome: Investigate relationship between anxiety/depression and HL Study design: RCT Study setting: Participants recruited in 3 hospital Rheumatology departments in UK. Measurement period: NR Follow-up duration: 1 week Completeness of follow-up: NR	Eligibility criteria: Included: Patients diagnosed by Rheumatologist as having rheumatoid arthritis and willing to take part in study Excluded: NR Sampling strategy: Convenience sample Sample size: N = 363 Intervention, n = 175 Control, n = 188 Age (SD): Intervention: 61.96 (12.23) Control: 61.57 (11.64) Gender, %: Female: Overall: 70.5 Intervention: 71.4 Control: 69.7 Race/Ethnicity: NR Income: NR Insurance status: NR Education, %: HS or equiv: 85 7th–8th: apprx. 11 < 7th: <4 *NR by intervention group Other characteristics: Disease duration, Mean (SD) Intervention: 13.7 (10.27) Control: 12.76 (10.85) English is 1st language: 97 *NR by intervention group Health literacy/numeracy levels: Overall REALM < 60: 15% REALM < 45: 4% REALM score, Mean (SD) Intervention: 62.26 (9.12) Control: 63.28 (7.96)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Knowledge Scale Questionnaire (KSQ) Anxiety Depression Covariates used in multivariate analysis: None Description of outcome measures: KSQ: The KSQ was adapted from an existing rheumatoid arthritis knowledge questionnaire for use in clinical settings. Eight sections comprised 40, true/false statements. The scoring system was +1 if correct, 0 if not completed or don't know, and -1 if incorrect. Possible scores ranged from -40 to +40. KSQ administered pre-intervention and post-intervention by telephone. Depression and Anxiety: Patients performed the Hospital Anxiety and Depression scale (HAQ and HAD) See Zigmond Acta Psychiatr Scand 1983; 67: 361-70. See Fries. Arthrit Rheum 1980; 23: 137-45. Data source(s) for outcomes: KSQ: pre-intervention, not clear if administered as a written survey or interview; post-intervention, interviewed by telephone HAQ/HAD: it isn't clear if administered as a written survey or interview. Attempts for control for confounding: Randomization ANOVA Blinding: NR Statistical measures used: Mann-Whitney U test used to compare mean increases in knowledge between intervention and control groups. Univariate analysis of variance with difference between KSQ scores as dependent variable and REALM score, age, intervention group, depression	Describe results: There was statistically significant difference in knowledge gained between participants who received mind map and booklet and those who received booklet only. People with higher REALM scores gained more knowledge, regardless of whether they were in intervention or control. Poor readers were significantly more anxious and more depressed than good readers. Effect in no exposure (i.e., adequate literacy) or control group, mean (CI): KQ2 (Control group) Increase in knowledge, 6.56 (3.36 - 8.75) KQ1 (good reader)* Depression: 6.5 (5.9-7.0)* Anxiety: 7.7 (7.1-8.2)* *read from a figure Effect in exposure (i.e., low/moderate literacy) or intervention: KQ2 (Intervention group): Increase in knowledge: 6.45 (3.78 – 10) KQ1 (poor reader)* Depression: 8.1 (6.8-9.5)* Anxiety: 9.4 (7.9-10.8)* *read from a figure Difference: Overall: -0.11, (unadjusted *P* > 0.3) Note: REALM score predicts change in knowledge, (adjusted *P* < 0.003)

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Walker et al., 2007[79] (continued)	Measurement tools including cutpoints: For the intervention: REALM as a continuous variable For the health outcomes of Depression and Anxiety: REALM >=60: good readers REALM < 60: poor readers

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Wallace et al., 2009[131] Research objective: Wallace: Evaluate impact of providing patients with literacy-appropriate diabetes education guide accompanied by brief counseling designed for use in primary care. Study design: Pilot study; one group pretest and posttest design Study setting: 3 academic internal medicine practices in CA, LA, NC Measurement period: August 2006 to June2007 Follow-up duration: 2, 4, and 12-16 weeks Completeness of follow-up: 230/250 (92%)	Eligibility criteria: Included: English & Spanish speaking patients >18 years Diagnosis of type 2 diabetes Contactable by phone Excluded: People who were not responsible for or capable of managing their own diabetes care (e.g., residents of skilled nursing facilities, those with significant cognitive impairments) Sampling strategy: All Spanish-speaking patients were recruited from the CA site. Patients were referred to the study by their health care providers Sample size: 250 Age, years (range): 56 (29-93) Gender, % (n): Female: 65 (162/250) Race/Ethnicity, %: African American: 45 Hispanic: 33 Caucasian: 22 Income: NR Insurance status, %: Self-pay: 48 Medicaid: 26 Medicare: 23 Private: 16 Education, %: <HS: 44 HS: 34 Some college: 15 > College: 7 Other characteristics, %: Diagnosed with diabetes: 9 years (range 0-35) Last A1C: 8.6 (CI: 4.2-16.8) BMI: 34.7 (CI: 12.9-73.4) Takes insulin: 44 Self-monitor glucose: 84 Has regular MD: 63 Hospitalized in past year: 29 Health literacy/numeracy levels, %: Adequate: 57 Marginal: 14 Inadequate: 29

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Wallace: Activation, self-efficacy, diabetes distress, self-care, diabetes-related knowledge Covariates used in multivariate analysis: None Description of outcome measures: Activation, self-efficacy, diabetes distress, self care: All measured with 4 orally administered instruments. All were validated scales providing Likert-type responses. Higher scores indicated better activation and self-efficacy, greater distress, and improved diabetes self-care behaviors. Activation: Used the PAM self-efficacy: Assessed diabetes self-efficacy using an 8-item measure asking respondents to rate their confidence in their ability to perform individual diabetes self-care activities, such as monitoring their blood glucose, getting medical attention, and taking care of their health diabetes distress Assessed using the DDS self-care: Assessed using a 5-item scale asking participants to rate their ability to manage their medications, monitor their blood glucose, maintain a diet, exercise, and conduct foot care Diabetes-related knowledge: Assessed with a 9-item instrument developed by authors to reflect guide's content. Data source(s) for outcomes: Self-reported Attempts for control for confounding: None Blinding: No Statistical measures used: Descriptive statistics: Independent t-tests and chi-square tests, paired t-tests. Change scores were also calculated for each outcome measure and were used to calculate standardized effect sizes (mean of change scores/SD of change scores) and to conduct analyses by literacy (adequate vs. inadequate/marginal) and language (English vs. Spanish). Differences in mean change scores by literacy and language were assessed using independent t-tests	Describe results: Both adequate and low/marginal literacy groups showed similar improvements for activation, self-efficacy, knowledge and self care, no SS differences between the 2 groups. Both adequate and low/marginal literacy groups showed similar reduction for total distress, but no SS differences between the 2 groups. Effect in no exposure (i.e., adequate literacy) or control group: % Knowledge questions correct: 56.78 Mean Diabetes Self-care Self-efficacy: 73.62 Effect in exposure (i.e., low/moderate literacy) or intervention: % Knowledge questions correct: 62.94 Mean Diabetes Self-Care Self-efficacy: 77.91 Difference: Overall Difference: Activation: +4.93, $P < 0.001$ Self-efficacy (unadjusted): +4.29, $P < 0.001$ Adequate literacy subgroup (unadjusted): 4.8, NR Inadequate literacy subgroup (unadjusted): +3.67, NR Unadjusted p for interaction by literacy subgroup: 0.29 Total distress: -5.25, $P < 0.001$ Knowledge: +6.16, $P < 0.001$ Self-care: +5.62, $P < 0.001$ Difference in Adequate literacy subgroup: Activation mean change: +4.6, NR Self-efficacy mean change: +4.8, NR Total distress mean change: -6.12, NR Knowledge mean change: +6.94%, NR Self-care mean change: +5.97, NR Difference in marginal/Inadequate literacy subgroup: Activation mean change: +5.34, NR Self-efficacy mean change: +3.67, NR Total distress mean change: -4.19, NR Knowledge mean change: +5.21%, NR Self-care mean change: +5.22, NR Note: no overall difference by literacy subgroups, p for interaction >0.05 in all cases

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Wallace et al., 2009[131] (continued)	Measurement tools including cutpoints: s-TOFHLA 0-36 scale 23-36: adequate literacy 17-22: marginal literacy 0-16: inadequate literacy Inadequate and marginal = lower literacy Adequate= Higher literacy

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Weiss et al., 2006[132] Research objective: Determine whether literacy education, provided along with standard depression treatment to adults with depression and limited literacy, would result in greater improvement in depression than would standard depression treatment alone Study design: RCT Study setting: Community health center Measurement period: NR Follow-up duration: 6-12 months Completeness of follow-up, %: Intervention: 33/38 (87) Control: 28/32 (88)	Eligibility criteria: Included: Scored positive on the PHQ-9 Limited literacy skills on REALM (score <60) Age > 18 Presentation to health center for something other than acute life-threatening emergency Excluded: Unable to communicate and converse meaningfully with project staff in English Currently under treatment for depression Diagnosis of dementia or other neuropsychiatric disorder Sampling strategy: Convenience sample Sample size: Intervention: 38 Control: 32 Age, mean (SD): Intervention: 41.4 (14.3) Control: 43.7 (15.3) Gender, %: Female: Intervention: 42.1 Control: 46.9 Race/Ethnicity, %: Intervention: White: 97.4 Hispanic: 2.6 Native American: 0 Control: White: 87.5 Hispanic: 6.3 Native American: 6.3 Income: NR Insurance status, %: Intervention: Medicaid/self-pay: 50 Medicare: 44.7 Private: 2.6 Other: 2.6 Control: Medicaid/self-pay: 59.4 Medicare: 37.5 Private: 3.1 Other: 0 Education: NR

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Depression severity: measured by PHQ-9 Literacy: measured by REALM Covariates used in multivariate analysis: NA Description of outcome measures: Depression severity: score on Patient Health Questionnaire (9 Question Version) health literacy: score on REALM Data source(s) for outcomes: Self report Chart reviews done to determine rates of counseling and treatment prescribed by physicians Attempts for control for confounding: Randomization Blinding: Report outcome assessor was blinded, but this is in question since REALM only administered to those in intervention group at f/u. Statistical measures used: Wilcoxon signed-rank test, 1-tailed Mann Whitney test, Spearman's correlation coefficients, Pearson's Chi square, Fisher's exact test, 2-tailed t tests Not ITT, b/c exclude people who didn't attend first f/u.	Describe results: Depression severity: individuals in the intervention group had significantly lower depression severity scores at the second and third follow-up measurements Health literacy: individuals in the intervention group had significantly higher literacy scores by the final follow-up measurement Effect in no exposure (i.e., adequate literacy) or control group: Depression severity: 1st follow-up: 8* 2nd follow-up: 9* 3rd follow-up: 10* Literacy score: NR *read from graph (Figure 2) Effect in exposure (i.e., low/moderate literacy) or intervention: Depression severity: 1st follow-up: 8* 2nd follow-up: 6* 3rd follow-up: 6* Literacy score: NR *read from graph (Figure 2) Difference: Absolute difference in PHQ (unadjusted): 1st follow-up: 0, $P = 0.25$ 2nd follow-up: -3, $P = 0.03$ 3rd follow-up: -4, $P = 0.04$ Note: baseline PHQ 9 1.5 pts higher in control group Literacy score: REALM score increased by a mean of 7 points from baseline to final follow-up in the intervention group ($P = 0.001$); NR for control group

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Weiss et al., 2006[132] (continued)	Other characteristics, %: Occupation Intervention: Employed (unskilled worker): 23.6 Small business owner: 0 Unemployed: 76.4 Control: Employed (unskilled worker): 28.0 Small business owner: 3.1 Unemployed: 68.9 Median PHQ9 scores: Intervention: 12.5 Control: 14 Health literacy/numeracy levels, mean (SD): Intervention: mean: 46.5 (11.9) Control: mean: 47.1 (15.9) Measurement tools including cutpoints: REALM - 0-18 19-44 45-60

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Wright et al., 2009[133] Research objective: Determine whether low numeracy participants would better understand risks presented using grouped dot or dispersed dot displays Study design: RCT Study setting: Internet survey in UK Measurement period: NR Follow-up duration: Immediate Completeness of follow-up: 140/140 (100%)	Eligibility criteria: Included: Registered with market research agency for internet surveys Smoker No history of Crohn's disease Excluded: NR Sampling strategy: Convenience sample Sample size: 140 Age, mean (SD): 44.3 (13.5) Gender: Female: 56.4 Race/Ethnicity: NR Income: NR Insurance status: NR Education, %: No formal educational qualifications: 8.6 Educational qualifications completed at age 16 (GCSEs/O Levels): 27.9 Educational qualifications completed at age 18 (A Levels): 24.3 University degree: 32.9 Other characteristics, mean: Nicotine dependence (HSI): 2.6. Health literacy/numeracy levels, %: Low: 41 (incorrect answer to 1st question on Lipkus numeracy scale) Measurement tools including cutpoints: Numeracy: eight question scale developed by Lipkus and colleagues (2001) because of psychometric properties (high variance, good item-total correlation, highest difficulty, high discrimination), the first item on the scale (biggest number: 1/10, 1/100, 1/1000) was used to distinguish between high and low numeracy participants (correct answer: high numeracy, incorrect answer: low numeracy); this is a nonvalidated approach

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Objective: risk comprehension also (although not of interest to this review): Subjective ease of understanding Perceived susceptibility to disease worry Covariates used in multivariate analysis: NR except interaction term for numeracy Description of outcome measures: Objective risk comprehension: assessed by asking participants "Which of the three sets of risk figures you were given was the biggest risk and which was the smallest risk" Subjective ease of understanding: assessed by asking participants "How easy did you find it to understand the information we gave you about the chances of developing Crohn's disease" (rated 1'very difficult' - 7 'very easy') Perceived susceptibility to disease: assessed with three items reflecting different aspects of susceptibility Susceptibility conditional on continued smoking Susceptibility conditional on quitting smoking Susceptibility relative to other smokers Worry: assessed by single item "how worried are you about getting Crohn's disease?" (rated 1: not at all to 7: extremely) Data source(s) for outcomes: Patient-completed internet survey Attempts for control for confounding: ANOVA ; logistic regression Blinding: NR Statistical measures used: ANOVA, logistic regression used interaction term for numeracy	Describe results: Participants with higher numeracy had significantly higher objective risk comprehension than participants with lower numeracy; display type (dispersed vs. grouped dots) did not moderate the effect Effect in no exposure (i.e., adequate literacy) or control group, %: Objective risk comprehension: Higher numeracy grouped display: 80.5 correct Lower numeracy grouped display: 51.9 correct Effect in exposure (i.e., low/moderate literacy) or intervention: Objective risk comprehension by display type: Higher numeracy: dispersed display - 82.9 correct Lower numeracy: dispersed display - 32.3 correct Difference, OR (CI): Grouped vs. dispersed dot icon arrays, adjusted OR comprehension: 2.26 (95% CI, 0.779 to 6.57) Comprehension with grouped dot icon array (unadjusted OR high vs. low numeracy): 3.830 (95% CI, 1.301-11.280; *P* = 0.015) Comprehension with dispersed dot icon array (unadjusted OR high vs. low numeracy): 10.2 (95% CI, NR) Dispersed vs. grouped format: 0.442 (0.152 to 1.284) Interaction term (display by numracy): NS

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Yates and Pena, 2006[134] Research objective: Assess differences in comprehension between standard and simplified head injury advice sheets Study design: RCT Study setting: Urban emergency department in New Zealand Measurement period: August 2003-December 2003 Follow-up duration: Immediate Completeness of follow-up: 200/200 (100%)	Eligibility criteria: Included: Aged 15 or more Presenting during "study shifts", a mixture of days, afternoons, and weekends Excluded: Unable to comprehend spoken or written English Severe illness or pain Triaged as needing to be seen immediately Significant eye condition or complaint Corrected visual acuity < font size 10 Sampling strategy: Convenience sample Sample size: 200 (100 intervention and 100 comparison) Age (mean and range): Intervention: 45 Control: 42 Gender, %: Female: Intervention: 48 Control: 58 Race/Ethnicity, %: New Zealand/European Intervention: 79 Control: 67 Income: NR Insurance status: NR Education: >12 years Intervention: 59 Control: 66 Other characteristics: NA Health literacy/numeracy levels, %: < 3rd grade: 0.5* 4th-6th grade: 1* 7th-8th grade: 14* > 9th grade: 84.5* Intervention: > 9th grade: 86 Control: > 9th grade 83 *Calculated by team using info from Figure 5

Evidence Table 3. Key Question 2: Intervention studies (continued)

Outcomes	Results
Main outcomes: Primary: comprehension score for advice sheet Secondary: health literacy level, demographic factors and form preference Covariates used in multivariate analysis: Gender Age Years of schooling Ethnicity Description of outcome measures: Comprehension score: score on a 10-item comprehension assessment Data source(s) for outcomes: Participant provided answers during interview with researcher Attempts for control for confounding: Yes: multivariate logistic regression (although text and table 2 are not entirely clear) Blinding: NR Statistical measures used: Mann-Whitney, logistic regression	Describe results: Simplified advice form yielded significantly higher comprehension scores. (Authors report no differences between different REALM groups, stating "whatever the REALM group, the simplified form improved comprehension scores.") Participants with REALM score > 9th grade had significantly higher comprehension scores than those with score < 9th grade. Effect in no exposure (i.e., adequate literacy) or control group, %: Median: 9 correct 10 correct: 41 9 correct: 37 <9 correct: 22 Effect in exposure (i.e., low/moderate literacy) or intervention: Median: 10 correct 10 correct: 73 9 correct: 18 <9 correct: 9 Difference, mean (CI): Median score: +1 correct (unadjusted): $P < 0.0001$ Adjusted OR comprehension (simplified versus std): 4.14 (2.19-7.81) OR comprehension (> 9th grade/< 9th grade): 2.91 (1.16-7.25) No interaction of comprehension of form by literacy level

Evidence Table 3. Key Question 2: Intervention studies (continued)

Study Description	Participant Characteristics
Author, year: Yates and Pena, 2006[134] (continued)	Measurement tools including cutpoints: REALM - < 3rd grade 4th-6th grade 7th-8th grade > 9th grade

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Appendix E. Characteristics of Studies with Poor Internal Validity

To assess the quality (internal validity or risk of bias) of studies, we used predefined criteria based on those described in the AHRQ Methods Guide for Comparative Effectiveness Reviews (ratings: good, fair, poor).[1] Elements of quality assessment for trials included, among others, the methods used for randomization, allocation concealment, and blinding; the similarity of compared groups at baseline; maintenance of comparable groups; overall and differential loss to followup; and the use of intention-to-treat analysis. We assessed observational studies based on the potential for selection bias (methods of selection of subjects and loss to followup), potential for measurement bias (equality, validity, and reliability of ascertainment of outcomes), adjustment for potential confounders, and statistical analysis.

In general terms, a “good” study has the least bias and results are considered to be valid. A “fair” study is susceptible to some bias but probably not sufficient to invalidate its results. The fair-quality category is likely to be broad, so studies with this rating will vary in their strengths and weaknesses. A “poor” rating indicates significant bias (stemming from, e.g., serious errors in design, analysis reporting large amounts of missing information, or discrepancies in reporting) that may invalidate the study’s results.

To systematically rate studies, we designed and used a structured data abstraction form. Trained reviewers abstracted data from each study and assigned an initial quality rating. A second reviewer read each abstracted article, evaluated the accuracy, completeness, and consistency of the data abstraction, and independently rated the quality. If differences in quality ratings could not be resolved by discussion, a third senior reviewer was involved. The full research team met regularly during the article abstraction period to discuss global issues related to the data abstraction process. The following lists all the studies reviewed and rated as poor quality, with their design and primary reasons for the final rating.

Study	Design	Primary Reasons for Poor-Quality Rating
Arozullah et al., 2006[2]	Cross-sectional	High potential for selection biases. A convenience sample with a low participation rate was used.
Bennett et al., 2006[3]	Retrospective cohort	High potential for selection and confounding biases. A convenience sample with no power calculation was used and there was no controlling for confounding in the analysis.
Bickmore et al., 2009[4]	RCT	High potential for selection and measurement bias. The process of randomization was inadequate, there was no allocation concealment, groups were not comparable at baseline, and there was inadequate controlling for confounding in the analysis.
Brock et al., 2007[5]	Uncontrolled experimental study (pre/post test)	This study received a fair rating for immediate outcomes but a poor rating for follow-up outcomes. There was a high risk for selection and confounding bias at followup due to high likelihood that the groups were no longer comparable and inadequate controlling for potential confounders in the analysis.
Campbell et al., 2007[6]	Cross-sectional	High potential for confounding and selection biases. A convenience sample was used.
Carbone et al., 2006[7]	Cross-sectional	High potential for measurement bias. Outcome measures were poorly described and could not be considered valid and reliable.
Clarke et al., 2005[8]	Cross-sectional	High potential for selection bias. Reporting of measures and statistical methods was inadequate. Important potential confounders were not considered.

Study	Design	Primary Reasons for Poor-Quality Rating
Conwell et al., 2003[9]	Cross-sectional	High risk for confounding bias: race, socioeconomic status, parental smoking status, behavioral status, or any other potential confounder, could be responsible for association between WRAT score and smoking status.
Cordasco et al., 2009[10]	RCT	False inclusions and attrition-introduced selection bias and residual confounding that was not controlled for in analysis.
DeWalt et al., 2007[11]	Cross-sectional	High potential for selection and confounding biases. A convenience sample with no power calculation was used and there was no controlling for confounding in the analysis.
DeWalt et al., 2009[12]	Uncontrolled experimental study (pre/post test)	High risk of measurement bias due to social desirability. There was also inadequate controlling for confounding in the analysis.
DeWalt et al., 2004[13]	Uncontrolled experimental study (pre/post test)	High risk of measurement and confounding bias. The lack of a control group carries a significant risk that any improvement in clinical symptoms was due to a Hawthorne effect or the use of cointerventions.
Donelle et al., 2008[14]	Cross-sectional	Literacy/numeracy groups very likely to be different and only age/gender controlled for as potential confounders. Furthermore, comprehension questions were nonvalidated and not clearly appropriate.
Drainoni et al., 2008[15]	Cross-sectional	High potential for measurement, selection, and confounding biases. Outcome measures were poorly described and could not be considered valid and reliable. A convenience sample with no power calculation was used and there was no controlling for confounding in the analysis.
Endres et al., 2004[16]	Cross-sectional	High potential for selection and confounding biases. A small convenience sample was used and there was no controlling for important potential confounders in the analysis.
Garcia-Retamero and Galesic, 2009[17]	Factorial RCT	This study received a fair rating for main effect but a poor rating for subgroup analyses, with no presentation of baseline characteristics by group. There was no control of potential confounders if participants exited, making selection and confounding major issues.
Garcia-Retamero and Galesic, 2010[18]	RCT	Lack of adequate reporting about study, unclear what the study design is for between-group comparisons, unclear sample size and baseline numeracy/graphical literacy. No control for confounding in between-group analyses and subgroup analyses (although not clear whether needed for main group analyses).
Gazmararian et al., 2010[19]	Nonrandomized trial	Nonrandomized trial with no baseline differences and no control for confounding. Additionally, the author stated that the trial was underpowered, but it is not clear for what difference/outcomes.
Ginde et al., 2008[20]	Cross-sectional	High potential for measurement and confounding biases. Outcome measures were poorly described and could not be considered valid and reliable. There was no controlling for important potential confounders in the analysis.
Ives et al., 2006[21]	Prospective cohort	High potential for confounding bias. Bivariate analysis was used with no controlling for important potential confounders in the analysis.
Jones et al., 2007[22]	Cross-sectional	High potential for measurement, selection, and confounding biases. Outcome measures were poorly described and could not be considered valid and reliable. A convenience sample with no power calculation was used and there was no controlling for confounding in the analysis.
Juzych et al., 2008[23]	Cross-sectional	High potential for confounding bias. Bivariate analysis was used with no controlling for important potential confounders in the analysis.
Kalichman et al., 2005[24]	Uncontrolled experimental study (pre/post test)	High risk of measurement and confounding bias due to social desirability and inadequate controlling for confounding in the analysis.
Kandula et al., 2009[25]	Cross-sectional; prospective cohort	High potential for measurement bias. Outcome measures were poorly described and could not be considered valid and reliable.

Study	Design	Primary Reasons for Poor-Quality Rating
Kleinpeter, 2003[26]	Cross-sectional	High potential for selection and confounding biases. A small convenience sample was used and there was no controlling for important potential confounders in the analysis.
Lincoln et al., 2008[27]	Cross-sectional	High potential for selection biases A small convenience sample was used and participation rate was low.
Mbaezue et al., 2010[28]	Cross-sectional	High potential for measurement and selection bias. Descriptive data in tables do not add to the total sample. A portion of the sample population that did not check its glucose was omitted, causing the multivariate model to be misspecified.
Morrow et al., 2006[29]	Cross-sectional	High potential for selection and confounding bias. Health outcome measure poorly described.
Muir et al., 2006[30]	Retrospective cohort	High potential for confounding bias. Bivariate analysis was used with no controlling for important potential confounders in the analysis.
Ntri et al., 2009[31]	Uncontrolled experimental study (pre/post test)	High potential for confounding and selection biases. There was no controlling for potential confounders in the analysis and no accounting for those lost to followup. A small convenience sample was used.
Persell et al., 2007[32]	Cross-sectional	High potential for confounding biases. There was no controlling for important potential confounders in the analysis.
Roth et al., 2005[33]	Cross-sectional	High potential for selection and confounding biases. A small convenience sample was used and there was no controlling for important potential confounders in the analysis.
Rutherford et al., 2006[34]	Cross-sectional	High potential for measurement and confounding biases. Outcome measures were poorly described and could not be considered valid and reliable. There was inadequate controlling for important potential confounders in the analysis.
Sanders et al., 2007[35]	Retrospective cohort	High potential for measurement bias. Outcome measures were poorly described and could not be considered valid and reliable.
Sarkar et al., 2006[36]	Cross-sectional	High potential for confounding biases. A convenience sample was used and there was inadequate controlling for important potential confounders in the analysis.
Sentell et al., 2003[37]	Cross-sectional	High potential for measurement and confounding biases. The outcome was measured by a single-item, self-reported survey question and there was inadequate controlling for important potential confounders in the analysis because only the bivariate analyses were relevant to the outcome of interest for this report.
Shieh et al., 2009[38]	Cross-sectional	High potential for confounding and measurement bias. Inadequate control for confounding and the outcome measure could not be considered valid and reliable.
van Servellen et al., 2003 & 2005[39,40]	RCT	High potential for measurement and confounding biases. Inadequate reporting. Important potential confounders and multiple comparisons were not considered in the analysis and the analysis was within not between groups.
Waldrop-Valverde et al., 2008[41]	Cross-sectional	High potential for measurement and selection biases. The sample was divided into literacy/cognition groups so the independent effect of literacy on adherence could not be determined.
Wallace et al., 2008[42]	Cross-sectional	High potential for confounding bias. Bivariate analysis was used with no controlling for important potential confounders in the analysis.
Wolf et al., 2004[43]	Cross-sectional	High potential for measurement and confounding biases. Outcome measures were poorly described and could not be considered valid and reliable. There was inadequate controlling for important potential confounders in the analysis.
Wolf et al., 2007[44]	Cross-sectional	High potential for measurement and confounding biases. Outcome measures were poorly described and could not be considered valid and reliable. There was inadequate controlling for important potential confounders in the analysis.

RCT= Randomized controlled Trial

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Appendix F. Strength of Evidence

KQ 1. Health literacy strength of evidence grade by domain and overall summary grade

Outcome for Health Literacy Studies	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
Hospitalization	6	Low literacy associated with increased hospitalization	Medium	Consistent	Direct	Precise	Moderate
Emergency Care Visit	9	Low literacy associated with greater emergency care use except in one study of urgent care visits (measured by self-report)	Medium	Consistent	Direct	Imprecise	Moderate
Colon Screening	5	Larger studies found lower probability of screening	Medium	Inconsistent	Direct	Imprecise	Low
Pap Smears	3	Low literacy associated with decreased probability of ever having a Pap smear	Medium	Inconsistent	Direct	Imprecise	Low
Mammogram	4	Low literacy associated with less use of mammography; measures and populations differed across studies	Medium	Consistent	Direct	Imprecise	Moderate
Sexually Transmitted Infection	1	Low literacy associated with greater odds of accepting HIV testing	Medium	Not Applicable	Direct	Precise	Low
Immunization: Influenza	4	Low literacy associated with lower probability of receipt of influenza vaccine	Medium	Consistent	Direct	Precise	Moderate
Immunization: Pneumococcal	2	Mixed results	Medium	Not Applicable	Direct	Imprecise	Insufficient
Access to Care	9	Mixed results for association with number of physician visits, dental and vision visits.	Medium	Inconsistent	Direct	Imprecise	Insufficient
Access to Insurance	1	Parental low literacy associated with having child without health insurance	Medium	Not Applicable	Direct	Precise	Low

HIV=human immunodeficiency virus; HL=health literacy; Pap=Papanicolau; PSA=prostate-specific antigen

KQ 1. Health Literacy strength of evidence grade by domain and overall summary grade (continued)

Outcome for Health Literacy Studies	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
Adherence	11	Mixed results depending on adherence measure, disease state, and adjustment for confounding	Medium	Inconsistent	Direct	Imprecise	Insufficient
Self-Efficacy	5	Mixed results in studies conducted within various sub-populations	Medium	Inconsistent	Direct	Imprecise	Insufficient
Smoking	2	Mixed results	Medium	Inconsistent	Direct	Imprecise	Insufficient
Drug and Alcohol Use	2	No effect on current alcohol consumption, higher health literacy associated with greater substance use in one study.	Medium	Inconsistent	Direct	Imprecise	Insufficient
Healthy Lifestyle (Physical Activity, Eating Habits, and Seat Belt Use)	3	Mixed results from 1 study each on exercise, diet, a composite measure, and seatbelt use	Medium	Inconsistent	Direct	Imprecise	Insufficient
Healthy Lifestyle (Obesity and Weight)	5	Mixed results,4 of 5 studies unadjusted	High	Inconsistent	Direct	Imprecise	Insufficient
Review of Prescription Information	1	Low health literacy associated with being less likely to read prescription information	Medium	Not Applicable	Direct	Precise	Low
HIV Risk and Sexual Behaviors	2	Mixed results	Medium	Inconsistent	Direct	Imprecise	Insufficient
Taking Medications Appropriately	6	Lower health literacy associated with poorer ability to demonstrate being able to take mediations appropriately	Medium	Consistent	Direct	Imprecise	Moderate
Interpreting Labels and Health Messages	3	Low literacy associated with poorer ability to interpret labels and health messages; smaller likelihood of giving an organized health narrative	Medium	Consistent	Direct	Precise	Moderate
Asthma Self-Care	1	Low literacy associated with poorer self-care skill in 1 study	Medium	Not Applicable	Direct	Imprecise	Low
Mental Health Symptomatology	10	Results in 8 of 10 studies found association between lower literacy and depression but control for confounding was limited	Medium	Consistent	Direct	Imprecise	Low
Chronic Disease Outcomes	7	Mixed results: 3 studies on association with chronic diseases generally and 4 on	Medium	Inconsistent	Direct	Imprecise	Insufficient

Outcome for Health Literacy Studies	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
		association with specific diseases					
HIV Severity and Symptoms	5	Results in 3 studies found no relationship but control for confounding was limited and sample sizes were small	Medium	Consistent	Direct	Imprecise	Low
Asthma Severity and Control	2	Mixed results; only unadjusted analysis of asthma control	High	Inconsistent	Direct	Imprecise	Insufficient
Diabetes Control and Related Symptoms	5	Glycemic control: 5 studies mixed results Complications: 1 study no relationship	Medium	Inconsistent	Direct	Imprecise	Insufficient
Hypertension Control	2	Mixed results	Medium	Inconsistent	Direct	Imprecise	Insufficient
Prostate Cancer Control	1	Patients with low HL more likely to have higher PSA (worse levels)	Medium	Not Applicable	Direct	Precise	Low
Health Status: All Adults	1	No relationship with global health status	Medium	Not Applicable	Direct	Precise	Low
Health Status and Quality of Life: Seniors	5	Lower health literacy associated with lower overall health status Mental and Physical functioning: mixed results	Overall: Moderate Mental/ Physical: moderate	Overall: Consistent Mental/ Physical: inconsistent	Direct	Overall: Precise Mental/ Physical: Imprecise	Overall: Moderate Mental/ Physical: Insufficient
Health Status and Quality of Life: Individuals with Specific Diseases	5	Mental and physical functioning by disease state and measure: mixed results	Medium	Inconsistent	Direct	Imprecise	Insufficient
Mortality: Seniors	2	Higher risk of mortality in the lower literacy group. Risk not elevated in the marginal literacy group (1study)	Low	Consistent	Direct	Precise	High
Costs of Health Care	2	Results mixed across payment source and patient populations	Medium	Inconsistent	Direct	Imprecise	Insufficient
Disparities	8	Health literacy mediates disparities in some specific health outcomes between black and white race but results were mixed. Health literacy not found to mediate the relationship between Hispanic and white race or males and females but little data available.	Black/ White and Health Outcome: Moderate Hispanic: Low Sex: Low	Black/White: Inconsistent Hispanic: Not Applicable Sex: Not Applicable	Black/White : Direct Hispanic: Direct Sex: Direct	Black/White :Precise Hispanic: Precise Sex: Precise	Black/ White: Low Hispanic: Insufficient Sex: Insufficient

HIV=human immunodeficiency virus; HL=health literacy; PSA=prostate-specific antigen

KQ1. Numeracy strength of evidence grade by domain and overall summary grade

Outcome	Number of Studies	Results	Risk of Bias	Domain: Risk of Bias	Domain: Directness	Domain: Precision	Overall Grade
Accuracy of Risk Perception	5	Perceived risk (n = 2): mixed results depending on length over which risk estimated Perceived treatment benefit (n = 4): Mixed results depending on numeracy level categories, 3 of 4 studies suggested low numeracy reduced accuracy of perceived benefit.	Medium	Inconsistent	Direct	Imprecise	Insufficient
Knowledge	4	Mixed results, partially dependent on type of knowledge, sample size, and adjustment for confounding	Medium	Inconsistent	Direct	Imprecise	Insufficient
Self Efficacy	1	Lower numeracy associated with lower self-efficacy in unadjusted analysis	High	Not Applicable	Direct	Precise	Insufficient
Behavior	1	Lower numeracy not related to self-care behavior in unadjusted analysis	High	Not Applicable	Direct	Precise	Insufficient
Skills	6	Mixed results depending on type of skill Skill in taking medication (n = 4): mixed results Skill in interpreting health information (n = 2): Lower numeracy related to lower comprehension	Skill in taking medication: Medium Skill in interpreting health information: Medium	Skill in taking medication: inconsistent Skill in interpreting health information: consistent	Skill in taking medication: Direct Skill in interpreting health information: Direct	Skill in taking medication: Imprecise Skill in interpreting health information: Precise	Skill in taking medication: Insufficient Skill in interpreting health information: Low
Disease Prevalence and Severity	3	BMI (n = 2), HbA1c (n = 1), illness requiring dietary restriction (n = 1): Mixed results	Medium	Inconsistent	Direct	Imprecise	Insufficient
Use of Healthcare Services	1	Mixed results, no adjustment for confounding	High	Inconsistent	Direct	Imprecise	Insufficient
Disparities	2	Numeracy appears to partially mediate the relationship between race and HgbA1c (n = 1) and between gender and HIV medication management capacity (n = 1)	Medium	Consistent	Direct	Imprecise	Low

BMI=body mass index; HbA1c=glycosylated hemoglobin; HIV=human immunodeficiency virus

KQ 2 specific interventions, strength of evidence grade by domain and overall summary grade

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
Alternative Document Design	2 RCTs examining multiple simplific-ations	Highlighting common quality features (n=1): No effect Providing a framework for quality features (i.e. chunking advantages and disadvantages; n=1): improved comprehension for high literacy, worsened comprehension for low literacy if long rather than short list of features Presenting only essential quality info (i.e. death rates, not satisfaction) (n=1): Improved comprehension and choice of higher quality plans Presenting essential quality info first (n=1): Improved comprehension for low literacy only. No effect on health plan choice.	Medium	Not Applicable	Direct	Imprecise	Insuf-ficient
Alternative Numerical Presentation	3 RCTs examining different numerical presentations	Presenting quality information such that the higher number (vs. lower number) is better: Improved comprehension and choices of higher quality options for low (but not high) numeracy individuals Presenting information about the baseline risk of disease and treatment benefit information with the same versus different numbers: Improved accuracy of risk perception with greater effect in low versus high numeracy group	Medium	Consistent	Direct	Imprecise	Low

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
		Presenting positive predictive values as natural frequencies rather than conditional probabilities: improved comprehension equally for low and high literacy individuals					
Alternative Pictorial Represen-tations	6 RCTs and 2 quasi-experimental studies examining (1) adding symbols to numerical information, (2) adding icon arrays to numbers, (3) adding illustrations to prose, (4) using different pictorial represent-tations for same concept	Adding symbols to numerical info (n=2): Mixed effects depending on the symbols and the information to which they were added. Plus/minus signs to indicate fewer/more had no overall effect, although there was an interaction by whether higher quality was indicated by higher or lower numbers. Black and white and colored traffic light circles had no effect on comprehension, but increased the proportion of individuals choosing high quality hospitals. However, there was an interaction by 1) whether essential (i.e. death rates) or both essential and non-essential (i.e. death rates and satisfaction) quality information was presented, and 2) by numeracy level.	Medium	Inconsistent	Direct	Imprecise	Insuf-ficient

RCTs=randomized controlled trials; info=information; vs.=versus; cRCT=cluster randomized controlled trial

KQ 2 specific interventions, strength of evidence grade by domain and overall summary grade (continued)

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
		Adding icon arrays to numbers (n=2): Improved understanding of both ARR and RRR presentations when icons were added. Interaction by 1) numeracy level, and 2) whether numbers and icon arrays depicted baseline risk and the risk following treatment with the same or different denominators. Adding illustrations to prose (n=2): No effect of mind map added to brochure or illustrations added to simple medication label text Using different pictorial representations for the same concept (n=2): No overall improvement with grouped (versus random) icon arrays, although interaction by numeracy level. Some teratogen warning symbols					
Alternative Media	4 RCT examining alternate media; 3 examining adding or substituting other media for print and 1 examining adding video to verbal narrative	Effect of adding or substituting for print (n = 3) : Effect for adding video, computer, or slide show presentations to print were mixed. Effect for simplified print were mixed depending on the reading level of the printed materials and study design and	Medium	Inconsistent	Direct	Imprecise	Insuf-ficient

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
		quality Effect of adding video to verbal narrative (n = 1) : Improved knowledge and preference for comfort care					
Alternative Readability and Document Design	6 RCTs, 1 quasi-experimental study with post-only data	Mixed results depending on degree of simplification, literacy level of population, and study quality	Medium	Inconsistent	Direct	Imprecise	Insufficient
Physician Notification of Patient Literacy Status	1 cRCT	No effect on patient level outcomes	Medium	Not Applicable	Direct	Precise	Low

KQ 2. Mixed interventions, strength of evidence grade by domain and overall summary grade

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
Use of Healthcare Services	4 RCTs, 1cRCT, and 1 quasi-experimental study	Preventive services (n=2): Increased use across literacy levels ED visits (n=2): Reduced use across literacy levels Hospitalizations (n=3): Reduced use (or trends toward reduced use) across literacy levels; greater reductions in low literacy population	Medium	Consistent	Direct	Precise	Moderate
Knowledge	3 RCTs and 7 quasi-experimental studies (including 2 with post-test only data on knowledge, which precluded conclusions)	Mixed results with 5 of 8 studies with interpretable data showing an effect on knowledge	Medium	Inconsistent	Direct	Imprecise	Insufficient

[a]Data from 2004 review modify overall strength of evidence to be moderate

RCTs=randomized controlled trials; HbA1c=glycosylated hemoglobin; BP=blood pressure; QoL=quality of Life; cRCT=cluster randomized controlled trial; ED=emergency department

KQ 2. Mixed interventions, strength of evidence grade by domain and overall summary grade (continued)

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
Self Efficacy	4 RCTs and 5 quasi-experimental studies	Mixed results depending on intensity of intervention; for intensive interventions although these analyses for these interventions weren't stratified by literacy level	Medium	Consistent	Direct	Precise	Insufficient
Skill	1 RCT	Improved label reading skill with greater effect in those with high literacy (However, 2 studies from review found mixed results)	Medium	Not Applicable	Direct	Imprecise	Insufficient
Behavior	2 RCTs and 1 quasi-experimental study	Improved self-management behaviors, greater improvement in adequate literacy group in the 1 study that performed analysis stratified by literacy level	Medium	Consistent	Direct	Imprecise	Moderate
Disease Prevalence and Severity	4 RCTs, 3 quasi-experimental studies	Self-management programs (n=3): mixed effects on biomarkers depending on study quality Disease management programs (n=2): improved HbA1c in low literacy group, improved BP across literacy levels Adult Basic and Literacy Education (n=1): improved depression severity across literacy levels	Self-manage-ment programs: Medium Disease manage-ment programs: Medium Adult Basic and Literacy Education: Medium	Self-management programs: Inconsistent Disease management programs: Consistent Adult Basic and Literacy Education: Not Applicable	Self-management programs: Direct Disease management programs: Direct Adult Basic and Literacy Education: Direct	Self-manageme nt programs: Imprecise Disease manageme nt programs: Precise Adult Basic and Literacy Education: Imprecise	Self-managemen t programs: Insufficient Disease manage programs: Moderate Adult Basic and Literacy Education: Low

KQ 2. Mixed interventions, strength of evidence grade by domain and overall summary grade (continued)

Outcome	Number of Studies	Results	Domain: Risk of Bias	Domain: Consistency	Domain: Directness	Domain: Precision	Overall Grade
Adherence	3 RCTs and 2 quasi-experimental studies (1 with post-test only data)	Mixed results related to the intensity of the intervention and measure of adherence	Medium	Inconsistent	Direct	Imprecise	Insufficient
Quality of Life	4 RCTs (1 measured QoL only post-test in intervention group)	Mixed results	Medium	Inconsistent	Indirect	Imprecise	Insufficient
Costs	2 RCT	Non-significant trend toward reduced cost across literacy groups	Low	Not Applicable	Indirect	Imprecise	Insufficient

Appendix G. Peer Reviewers

We gratefully acknowledge the following individuals who reviewed the initial draft of this report and provided us with constructive feedback. External reviewers comprised clinicians, researchers, representatives of professional societies, and potential users of the report. We would also like to extend our appreciation to our Associate Editor, Robert L. Kane, MD, Director of Minnesota Evidence-based Practice Center for his review and advice on improving the initial draft. Our peer review panel includes four members of the TEP: David Baker, Cindy Brach, Darren DeWalt, and Joanne Schwartzberg. Peer review was a separate duty for these individuals and not part of their commitment as TEP members. All are active professionals in the field. The peer reviewers were asked to provide comments on the content, structure, and format of the evidence report and to complete a checklist. The peer reviewers' comments and suggestions formed the basis of our revisions to the evidence report. Acknowledgments are made with the explicit statement that this does not constitute endorsement of the report.

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Appendix H. Excluded Studies

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Studies examining normal reading development in children

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Studies about dyslexia

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Studies answering KQ1 where literacy is measured (not numeracy) and the only study outcome is knowledge

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13. Wolf MS, Davis TC, Arozullah A, et al. Relation between literacy and HIV treatment knowledge among patients on HAART regimens. *AIDS Care*. 2005;17(7):863-73.

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15. Fang MC, Panguluri P, Machtinger EL, Schillinger D. Language, literacy, and characterization of stroke among patients taking warfarin for stroke prevention: Implications for health communication. *Patient Educ Couns*. 2009;75(3):403-10.

16. Huizinga MM, Carlisle AJ, Cavanaugh KL, et al. Literacy, numeracy, and portion-size estimation skills. *Am J Prev Med*. 2009;36(4):324-8.

17. Marks JR, Schectman JM, Groninger H, Plews-Ogan ML. The association of health literacy and socio-demographic factors with medication knowledge. *Patient Education and Counseling*. 2010;78(3):372-376.

Studies in which the outcome is limited to dementia or cognitive impairment

1. Manly JJ, Touradji P, Tang MX, Stern Y. Literacy and memory decline among ethnically diverse elders. *J Clin Exp Neuropsychol*. 2003;25(5):680-90.

2. Martin RC, Annis SM, Darling LZ, Wadley V, Harrell L, Marson DC. Loss of calculation abilities in patients with mild and moderate Alzheimer disease. *Arch Neurol*. 2003;60(11):1585-9.

3. Mehta KM, Simonsick EM, Rooks R, et al. Black and white differences in cognitive function test scores: what explains the difference? *J Am Geriatr Soc*. 2004;52(12):2120-7.

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Studies published in abstract form only

1. Baird AD, Ford M, Podell K. Ethnic differences in functional and neuropsychological test performance in older adults. *Arch Clin Neuropsychol*. 2007;22(3):309-18.

Ecological data only

1. Anand S, Barnighausen T. Health workers and vaccination coverage in developing countries: an econometric analysis. *Lancet*. 2007;369(9569):1277-85.

2. Berhane Y, Wall S, Fantahun M, et al. A rural Ethiopian population undergoing epidemiological transition over a generation: Butajira from 1987 to 2004. *Scand J Public Health*. 2008;36(4):436-41.

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Unable to obtain the article

1. Osborne H. In other words... Building healthy literacy programs one step at a time. *On Call*. 2004;7(6):16-17.

Appendix I. Articles by Database Search

Articles by Database Searched-add space between each reference

CINAHL = 93 (excluding duplicates)

1. Bridging the gulf between health care providers and back pain sufferers: understanding health literacy. Bone & Joint. 2004 09;10(8):94-.

2. Understanding how health literacy impacts patient safety. Briefings on Patient Safety. 2004 07;5(7):1-8.

3. Health care literacy gap is addressed. Same Day Surg. 2007 04/02/:4-.

4. The library column. Health literacy: why should dental hygienists be concerned about literacy? Canadian Journal of Dental Hygiene. 2007 07;41(4):202.

5. Making the message clear... Fyalka T. Uncovering the secret nearly 50% of your patients may be keeping. Ill Dent News Sept, pp 4-5, 2006. Dent Abstr. 2007 03;52(2):80-.

6. Patient confusion over health info. World of Irish Nursing & Midwifery. 2007 12;15(11):53-.

7. Strategies for improving health literacy. Joint Commission Perspectives on Patient Safety. 2008 03;8(3):8-9.

8. AHRQ introduces new Pharmacy Health Literacy Center. AHRQ Research Activities. 2009(352):21-.

9. Better educational materials are needed to boost the health literacy of individuals who are deaf. AHRQ Research Activities. 2009(352):8-.

10. Bulletin board AHRQ launches health literacy measurement tools. J AHIMA. 2009;80(3):12.

11. Concept Analysis of Health Literacy. Journal of Nursing. 2009;56(5):93-7.

12. Family council can help make materials readable: revamping written handout distribution. Patient Education Management. 2009;16(4):42.

13. For best results, create systemwide plan for overcoming literacy barriers: organized committee tackles specific projects along the lines of members' expertise. Patient Education Management. 2009;16(11):121-3.

14. A health literacy example: revising a HIPAA privacy notice. ASHA Leader. 2009;14(2):29.

15. Health literacy is linked to personal happiness. AHRQ Research Activities. 2009(350):12-.

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Appendix J. Summary of KQ 1 Findings from Literacy and Health Outcomes Report

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1)

Study	Design	Health Measure	Literacy Measure	Results
		Use of Health Care Services		
		Knowledge of Health Care Services		
Davis et al., 1996[1]	Cross-sectional	Knowledge and attitudes regarding mammography screening	REALM	Higher literacy level was associated with reasons why women get mammograms.
Lindau et al., 2002[2]	Cross-sectional	Cervical cancer screening practices	REALM	Higher literacy was associated with being more knowledgeable of the purpose of Pap test.
Miller et al., 1996 [3]	Cross-sectional	Adequacy of clinical trials information (informed consent)	WRAT	Higher literacy level was moderately correlated with understanding informed consent.
Moon et al., 1998[4]	Prospective cohort	Understanding of medical information and ability to follow therapy prescribed for child	REALM	No correlation between literacy and parental knowledge of health maintenance procedures or child health measures.
Spandorfer et al., 1995[5]	Prospective observational cohort	Emergency department discharge instructions	WRAT	Higher literacy level was associated with comprehension of instructions.
TenHave et al., 1997[6]	Cross-sectional	Heart health knowledge	CARDES	Higher literacy level was associated with greater knowledge of matters relating to use of these health services.
Risk of Hospitalization				
Baker et al., 2002[7]	Prospective cohort	Hospitalization	S-TOFHLA	Patients with inadequate literacy were more likely than patients with adequate literacy to be hospitalized.
Baker et al., 1998[8]	Prospective cohort	Hospitalization	TOFHLA	Patients with inadequate literacy were more likely than patients with adequate literacy to be hospitalized.
		Physician Visits		
Baker et al., 1997[9]	Cross-sectional	Self-reported health and use of health services	TOFHLA	There was no association between literacy status and self-reported access to physician visits after adjusting for age, health status, and economic indicators.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Screening and Prevention				
Fortenbury et al., 2001[10]	Cross-sectional	Receipt of a screening for gonorrhea in the past year	REALM	Higher literacy was associated with an increase in the probability of having a gonorrhea test in the past year.
Scott et al., 2002[11]	Cross-sectional	New Medicare enrollees in a national managed care organization preventive care utilization	S-TOFHLA	Patients with inadequate literacy were more likely to have never had a Pap smear or a mammogram in the past 2 years. Patients with inadequate literacy were less likely to have had either an influenza or pneumococcal immunization.
Health Outcomes				
Knowledge or Comprehension of Outcomes				
Arnold et al., 2001[12]	Cross-sectional	Knowledge, attitudes, and practice of tobacco use among pregnant women	REALM	Literacy was a predictor for knowledge of effects of smoking and secondhand smoke.
Conlin and Schumann, 2002[13]	Cross-sectional	Analysis of standard discharge instructions and forms for open heart surgery after recovery from open heart surgery	REALM	Literacy level was correlated with understanding standard discharge instructions and forms.
Gazmararian et al., 1999[14]	Cross-sectional	Family planning knowledge and practices among Medicaid managed care enrollees	S-TOFHLA	Women wanting to know more about birth control were more likely to have low reading skills. Incorrect knowledge of “time of month most likely to get pregnant” was higher among women with low reading skills.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Kalichman et al., 2000[15]	Cross-sectional	HIV-infected patients' knowledge and understanding of their status and perceptions of treatment effects on transmission risks	Modified TOFHLA	Lower literacy was associated with not understanding CD4 counts or meaning of viral load. Lower literacy was associated with incorrect beliefs about HIV treatments and transmission risks.
Kalichman and Rompa, 2000[16]	Cross-sectional	Health status awareness and understanding of HIV infection status, disease, and treatment-related knowledge	Modified TOFHLA	Lower literacy was associated with lack of knowledge and understanding of HIV-related health markers. Higher literacy group had higher knowledge of HIV disease and treatment than lower literacy group. Lower literacy group had more negative perceptions and experiences related to HIV-AIDS.
Kalichman et al., 2000[17]	Cross-sectional	Reliability and validity of self-reported HIV-related health markers in HIV-infected adults	Modified TOFHLA	Lower literacy was more likely to have discrepant self-reported CD4 counts or viral loads.
Miller et al., 2003[18]	Prospective cohort	Dosing and compliance of HIV-infected individuals taking antiretroviral medication	S-TOFHLA	Lower medication knowledge was significantly associated with lower literacy.
Williams et al., 1998[19]	Cross-sectional	Chronic disease and treatment among patients with diabetes or hypertension	TOFHLA	Patients with low literacy had less knowledge about diabetes and hypertension.
Williams et al., 1998[20]	Cross-sectional	Knowledge about asthma	REALM	Knowledge increased with literacy.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Wilson and McLemore, 1997[21]	Cross-sectional	Patients hospitalized for knee or hip surgery "self-care" knowledge after education with written discharge instructions	REALM	The relationship between literacy and self-care knowledge after written education materials was not significant.
Health Behaviors and Adherence				
Arnold et al., 2001[12]	Cross-sectional	Knowledge, attitude, and practices of tobacco use among pregnant women	REALM	No difference in the unadjusted rates of smoking according to literacy status.
Davis et al., 1999[22]	Cross-sectional	Violent behavior in adolescents	Slosson Oral Reading Test	Youth who were more than two grades behind expected reading level were more likely than others to carry a weapon including a gun, take a weapon to school, miss school because it was unsafe, and be in a physical fight that required medical treatment.
Frack et al., 1997[23]	Cross-sectional	Compliance with research protocols in a clinical trial	Cloze procedure	Patients who followed up as directed had a higher average literacy score than those who never followed up.
Fredrickson et al., 1995[24]	Cross-sectional	Breast-feeding	WRAT	An association was found between low reading ability and never breast-feeding.
Fredrickson et al., 1995[24]	Cross-sectional	Smoking	WRAT	An association between low reading ability and smoking.
Golin et al, 2002[25]	Prospective cohort	Adherence among HIV-infected patients taking antiretrovirals	S-TOFHLA	No relationship between literacy and adherence was found.
Hawthorne, 1996[26]	Cross-sectional	Tobacco use among 11 and 12 year olds	NR	A relationship between literacy and ever having used tobacco among boys but not among girls. The relationship between literacy and using tobacco in the past month was strong among both boys and girls.
Hawthorne, 1996[26]	Cross-sectional	Alcohol use in adolescence	NR	Odds of having misused alcohol were higher among boys with lower literacy levels than among boys with higher literacy levels. No significant relationship emerged for girls by literacy level.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Kalichman et al., 1999[27]	Cross-sectional	Adherence to treatment for HIV and AIDS	Modified TOFHLA	Lower literacy was associated with greater odds of poor adherence.
Kaufman et al., 2001[28]	Cross-sectional	Breast-feeding	REALM	Women with literacy levels at or above 9th grade were more likely to breast-feed for at least 2 months than mothers with literacy at the 7th or 8th grade level.
Li et al., 2000 [29]	Retrospective case study	Adherence to breast conservation therapy in women with early-stage breast cancer	REALM	Literacy did not ignore predict adherence to radiation, chemotherapy, or clinical appointments.
Stanton et al., 1990[30]	Prospective cohort	Problem behavior in children	Burt Word Reading Test	Reading ability was an independent predictor of teacher-reported problem behavior.
Williams et al., 1998[20]	Cross-sectional	Correct use of metered dose inhaler by patients with asthma	REALM	Patients with higher literacy had better metered dose inhaler technique.
Biochemical and Biometric Health Outcomes				
Battersby et al., 1993[31]	Case-control	Diagnosis of hypertension	Schonell Graded Word Reading Test	No difference in reading ability between patients with or without hypertension was found.
Kalichman and Rompa, 2000[32]	Cross-sectional	HIV infection	Modified TOFHLA	No significant association between reading comprehension and undetectable viral load.
Kalichman et al., 2000[15]	Cross-sectional	HIV infection, optimism, and perceptions of care	Modified TOFHLA	Patients with better reading comprehension had greater odds of having an undetectable viral load than those with worse reading comprehension. No significant association between reading comprehension and undetectable viral load was found. Patients with lower literacy tended to be more optimistic about their future living with HIV.
Kalichman and Rompa, 2000[16]	Cross-sectional	HIV infection, optimism, and perceptions of care	Modified TOFHLA	Better readers had greater odds of having an undetectable viral load than worse readers. Worse readers had greater odds of having a CD4 count less than 300 than did better readers. Patients with lower literacy had more distrust of providers and were less likely to believe that treatment helps.
Ross et al., 2001[33]	Cross-sectional	Glycemic control in children with type 1 diabetes	WRAT3, children; NART, mothers	No significant correlation between literacy in children aged 5 to 17 and glycemic control. Parent's literacy was correlated with the child's glycemic control.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Schillinger et al., 2002[34]	Cross-sectional	Glycemic control in adults with type 2 diabetes	S-TOFHLA	Patients with lower literacy had worse glycemic control. The glycemic level was found to be inversely related to literacy.
Williams et al., 1998[19]	Cross-sectional	Glycemic control in adults with type 2 diabetes	TOFHLA	Knowledge of diabetes was lower for patients with a low literacy status. No differences were found in the control of diabetes according to literacy status.
Williams et al., 1998[19]	Cross-sectional	Patients diagnosed with hypertension	TOFHLA	Knowledge of hypertension was lower for patients with low literacy status. No differences were found in the control of hypertension according to literacy status.
Measures of Disease Prevalence, Incidence, or Morbidity				
Andrasik et al., 1988[35]	Case-control	Children with and without migraines	WRAT	No significant difference in literacy scores between the two groups was found.
Bennett et al., 1998[36]	Cross-sectional	Stage of presentation of prostate cancer	REALM	Men with lower literacy were more likely to present with late-stage prostate cancer than those with higher literacy. After adjusting for race, age, and location of care, the investigators found that the relationship between literacy and stage of presentation was smaller and no longer statistically significant.
Fisch et al., 1998[37]	Cross-sectional	Emotional balance after receiving informed consent materials for a bone marrow transplant	WRAT	No significant relationship between the patterns of affects changes and literacy.
Gazmararian et al., 2000[38]	Cross-sectional	Self-reports of depression in a Medicare population	S-TOFHLA	The odds of being depressed were greater for those people with inadequate literacy compared to those with adequate literacy. After adjusting for demographic, social support, health behavior, and health status factors, the correlation was no longer statistically significant. A significant relationship between literacy and depression could not be observed. No significant relationship was found after adjusting for age and health status.
Gordon et al., 2002[39]	Cross-sectional	Arthritis and functional status of patients with rheumatoid arthritis	REALM	Health activity did not differ according to literacy dichotomized at the 9th grade level.
Gordon et al., 2002[39]	Cross-sectional	Self-report of depression in patients with rheumatoid arthritis	REALM	Patients with more anxiety and depression were greater among those who read below the 9th grade level than among those who read at or above the 9th grade level.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Kalichman and Rompa, 2000[32]	Cross-sectional	Self-reported depression in HIV-infected patients	Modified TOFHLA	Total scores on the depression scales did not differ by literacy status. Some depression subscales were higher (representing more depression) for participants with lower literacy.
TenHave et al., 1997[6]	Cross-sectional	Self-reports of depression in adults participating in a cardio-vascular dietary education program	CARDES	Lower scores on the literacy assessment were statistically significantly associated with higher scores on the depression assessment after adjusting for age, suggesting a greater propensity for depression among those with lower literacy.
Zaslow et al., 2001[40]	Cohort	Mothers' reports of child's depression and antisocial behavior	Test of Applied Literary Skills	Risk of depression was higher among mothers who had lower literacy skills. No relationship was detected between maternal literacy and depression or antisocial behavior among their children.
Global Health Status Measures				
Baker et al., 1997[9]	Cross-sectional	Overall health status	TOFHLA	Patients with inadequate literacy had about twice the odds of reporting poor health than patients with adequate literacy.
Gazmararian, et al., 1999[41]	Cross-sectional	Medicare managed care health plan	S-TOFHLA	Patients with inadequate literacy were significantly more likely to self-report fair or poor health than patients with adequate literacy.
Sullivan et al., 1995[42]	Cross-sectional	General health status of patients with type 2 diabetes	QLS	No difference in scores on the SF-36 according to whether the subject "passed" or "failed" the QLS.
Weiss et al., 1992[43]	Cross-sectional	Health status	Tests of Adult Basic Education and Mott Basic Language Skills Program	People with lower literacy scored worse than those with higher literacy on both the physical and psychosocial subcomponents.
Cost of Health Care				
Weiss et al., 1994[44]	Retrospective cohort	Costs of health care in Medicaid patients	Instrument for the Diagnosis of Reading	No relationship between literacy and Medicaid charges.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Disparities in Health Outcomes or Use of Health Services				
Bennett et al., 1998[36]	Cross-sectional	Men who presented with late-stage prostate cancer	REALM	Black patients were significantly more likely than white patients to present with late-stage cancer. After adjusting for literacy, age, and location of care, the odds ratio was smaller and no longer statistically significant.

Note: REALM=Rapid Estimate of Adult Literacy in Medicine; WRAT=Wide Range Achievement Test; CARDES=Cardiovascular Education Dietary System; TOFHLA=Test of Functional Health Literacy in Adults; S-TOFHLA=Short-TOFHLA; NR=not reported.

Table 8. Studies of knowledge or comprehension of health service use (KQ 1a)

Study	Population	Results
Davis et al., 1996[1]	Low-income women at an ambulatory clinic at Louisiana State University at Shreveport	Lower literacy correlated with lower knowledge about mammograms (adjusted)
Lindau et al., 2002[2]	Women in women's health clinics at an academic medical center in Chicago, predominantly Medicaid insurance	Higher literacy associated with more knowledge about cervical cancer screening (adjusted)
Miller et al., 1996[3]	Participants enrolling in anti-infective clinical trials	Moderate correlation between literacy and understanding of informed consent (unadjusted)
Moon et al., 1998[4]	Parents of children in urban and suburban pediatric practices in Washington, DC	No correlation between literacy and parental knowledge of health maintenance procedures or child health measures (adjusted)
Spandorfer et al., 1995[5]	Impoverished inner-city patients at an emergency department in Philadelphia	Reading ability was best predictor of knowledge of discharge instructions (adjusted)
TenHave et al., 1997[6]	Community members coming to a cholesterol screening at a local supermarket	Higher literacy associated with more "Heart Healthy Knowledge" (*P* value not reported) (unadjusted)

Table 9. Studies of knowledge or comprehension of health outcomes (KQ 1b)

Study	Population	Results
Arnold et al., 2001[12]	Predominantly Medicaid or uninsured pregnant women	Low literacy predicted lower knowledge about smoking effects (adjusted)
Conlin and Schumann, 2002[13]	Patients recovering from open heart surgery at a teaching hospital	Lower literacy correlated with lower score on knowledge test of discharge instructions (unadjusted)
Gazmararian et al., 1999[14]	Female Medicaid managed care enrollees in Memphis, Tennessee	Lower literacy associated with less knowledge of time most likely to get pregnant during menstrual cycle (adjusted)
Kalichman et al., 2000[15]	HIV-infected individuals living in Atlanta, Georgia	Higher literacy associated with higher likelihood of understanding the meaning of the CD4 count or viral load (adjusted)
Kalichman and Rompa, 2000[16]	HIV-infected individuals living in Atlanta, Georgia	Lower literacy associated with less understanding of meaning of CD4 counts and viral load; lower literacy associated with less knowledge of disease and treatment based on 14-item questionnaire (adjusted)
Kalichman et al., 2000[17]	HIV-infected individuals living in Atlanta, Georgia	Higher literacy associated with knowledge of CD4 counts and viral load (adjusted)
Miller et al., 2003[18]	HIV-infected patients in a public hospital affiliated clinic	Literacy associated with knowledge of antiretroviral medication (unadjusted)
Williams et al., 1998[19]	Patients with diabetes or hypertension attending a primary care clinic at a public hospital in Los Angeles or Atlanta	Higher literacy associated with more knowledge about hypertension and diabetes (adjusted)
Williams et al., 1998[20]	Adult asthma patients in the emergency department at Grady Memorial Hospital	Higher literacy associated with more asthma knowledge (adjusted)
Wilson and McLemore, 1997[21]	Patients hospitalized for knee or hip surgery	No correlation between literacy level and patients' level of knowledge about self-care after receiving written education materials (unadjusted)

Table 10. Studies of the relationship between literacy and depression (KQ 1b)

Study	Population	Results
Gazmararian et al., 2000[38]	Elderly persons without dementia in a Medicare health plan	Marginal literacy associated with lower rate of depression (adjusted)
TenHave et al., 1997[6]	Mostly black middle-aged and elderly persons attending a supermarket cholesterol screening	Lower literacy associated with higher depression scores (adjusted)
Kalichman and Rompa, 2000[32]	Mostly black middle-aged HIV-positive patients	Lower literacy associated with more symptoms of depression (unadjusted)
Gordon et al., 2002[39]	Mostly white middle-aged rheumatoid arthritis patients	Lower literacy associated with higher rate of depression (unadjusted)
Zaslow et al., 2001[40]	Black young adult mothers who qualified for Aid to Families with Dependent Children	Lower literacy associated with higher rate of depression (unadjusted)

Table 11. Studies of the relationship between literacy and global health status (KQ 1b)

Study	Population	Results
Weiss et al., 1992[43]	Young English-speaking adult students in an adult education class	Lower literacy associated with poorer health status score (adjusted)
Baker et al., 1997[9]	Middle-aged English- and Spanish-speaking patients of hospital walk-in clinics or emergency departments	Lower literacy associated with poorer health status rating (adjusted)
Sullivan et al., 1995[42]	Middle-aged and elderly patients with type 2 diabetes	No difference in physical functioning and literacy
Gazmararian et al., 1999[41]	Elderly Spanish- and English-speaking Medicare beneficiaries without dementia	Lower literacy associated with poorer health status rating (unadjusted)

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