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Prepared by:
University of Ottawa Evidence-based Practice Center at the
University of Ottawa, Ottawa, Canada
David Moher, MSc
Howard M Schachter, PhD
Co-directors

Investigators
Howard M Schachter PhD
Vasil Mamaladze MD
Gabriela Lewin MD
Larry Paszat MD
Shailendra Verma MD
Cathy DeGrasse MScN
Ian Graham PhD
Melissa Brouwers PhD
Margaret Sampson MLIS
Andra Morrison BSc
Li Zhang BSc
Peter O'Blenis MBA
Chantelle Garrity BA

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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 healthcare in the United States. The National Cancer Institute, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention requested and provided funding for this report. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new healthcare 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 healthcare 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 healthcare system as a whole by providing important information to help improve healthcare 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.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Andrew C. von Eschenbach, M.D.
Director
National Cancer Institute

Julie L. Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Jean Slutsky, P.A., M.S.P.H
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Kenneth S. Fink, M.D., M.G.A., M.P.H.
Director, EPC Program
Agency for Healthcare Research and Quality

Ernestine W. Murray, B.S.N, R.N., M.A.S.
EPC Program Task Order Officer
Agency for Healthcare Research and Quality

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Structured Abstract

Context: It has been suggested that, on average, the quality of health care received by Americans, including breast cancer care in women, is less than ideal. Quality measurement can identify gaps in such patterns of care.

Objectives: The purpose of this systematic review of the scientific-medical literature was to survey the range of quality measures assessing the quality of breast cancer care in women, and to characterize specific parameters potentially affecting their suitability for wider use. Specific emphasis was placed on diagnosis, treatment (including supportive care), followup, and documentation of this care. Screening and prevention fell outside the review scope. Quality measures quantify adherence to standards of care, or quality indicators (e.g., percentage of women receiving radiotherapy after breast-conserving surgery), and can vary in terms of the extent of their scientific development.

Data Sources: A comprehensive literature search was conducted in: Medline, Cancerlit, Healthstar, Premedline, Embase, CINAHL, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness, Cochrane Central Register of Controlled Trials, and Health and Psychosocial Instruments. Search elements included: diagnosis and treatment of breast cancer; quality measures; systematic reviews; clinical practice guidelines; and, commentaries or editorials. Additional published and unpublished literature was sought through manual searches of reference lists of included studies and key review articles, web sites, and from the files of content experts. ASCO was asked to contribute quality measures currently under development.

Study Selection: Studies met eligibility criteria if they described evidence-based quality measures evaluating adherence to standards of breast cancer care. The population of interest was female adults diagnosed with, or in treatment for, any histological type of adenocarcinoma of the breast, including both in situ and invasive cancer. Three levels of screening, with two reviewers at each level, were employed. Disagreements between reviewers were resolved by forced consensus and, if necessary, third party intervention.

Data Extraction: Three reviewers independently abstracted data (i.e., characteristics of the report, study, population, quality indicators used in quality measurement [e.g., validational history, data sources used], and adherence rate [e.g., overall, by age and race]), and then checked each other's work. A scheme was developed, then applied independently by two assessors, to examine the extent, and soundness, of the scientific development of each quality measure.

Data Synthesis: Sixty relevant reports identified 58 studies and 143 quality indicators used to measure the quality of breast cancer care. Measures reflecting processes of care were the most frequently evaluated. Not all predefined types of care were assessed using quality measures. Only a qualitative synthesis was undertaken, given the virtual lack of scientifically developed quality measures (n = 12). Most of these assessed patient-reported quality of life.

Conclusions: While some studies revealed patterns of underuse of care, these and all other adherence data require confirmation using scientifically validated quality measures. Current

attempts by ASCO to formally develop a set of quality measures relating to breast cancer care may hold the key to conducting these definitive studies.

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Evidence Report

Chapter 1. Introduction

This evidence report by the University of Ottawa's Evidence-Based Practice Center (UO-EPC) describes the results of a systematic review of the scientific-medical literature designed to survey the range of quality measures assessing the quality of breast cancer care in women, and to characterize specific parameters potentially affecting their suitability for wider use. Specific emphasis was placed on diagnosis, treatment (including supportive care), followup, and the reporting/documentation of this care. The population of interest was female adults diagnosed with, or in treatment for, any histological type of adenocarcinoma of the breast, including both in situ and invasive cancer. This report was requested by a Federal collaboration comprising the Agency for Healthcare Research and Quality's (AHRQ) Center for Quality Improvement and Patient Safety (CQuIPS), the National Cancer Institute (NCI), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS). The National Quality Forum (NQF) is joined with these Federal agencies in a public-private initiative to identify and promote the use of evidence-based quality measures of cancer care. In addition to informing the research community and the public on the availability and utility of quality measures of breast cancer care, it is anticipated that the findings of this report will be used to help define an agenda for future research.

In this chapter, terms central to the present project are defined, followed by a brief overview of the burden of breast cancer, its range of care, and issues concerning the latter's documentation. The topics of breast cancer screening and prevention will be addressed in a separate task order. Subsequent chapters describe the methods used to identify and review studies, the cataloguing and appraisal of attempts to measure the quality of breast cancer care, and recommendations for future research in this area.

Overview of the Healthcare Quality Received by Americans

The quality of healthcare refers to "the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] It is estimated that more than one trillion dollars is spent annually on healthcare in the United States, yet there are few systematic and comprehensive data on how well this care is provided by practitioners, organizations, and systems.[2] Various sources (e.g., healthcare professionals, hospitals, health plans) have provided some data on healthcare, including its quality. However, the absence of a coordinated national quality measurement and reporting system has meant that these data are likely too inconsistent and incomplete to permit derivation of a national overview of problems in healthcare quality that could potentially serve to inform the public about the quality of its healthcare choices.[3]

Nevertheless, two recent publications have suggested that the quality of healthcare received by Americans is less than ideal.[4,5] For example, in a survey of 30 health conditions ranging from osteoarthritis to prenatal care, McGlynn et al. observed that, on average, Americans have received about half (54.9%) of the recommended medical care processes.[5] They also noted greater problems with underuse (46.3% of participants failed to receive recommended care) than

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.goc/clinic/epcindex.htm

with overuse (11.3% received care that was not recommended, some of which was potentially harmful). These are important findings given that they are based on a comprehensive view of the healthcare quality received by a representative sample of the American population across a broad spectrum of conditions, rather than on some narrowly defined healthcare condition, care, or population.

In the study by McGlynn and colleagues, a total of 439 standards of care, or quality indicators, represented 30 acute and chronic conditions, in addition to preventive care.[5] For each of the health conditions, data were presented as aggregates, including as few as three (i.e., osteoarthritis) and as many as 39 indicators of quality care (i.e., prenatal care). Adherence to the aggregate indicators ranged from 10.5% for alcohol dependence, to 78.7% for senile cataracts. The breast cancer care data are systematically reviewed in this report.

Although the reported adherence rates may have been somewhat higher had McGlynn et al. used data sources other than medical records supplemented with interviews regarding participants' health history (e.g., audiotapes of encounters), their overarching observation highlights a gap between ideal and actual care—that is, between what evidence has identified as recommended care and what Americans actually receive.[5] McGlynn et al. point out that such a deficit endangers the health and well-being of the American public. However, they also acknowledge that there are ways to begin to change this state of affairs.

An important first step would be to collect, synthesize, and make available data regarding the performance of healthcare professionals and healthcare systems.[5] This information would help to identify specific problems with healthcare quality, to establish bases upon which to determine accountability, and to serve as the focus of research to develop new knowledge about healthcare systems. In addition, these data could serve as a national baseline against which results of attempts to improve the quality of care could be compared.[6,7] Accountability, improvement, and research constitute the three broadly stated purposes of quality measurement.[8] Attempts to collect performance data could shed light on the overuse, underuse, misuse, or wide variability in use of care,[6,9] ultimately contributing to correcting disparities in the quality of care received by different populations or subpopulations.[10]

The Measurement of Healthcare Quality

The measurement of healthcare quality begins ideally with the establishment of an evidence-based performance standard, or criterion, relative to which adherence data can be ascertained.[11] Such a standard is an indicator of quality care, or a "quality indicator" (e.g., radiotherapy after breast-conserving surgery). An evidence-based standard is one supported by study evidence, not mere opinion or conjecture, demonstrating that this care is linked to improved patient outcomes.[12]

Identifying a quality indicator ideally requires a systematic review of the pertinent scientific-medical evidence, followed by an expert panel consensus process to ensure that the recommended care highlighted by the synthesis of findings is clinically relevant, up-to-date, and practical to deliver. Without a systematic review process to minimize or correct for possible bias, both in the way in which relevant evidence is captured and appraised (e.g., multiple appraisers of data) and in the evidence base itself (e.g., reviewing unpublished material with the potential to influence a synthesized result), a peer consensus process can draw a skewed conclusion based on idiosyncratic interpretations of the evidence base, including appraisals of

subsets of data. A recent study found that, without the findings of a systematic review process to guide it, participants in a consensus conference process merely relied on their favourite articles to substantiate their views.[13]

The quality indicators employed by McGlynn et al. in their recent comprehensive study[5] were derived systematically and rigorously using RAND's Quality Assessment Tools system.[14] After RAND staff identified conditions representing the leading causes of illness, death, and utilization of healthcare, RAND staff physicians systematically searched the medical literature (via Medline) and reviewed related established national guidelines. Following this, quality indicators were proposed.[15] Nine-member, multispecialty expert panels then assessed the clinical appropriateness of the quality indicators using the RAND-UCLA modified Delphi method.[16] Ten evidence-based quality indicators pertaining to breast cancer care were derived, with one evaluating breast cancer screening.[17]

This rigorous, evidence-based process accurately illustrates what is required to systematically develop quality indicators for use in quality measurement.[17] Questions concerning the quality of healthcare can then be evaluated by measuring the adherence to these standards of care. An example of such a question is: "how many women qualifying to receive a standard of breast cancer care (i.e., by virtue of their clinical situation) actually receive it (in timely fashion)?" Or, from the healthcare provider perspective, "how many healthcare professionals, when attending to women qualifying to receive a standard of breast cancer care (i.e., by virtue of their clinical situation), actually deliver it (in timely fashion)?"

Yet, an additional step determines whether or not the quality indicator used as the performance standard to assess adherence can be considered a formally-, or fully-developed quality measure, that is, one which exhibits the scientific properties required to instil confidence in the observations it generates.[18] Two key properties of a quality measure are "reliability" and "validity." Data referring to other properties, such as sensitivity (i.e., how sensitive a diagnostic test is at detecting disease) or specificity (i.e., how good a test is at rejecting samples that are not diseased), were not identified by the present review.[18]

When a measure is said to be reliable, it means that if multiple observers, or the same observer (at different points in time), implement this measure, the observations it yields should be highly consistent, if not identical. "Reliability" asks whether the observations produced by the measure are repeatable, or reproducible, across different situations.[18] For example, would a diagnostic test of cancer yield the same observation when administered two times, 6 hours apart? Reliability is thus a key characteristic of a measure.

The validity of a measure, and hence its measurements, is closely related to its reliability. "Validity" asks whether the measure is assessing what it was intended to measure.[18] For example, does a diagnostic test accurately, and only, measure the characteristic known to indicate the presence of cancer? Or, does the depression scale accurately and exclusively measure the signs and symptoms of depression? If the measure has a history of exclusively generating empirical evidence regarding the target characteristic, then it is considered valid. Without evidence to support its validity, it does not matter how perfectly or how often independent observations afforded by this measure actually agree, because what it quantifies may not be what the user intends it to measure. For example, a purported measure of depression may actually identify reliably the signs and symptoms of anxiety.

Prior to the dissemination and wider use of quality indicators as standards against which to measure adherence to recommended health care, a formal scientific process to establish the requisite properties is thus recommended. With respect to breast cancer, for example, this means

defining a quality indicator, or standard, using appropriate evidence, followed by establishing its reliable and valid use through pilot-testing with data sources containing breast cancer care data (e.g., medical records, cancer registries).[18]

In the absence of consistent and strong data concerning each of these two "psychometric" properties, it is difficult to interpret the meaning of quality measurements with any confidence. Thus, while it can be argued that any attempt to measure adherence to a quality indicator amounts to quality measurement, unless the indicator is subjected to a scientific-validational process by which any measure should be developed, and where evidence for each property is shown to be strong and consistent, the measure cannot be considered to be a sound (i.e., reliable and valid) one. A quality measure's scientific soundness, and thus its advantage over an unvalidated one, is conferred by these properties.[9] Three other criteria with which quality measures can be evaluated are described in The Ideal Quality Measure section in this chapter. More is said about the validational process in the Discussion.

The following example is taken from AHRQ's National Quality Measures Clearinghouse (NQMC) web site.[8] Since it focused on breast cancer screening, it was not eligible for inclusion in the present review. The quality indicator is expressed as "women 50-69 years of age having one or more mammograms during the measurement year or the year prior to the measurement year." The quality indicator asserts the standard, or recommended, care. From this, the quality measure is defined as: "the percentage of women 50-69 years of age who had one or more mammograms during the measurement year or the year prior to the measurement year." It quantifies adherence to the standard.

Each element of the definition is clearly and specifically described. These include the population to which the indicator applies, and the time frame. But, on the NQMC web site there is also a clear indication of those women for whom this standard should not be applied (e.g., women who had a bilateral mastectomy and for whom administrative data do not indicate that a mammogram was performed). The specificity, completeness and clarity of the wording of a quality indicator are necessary to assure that different users share the same meaning, and thereby yield the same or consistent observations (i.e., its "reliability" as a measure) when, on different occasions, they consult specific data sources (e.g., medical records) to obtain adherence data; and, that these observations unambiguously reflect what the quality indicator was intended to identify (i.e., its "validity" as a measure).

The NQMC web site also provides information on the relevant data sources (i.e., administrative data, and medical records), as well as a description of any allowances for patient factors (i.e., this quality measure requires that separate rates be reported for commercial, Medicare, and Medicaid plans). While having all these details made explicit may contribute to consistent observations, the extent of the testing of the quality measures was described as "unspecified," raising doubts that reliability and validity data had ever been obtained for this quality measure via a formal validational process.

Thus, in light of this example, a formal definition of a quality measure, and how it differs from a quality indicator, can be stated. A quality measure may be defined formally as a mechanism to quantify the quality of a selected aspect of care by comparing it to a criterion (e.g., "percentage of women 50-69 years of age who had one or more mammograms during the measurement year or the year prior to the measurement year").[8] One practical understanding is that it is a mechanism to quantify the degree of adherence to a standard of care, or quality indicator (i.e., "women 50-69 years of age having one or more mammograms during the measurement year or the year prior to the measurement year"). A quality indicator essentially

becomes a quality measure in the act of measuring adherence to this standard. According to McGlynn:

> Quality measures generally consist of a descriptive statement or indicator…, a list of data elements that are necessary to construct and/or report the measure, detailed specifications that direct how the data elements are to be collected (including the source of data), the population on whom the measure is constructed, the timing of data collection and reporting, the analytic models used to construct the measure, and the format in which the results will be presented. Measures may also include thresholds [minimal], standards, or other benchmarks of performance.[12]

Yet, what happens after a quality measure has been developed formally is also important. Studies should test the stability of the recommended care's links to improved clinical or patient-reported outcomes (e.g., survival, quality of life [QOL], satisfaction with care). Although improved outcomes initially helped support it, additional evidence for links to improved outcomes can reinforce the quality measure's clinical appropriateness and thereby justify its continued use. Subsequent applications to data sources could also reveal that its appropriateness is actually restricted to certain subpopulations (e.g., minority groups).

There are thus two meanings of the term "links to outcomes." First, a quality indicator needs to be supported by an optimal strength of evidence (i.e., the design types, power, quality/validity, effect sizes, and number of research studies) indicating that improved outcomes are associated with receipt of the type of care to which the quality indicator refers. Its links to improved outcomes essentially define the clinical "appropriateness" of this care. An abandoned attempt to investigate this definition of "links to outcomes" is described in Chapter 2.

Second, in studies quantifying the adherence to a standard, it may also be possible to prospectively or retrospectively obtain data regarding this care's links to patient outcomes. This would elucidate whether *study* patients receiving the standard of care experience improved outcomes when compared with those failing to receive it. This second definition of "links to outcomes" reflects one key aspect of the present project's scope.

Types of Quality Measure

There are various types of quality measure. Structural measures include characteristics of clinicians (e.g., years of experience, board certification), organizations or systems (e.g., type of available equipment, staffing patterns), and patients (e.g., type of insurance, severity of illness).[17] These measures reflect the elements of a healthcare delivery system, which precede the interaction of a clinician and a patient, and are implied by questions pertaining to the "availability" of a certain healthcare "capacity." Outcome measures of quality index changes in a patient's current and future health status, including functional status, QOL, and satisfaction with care.[17] In providing the patient perspective on quality of care, such measures can reflect the impact of a single intervention (e.g., a diagnostic procedure) or the cumulative effect of various types or processes of care.[8]

Process measures assess the degree to which a healthcare provider competently and safely delivers appropriate and timely care.[19,20] This includes the ways in which clinicians and patients interact (e.g., providing information, answering questions), as well as the appropriateness,

timeliness, and convenience of a medical intervention for a specific patient.[17] "Appropriate use" denotes receipt/delivery of care that is indicated (i.e., given specific, observed conditions or circumstances), and often within an optimal time period. "Quality" of use refers to how well the care is delivered. Ways of indexing a patient's attainment of timely and appropriate healthcare have also been called access measures.[8] Process measures are often used to evaluate adherence to recommendations from clinical practice guidelines,[8] a view consistent with the Institute of Medicine's definition of performance measures as methods or instruments to estimate or monitor the extent to which the actions of a healthcare practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality.[21]

McGlynn et al.'s above-noted quality indicators were primarily of the process variety.[5] These types of measure more readily identify specific areas of care requiring quality improvement than do, for example, outcome measures.[22] The latter typically necessitate additional investigation to discover the structures or processes requiring quality modification. Nevertheless, to derive a comprehensive understanding of the quality of the delivery of healthcare, it is likely important to link, whenever possible, data obtained from measures of structure, process, and outcome, in addition to data relating to cost, or burden.[9]

The Ideal Quality Measure

Four sets of criteria can be used to evaluate quality measures,[6,8,12] and these are attributes of the ideal quality measure. Each one should be scientifically sound, important, usable, and feasible.

As introduced above, scientific soundness refers to the specific properties of a measure that allow for its consistent use, across various situations, to observe what is intended (i.e., reliability and validity). This requires that the measure's description be precise and detailed. However, seen in light of the example from AHRQ's NQMC web site, quality measurement can merely entail the definition of a quality indicator as a standard against which performance is measured—that is, without the implementation of a formally developed quality measure with strong and consistent evidence for its reliability and validity. Thus, although any synthesis of the quality measurement literature will likely identify evidence derived from the two basic approaches to measuring the quality of health care, that is, with and without the use of validated quality measures, this is, in all likelihood, an artificial dichotomy. In spite of our illustration of two basic paths to achieve quality measurement (see Analytic Framework: Chapter 2), quality measures may be more realistically understood as being situated at various points along a trajectory of scientific development: from measures having received no formal development of their psychometric properties (e.g., reliability and validity), to those exhibiting weak or inconsistent evidence for these properties, and culminating ideally in reliable and valid quality measures. A scheme to evaluate the scientific soundness of each quality measure was derived for use in this review (see Trajectory of Scientific Development of Quality Measures: Chapter 2).

Following the definitions used in the domain of inquiry relating to the measurement of healthcare quality, for a quality measure to be "important" it must relate to an established national goal for quality care, represent a significant leverage point for achieving that goal, demonstrate that the quality of care is below standard or that there is considerable (e.g., demographic) variation in the quality of the provided care, or, show that the information produced by its application is useful for a stakeholder in the healthcare system.[12] The "usability"

of a quality measure denotes the meaningful interpretability of the observations yielded by its application and, whether or not, and how, such interpretations afford decisions and actions regarding the delivery of healthcare. Finally, a quality measure must be "feasible" to implement, that is, the data the measure yields should be readily available for collection within the normal flow of clinical care. A measure's feasibility is related to its adaptability, that is, its potential for appropriate use across various contexts and settings.

These four sets of criteria likely comprise a hierarchy by which quality measures can be appreciated:

> If a measure is not important, its other characteristics are less meaningful. If a measure is not scientifically acceptable, its results may be at risk for improper interpretations. If a measure is not interpretable, we probably do not care if it is feasible. If a measure is not feasible, alternative approaches to acquiring important information should be considered.[12]

Reasons for not being able to evaluate criteria other than scientific soundness are described in the Trajectory of Scientific Development of Quality Measures section in Chapter 2.

The President's Advisory Commission on Consumer Protection and Quality in the healthcare industry recommended the identification, development, and promotion of a common, or national, set of quality measures to assure accountability and quality improvement.[23] Yet, while measurement may be necessary, it is not sufficient to guarantee achievement of these objectives.[24] Barriers to the translation of evidence into accountability for, and improvements in, the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitableness of healthcare[4] include a lack of knowledge, skill, motivation, and resources available to those individuals, organizations, and systems who could bring about this change.[24] Solutions likely require modification of the ways in which health information is collected and reported.[5] James has suggested automating both data entry and its retrieval.[25]

Burden of Breast Cancer in Women

Other than skin cancer, breast cancer remains the most common cancer in women and the second leading cause of cancer-related death.[26] In the United States, it is estimated that, in 2003, over 211,000 women will be diagnosed with breast cancer, and approximately 40,000 will die from the disease.[26] Although much less common, breast cancer also occurs in men, accounting for less than 1% of all breast cancers (approximately 1600 cases in 2003).[26] According to data compiled by the Surveillance, Epidemiology and End Results Program (SEER), 1 in 8 women will develop breast cancer during their lifetime, with the risk increasing with age.[27] Although breast cancer occurs more often in white women than in black or Asian women, cancer survival rates have been estimated to be 15% lower in black women compared with white women.[27] Recent statistics (1992 - 1996) indicate that breast cancer-related deaths are declining, with the largest decrease observed in younger women, both white and black. The decline in death rates is attributed to earlier detection and improved treatment. Currently, it is recommended that all women over the age of 40 receive regular mammograms (every 1 to 2 years).[26,27] What follows is a brief overview of the range of breast cancer care, including some reference to available evidence.

Diagnosis

Primary Diagnosis

Suspicious breast abnormalities are often detected by women themselves, either during self-screening or by accident, or by clinical examination or routine mammography screening. A physical examination cannot, however, distinguish between a benign change and malignant tumor.[28] Although additional characteristics such as indistinct borders, skin dimpling or nipple retraction may indicate a malignancy, additional diagnostic techniques must be performed to confirm a diagnosis.[29,30]

Mammography remains one of the primary tools used to evaluate a palpable breast mass or other signs of breast disease although, in itself, it is not enough to diagnose a malignancy. In addition, mammography is not particularly useful for women with dense breast tissue—this is particularly true for younger women (i.e., under the age of 30), who tend to have dense breast tissue.[31]

Ultrasound has emerged as an important tool to assess a palpable mass in women with dense breast tissue and/or to complement mammography.[32,33] Ultrasound relies on high-frequency sound waves to form images of the breast, regardless of breast density. It is particularly useful at differentiating between solid-mass tumors and fluid-filled cysts, and hence it is often used to further evaluate suspicious abnormalities seen by mammography.

A number of additional imaging techniques, particularly magnetic resonance imaging (MRI) and positron emission tomography (PET), are sometimes also used, usually to complement mammography. They are employed to get more information about the abnormality and, if it is cancer, to determine if it has metastasized. Their usefulness as an alternative to mammography remains unclear.[34,35]

Although imaging techniques, particularly mammography and ultrasound, are used to suggest an initial diagnosis of breast cancer, a biopsy is performed to confirm the presence of cancerous cells. A biopsy is a procedure in which a sample of breast tissue is removed for microscopic examination by a pathologist. Breast biopsies assist physicians in confirming the presence of cancer cells, and if cancerous, the type and extent of the cancer. Breast biopsies can be removed using a needle or by surgery. There are many types of breast biopsy including: fine needle aspiration, core needle biopsy (ultrasound-guided, and stereotactic or X-ray guided), or surgical biopsy. Fine needle aspiration biopsy involves removing cells using a very thin needle, which is inserted into the suspicious tissue. A core biopsy uses a larger needle so as to remove actual pieces (cores) of breast tissue for microscopic analysis. Ultrasound or X-ray (stereotactic) guidance is used to locate the suspicious area of breast tissue. Stereotactic biopsy is used to biopsy very small areas such as microcalcifications or other suspicious areas that cannot be visualized on ultrasound. A surgical biopsy can be conducted when core needle biopsy is not possible, is inconclusive, or is discordant with imaging or expert opinion. A portion of the suspicious area may be excised and is known as an incisional biopsy, or, an excisional biopsy may be completed where the entire area is removed.

Secondary Diagnosis

Once breast cancer has been diagnosed, a number of tests are available to assess if and/or to what extent the primary breast cancer has metastasized to other parts of the body. X-rays of the

chest may be performed to determine if the cancer has spread to the lungs. Bone scans are performed to detect the presence of bone metastases. CT scans, PET scans and MRI are also available to assist in the staging of the cancer and to best guide the physician in choosing the best treatment option. Blood tests are also performed to detect the presence or absence of tumor markers that may indicate cancer activity in other parts of the body.[36]

Risk Factors

Although the cause of breast cancer is unknown, a number of factors are emerging as actual or potential risk factors. Risk factors make some people more likely than others, to develop a particular disease. Risk factors for breast cancer may include:

- Being female
- Increasing age
- Race
- Socioeconomic status
- Proliferative breast disease (atypical ductal hyperplasia, lobular carcinoma in situ)
- Personal history of breast cancer
- Family history of breast cancer
- History of mantle radiation
- Reproductive history (nulliparity, age at first live birth), age at menarche and menopause, history of breast feeding)
- Lifestyle (i.e., diet, alcohol, inactivity)
- Obesity after menopause
- Use of hormone replacement therapy

Most recently, the role of genetic factors has been more closely examined given the discovery that inherited alterations in the genes, BCRA1 and BRCA2, are linked to a predisposition to breast and/or ovarian cancer.[37,38] It has been estimated that approximately 5% to 10% of women with breast cancer have a hereditary form of the disease.[39] Most of these women have a strong family history of breast cancer, that is, close family members who have had breast and/or ovarian cancer, with the breast cancer having developed before the age of 50. For those considered to be high-risk, genetic testing is available to determine whether the woman carries the altered BCRA1 and/or BCRA2 genes.

Breast cancer prevention is becoming an important area of clinical practice, education and research. Breast cancer chemoprevention is the use of drugs (e.g., anti-estrogens) to lower the risk of developing breast cancer. For example, tamoxifen has proven to lower the risk of developing breast cancer in women considered to be high-risk.[40] Other options for lowering breast cancer risk include oophrectomy and prophylactic mastectomy. Women and their healthcare providers must carefully assess the risks and benefits of primary and secondary breast cancer prevention strategies, including the lowering of risk, and, risk-appropriate surveillance.

Treatment

There are essentially two approaches to the treatment of early breast cancer: localized (regional) treatment and systemic treatment. Local treatment specifically targets the breast and the adjacent lymph nodes. Options include surgery to remove the entire breast (mastectomy) or only part of the breast tissue containing the tumor and some of the normal surrounding tissue (lumpectomy or breast-conserving surgery), as well as radiation therapy (radiotherapy). Radiation therapy is highly focused, relying on a radioactive beam or radioactive "seeds" to locally destroy cancerous cells. Since the radiation is highly focused, side effects are limited to the area being treated.

Systemic treatment is directed to the entire body and is used to destroy any malignant cells that may have spread to other parts of the body. There are currently three different classes of systemic therapy: chemotherapy, hormonal therapy, and immunotherapy. Systemic therapy can be administered following surgery (adjuvant therapy) or before surgery, to reduce the size of the cancer (neoadjuvant therapy).

The decision on which treatment approach will be used depends on a number of prognostic factors that include: (1) stage of the cancer (2) whether it is an invasive or non-invasive cancer, and (3) whether the lymph nodes have been affected. Clinical staging of breast cancer is based on the TMN (tumor, node, metastasis) system, which assesses the size of the tumor, level of lymph node involvement, and the presence or absence of metastases.[41] In addition, the tumor is assessed for the presence or absence of specific prognostic tumor markers that will further guide the treatment protocol. Currently, tumors are assessed for estrogen receptor (ER) expression, and overexpression of the human epidermal growth factor receptor 2 (HER2) protein.

Treatment of advanced metastatic breast cancer specifically targets the relief of symptoms and maintenance of function and QOL. A number of treatments are considered for advanced breast cancer, including hormonal therapy and chemotherapy.[42]

Local Therapy

Surgery remains the primary treatment of choice for women with early breast cancer. Results of a recent 20-year followup study indicate that the longterm survival rate was the same among women who underwent breast-conserving surgery as for those who underwent radical mastectomies, suggesting that breast-conserving surgery is the treatment of choice for women with relatively small breast cancers.[43] However, the decision on whether the patient should have breast-conserving surgery or a mastectomy is made based on the size and pathological characteristics of the tumor. Patient choice should be considered and respected, particularly when surgical options have equivalent longterm benefits. For both surgical approaches, the

lymph nodes in the axilla closest to the cancerous breast are also removed (axillary node dissection). Removal of the lymph nodes, however, causes side effects in some patients, such as swelling in the arm (lymphedema). The removed breast and lymph tissues are then examined by a pathologist to ensure that enough of the cancerous tissue has been removed, and that there are no cancerous cells at the margins or outer edges of the tissue (i.e., clear surgical margins).

A relatively new, less invasive technique called sentinel lymph node biopsy involves the removal and examination of the sentinel nodes—the first lymph node(s) to which cancer cells are likely to spread from the primary tumor. If sentinel nodes are found to be positive, then the rest of the lymph nodes are removed in a lymph node dissection. A recent study has demonstrated that this procedure is as effective as axillary node dissection at detecting whether early breast cancer has spread, although it is not yet clear if it increases survival.[44] If the sentinel nodes are found to be negative, no further lymph node surgery is undertaken.

To reduce the risk of local recurrence, breast-conserving surgery should be followed by radiotherapy in order to eliminate any cancerous cells that may still be present in the breast tissue.[45] The Early Breast Cancer Trialists' Collaborative Group has concluded that, in women with early breast cancer, radiotherapy reduced the risk of local recurrence by two-thirds and produced an absolute increase in 20-year survival of approximately 2% to 4%. However, they estimated that the hazard risk associated with the treatment could reduce this 20-year survival benefit in young women.[45,46] Partial breast irradiation using brachytherapy implants (i.e., radioactive seeds placed directly into the tumor bed) or local intraoperative radiation may also provide local control,[47,48] although these techniques have not been evaluated in randomized trials. In some circumstances, radiation therapy also benefits patients treated with mastectomy.

Systemic Therapy

Adjuvant chemotherapies have been demonstrated to reduce the risk of recurrence and mortality in patients with early-stage breast cancer.[49,50] In the US, anthracycline-based regimens (e.g., doxorubicin, epirubicin) are the most widely-used for the treatment of early breast cancer.[51] The addition of taxanes, including paclitaxel, to adjuvant chemotherapy programs appears to improve disease-free survival rates[52,53] and overall survival rates when compared with anthracycline-based regimens alone.[51,52,54]

Adjuvant hormonal therapy is used to inhibit the effects of hormones such as estrogen and progesterone, which promote the growth of breast cancer cells. The anti-estrogenic compound, tamoxifen, is currently the most commonly used anti-estrogenic therapy (with or without chemotherapy) to treat both pre- and postmenopausal women with ER-positive primary breast cancer.[55] Adjuvant tamoxifen therapy is generally administered for five years in patients with hormone-receptor positive breast cancer.[51] Longterm followup of randomized controlled trials has indicated that, beyond 5 years of treatment with tamoxifen, there is no added benefit,[56-58] pending results of ongoing trials in Europe (i.e., ATLAS and aTTom trials). The benefit of adjuvant tamoxifen in women with ER-negative tumors remains to be determined.[59] Hormone suppression by ovarian ablation may also be considered in premenopausal women. Recently, the Early Breast Cancer Trialists' Collaborative Group concluded that, for women under the age of 50, ovarian ablation significantly improves longterm survival, at least in the absence of chemotherapy.[60] Further analysis is required to assess the relevance of ovarian ablation and hormone-receptor status.

Aromatase inhibitors (e.g., anastrozole, letrozole) are also emerging as an effective treatment option for ER-positive breast cancers in postmenopausal women.[61,62] However, there are limited data available regarding longterm toxicity.[63] Aromatase inhibitors bind to the aromatase enzyme, inhibiting the conversion of androgen to estrogen. Recent results of the NCI-C MA17 trial have shown a benefit, in terms of disease-free survival, for continuation of endocrine therapy with letrozole in women who remained free of disease recurrence after 4.5 - 6 years of adjuvant tamoxifen.[64,65]

Immunotherapy involves a relatively new class of agents that target the body's immune system. Currently, trastuzumab is the only immune therapy approved for the treatment of breast cancer. The FDA has approved it for the treatment of women with metastatic HER2-positive breast cancer or, through clinical trials, for women with early-stage HER2-positive breast cancer involving the lymph nodes.[66,67] Overexpression of HER2 protein results in increased cell division and a higher rate of cell growth. Trastuzumab is a monoclonal antibody that specifically binds to the HER2 protein, slowing the growth of HER2-expressing cells. It is estimated that HER2 is overexpressed in 25% of breast cancers.[68]

For patients with metastatic breast cancer, hormonal therapy (i.e., tamoxifen and/or ovarian ablation)[69] is considered in premenopausal women who are ER-positive; aromatase inhibitors are used for postmenopausal women. Both anastrozole and letrozole have recently been approved as first-line agents for the treatment of women with metastatic breast cancer, and trials are currently underway to investigate their potential as treatment for early breast cancer, both in the adjuvant and neoadjuvant setting.[70] For women with metastatic disease who are ER-negative, or those with rapidly progressive, life-threatening disease, or with visceral involvement, chemotherapy is indicated.

Neoadjuvant treatment with chemotherapy or endocrine agents is being used increasingly to downstage locally advanced and large operable breast cancers.[71-73] Neoadjuvant treatment may allow for inoperable breast tumors to become resectable, and for operable tumors initially requiring mastectomy to be successfully removed by breast-conserving surgery.

Followup

The goal of patient followup is to detect new or recurrent disease, and to assess treatment outcome. What constitutes followup care following primary breast cancer treatment, however, varies from center to center. In general, routine patient followup procedures include regular physical examinations, annual mammograms and pelvic exams.[74,75] Historically, followup has also entailed a more intensive diagnostic evaluation, including chest X-rays, bone scans, liver ultrasound, CT scan, and complete blood work (including cancer tumor markers) to detect early signs of disease recurrence. However, in women who do not report any symptoms that may indicate disease recurrence, these tests are currently not considered appropriate and cost-effective since they have not been shown to affect survival.[74-77]

In addition to clinical followup procedures, QOL issues are becoming an increasingly important part of the post-breast cancer treatment followup process.[78] Following primary breast cancer treatment, many breast cancer survivors experience longterm therapy-related complications (e.g., lymphedema, early onset menopause) that can have a significant impact on their QOL. For women who underwent a mastectomy, having lost a breast may have a significant impact on their emotional well-being. Concern about the breast cancer risk of family members, such as children, is a common apprehension of these women.

Supportive Care

The diagnosis of breast cancer is often accompanied by supportive care interventions, such as physical, emotional, spiritual, psychosocial and practical care. These are required to support women and their significant others through this distressing time.[79,80] Supportive care needs vary from individual to individual, and may change over time. The disease and its treatment may result in ongoing sadness, fear, anxiety and anger, and supportive care interventions often make an important difference to how patients cope with their illness over time.

Effective supportive care can be a component integral to producing an optimal treatment outcome in a patient with breast cancer. For example, preventing or controlling treatment-limiting side effects, such as nausea and vomiting, improves patients' QOL and allows greater tolerance of chemotherapeutic regimens.[81] This, in turn, may improve outcomes by preventing premature withdrawal from potentially life-saving chemotherapy regimens. For women with end-stage breast cancer, palliative care will include management of chronic pain associated with advanced disease, as well as other supportive care interventions.[82]

Reporting

The optimal management of patients with breast cancer relies on an accurate pathology diagnosis as well as appropriate monitoring and evaluation of the treatment program. Hence, reporting prognostically-significant information is critical. Standardizing the reporting with a typical set of data obtained from each patient, using the same terminology and diagnostic criteria, would facilitate this process. The adequate and complete documentation of treatment helps clinicians (and researchers) observe important covariations among clearly defined types of care and outcomes.

Chapter 2. Methods

Overview

The UO-EPC's evidence report on quality measurement relating to the diagnosis and treatment of breast cancer in women is based on a systematic review of the healthcare literature to identify, and synthesize the results from, studies addressing key questions. Together with content experts, UO-EPC staff identified specific issues integral to the review. A Technical Expert Panel (TEP) helped refine the research questions, as well as highlighted key variables requiring consideration in the evidence synthesis. For example, given the objective of this review, adherence data—potentially indicating gaps in care—were to be de-emphasized. Central to the project was identifying the quality measures and their key characteristics.

Evidence tables presenting the key study characteristics and results were developed. Question-specific summary tables were derived from evidence tables, to facilitate the qualitative synthesis of measurement-related data (e.g., types; purpose). Also appraised was the extent of the scientific development of the quality measures employed to measure quality.

Some of the conventions (e.g., definitions and terms) adopted in the present synthesis of the evidence reflect the conceptual and practical perspectives used within AHRQ's NQMC[8] because its developers evaluated, then integrated these elements from many sources, including: the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Foundation for Accountability (FACCT), the Institute of Medicine (IOM), the U.S. Department of Health and Human Services (HHS), the Performance Measures Coordinating Council, the Physician Consortium, Australia's National Health Performance Committee, United Kingdom's National Health Service (NHS), and, the German Agency for Quality in Medicine.

Key Questions Addressed in This Report

The purpose of this evidence report was to synthesize information from relevant studies to address the following questions:

- What measures of the quality of care are available to assess the quality of diagnosis of breast cancer in women, including:
    - Appropriate use and quality of diagnostic imaging; breast biopsy; sentinel node biopsy;
    - Appropriate use of chest x-ray; bone scan; CT scans; MRI; and, blood tests;
    - Availability and accuracy of pathology staging, and, tumor marker status;

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.goc/clinic/epcindex.htm

    - Availability, accuracy and appropriate use of genetic testing; and,
    - Patient-reported QOL, and, patient satisfaction? (Question 1)
- In what patient populations have these quality measures been used? (Question 1a)
- For what diagnosis-related purposes have these quality measures been used? (Question 1b)
- What quality measures, if any, are available to assess differences in the quality of diagnosis of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? (Question 1c)
- What is the evidence supporting the use of quality measures for the diagnosis of breast cancer in women, exhibited in terms of:
    - the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? (Question 1d)
    - their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? (Question 1e)
- What measures of the quality of care are available to assess the appropriate use and quality of treatment for breast cancer in women, including:
    - Breast-conserving surgery;
    - Mastectomy (including adequacy of surgical margins);
    - Lymph node surgery;
    - Reconstructive surgery;
    - Radiation therapy after breast conserving surgery and post-mastectomy;
    - Adjuvant and neoadjuvant systemic therapy (chemotherapy and hormone therapy);
    - Hormonal and chemotherapy management of metastatic disease;
    - Dosing of radiation and chemotherapy;
    - Supportive care; and,
    - Patient-reported QOL, and, patient satisfaction? (Question 2)

- In what patient populations have these quality measures been used? (Question 2a)
- For what treatment-related purposes have these quality measures been used? (Question 2b)
- What quality measures, if any, are available to assess differences in the quality of treatment of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? (Question 2c)
- What is the evidence supporting the use of quality measures for the treatment of breast cancer in women, exhibited in terms of:
    - the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? (Question 2d)
    - their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? (Question 2e)
- What measures of the quality of care are available to assess the appropriate use and quality of followup for breast cancer in women, including patient-reported QOL, and, patient satisfaction? (Question 3)
- In what patient populations have these quality measures been used? (Question 3a)
- For what followup-related purposes have these quality measures been used? (Question 3b)
- What quality measures, if any, are available to assess differences in the quality of followup of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? (Question 3c)
- What is the evidence supporting the use of quality measures for the followup of breast cancer in women, exhibited in terms of:
    - the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? (Question 3d)
    - their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? (Question 3e)
- What measures are available to assess the adequacy and completeness of documentation of pathology, operative, radiation, and chemotherapy reports? (Question 4)

While it was thought to provide additional value, a plan to significantly increase the scope of the original request for task order was eventually dropped for practical reasons. It involved

identifying, then classifying quality indicators according to their potential for development as formal quality measures. The strategy entailed identifying, then synthesizing evidence-based quality indicators derived from evidence-based practice guidelines, systematic reviews, as well as from empirical evidence either highlighted in key journal published commentaries or nominated by clinical experts as having the potential to overturn or modify a recommended standard of care. This evidence was to be organized within a Recommendations Matrix,[83] from which unique evidence-based quality indicators not yet developed as quality measures could be identified. The exact clinical content or meaning, quality (i.e., rigor of development of practice guidelines; quality of systematic reviews; internal validity of studies with the potential to impact a recommendation about care), and up-to-datedness of the evidence were also to be assessed.[84-89] The strength of the evidence (i.e., the design types, power, quality/validity, effect sizes, and number of research studies) supporting a quality indicator would then be used to define its clinical "appropriateness" where, the stronger the evidence (e.g., several well-powered, high quality randomized controlled trials supporting a given treatment), the greater the potential for its scientific development as a measure. The TEP agreed on the value of expanding the scope in this way, and great support was received from the Guidelines International Network, for example.

Literature searches and two levels of dual-reviewer relevance assessments were then conducted in accordance with the expanded scope. However, given the amount of published evidence that was identified, and the time estimated to compose the Recommendations Matrix and complete the work it would afford (i.e., identify, then appraise unique quality indicators based on potentially overlapping or contradictory data from different data sources; evaluate the strength of each indicator's evidence), it was decided that the burden was too great to achieve within the present project's timeline. The TEP concurred, and the original project, with a few additional foci recommended by the TEP, became the basis for the evidence report. Added to the project were topics such as supportive care, followup, and, both QOL and patient satisfaction. The latter two constructs are addressed with reference to breast cancer diagnosis, treatment, and followup. They capture key patient-centered definitions of the quality of breast cancer care.

The narrowing of the scope had several consequences. Methodology-related ones are outlined in the present chapter. The larger consequences are highlighted as limitations of the review (Discussion).

Analytic Framework

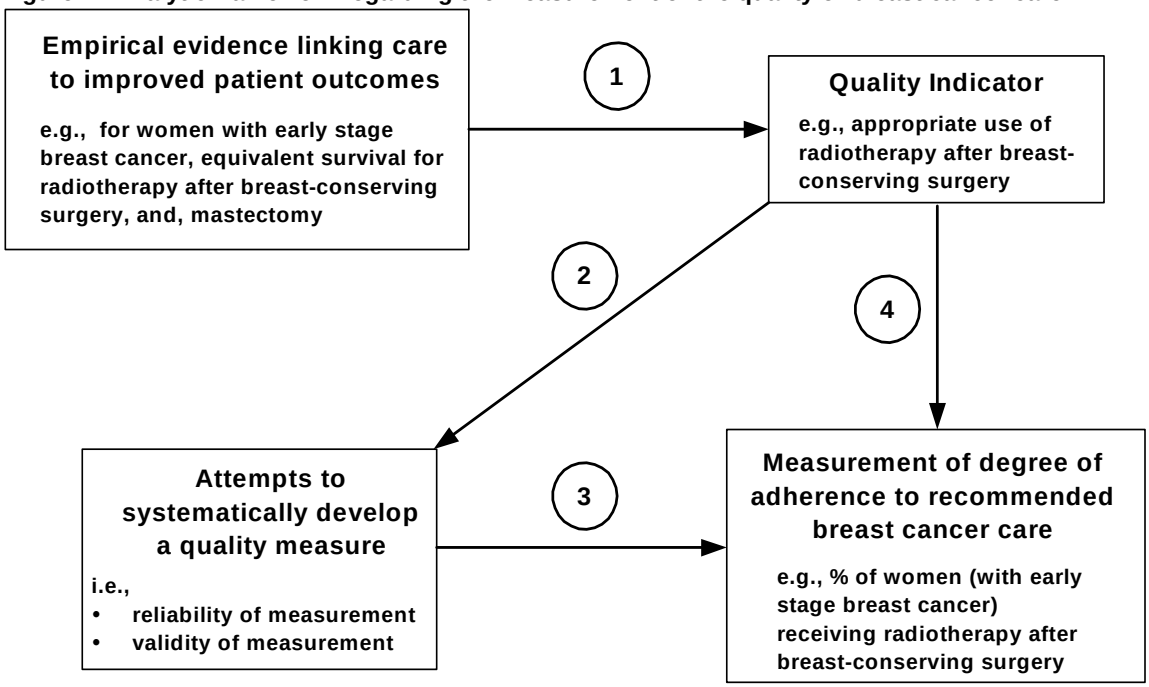
This systematic review aimed to identify and synthesize evidence concerning measures assessing the quality of breast cancer diagnosis, treatment, followup, and, the documentation of this care. The analytic framework (Figure 1) illustrates the review's larger conceptual context, including key constructs and their relationships. Quality measurement refers to the broad class of events involving the quantification of the degree of adherence to an evidence-based indicator of quality (i.e., recommended) care (e.g., "percentage of women receiving radiotherapy after breast-conserving surgery"); and, quality indicators (e.g., "radiotherapy after breast-conserving surgery") vary in terms of the extent to which they have been developed scientifically as measures. To simplify matters though, here it is assumed that there are two basic paths leading from an evidence-based quality indicator to quality measurement, with each involving the same

population of interest, that is, female adults diagnosed with, or in treatment for, any histological type of adenocarcinoma of the breast, including both in situ and invasive cancer.

An evidence-based quality indicator, such as a recommendation in a clinical practice guideline or systematic review, requires clearly referenced, empirical evidence demonstrating its links to improved patient outcomes, and, irrespective of whether a peer consensus assessment of its appropriateness has been conducted (linkage 1).[17] This approach is consistent with the view that any national quality measurement and reporting system should be evidence-based,[90] and with the goal of the above-noted public-private initiative (i.e., AHRQ-CQuIPS, NCI, CDC, CMS, NQF) to identify and promote evidence-based quality measures of cancer care.

One path (via linkages 2 and 3) culminates in the quantification of the degree of adherence to quality indicators that have been formally developed to some extent as quality measures. This is the ideal approach to quality measurement given the sound psychometric foundation of the quality measures, established through pilot-testing with relevant cases obtained from specific data sources (e.g., cancer registries; medical records).

Figure 1. Analytic framework regarding the measurement of the quality of breast cancer care



A second path (linkage 4) also entails quantifying the degree of adherence to a quality indicator, yet where the performance standard has not yet received formal scientific attention to develop it as a measure. Nevertheless, when applied to appropriate data sources, even this path can yield psychometric data (e.g., inter-abstractor reliability). Either path can provide additional evidence, via studies evaluating adherence to standard care, confirming linkages of this care to improved patient outcomes.

Study Identification

Search Strategy

A search was undertaken to find quality measures in breast cancer diagnosis, pathology, staging, treatment (including chemotherapy, surgery and breast reconstruction), followup and continued surveillance, and supportive care. Bibliographic databases searched were: Medline (1966 to September Week 2, 2003), Cancerlit (1975 to October 2002), Healthstar (1987 - March 2003), Premedline (September 12, 2003), Embase (1980 to 2003 Week 18), CINAHL (1982 to April Week 2 2003), Cochrane Database of Systematic Reviews (1st Quarter 2003), Database of Abstracts of Reviews of Effectiveness (DARE) (1st Quarter 2003), Cochrane Central Register of Controlled Trials (1st Quarter 2003), and, Health and Psychosocial Instruments (HAPI) (1985 to September 2002).

The main search strategy (Appendix A) was designed to retrieve items, published after 1992, relevant to breast cancer diagnosis and treatment, and, quality measures. This strategy was developed in Medline and used, with minor adjustments, in all of the other databases except HAPI. The Cancerlit and Healthstar searches were limited to exclude items also found in Medline. The Embase search was limited to non-English articles or articles with an entry week in the six months preceding the search. The search strategy used for the HAPI database (Appendix A) included only disease and quality concepts, since HAPI is a database of information concerning measurement instruments. Based on these searches, 3717 citations were downloaded into Reference Manager, where duplicate citations were removed, leaving 3313 unique citations. These searches were undertaken via the Ovid interface.

A third search strategy (Appendix A) was developed to retrieve systematic reviews of breast cancer treatment or diagnosis. Lines 1-46 of this search are an Ovid translation of the National Library of Medicine's Systematic Reviews Subset Strategy.[91] The remaining lines represent the cancer treatment and diagnosis concepts from this project's main search strategy. The search was executed in Medline (1966 to May Week 3, 2003) and Cancerlit (1975 to October 2002), yielding 509 and 29 items, respectively, and limited retrieval to material with publication years of 1994 and later. Items not retrieved by the main search in Medline or Cancerlit were downloaded. The downloaded set was then de-duped against the main result set, with 526 unique items retained.

Reference lists of included studies, book chapters, and narrative or systematic reviews retrieved after having passed the first level of relevance screening, were manually searched to identify additional unique references. Through contact with content experts, attempts were made to identify both published and unpublished studies. A letter was written to an ASCO representative to obtain data concerning their quality measures currently under development (Appendix B). Searched for quality measurement evidence were the following web sites: AHRQ's National Quality Measures Clearinghouse (Last accessed on October 1, 2003 at http://www.qualitymeasures.ahrq.gov/resources/measure_use), the American Society of Clinical Oncology (Last accessed on October 1, 2003 at http://www.asco.org), the National Committee for Quality Assurance (Last accessed on October 1, 2003 at http://www.ncqa.org), the Institute of Medicine (Last accessed on October 1, 2003 at http://www.iom.edu), the Foundation for Accountability (Last accessed on October 1, 2003 at http://www.facct.org), the National Comprehensive Cancer Network (Last accessed on October 1, 2003 at http://www.nccn.org), and, Blue Cross of California (Last accessed on October 1, 2003 at

http://www.bluecrossca.com). Records obtained from all additional searches were downloaded and de-duped against those previously retrieved. A final set of 3,848 unique bibliographic records was identified.

Eligibility Criteria

The population of interest was female adults diagnosed with, or in treatment for, breast cancer. This covered all histological types of adenocarcinoma of the breast, including in situ and invasive cancer. Exclusions decided upon by the Federal Partners, and accepted by our TEP, encompassed inflammatory breast cancer, Paget's disease, and, phyllodes tumors. Relevant breast cancer care included diagnosis, treatment (including supportive care), followup, and, the documentation of this care (i.e., pathology, operative, radiation, and chemotherapy reports). Screening and prevention fell outside the scope of the present review.

Quality measurement entails the quantification of the degree of adherence to an evidence-based standard of quality (i.e., recommended) care, or quality indicator. A study, conducted in any country, was relevant only if it reported having measured adherence to at least one evidence-based standard. The decision was made in consultation with our TEP. In a relevant study, specific mention had to be made of the reference standard substantiating the care (e.g., clinical practice guideline), and adherence measured with respect to at least one data source (e.g., medical records). Reference to some form of empirical evidence, indicating that receipt of this care reliably results in improved patient outcomes, was required to support it as a standard. Quality indicators could index any domain (e.g., structure, process/access, outcome), come from any reference standard (e.g., clinical practice guideline; systematic review), and have been subjected to *any* degree of scientific development as a quality measure (i.e., from none to complete). Given the unique physical and psychosocial issues related to breast cancer (e.g., body image; self-esteem), measures of QOL and patient satisfaction had to have been adapted or developed for (past or present) use with breast cancer patients.

The standard of care had to have been published prior to the quality measurement effort, and to have been available to guide care in those geographic locations whose population's patterns of care were assessed using this standard. Only under these conditions would patients, as well as healthcare practitioners, organizations, and systems have had access to these recommendations to guide decisions about practice. This likely constitutes the most meaningful assessment of performance relative to standards. So, in before-after studies evaluating the impact on patterns of care of a standard (e.g., a clinical practice guideline) employed as an intervention, only post-intervention adherence results were relevant. Thus, excluded from the review were studies where adherence to a standard published in 1998, for example, was evaluated using data collected prior to the standard's publication (e.g., 1985); or, where a standard (e.g., a recommendation from a national clinical practice guideline in the United States) had not been adopted in the location (e.g., Russia) involving the population whose patterns of care were assessed via this standard.

Results of efforts to collect quality measurement data had to have been made available or actively disseminated (e.g., published) starting in 1993, given the relatively recent increase in interest in quality measurement over the past ten years. This cut-off date was established in consultation with our TEP. It was also assumed that standards of care identified prior to 1993 could be used to measure quality after this date, providing these quality indicators continued to reflect standard, or recommended, care.

Before the project was narrowed to exclude UO-EPC's proposed secondary goal (i.e., to identify quality indicators with the potential for development as measures), also considered relevant were evidence-based clinical practice guidelines and systematic reviews published starting in 1996 and 1994, respectively. The extended temporal focus on systematic reviews was decided upon to cover the period of development of the clinical practice guidelines. The scope of the project was modified, however, before any formal literature searches for key journal published commentaries were conducted, and before empirical evidence with the potential to overturn standards of care (e.g., very recent studies) was solicited from content experts such as review team and TEP members.

Study Selection Process

The results of literature searches were posted to an internet-based software system for review. To enhance the speed and efficiency of conducting and managing the systematic review process, this software, which resides on a secure web site, was used to enable the electronic capture and internal comparison (relative to explicit criteria) of multiple reviewers' responses to relevance screening questions, and to requests to abstract specific data (e.g., population parameters) from bibliographic records or full reports.

Following a calibration exercise which involved screening five sample records using an electronic form developed and tested especially for this review (Appendix C), two reviewers independently broad screened the title, abstract, and key words from each bibliographic record for relevance by liberally applying the eligibility criteria. The record was retained if it appeared to contain pertinent study information. If the reviewers did not agree in finding at least one unequivocal reason for excluding it, it was entered into the next phase of the review. The reasons for exclusion were noted using a modified QUOROM format (Appendix D).[86]

Print or electronic copies of the full reports were then retrieved. After completing a calibration exercise involving the evaluation of five sample reports using the same eligibility criteria (Appendix C), the rest of the reports were independently assessed by two reviewers. Reports were not masked given the equivocal evidence regarding the benefits of this practice.[92] To be considered relevant, all eligibility criteria had to be met. Disagreements were resolved by forced consensus and, if necessary, third party intervention. Excluded reports were noted as to the reason for their ineligibility (Listing of Excluded Studies at Level 2).

After the scope of the project was narrowed, the screening protocol had to be modified in two ways. First, a third level of screening was added to exclude previously included articles reporting practice guidelines or systematic reviews. Excluded reports were noted as to the reason for their ineligibility (Listing of Excluded Studies at Level 3). Second, with the objective of wanting to avoid ordering articles which, because of the narrowed scope, were no longer relevant to the review, bibliographic records describing practice guidelines or systematic reviews that were newly identified via an updated application of the original search strategy became excludable via level 1 screening. These exclusions are noted in relation to level 1 screening activity in the modified QUOROM flow diagram (Appendix D). For each of these additional screening tasks, a calibration exercise involving two reports preceded the independent screening of the remaining reports by two reviewers. Disagreements were resolved by forced consensus and, if necessary, third party intervention.

Data Abstraction

Following a calibration exercise involving two studies, three reviewers independently abstracted the contents of each included study using an electronic Data Abstraction form developed especially for this review (Appendix C). Abstracted data were checked by a second reviewer. Data included the:

- report characteristics (e.g., publication status, language of publication, year of publication);

- study characteristics (e.g., quality indicators; data sources; period in which measurements were conducted; location of study; funding source);

- population characteristics (e.g., case characteristics [size of tumor; level of lymph node involvement; presence/absence of metastasis]);

- characteristics of the quality indicators used in quality measurement (e.g., definition; type [diagnosis; treatment, including supportive care; followup; reporting]; evidence-based source [name and publication date of clinical practice guideline]; developmental history, including psychometric data, and, data reflecting links to clinical or patient-reported outcomes; domain [structure, process/access, outcome]; purpose of measurement [e.g., accountability; improvement; research]; current status); and,

- quality measurements (e.g., overall adherence rate; variations in rate based on review-relevant stratifications [age; race; ethnicity; socioeconomic status]).

Summarizing the Evidence

Overview

The evidence is presented in two ways. Evidence tables in the appendices offer a detailed description of the included studies (e.g., definition of quality indicator; sample characteristics; data sources), with a study represented only once. Evidence tables could not be organized on the basis of the type of care (i.e., diagnosis, treatment, followup, reporting) because a given study could include quality indicators reflecting more than one type of care. Instead, question-specific summary tables in the text are organized by type of quality indicator (e.g., radiotherapy after breast-conserving surgery), and highlight key data (e.g., sample description) to compare studies having implemented a given quality indicator. A study can appear in more than one summary table because it can report data regarding various quality indicators. For a given quality indicator, rather than being organized alphabetically by the first author in the summary table, studies are ordered first according to the type of population (e.g., exact diagnosis) and then in reverse chronological order.

The reference standards (e.g., clinical practice guidelines) used by investigators to measure the quality of breast cancer care are identified in per-study evidence tables and are also organized

in a Listing of Reference Standards Used to Measure Quality of Breast Cancer Care in Included Studies. The latter includes citations, which refer to the reference standards, gleaned primarily from included studies. This Listing follows the Listing of Quality Indicators Used to Measure Adherence to Standards of Breast Cancer Care (Appendix G).

Trajectory of Scientific Development of Quality Measures

It was decided to appraise the quality indicators implicated in quality measurement efforts, with four criteria presented in Chapter 1 having the potential to be used for this purpose: scientific soundness, importance, usability, and feasibility.[12] However, three of these could not be assessed.

There are several ways to define a quality measure's importance. However, to evaluate whether the standard of care to which it refers is an established national goal would require conducting a systematic review of all evidence concerning national goals, to permit the classification of each measure. This is a task clearly falling outside the scope of the present project. Second, to evaluate whether a quality measure represents a significant leverage point for achieving a national goal requires reliable and valid data supporting this goal; and, these data require the very reliable and valid quality measures this review sought to identify. Likewise, without the scientifically sound means to do so, no reliable and valid evidence regarding notable gaps, or variations, in care could be used to define this care's importance. Finally, to evaluate whether the data produced by the application of a quality measure is useful to a stakeholder in the healthcare system also requires the validated measures this review was seeking. Thus, these definitions of the importance of a quality measure cannot be meaningfully assessed until the reliable and valid means to do so are identified. The same state of affairs confounds attempts to determine the usability of a quality measure, defined as the meaningful interpretability of the observations and, whether or not, and how, such interpretations afford decisions concerning the delivery of healthcare.

Feasibility is the ability to collect healthcare quality data within the normal flow of clinical care. However, given that this capacity can vary greatly across contexts in which breast cancer care is provided (e.g., a physician's small private practices vs a large regional cancer center), and in no small measure because of differences in resource capacity (e.g., personnel), the assessment of this construct would yield multiple grades. Each would reflect a different practice context. The multiple grades would then need to be organized somehow to convey an overarching picture of a quality measure's feasibility. Deriving a single grade (e.g., the modal value) would likely misrepresent the potentially wide variability in the grades, however. It was decided that feasibility could not be easily evaluated.

It was deemed possible based on data likely to be included in review-relevant studies, or through reference to companion reports, to assess the extent of scientific development of measures employed in quality measurement. A scheme was derived to situate studies' individual quality measures on an hypothetical trajectory, from no attempts to establish reliability and validity, to a consistent demonstration of the soundness of these properties (Appendix C). It also considered the timing of the collection of these psychometric data (i.e., prior to the study for which the quality indicator was used to measure quality and/or within the present study in which it was used to measure quality). Data generated while the measure was implemented in a study assessing adherence to standard care may be collected in a less rigorous fashion.

After a calibration exercise involving two relevant studies, two assessors independently evaluated each of the quality measures. Disagreements were resolved via forced consensus. Inter-assessor reliability data indicated that, in 95.5% of cases (n = 128/134), both assessors agreed on the grade. Perfect agreement was achieved when a quality measure in one of the adherence studies did not report a past or present history of validation (n = 122). However, when quality measures had reliability and/or validity data reported in support of their scientific soundness, agreement fell to 50% (n = 6/12). McGlynn et al. noted sound inter-rater reliability for a randomly selected 4% sample of their full complement of participants.[5] However, kappa values were not reported for individual quality indicators exclusively relating to women's breast cancer care, thereby precluding an assessment of the on-study soundness of their psychometric development. As a result, their 9 quality indicators relating to breast cancer care were excluded from the calculation of the percent agreement between independent users of the present scheme. This scheme requires rigorous validational efforts to justify its use elsewhere.

The trajectory level achieved by each quality indicator is noted in summary tables in the text, in per-study evidence tables (Appendix E), and in the Listing of Quality Indicators Used to Measure Adherence to Standards of Breast Cancer Care (Appendix G).

Data Synthesis

An overarching qualitative synthesis describes the progress of each citation through the stages of the systematic review. Data from relevant studies are then synthesized qualitatively in response to key questions. Since the present review was concerned with cataloguing and describing certain characteristics of quality indicators implicated in quality measurement, quantitative syntheses were considered to be outside the present scope.

Chapter 3. Results

Overview

Several perspectives on the results of the systematic review are presented in this chapter. Highlighted first are the results of the literature search and the status of bibliographic records, then full-text articles, as they progressed through the stages of the review. An overview of the numbers and types of quality indicator involved in the relevant quality measurement efforts follows next. The key questions are then answered, with questions organized by the larger categories of diagnosis, treatment (e.g., supportive care), followup, and documentation of this care. Summary tables accompany textual descriptions, and present various attempts at quality measurement organized by subcategory of care (e.g., chemotherapy-related care). Given that a quality indicator pertains to a particular population, questions addressing the identity of the quality indicator, and the population with which it was employed, are answered concurrently. There are a number of instances when a quality measurement, although pertinent to the topic of breast cancer care, does not fit perfectly within the categories of care outlined in the key questions. When available, these data fall under a "general category" placed at the end of a section responding to a given question. The meanings of acronyms and abbreviations used in summary tables appear in the first summary table within each new section of the present chapter.

Results of Literature Search

Regardless of its source, the progress of each bibliographic record through the stages of the systematic review is illustrated in the modified QUOROM flow chart (Appendix D). Ideally, a record included an abstract and key words, in addition to a citation. When a citation was discovered, for example through a manual search of a reference list, its complete bibliographic record was sought (e.g., Pubmed) and then entered into the first level of screening.

Of 3,848 records entered into the initial screening for relevance, 2,937 were excluded. Reflecting the specific eligibility criteria, the reasons for exclusion were: a. not breast cancer in women (n = 928); b. not breast cancer diagnosis or treatment (or followup or reporting/documentation) (n = 1,137); c. not a quality measure/ment, clinical practice guideline, systematic review, or, commentary/editorial (n = 860); and d., not a quality measure/ment (i.e., a clinical practice guideline, systematic review, or, commentary/editorial) (n = 12). The records associated with this last reason for exclusion refer to those rejected via the initial screening of the bibliographic records yielded by the search update, and owing to the narrowed scope of work. All but 16 reports for the remaining 911 records were then retrieved and subjected to a more detailed relevance assessment. Four reports were never retrieved,[93-96] and 12 arrived too late to assess them further before this evidence report was completed.[97-108]

The second relevance screening then excluded 610 reports, with the following noted reasons for exclusion: a. not breast cancer in women (n = 52); b. not breast cancer diagnosis or treatment (or followup or reporting/documentation) (n = 40); and c. not a quality measure/ment, clinical practice guideline, systematic review, or, commentary/editorial (n = 518) (Listing of Excluded

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.goc/clinic/epcindex.htm

Studies at Level 2). Required because of the change in the scope of the project, a third level of screening excluded 225 reports for the following reasons: a. not a quality measure/ment (clinical practice guideline) (n = 94); b. not a quality measure/ment (systematic review) (n = 115) and c. not a quality measure/ment (commentary/editorial) (n = 16) (Listing of Excluded Studies at Level 3). In total, 60 reports, describing 58 quality measurement studies, were deemed relevant for the systematic review.[5,109-167]

Two studies were each described by two reports. One study was described by two published reports.[151,166] A second study was referred to by a published report[158] and an abstract.[157] [When more than one author is placed in a row in a summary table, this indicates that more than one report refers to the study.] The latter was the only included abstract, with all other reports having been published as journal articles. Two reports required translation, one from Danish[118] and the other from German.[168] Only the former was included in the final collection of relevant studies. Finally, ASCO decided to wait to share details concerning their quality measures until the results of their developmental process are formally disseminated.

Overview of Quality Indicators Used in Quality Measurement

The 60 relevant reports, describing 58 relevant studies, identified 143 quality indicators used to measure quality (see Appendix E for Evidence Tables and Appendix G for Listing of Quality Indicators Used to Measure Adherence). Other than a small number of studies (n = 11) employing different measures primarily of QOL (n = 12), virtually no validated quality measures were found.[110,113,115,117,123,129,139,148,149,153,156] Thus, almost all efforts in quality measurement entailed quality indicators for which no reference was made, or data reported, indicating that they had been developed scientifically as measures. These quality measures are identified in response to the research questions concerning psychometric properties with respect to each category of care.

Of the 12 validated quality measures, all but one were used with reference to treatment, and all but one assessed quality of life. The Patient Satisfaction Questionnaire was used to investigate the impact of treatment.[148] The breast cancer-specific Functional Assessment of Cancer Therapy Scale (FACT-B, version 3) evaluated the quality of life associated with a diagnosis of breast cancer.[115] The remaining quality of life instruments were used to assess the effects of treatment. Of these, the only breast cancer-specific tool was the European Organization of Research and Treatment of Cancer (EORTC) QLQ-BR23.[148] Generic forms (i.e., not breast cancer-specific) included: the Short Form-36 (SF-36);[113,117,129,139,149] EORTC-C30;[117,153] Medical Outcomes Scale (MOS-20);[129,148] Spitzer Quality of Life Index (QLI);[156] Uniscale;[156] Ferrans Quality of Life scale;[123] Psychosocial Adjustment to Illness Scale (PAIS);[123] Guttman Health Status Questionnaire;[129] and, the Linear Analogue Self-Assessment Scale (LASA).[110] Any adaptations required to employ these generic scales with breast cancer patients were reported as having been achieved. No validated quality measures were described as having been used to assess the quality of followup care or reporting/documentation. The "trajectory of scientific development" scheme allowed us to identify 3 (of 12) validated measures, each assessing quality of life in treatment studies, that failed to report study-related psychometric data despite noting or referencing their psychometric histories: Ferrans Quality of Life scale,[123] the PAIS,[123] and the LASA.[110] All other quality indicators received a grade indicating no history of formal scientific validation (i.e., Level IV).

In the diagnosis category, 26 quality indicators were identified, with most pertaining to the general category (n = 11), followed by breast biopsy (n = 7), pathology staging (n = 3), and diagnostic imaging (n = 2); QOL and patient satisfaction relating to diagnosis were each assessed once. Types of care represented in the task order for which no quality measurements meeting eligibility criteria were found, include: sentinel node biopsy, chest X-ray, bone scan, CT scan, MRI, blood tests, tumor marker status, and genetic testing.

It should be recalled that the general category refers to quality indicators not fitting into the predefined categories established in the task order. The types of care indexed in the general category pertaining to diagnosis, included recommendations that women be seen by specific types of healthcare professional, for specific reasons, and within certain time frames (Summary Tables 5 & 6). The greatest number of studies evaluating any given diagnosis-related quality indicator focused on a recommendation pertaining to the appropriate use of preoperative diagnosis by fine-needle aspiration cytology, needle biopsy or biopsy (n = 4) (Summary Table 2). Other than those involved in the assessment of QOL or patient satisfaction (n = 2), most of the quality indicators referred to the delivery or receipt of indicated diagnostic care (75%: 18/24). Only five quality indicators addressed the quality with which specific diagnostic care was delivered. Virtually all measurements were conducted retrospectively.

Many more quality indicators were employed in the measurement of treatment quality (n = 67). Of these, the most frequently assessed were adjuvant systemic therapy (n = 25), and radiation therapy (n = 16). Other categories were evaluated less often, including the general category (n = 11), QOL relating to treatment (n = 5), patient satisfaction relating to treatment (n = 3), surgery in general (n = 2), breast-conserving surgery (n = 2), mastectomy (n = 1), and (axillary) lymph node surgery (n = 1). Quality measurements were not found relating to two types of treatment, that is, reconstructive surgery, and neodjuvant systemic therapy.

The general category included several perspectives on care that did not fit readily into more narrowly defined categories of quality indicator. For example, the appropriate use of treatment sequences according to guidelines included surgery, radiotherapy, chemotherapy, hormone therapy, initial examination, and followup. This quality indicator was evaluated in four studies (Summary Table 37). The greatest number of studies employing any given treatment-related quality indicator evaluated the appropriate use of breast-conserving surgery (n = 18: Summary Table 8), and the appropriate use of radiotherapy after breast-conserving surgery (n = 19: Summary Table 12). Other than those involved in the assessment of QOL or patient satisfaction (n = 8), most of the quality indicators referred to the delivery or receipt of indicated treatment (70.1%: 47/67). Nine quality indicators assessed the quality with which specific treatment care was delivered, and three referred to a structural variable (e.g., availability of a procedure manual for chemotherapy: Summary Table 29). Virtually all measurements were conducted retrospectively.

Followup care was the focus of efforts to measure quality using five quality indicators. Specific types of care were not predefined in this project for this category. Two studies evaluated the appropriate use of guidelines for followup surveillance of breast cancer (Summary Table 39). Measurements were taken retrospectively.

A considerable number of quality indicators were employed in quality measurement relating to reporting/documentation (n = 45). By far, pathology reporting was the most frequently assessed type of practice (n = 42), with chemotherapy reports (n = 2) and imaging reports (n = 1) barely represented. Neither surgical reporting nor radiotherapy reporting were the focus of quality measurement attempts. Two types of quality indicator were each evaluated in five

studies: reporting the assessment of microscopic margins (Summary Table 53), and reporting histological type (microscopic: Summary Table 55).

Evidence identified in this review is now used to specifically address each of the predefined questions. Adherence rates obtained through quality measurement are presented, yet are de-emphasized. These were not subjected to quantitative synthesis. Supporting data regarding studies may be found in the evidence tables (Appendix E).

Question 1: What measures of the quality of care are available to assess the quality of diagnosis of breast cancer in women, including all foci ranging from appropriate use and quality of diagnostic imaging, to patient-reported QOL and patient satisfaction?

1a: In what patient populations have these quality measures been used? With respect to the topic of the appropriate use and quality of diagnostic imaging (Summary Table 1), McGlynn et al. employed a process quality indicator outlining appropriate care following detection of a palpable breast mass.[5] They collected data via telephone survey and medical records. Data for a small number of women to whom this indicator applied, and drawn from a random sample of women living in 12 metropolitan US areas, indicated an adherence rate of 89.1% to the timely (i.e., within 3 months) completion of at least one of five types of care. Evidence was based on observational studies in addition to expert opinion.

Summary Table 1: Preoperative diagnosis

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use: If a palpable breast mass has been detected, at least one of the following procedures should be completed within 3 months: fine-needle aspiration, mammography, ultrasound, biopsy, and/or a followup visit[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	77	1998-2000	89.1%/NA
Appropriate use of preoperative mammographic evaluation[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994; ≤3 mo prior mass excision	727	1995-1996	91.5%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	88%/Age: <70 y: 88.5%; ≥70 y: 86.2%/ Race/ethnicity: White: 88.4%; Black-H: 86.5%/Payer: Government: 87.7%; Private: 88.7%

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; QOL = quality of life ; DCIS = ductal carcinoma in situ; S = significant difference; NS = nonsignificant difference; Mx = mammography; F = followup; b = baseline; HMO = Health Maintenance Organization; H = Hispanic; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Another process indicator was identified whose performance was measured in two different studies conducted in the United States.[162,166] The recommended care pertains to the appropriate use of the preoperative mammographic evaluation, that is, the delivery of this care where it was indicated. Shank et al. specified that mammography take place no more than 3 months prior to the excision of a mass,[162] whereas White et al. did not identify a time frame.[166] Both studies

evaluated data from women with stage I-II breast cancer. Shank et al. selected a random sample of women from their medical records and surveys, whereas White et al. evaluated a convenience sample of women from cancer registries of 842 hospitals. Both studies entailed retrospective review, and employed the standards for breast-conservation treatment jointly developed in 1992 by the American College of Surgeons (ACOS), American College of Radiology (ACR), College of American Pathologists (CAP), and the Society of Surgical Oncology (SSO). The overall adherence rates were similar, although Shank et al.'s 91.5% was associated with a much smaller sample than was White et al.'s 88%.

Cheung assessed adherence to an access (process) indicator recommending that imaging and/or cytology or needle biopsy, if required, be performed at the initial visit (Summary Table 2).[116] The convenience sample included women with operable breast cancer, and a tumor size of <5 cm. Data were collected from the author's medical records using the standards established by the British Association of Surgical Oncology (BASO: 1995). While the measurement period was not reported, it was noted that performance was assessed after the implementation of the guidelines. The overall adherence rate was 0% as the research site did not have a radiology service available at the initial visit.

Summary Table 2: Preoperative diagnosis

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use of imaging &/or cytology or needle biopsy, if required, to be performed at the initial visit[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	0%/NA
Appropriate use of preoperative diagnosis by fine-needle aspiration cytology, needle histology or biopsy[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y (range): 63% - 87%(Minimum: ≥70%; Standard: ≥90%))/NA
Christensen, 2002, Denmark	Convenience sample women with positive mammography screening followed by surgery in Copenhagen	4,111	1991-1997	NA/100%
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	82% (Standard: 90%)/NA
McCarthy, 1997, UK	Convenience sample women with operable BC, <70 y treated at Nottingham City Hospital's	83	1994	86.7% (Standard: ≥70%)/NA
Appropriate use: A biopsy or fine-needle aspiration should be performed within 6 weeks either when the mammography suggests malignancy or the persistent palpable mass is not cystic on ultrasound[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	33	1998-2000	50.2%/NA
Appropriate use: If a breast mass has been detected on two separate occasions, then either a biopsy, fine-needle aspiration or ultrasound should be performed within 3 months of the second visit[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	13	1998-2000	81.6%/NA
Quality of fine-needle aspiration samples from lesions, which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist[IV]				
Cheung, 1999, Hong Kong	Convenience sample women with operable primary BC < 5 cm; attended by the author	100	NR	99% (Standard: >90%)/NA

A process indicator relating to breast biopsy was evaluated in four different studies. It refers to the appropriate use of preoperative diagnosis via fine-needle aspiration cytology or needle histology (Summary Table 2). Sauven et al. specified a minimum and a target standard of ≥70 % and ≥90%, respectively.[160] Christensen et al. also included core biopsy among the preoperative diagnosis procedures.[118] Cheung referred to palpable tumors and set the standard at 90%.[116] McCarthy et al. defined the benchmark at ≥70%.[147] The study populations varied slightly, with Sauven et al. including a population-based sample of women with breast cancer detected by mammography screening. Christensen et al. evaluated a convenience sample of women with an abnormal result in the screening mammogram. Cheung selected a convenience sample of women with operable breast cancer and a tumor size of <5 cm. McCarthy et al. only included patients younger than 70 years of age. Sauven et al. conducted a prospective and retrospective review using regional boundaries and medical records in United Kingdom, Wales, Scotland, and Ireland, while employing the surgical standards of the National Health Service Breast Screening Programme (NHSBSP: 1992). McCarthy et al. completed a retrospective review of data from hospital databases using the same standards. Christensen et al. completed a retrospective review of data from patients selected from hospital registries, and utilized the standards of the European Guidelines for Quality Assurance in Mammography Screening (1996) and the Guidelines for cytology and reporting in breast cancer screening (1993). Cheung used the BASO standards (1995). The overall adherence rates ranged from 63% to 100%.

From a random sample of women living in 12 metropolitan US areas, McGlynn et al. abstracted data for two process quality indicators (Summary Table 2).[5] They observed that 50.2% of eligible women had had a biopsy or fine-needle aspiration performed within 6 weeks, either when the mammography suggested malignancy or the persistent palpable mass was not cystic on ultrasound. They also noted that 81.6% of eligible cases had had either a biopsy, fine-needle aspiration or ultrasound performed within 3 months of the second visit if a breast mass had been detected on two separate occasions. Both indicators were supported by data from observational studies and, expert opinion. Cheung employed a process indicator recommending that the quality of fine-needle aspiration samples from lesions, which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist.[116] The overall adherence rate was 99%, exceeding the target standard of ≥90%.

Regarding surgical procedures, McGlynn et al. found that, in 100% of very few cases, women had a biopsy performed within 6 weeks if fine-needle aspiration could not rule out malignancy (Summary Table 3).[5] Support for this indicator came from observational studies and expert opinion. McCarthy et al. collected performance data relating to the appropriate use of the first localization biopsy operation to correctly identify impalpable lesions.[147] The target standard (≥95%) was surpassed by the overall, perfect performance (i.e., 100%). Cheung also evaluated a process indicator reflecting the quality of breast biopsy care, whereby a primary operable breast cancer receives a frozen section.[116] The overall adherence rate was 0%, with the target set at <10%.

Summary Table 3: Surgical procedures

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use: A biopsy should be performed within 6 weeks if fine-needle aspiration cannot rule out malignancy[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	2	1998-2000	100%/NA
Appropriate use of first localization biopsy operation to correctly identify impalpable lesions[IV]				
McCarthy, 1997, UK	Convenience sample women operable BC, <70 y at Nottingham City Hospital's	11	1994	100% (Standard: >95%)/NA
Quality of breast biopsy: primary operable breast cancer receives a frozen section[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	0% (Standard: <10%)/NA
Quality of technique to determine histological node status for all invasive tumors, either by sampling or clearance[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y (range): 81%-93%)/NA
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	100%/NA
Quality of sampling nodes for invasive breast cancer, to include ≥ 4 nodes[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y (range): 89%-95%)/NA
Quality of hormone receptor assay[IV]				
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	85%/by hospital: 56-99 %

Three process indicators, relating to pathology staging, were investigated (Summary Table 3). The quality of the technique determining the histological node status for all invasive tumors, either by sampling or clearance, was evaluated by Sauven et al.[160] and Cheung.[116] The former's adherence rates increased from 81% to 93% over time, whereas Cheung's rate was 100%. Sauven et al. assessed adherence to the recommendation indicating that the quality of sampling nodes for invasive breast cancer requires at least four lymph nodes.[160] The adherence rate increased from 89% in 1996/1997, to 95% in 2000/2001. Bickell et al's process indicator pertained to the quality of hormone receptor assays performed.[111] Their convenience sample of women with stage I-II breast cancer was selected from tumor registries from four New York city hospitals. The standards were the Mount Sinai Health Final Guidelines (1994-1995). The adherence rate was 85%, with a range of 56% to 99% across the hospitals.

Northouse et al. conducted a study assessing possible changes in QOL after the diagnosis of breast cancer (Summary Table 4).[115] The instrument employed in a convenience sample of black women was a validated breast cancer specific scale, the 37-item Functional Assessment of Cancer Therapy Scale (FACT-B), version 3. It assesses five factors: physical well-being, family well-being, relationship with the doctor, emotional well-being and functional well-being. The

overall change in the scale, on average, reflected improved QOL. However, women with positive (versus negative) lymph nodes, or women with (versus without) recurrence, experienced a lower QOL after a diagnosis of breast cancer. Any improvement in QOL might reflect the positive impact of relationships with healthcare professionals.

Summary Table 4: QOL and patient satisfaction relating to diagnosis

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Change in QOL after diagnosis of breast cancer[iac]				
Northouse, 1999, US	Convenience sample black women with a confirmed diagnosis of BC who were at least 1 mo post-diagnosis, Southeastern region in Michigan	98	NR	NR (Average: fairly high QOL scale/Variables: Node (+): lower QOL (Mean: 110.8) than node (-) (Mean: 120.7); Recurrence of cancer: lower QOL (Mean: 107.1) than not recurrence (Mean: 118.2))/NA
Women reporting an overall satisfaction with the quality of breast care[iv]				
Haas, 2000, US	Convenience sample women referred for at least 1 visit GP, 1 y prior to Mx; abnormal screening Mx or Mx for a clinical breast concern (lump, thickening, breast pain) in Greater Boston Area	579 (baseline); 447 (followup survey)	1996 -1997	Excellent care: 46.8%(b) 45.8% (F)/Age: < 50 y: 44.4% (b); 46.6% (F); ≥ 50 y: 49.3% (b); 44.9% (F)/Race/ethnicity: White: 51.9% (b); 49.8% (F); Black: 35.9% (b); 35.6% (F); Hispanic: 33.3% (b); 25% (F)/Payer: HMO: 42.9% (b); 42.4% (F); Other: 52.8% (b); 50.7% (F)

A second outcome indicator was used to assess whether patients reported an overall satisfaction with the quality of breast cancer care (Summary Table 4). Haas et al. evaluated women referred for at least one visit to the general practitioner during the year prior to the index mammogram, an abnormal screening result, or receiving a mammogram for a breast complaint (e.g., lump, thickening, or prolonged pain).[133] Data were prospectively collected through patient-reported surveys at baseline, after the mammogram, and then after 7 months. Rated from poor to excellent, patient satisfaction was assessed by a questionnaire based on the Harvard Risk Management Foundation Guidelines (1995). The excellent care rates were 46.8% and 45.8% at baseline and followup, respectively.

A process indicator was identified under the general category (Summary Table 5). It refers to the appropriate use of referrals to a surgeon by a general practitioner according to breast referral guidelines. Cochrane et al. selected a random sample of women with breast complaints (e.g., breast lump, nipple discharge, or breast pain) referred to the Rapid Access Breast Clinic in Cardiff, United Kingdom.[119] The population was selected from the referral databases in a retrospective fashion during 8 months in 1995. The standards were taken from the NHSBSP breast referral guidelines (1995), indicating a short period between the implementation of the standards and the performance measurement. This may account for the adherence rate of 60%.

Summary Table 5: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines[IV]				
Cochrane, 1997, UK	Random sample women >35 y breast problems referred to a surgeon by GP, Rapid Access Breast Clinic	2,332 (BC = 147)	1995	60%/Age: <40 y: 54%; >40 y: 64% S
>90% of women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography[IV]				
McCarthy, 1997, UK	Convenience sample women operable BC, <70 y at Nottingham City Hospital's	75	1994	42.7%/NA
Patients attending for diagnostic purposes seen on at least 1 occasion by a breast specialist surgeon[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	100%/NA
<10% of all new cases of women with breast cancer should attend the clinic/hospital on > 2 occasions for diagnostic purposes[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	41%/NA
Urgent referrals of women with breast cancer to be seen within 5 working days[IV]				
Khawaja, 2001, UK	Convenience sample women BC referred by GP to specialist to diagnose: breast lump; suspicion of malignant change; other breast symptoms in Eastbourne	22	3 mo (1998)	82% (Standard: > 80%)/Age: 41-65 y: 27.3%; >65 y: 54.5%
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	95% (Standard: >80%)/NA
Women with breast cancer to be seen by specialist in timely fashion post referral for diagnostic purposes[IV]				
Khawaja, 2001, UK	Convenience sample women BC referred by GP to specialist to diagnose: breast lump; suspicion of malignant change; other breast symptoms in Eastbourne	22	3 mo (1998)	100% (Standard: ≥80%)/ Age: >65 y: 18.2%
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC < 5 cm; attended by the author	100	NR	50% (Standard: 70%)/NA

A process/access indicator appraised by McCarthy et al. related to the recommendation that women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography (Summary Table 5).[147] Taking into account the fact that the target standard was ≥90%, and the overall adherence rate was 42.7%, the system failed to reach the desired level.

The performance of a process/access variable, indicating that patients attending for diagnostic purposes be seen on at least one occasion by a breast specialist surgeon, was measured by Cheung (Summary Table 5).[116] The overall adherence rate was 100%. The same investigator also evaluated the performance of the recommendation that less than 10% of all new cases of women with breast cancer should attend the clinic/hospital on more than two occasions for diagnostic purposes. The overall adherence rate was 41%, indicating a failure to meet the standard.

The urgent referral of women with breast cancer to be seen within 5 working days (process/access) was measured in two studies (Summary Table 5). Khawaja et al. retrospectively collected data from referrals of women with breast symptoms, to the Fast-Access Breast Clinic,[141] whereas Cheung assessed a convenience sample of women with operable breast cancer.[116] The BASO (1995) standards were employed by both authors. Cheung's 95% and Khawaja et al.'s 82% each met the target standard of $\geq$80%. The same investigators also measured adherence to a standard recommending that women with breast cancer be seen in timely fashion by a specialist, post-referral, for diagnostic purposes (process/access). Based on the BASO (1998) and BASO (1995) standards, Khawaja et al. and Cheung specified timely as within 2 weeks of referral and within 15 working days, respectively. The adherence rate was 100% in Khawaja et al.'s study (target standard: $\geq$80%), whereas Cheung's rate of 50% failed to reach its standard (70%).

Sauven et al. investigated adherence to the recommendation that the management of cases coming to surgery from the screening program should only be carried out by surgeons with the necessary specialist knowledge (structure) (Summary Table 6).[160] The adherence rate was stratified by year and surgeon screening caseload per annum. The proportion of women treated by a surgeon with a screening caseload of more than 30 patients per annum rose from 63% in 1996/1997, to 72% in 2000/2001. On the other hand, for low caseload surgeons ($\leq$10 patients per annum), the rate did not change significantly from 1996/1997 (8%) to 2000/2001 (5%).

Summary Table 6: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Management of cases coming to surgery from the screening program carried out by surgeons who have acquired the necessary specialist knowledge[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y & case load range): > 30pts/y, high*: 63%-72%; < 10 pts/y, low: 5%- 8%)/NA
≥90% of women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	2,979	1996-2001	NR (Overall by y (range): 52%-60%)/NA
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	68%/NA
McCarthy, 1997, UK	Convenience sample women operable BC, <70 y treated at Nottingham City Hospital's	11	1994	45.5%/NA
≥90% of women with breast cancer or with an abnormality requiring diagnostic operation need to be told of this within 5 working days of investigations leading to this diagnosis[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC < 5 cm; attended by the author	100	NR	67%/NA
Appropriate use of an evaluation in compliance with guidelines[IV]				
Haas, 2000, US	Convenience sample women referred for at least 1 visit GP, 1 y prior to Mx; abnormal screening Mx or Mx for a clinical breast concern (lump, thickening, breast pain) in Greater Boston Area	579	1996-1997	69.1%/Age: <50 y: 63.8%; >50: 74.5 %/ Race/ ethnicity: White: 71%; Black: 59.5%; Hispanic: 75.8%/Payer: HMO: 73.3%; other: 62%
Appropriate use of initial examination[IV]				
Ray-Coquard, 1997, France	Random sample women with newly diagnosed localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	71	1995	86%/NA

Three studies evaluated the process/access variable indicating that women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision (Summary Table 6). Each failed to achieve a target standard of ≥90%. Sauven et al. stratified the results by year of audit and reported a rate of 60% for 1996/1997 and 47% for 2000/2001.[160] McCarthy et al.[147] and Cheung's[116] respective rates were 45.5% and 68%.

Relative to a standard set at ≥90%, Cheung observed an adherence rate of 67% with respect to the recommendation that women with breast cancer or with an abnormality requiring a diagnostic operation should be told of this within 5 working days of the investigations leading to this diagnosis (process/access) (Summary Table 6). Haas et al. observed a 69.1% adherence rate with respect to the appropriate use of an evaluation that was in compliance with guidelines (process).[133] Variations in the rate depended on the type of consultation: women with an abnormal mammography (74%); and, women with a clinical breast complaint (58.8%). Ray-Coquard et al. found that, according to randomly sampled medical records, 85% of women with

newly diagnosed, localized breast cancer had received an initial examination according to practice guidelines developed in 1993 and implemented in 1994 (process).[158]

1b: For what diagnosis-related purposes have these quality measures been used? The evidence is organized according to three broad categories of purpose. The measurements relating to the following quality indicators were undertaken to achieve external quality oversight:

- appropriate use: "If a palpable breast mass has been detected, at least one of the following procedures should be completed within 3 months: fine-needle aspiration, mammography, ultrasound, biopsy and/or a followup visit" (preoperative diagnosis);[5]

- appropriate use: "If a breast mass has been detected on two separate occasions, then either a biopsy, fine-needle aspiration or ultrasound should be performed within 3 months of the second visit" (preoperative diagnosis);[5]

- appropriate use: "A biopsy or fine-needle aspiration should be performed within 6 weeks either when the mammography suggests malignancy or the persistent palpable mass is not cystic on ultrasound" (preoperative diagnosis);[5]

- appropriate use: "A biopsy should be performed within 6 weeks if fine needle aspiration cannot rule out malignancy" (surgical procedures);[5]

- "appropriate use of preoperative mammographic evaluation" (diagnostic imaging);[162,166]

- "quality of sampling nodes for invasive breast cancer, to include at least four nodes" (pathology staging);[160]

- "quality of hormone receptor assay" (pathology staging);[111]

- "appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines" (general category);[119]

- "management of cases coming to surgery from the screening program carried out by surgeons who have acquired the necessary specialist knowledge" (general).[160]

The measurements relating to the following quality indicators were made to afford internal quality improvement:

- "appropriate use of imaging and/or cytology or needle biopsy, if required, to be performed at the initial visit" (diagnostic imaging);[116]

- "quality of fine-needle aspiration samples from lesions which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist" (breast biopsy);[116]

- "quality of breast biopsy: primary operable breast cancer receives a frozen section" (breast biopsy);[116]

- "appropriate use of first localization biopsy operation to correctly identify impalpable lesions" (breast biopsy);[147]

- "change in QOL after diagnosis of breast cancer" (QOL);[115]

- "women reporting an overall satisfaction with the quality of breast cancer care" (patient satisfaction);[133]

- "more than 90% of women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography" (general);[147]

- "patients attending for diagnostic purposes seen on at least one occasion by a breast specialist surgeon" (general);[116]

- "less than 10% of all new cases of women with breast cancer should attend the clinic/hospital on more than 2 occasions for diagnostic purposes" (general);[116]

- "urgent referrals of women with breast cancer to be seen within 5 working days" (general);[116,141]

- "women with breast cancer to be seen by specialist in timely fashion post referral for diagnostic purposes" (general);[116,141]

- "at least 90% of women with breast cancer or with an abnormality requiring diagnostic operation need to be told of this within 5 working days of investigations leading to this diagnosis" (general);[116]

- "appropriate use of an evaluation in compliance with guidelines" (general).[133]

Some studies evaluating the performance of a given quality indicator varied in terms of the diagnosis-related purposes they were intended to achieve. References to studies designed to achieve each purpose are made explicit:

- "appropriate use of preoperative diagnosis using fine-needle aspiration cytology, needle histology, or biopsy" (breast biopsy): external quality oversight[118,160]; internal quality improvement;[116,147]

- "quality of technique to determine histological node status for all invasive tumors, by either sampling or clearance" (pathology staging): external quality oversight;[160] internal quality improvement;[116]

- "at least 90% of women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision:" external quality oversight;[160] internal quality improvement;[116,147]

- "appropriate use of initial examination" (general): both internal quality improvement and external quality oversight.[158]

1c: What quality measures, if any, are available to assess differences in the quality of diagnosis of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? The reader is referred to the summary tables provided in response to Questions 1 and 1a. While quality measures to assess any of the above-noted differences have not been developed scientifically to achieve this goal, a number of diagnosis-related quality measurements have been conducted which capture such disparities. Results relating to specific quality indicators are reported from studies having conducted tests of significance to highlight possible gaps in care.

Regarding age, one study observed that, relative to older women, younger women with breast cancer were significantly more likely to receive "a preoperative mammographic evaluation" (diagnostic imaging) (<70 vs. ≥70 years).[166] Yet, two studies reported that, relative to younger women, older women with breast cancer were significantly more likely to receive the following diagnosis-related care:

- "appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines" (general) (<40 vs. ≥40 years);[119]

- "appropriate use of an evaluation in compliance with guidelines" (general) (<50 vs. ≥50 years).[133]

Where a test of significance was performed, one study observed no difference with respect to age for "women reporting an overall satisfaction with the quality of breast care" (patient satisfaction) (<50 vs. ≥50 years).[133]

With respect to race or ethnicity, no studies observed that, relative to white women, black women were significantly more likely to receive specific diagnosis-related care. On the other hand, one study reported that, relative to black women, white women were significantly more likely to "report an overall satisfaction with the quality of breast care" (patient satisfaction).[133] In studies where tests of statistical significance were performed, no difference was observed with respect to race or ethnicity regarding the "appropriate use of a preoperative mammographic evaluation" (diagnosis imaging).[166]

With respect to definitions of socioeconomic status based on healthcare coverage, one study observed that, relative to women with private insurance, women with governmental coverage were significantly more likely to "report an overall satisfaction with the quality of breast care" (patient satisfaction) (HMO vs. other).[133] Conversely, one study reported that, relative to women

with governmental coverage, women with private insurance were significantly more likely to receive "a diagnostic evaluation in compliance with guidelines, when indicated" (general) (<50 vs. ≥ 50 years) (HMO vs. other).[133] A nonsignificant difference between women receiving these two types of coverage was observed with respect to the "appropriate use of the preoperative mammographic evaluation" (diagnosis imaging).[166]

1d: What is the evidence supporting the use of quality measures for the diagnosis of breast cancer in women, exhibited in terms of the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? It is assumed that the care captured by each quality indicator included in the present review was identified on the basis of it having been shown to have linkages to improvement in clinical or patient-reported outcomes. And, only associations with improved outcomes observed in the included studies could be described here and in later sections addressing this same issue. However, with respect to the topic of diagnosis, no studies reported having evaluated whether or not those patients having received recommended care experienced improved outcomes relative to those failing to receive this care.

1e: What is the evidence supporting the use of quality measures for the diagnosis of breast cancer in women, exhibited in terms of their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? Northouse et al assessed QOL after the diagnosis of breast cancer using a validated quality instrument (Summary Table 4).[115] The breast cancer-specific version of the Functional Assessment of Cancer Therapy Scale (FACT-B, version 3) has a sound psychometric history, including evidence for construct validity, internal consistency, and test-retest reliability. The overall (.90) and subscale internal consistency coefficients (.51-.88) observed in their study indicated sound reliability.

Question 2: What measures of the quality of care are available to assess the appropriate use and quality of treatment for breast cancer in women, including all foci ranging from breast-conserving surgery, to patient-reported QOL and patient satisfaction?

2a: In what patient populations have these quality measures been used? Quality indicators relating to treatment are organized by type of care, including surgery (breast conserving, mastectomy, axillary node dissection), radiotherapy, adjuvant systemic therapy, QOL, as well as patient satisfaction with care, and a general category describing care not delineated in the original request for task order.

From a random sample of women living in 12 metropolitan US areas, McGlynn et al. abstracted data for a process quality indicator (Summary Table 7).[5] They observed that 50.2% of eligible women with stage I or stage II breast cancer had been offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery were present. Randomized controlled trial evidence supported this indicator.

Summary Table 7: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women with stage I or stage II breast cancer should be offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery are present[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	13	1998-2000	50.2%/NA
Appropriate use of all surgery[IV]				
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	92%/NA
No breast-conserving surgery or mastectomy in metastatic disease[IV]				
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia	NR (Total = 1,159)	1995	65%/NA

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; CT = chemotherapy; RT = radiotherapy, BC = breast cancer; BCS = breast-conserving surgery; HT = hormone therapy; NR = not reported; ESBC = early stage breast cancer; QOL = quality of life; Dx = diagnosis; DCIS = ductal carcinoma in situ; S = significant difference; NS = nonsignificant difference; QLI = quality of life index; LCIS = lobular carcinoma in situ; CME = continuing medical education; ALND = axillary lymph node dissection; LN = lymph node; (+) = positive; (-) = negative; ER = estrogen receptor; HR = hormone receptor; RI = Rhode Island; MA = Massachusetts; MN = Minnesota; CMF = cyclophosphamide, methotrexate, 5-fluorouracil; M0 = nonmetastatic; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

A process indicator pertained to the appropriate use of all surgery (Summary Table 7), and was assessed in terms of a random sample of women with newly diagnosed, localized breast cancer (DCIS to nonmetastatic invasive carcinoma) in a cancer center in the Rhone Alpes area of France.[158] Retrospective data were collected by Ray-Coquard et al. in 1995 from medical records, to assess the impact of the implementation in 1994 of a regional practice guideline. No other information was reported about this performance standard. The adherence rate was 92%. Hislop et al. noted that only in 65% of cases of women with metastatic disease was the recommendation not to perform breast-conserving surgery or mastectomy followed.[136]

Eighteen studies evaluated the process indicator referring to the appropriate use of breast-conserving surgery (Summary Table 8). Of these, 12 were conducted in the United States,[111,114,132,140,142-146,150,151,164] three in Canada,[135,136,165], two in Europe,[127,154], and one in Hong Kong.[116] White et al.[166] reported the patterns of local therapy data included in the Morrow et al. publication.[151] Keating et al.[140] and Guadagnoli et al.[132] included a subset of the same patients treated in the states of Massachusetts and Minnesota. Lazovich et al.[143] included the subset of women whose data were analyzed in Lazovich et al.[142] Mandelblatt et al.[145] and Mandelblatt et al.[146] accessed the same data source to investigate data from some of the same patients as well. Fourteen studies involved women diagnosed with Stage I-II breast cancer.[111,114,132,135,140,142-146,150,151,164,166] Tyldesley et al. described their population as women with ductal carcinoma in situ (DCIS) and early stage breast cancer, which included diagnoses of stage I-IIIA.[165] Cheung included a population of women with operable primary breast cancer <5 cm although, with respect to breast-conserving surgery, he focused exclusively on women with tumors <3 cm.[116] Ottevanger et al. analyzed data from premenopausal women with stages II-IIIA, node positive, breast cancer.[154] Both Engel et al.[127] and Hislop et al.[136] evaluated data from any stage breast

cancer, meaning that they evaluated some cases of women for whom breast-conserving surgery was not indicated. In the latter two cases, a complete description of sample sizes was not provided. Inexact or missing age data in reports made it impossible to meaningfully compare studies on this basis. On many occasions, age information referred to ranges of subpopulations (e.g., <70 vs. $\underline{\geq}$70 years of age) without specifying the complete range. On the other hand, two studies did stand out for their exclusive focus on older women. Mandelblatt et al. assessed data from women at least 67 years of age with stage I-II breast cancer.[145,146]

Summary Table 8: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of breast-conserving surgery[IV]				
Mandelblatt, 2001, US	National random sample, Medicare beneficiaries, ≥ 67 y, newly diagnosed with ESBC 1992-1994; treating surgeons	3,851	1992-1998	35.5%/NA
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II BC	1,833	1994	33%/Race/ethnicity: Black: 31%; White: 35%
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	59%/NA
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	73.8% (MA) vs. 48% (MN)/NA
Guadagnoli, 1998b, US	Convenience sample women BC stage I or II in hospitals of 2 US states (MA & MN)	1,299 (MA); 836 (MN)	1993-1995	74% (MA) vs. 48% (MN)/ Age (vs. <50 y)(OR): 50-59 y: NS (MA & MN); 60-69 y: NS (MA & MN); 0.7 NS (MN); 70-79 y: NS (MA); S (MN); ≥80 y: NS (MA); S (MN) /Residence (vs. non-urban): Urban: NS (MA); S (MN)/Income: <$40,000: 0.7 NS (MA & MN)/HMO member: NS (MA & MN)/Education (% High school): 70-79: NS (MA & MN); 80-89: NS (MA & MN) ≥ 90: NS (MA & MN)
Lazovich, 1999, US	National population-based sample women stage I-II diagnosed 1983-1995, 9 US regions	109,880	1990-1995	NR/Age: <50 y: 48%; 50-59 y: 49%; 60-69 y: 44.6%; 70-79 y: 39.2%; ≥80 y: 34.7%/Race: White: 44.5%; Non-white: 43.1%
White, 2003, US Morrow, 2001, US	Convenience sample women stage I-II BC receiving their diagnosis and initial course of treatment at any of 842 hospitals	16,643	1994	42.6%/Age: < 70 y: 46%; ≥ 70 y: 34%/ Race/ethnicity: White: 43%; Black + Hispanic: 44%/Payer: Government: 36.9%; Private: 48.4% S
Brenin, 1999, US	National convenience sample women BC, stage I or II treated in 1994, in US hospitals	17,151	1994	44.5%/NA
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 90.9%; ≥70 y: 80.1%
Lazovich, 1997, US	National population-based sample women ESBC stage I or II diagnosed 1983-1993, 13 western Washington counties	13,541	1990-1993	NR (Stage: I: 54.9%; II: 35.2%) /Age: < 50 y: 52.1%; 50-59 y: 54.9%; 60-69 y: 47.4%; 70-79 y: 39.1%; ≥ 80 y: 31.7%/Education: Lowest tertile: 44.9%; Middle tertile: 49.9%; Highest tertile: 50.9% S

Summary Table 8: Surgery (continued)

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of breast-conserving surgery[IV]				
Mor, 2000, US	Random sample women > 60 y with BC stage I or II diagnosed at 6 hospitals in Providence, RI	350	1992-1997	64.1%/NA
Tyldesley, 2003, Canada	Population-based samples women ESBC eligible for BCS in North American population (DCIS; stage I-IIIA)	NR	NR	NR (Stage: DCIS: 63%; I: 57%; II: 52%; IIIA: 27%)/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author. For BCS, tumor size < 3 cm	100	NR	32%/NA
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	254	1993-1998	55.5%/NA
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR/NA (No breakdown for stages for which BCS is indicated)
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia.	NR (Total = 1,159)	1995	NR (Incomplete breakdown for M0 invasive pts for whom BCS is indicated)/Age: < 40 y: 42%; 40-49 y: 51%; 50-59 y: 58%; 60-69 y: 50%; 70-79 y: 42%; ≥ 80 y: 41%/By family income: <$35,000: 44%; $35,000-$44,999: 46% $45,000-$54,999: 46%; ≥$55,000: 55%
Lagorreta, 2000, US	Convenience sample women ≥ 21 y with invasive carcinoma; DCIS; stages 0-II; tumor ≤ 5 cm; eligible for BCS, California	748	1994-1996	63%/NA
Solin, 1999, US	Convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC < 5cm	95	1993-1994	65%/NA

Data sources for case identification varied greatly across the 18 studies for the quality indicator pertaining to the appropriate use of breast-conserving surgery. These included national cancer registries (e.g., SEER), Medicare claims data, regional tumor registries, medical records, and various others. Likewise, the sampling strategies exhibited considerable variation, including regional or national random samples, convenience samples, and, population-based samples. The most frequently used performance standard was the NIH Consensus Development Conference (1990). It was employed as the sole source definition of the quality indicator in 11 studies.[114,127,132,135,140,142-146,164] Where overall adherence rates were reported, the appropriate use of breast-conserving surgery ranged from 32% in a random sample of medical records,[116] to 65% in Solin et al.'s convenience sample of data from an HMO claims database supplemented by medical record data.[164] One notable finding with respect to variations in rate linked to variables other than those discussed in relation to Question 2c (below), is the higher rate associated with stage I as opposed to stage II breast cancer.[142,143,165]

Another quality indicator asserted that women undergoing breast-conserving surgery should have no more than two therapeutic operations, likely to spare the patient (Summary Table 9). Examining his own medical records, yet providing no age data regarding this process indicator, Cheung reported 100% adherence to this standard from the BASO guidelines (1995).[116]

Summary Table 9: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate number of therapeutic operations (≤ 2) for women having breast-conserving surgery[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author. For BCS, only tumor size < 3 cm	100	NR	100% (Standard: 90%)/NA
Appropriate use of mastectomy[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	254	1993-1998	44.5%/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	68%/NA

Two retrospective studies evaluated the appropriate use of mastectomy (Summary Table 9). Neither reported specific age data for this process indicator. Cheung included a convenience sample of women with operable primary breast cancer <5 cm.[116] He assessed his medical records using BASO (1995) guidelines and found a 68% adherence rate. Ottevanger et al. analyzed data from premenopausal women with stages II-IIIA, node positive, breast cancer.[154] Their population-based sample data revealed a 44.5% rate relative to Dutch regional guidelines (i.e., Comprehensive Cancer Center East: CCCE).

Eight studies measured the appropriate use of axillary lymph node dissection, a process quality indicator (Summary Table 10).[111,114,121,126,131,135,146,152] Six were conducted in the United States,[111,114,126,131,146,152] one in Canada,[135] and the last one in Australia.[121] Five involved data from women with stage I-II breast cancer.[111,114,131,135,146] Edge et al. included data from women with stages I-IIIA breast cancer,[126] Craft et al. simply described their convenience sample as including women with newly diagnosed, localized and invasive breast cancer.[121] Nattinger et al. evaluated women at least 30 years of age at the time of first diagnosis of invasive, local or regional, unilateral breast cancer.[152] Mandelblatt et al.[146] and Edge et al.[126] exclusively evaluated older patients (i.e., ≥67 years).

Summary Table 10: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of axillary lymph node dissection[IV]				
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	190	1997-1998 (14 mo)	91%/NA
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	87%/NA
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	81% (MA) vs. 94% (MN)/Age (vs. < 50y) (OR): 50-59 y: NS (MA & MN); 60-69 y: NS (MA & MN); 70-79 y: S (MA &MN); >80 y: S (MA &MN)
Brenin, 1999, US	National convenience sample women BC, stage I or II treated in 1994, in US hospitals	17,151	1994	93.2%/Age: < 70 y: 97%; > 70 y: 86%/Payer: Private vs. Government: OR 1.4 S
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 82.4%; ≥70 y: 46.9%
Edge, 2002, US	Convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed invasive BC who underwent BCS	464	1995- 1997	63.4%/Age: 67-69 y: 84%; 70-74 y: 73%; 75-79 y: 62%; ≥ 80 y: 33% S/Race/ethnicity: White: 64%; Black: 60% NS/ Education: < high school: 60%; ≥ high school: 66%/Payer: HMO: 64%; Private: 65%
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II	1,833	1994	86%/Race/ethnicity: Black: 88%; White: 84%
Nattinger, 2000, US	National population-based sample women ≥30 y at the time of first diagnosis of invasive local or regional unilateral BC	144,759	1995	97.3%/NA

Data sources varied, including hospital or provincial tumor registries, Medicare claims data, and the SEER registries, among others. Sampling strategies ranged from local convenience samples to national population-based samples. Six studies employed the standard from the NIH Consensus Development Conference (1990),[114,126,131,135,146,152] whereas others tended to use regional guidelines. Craft et al.'s was a prospective, longitudinal study.[121] Where overall adherence rates were reported, the appropriate use of axillary lymph node dissection ranged from 63.4% in the Edge et al.[126] study to 97.3% in the Nattinger et al. investigation.[152] As with Mandelblatt et al.'s sample,[146] Edge et al. included only women at least 67 years of age.[126] The Mandelblatt et al. research involved the second lowest adherence rate (86%).[146] The highest rate, found by Nattinger et al., included women at least 30 years of age.[152] They included any-stage breast cancer patients.

Three studies assessed the appropriate use of radiotherapy across various indications (Summary Table 11). Ray-Coquard et al.'s French investigation[158] and Foroudi et al.'s Canadian study[128] each included women with any-stage breast cancer. Solin et al. examined process data

from American women at least 65 years of age, with a diagnosis of stage 0-II breast cancer, and tumors <5 cm.[164] The sampling strategies varied, including Ray-Coquard et al.'s random sample, Solin et al.'s convenience sample, and Foroudi et al.'s synthesis of population-based sample data. Ray-Coquard et al. employed a regional practice guideline to set the standard, whereas Foroudi et al. completed a systematic synthesis based on numerous standards and Solin et al. used the NIH Consensus Development Conference statement (1990). Ray-Coquard et al. reported an adherence rate of 93%, whereas the other two groups of researchers qualified their data. Foroudi et al. observed an adherence rate of 66.4%, with rates of radiotherapy, done initially as opposed to later over the course of the disease, estimated at 57.3% and 9.1%, respectively. Solin et al. found that 60% of women with ductal carcinoma in situ and 91% of those with stage I-II breast cancer appropriately received this care.

Summary Table 11: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of radiotherapy[IV]				
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	93%/NA
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population	NR	NR	66.4% (Initial RT: 57.3%; Late RT: 9.1%; Stage: IV, brain metastases at dx: 1.8%; IV; symptomatic bone metastasis at dx: 10%; IV, delayed symptoms bone metastasis: 10.4-21.7%; IV, delayed brain metastasis: 4.8-10%; IV, delayed cord compression: 0.4-0.8%)/NA
Solin, 1999, US	Convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC < 5cm	DCIS: 5 Stage I & II: 57	1993-1994	NR (Stage: DCIS: 60%; stage I & II: 91%)/NA

McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 45.3% adherence to a process indicator asserting that women with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if the patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of the treatment (Summary Table 12).[5] This indicator was supported by observational study data and, expert opinion. Eighteen studies also evaluated process data concerning the appropriate use of radiotherapy following breast-conserving surgery, albeit with fewer details than were described by McGlynn et al.[111,121,126-128,131,135,136,138,142,143,145,146,150,152,154,164,166]

Summary Table 12: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if the patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	10	1998-2000	45.3%/NA
Appropriate use of radiotherapy after breast-conserving surgery[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	141	1993-1998	100%/NA
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR/NA (No breakdown for stages for which BCS is indicated)
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population	NR	NR	NR (Stage: In situ; moderate risk: 37.7%; I (pN0): 57%; II (pN0): 52.2%; II (pN1): 31.1%; IIIA: 27.8%)/NA
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia	NR (Total = 1,159)	1995	NR (Stage: M0 invasive: 38% DCIS: 13% [Incomplete breakdown for M0 invasive pts for whom BCS is indicated])/ Family income: <$35,000: 100%; $35,000-44,999: 80%; $45,000-54,999: 89%; ≥$55,000: 82%
Mandelblatt, 2001, US	National random sample, Medicare beneficiaries, ≥ 67 y, newly diagnosed with ESBC 1992 -1994; treating surgeons	3,851	1992-1998	72.1%/NA
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	87	1997-1998 (14 mo)	98%/NA
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	81%/NA
Lazovich, 1999, US	National population-based sample women stage I-II diagnosed 1983-1995, 9 US regions	109,880	1990-1995	81.5%/Age: < 50 y: 82.4%; 50-59 y: 86.1%; 60-69 y: 86.6%; 70-79 y: 80.2%; ≥ 80 y: 48.5% S/Race/ethnicity: White: 81.7%; Non-white: 80.7%
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	84% (MA) vs. 86% (MN)/Age (vs. < 50 y) (OR): 50-59 y: S (MA); NS (MN); 60-69 y: NS (MA &MN); 70-79 y: S (MA); NS (MN); >80 y: S (MA & MN)

Summary Table 12: Radiotherapy (continued)

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if the patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment[IV]				
Guadagnoli, 1998b, US	Convenience sample women BC stage I or II in hospitals of 2 US states (MA & MN)	1,299 (MA); 836 (MN)	1993-1995	84% (MA) vs. 86% (MN)/NA
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 89.6%; ≥70 y: 59%
Lazovich, 1997, US	National population-based sample women ESBC stage I or II diagnosed 1983-1993, 13 western Washington counties	13,541	1990-1993	94.1%/NA
White, 2003, US Morrow, 2001, US	Convenience sample women stage I-II BC receiving their diagnosis and initial course of treatment at any of 842 hospitals	7,097	1994	85.9%/Age: <70 y: 88.4%; ≥70 y: 78.9%/Race/ethnicity: White: 86.3%; Black-Hispanic: 83.2%/ Payer: Government: 83.3%; Private: 88.6% S
Edge, 2002, US	Convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed invasive BC who underwent BCS	464	1995-1997	77.8%; with ALND: 54.7%/NA
Mor, 2000, US	Convenience sample of women >60 y with BC stage I or II diagnosed at 6 hospitals in Providence, RI	350	1992-1997	70.4 %/Age: 60-69 y: 94%; 70-79 y: 83%; ≥ 80 y: 34% S
Solin, 1999, US	Convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC < 5cm	62	1993-1994	89%/NA
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II BC	599	1994	66.6%/Race/ethnicity: Black: 61%; White: 72.2% (S)
Nattinger, 2000, US	National population-based sample women ≥30 y at the time of first diagnosis of invasive local or regional unilateral BC	144,759	1995	65%/NA

White et al.[166] reported the patterns of radiotherapy after breast-conserving surgery data included in the Morrow et al. publication (Summary Table 12).[151] Guadagnoli et al.[131] and Guadagnoli et al.[132] reported the same data with respect to the states of Massachusetts and Minnesota. Lazovich et al.[143] included the subset of women whose data were analyzed in Lazovich et al.[142] Mandelblatt et al.[145] and Mandelblatt et al.[146] accessed the same data source to investigate data from some of the same patients as well. Fifteen studies were conducted in North America, including four in Canada[128,135,136,138] and eleven in the United

States.[111,126,131,142,143,145,146,150,152,164,166] Stage I-II breast cancer was the most frequently established population definition. It was used in eleven investigations.[111,126,131,135,142,143,145,146,150,164,166] Ottevanger et al. included women with stage II-IIIA, node positive breast cancer.[154] Engel et al.[127] as well as Foroudi et al.[128] included data from women with any stage of breast cancer. Hislop et al. evaluated women with nonmetastatic breast cancer,[136] Craft et al. studied those with primary, localized invasive breast cancer,[121] and Nattinger et al. analyzed data from women with invasive, local or regional and unilateral breast cancer.[152] However, in none of these latter three studies were the exact stages of breast cancer indicated. Jackson et al. did not report any information about their population's tumor characteristics.[138] Four studies exclusively assessed women at least 65 years of age.[126,145,146,164] Data sources ranged from regional medical records to large, national registries. Sampling strategies yielded random samples, convenience samples, or population based samples. All but the Craft et al.[121] study were retrospective. Adherence rates ranged from 65% in the very large population-based sample of American women (n = 144,759) assessed by Nattinger et al.,[152] to 100% in the small sample of women in the Netherlands (n = 141) studied by Ottevanger et al.[154]

Jackson et al. reported process data regarding the quality of delivered care indicating that, with reference to the 98.3% of women in their population-based sample having received prescribed care, 95% of the radiotherapy courses had followed guideline recommendations (British Columbia Cancer Agency) (Summary Table 13).[138]

Summary Table 13: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of radiotherapy after breast-conserving surgery (following guidelines)[IV]				
Jackson, 1999, Canada	Population-based sample women receiving radical or adjuvant postoperative RT treatments for BC, 3 clinics in British Columbia	9,351	1985-1996	95% (69%-99.5%)/NA
Appropriate use of radiotherapy after mastectomy[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR (Region: 10.4%-32.2%)/NA
Jackson, 1999, Canada	Population-based sample women receiving radical or adjuvant postoperative RT treatments for BC, 3 clinics in British Columbia	9,351	1985-1996	82.5% (4%-95.5%)/NA
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population	NR	NR	NR (Stage: I (pN0): 0.6-0.8%; II (pN0): 0.77-0.83%; II (pN1); <4N(+):0. 3%; II (pN1); >3N(+): 5.7-6.1%; IIIA, < 4N(+): 0.24-0.35%; IIIA; >3N(+): 5.1-7.4%; IIIB (pT4 or pN3): 42%)/NA

The appropriate use of radiotherapy after mastectomy was evaluated in three studies, with two undertaken in Canada,[128,138] and the other in Germany (Summary Table 13).[127] Two of these investigations assessed process data from women with any stage of breast cancer,[127,128] whereas the third reported no tumor characteristics data.[138] Data sources varied, including large, population-based registry data and surgery report data. Sampling strategies yielded two population-based samples and one convenience sample. The three studies employed different

performance standards, with one using the NIH Consensus Development Conference statement (1990).[127] Only two studies reported overall adherence data. Jackson et al.[138] observed a rate of 82.5%, whereas Engel et al. reported a range of 10.4% to 32.2% across six regions.[127]

As part of preparations to deliver quality radiotherapy care, White et al. assessed whether or not women in a convenience sample, and diagnosed with stage I-II breast cancer, had their treatment planned on a dedicated simulator (Summary Table 14).[166] The adherence rate was 88.9% when assessed in light of guidelines regarding process, and established by the ACR, ACOS, CAP, and the SSO. Moreover, White et al.'s adherence rate with respect to the process standard of delivering radiotherapy five days per week was 97.4%.

Summary Table 14: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of radiotherapy via planning on a dedicated simulator[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	88.9%/Age: <70 y: 89%; ≥70 y: 88.8%/Race/ethnicity: White: 89%; Black-Hispanic: 87.7%/ Payer: Government: 89.1%; Private: 88.8%
Quality of radiotherapy: done 5 days/week[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	97.4%/Age: <70 y: 97.4%; ≥70 y: 97.4%/Race/ethnicity: White: 97.5%; Black-Hispanic: 97.5%/ Payer: Government: 97.1%; Private: 97.1%
Quality of radiotherapy: homogenous dose distribution of radiotherapy[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	96.6%/Age: <70 y: 96.6%; ≥70 y: 96.8%/Race: White: 96.6%; Black-Hispanic: 96.5% /Payer: Government: 96.7%; Private: 96.7%
Quality of radiotherapy: use of wedges on tangent breast fields[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	93.4%/Age: <70 y: 93.3%; ≥70 y: 93.8%/Race/ethnicity: White: 93.5%; Black-Hispanic: 92.1%/ Payer: Government: 93%; Private: 93.8%
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	92.8%/NA

The homogeneous dose distribution of radiotherapy delivered to patients was evaluated in two studies (Summary Table 14). White et al. reported an adherence rate of 96.6%,[166] whereas Shank et al. observed a rate of 95%.[162] The studies analyzed process data from different data sources yet employed the same guidelines established by the ACR, ACOS, CAP, and the SSO. Shank et al. observed an adherence rate of 92.8% with regards to the use of wedges on tangent breast fields. White et al.'s corresponding rate was 93.4%.

The appropriate use of radiotherapy on the axilla following axillary lymph node dissection, and to deal with increased risk of local recurrence (i.e., extracapsular extension; at least four positive lymph nodes), was investigated in three studies (Summary Table 15). However, only one of the three groups provided process data for both indications. Ottevanger et al. did not specify how many of the women with at least four positive nodes received this care.[154] Yet, they reported an adherence rate of 84.7% for women exhibiting extracapsular extension. Brenin et al.

only reported data (53.9%) with regards to at least four positive lymph nodes.[114] Jackson et al.'s data varied widely across both hospitals and years, with an overall rate of 75%.[138] Ottevanger et al. also looked at the appropriate use of parasternal radiotherapy for tumors located in the medial part of the breast, and noted an adherence rate of 49.1%.[154]

Summary Table 15: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of radiotherapy on axilla following axillary lymph node dissection, to deal with increased risk of local recurrence (i.e. extracapsular extension; ≥ 4 positive nodes)[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	85	1993-1998	84.7%/NA
Jackson, 1999, Canada	Population-based sample women receiving radical or adjuvant postoperative RT treatments for, 3 clinics in British Columbia	9,351	1985-1996	75% (3%-92%)/NA
Brenin, 1999, US	National convenience sample women BC, stage I or II, in US hospitals	899	1994	53.9%/NA
Appropriate use of parasternal radiotherapy for tumors located in the medial part of breast[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	114	1993-1998	49.1%/NA
Appropriate use of palliative radiotherapy for women with progression or recurrence[IV]				
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population; later RT	NR	NR	NR (Stage: I & II (pN0), postmastectomy: 2.9-4.2%;II (pN1); postmastectomy: 0.5%; e III; postmastectomy: 0.39-0.57%)/NA
Regional recurrence needing further surgery or radiotherapy[IV]				
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population; late RT	NR	NR	NR (Stage: DCIS: 0.02-0.1%; DCIS, recur with DCIS or invasive carcinoma: 1.2%; I & II (pN0), postmastectomy: 1.3-1.9%; II (pN1); postmastectomy: 1.35%; III; postmastectomy: 1.2-1.7%; LCIS; recur with DCIS or invasive carcinoma: 0.7%)/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	0% (Standard at 5 y: <10%)/NA

Foroudi et al. did not report overall adherence data with regards to the appropriate use of palliative radiotherapy for the progression or recurrence of breast cancer (Summary Table 15).[128] They did differentiate the process-related rates by stage, with the proportions decreasing as a function of stage (Evidence Table: Appendix E). These authors also obtained performance data relating to an outcome indicator titled regional recurrence needing further surgery or radiotherapy. Again, they only provided data broken down by stage (Evidence Table: Appendix E). Cheung, on the other hand, employed a standard of less than 10% of women requiring further surgery or radiotherapy at 5 years, and reported that no women required such care.[116]

Shank et al. reported a rate of 99.9% relating to the daily treatment of both tangent fields (Summary Table 16). They also observed a rate of 99% with respect to the delivery of 4,500-5,000 cGy total breast dose via 180-200 cGy fractions. Finally, these same investigators noted a 94% rate related to the electron beam radiation of the breast. These last three quality indicators assessed the quality of the care delivered to patients.

Summary Table 16: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of radiotherapy: both tangent fields treated daily[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	725	1995-1996	99.9%/NA
Quality of radiotherapy: receiving 4,500-5,000 cGy total breast dose given in 180-200 cGy fractions[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	725	1995-1996	99%/NA
Quality of radiotherapy: electron beam breast radiation used[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	725	1995-1996	94%/NA

The appropriate use of any form of adjuvant systemic therapy (i.e., chemotherapy and/or hormone therapy) was examined in six projects, entailing one random sample from Hebert-Croteau et al.,[135] and convenience samples from each of Mor et al.,[150] Bickell et al.,[111] Craft et al.,[121] Silliman et al.,[163] and Guadagnoli et al.[130] Five studies investigated data from women with stage I-II breast cancer (Summary Table 17).[111,130,135,150,163] Small data sources were most common, including medical records or local cancer registries, for example.[111,121,130,150,163] Adherence rates ranged from 67.3% (n = 303) to 96% in a small number of cases (n = 99).[121]

Summary Table 17: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of any adjuvant systemic therapy[IV]				
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	99	1997-1998 (14 mo)	96%/NA
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	78%/Age: < 50 y: 59-87 %; ≥ 50 y: 65-85 %
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 74.2%; ≥70 y: 72.1%
Silliman, 1999, US	Convenience sample women ≥55 y newly diagnosed stage I or II BC treated 1 center in Boston	303	NR	67.3% (HT: 76%; CT: 13%; HT + CT: 11%)/ Income: ≤U$14,999: 64%; 15,000 -29, 999: 60%; 30,000-49,999: 77%; ≥50,000: 73%/Education: < high school: 60%; high school: 68%; some college: 64%; college: 72%
Mor, 2000, US	Convenience sample of women >60 y with BC stage I or II diagnosed between 1992 - 1997 at 6 hospitals in Providence, RI	350	1992-1997	81.9%/Age: 60-69 y: 88%; 7-79 y: 82%; ≥ 80 y: 77% S
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed ESBC node (+); stage I-II, 30 hospitals in MN	632	1993	71%/Age: 50-59 y: 61%; 60-69 y: 70%; 70-79 y: 81%; >80y: 74% S

McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 85.1% adherence to a process indicator asserting that women with invasive breast cancer that is node-positive, or node-negative and primary tumor at least 1 cm, should be treated with adjuvant systemic therapy, including combination chemotherapy (and/or tamoxifen, 20 mg/d) (Summary Table 18).[5] This indicator was supported by randomized controlled trial evidence. Randomly sampling cases by age from the SEER registries, Harlan et al. evaluated the appropriate use of any adjuvant systemic therapy for women with node-positive stages I-IIIA breast cancer, using the NIH Consensus Conference statement (1990) to define its standard.[134] They reported an overall adherence of 70%. Using medical records and interview data seen in light of the Early Breast Cancer Trialist Collaborative Group's meta-analytic results (1992), Guadagnoli et al. observed a rate of 92%.[130]

Summary Table 18: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women with invasive breast cancer that is node-positive, or node-negative and primary tumor ≥1 cm, should be treated with adjuvant systemic therapy to include combination chemotherapy (and/or tamoxifen, 20 mg/d)[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	13	1998-2000	85.1%/NA
Appropriate use of any adjuvant systemic therapy in women with node (+) breast cancer[IV]				
Harlan, 2002, US	Random sample from population-based databases women stage I, II & IIIA BC diagnosed in 1987-1991 & 1995	7,724	1987-1991 & 1995	70%/Age: <51 y: 82%; 51-64 y: 73%; ≥65 y: 63%
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed ESBC; stage I-II, 30 hospitals in MN	632	1993	92%/Age: 50-59 y: 93%; 60-69 y: 96%; 70-79 y: 89%; >80y: 85% NS
Appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer[IV]				
Harlan, 2002, US	Random sample from population-based databases women stage I, II & IIIA BC diagnosed in 1987-1991 & 1995	7,724	1987-1991 & 1995	53%/Age: <51 y: 45%; 51-64 y: 46%; >65 y: 41% NS/ By Race/ethnicity: White: 44%; Black: 40%; Other: 45%
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed ESBC; stage I-II, 30 hospitals in MN	632	1993	62%/Age: 50-59 y: 73%; 60-69 y: 67%; 70-79 y: 56%; >80y: 36% S

Harlan et al. failed to report an overall rate for the appropriate use of any adjuvant systemic therapy for node-negative breast cancers (Summary Table 18) although age-related data are presented in a later section. Guadagnoli et al. found that 62% of node-negative cases appropriately received adjuvant systemic therapy.

Two studies looked at the appropriate use of adjuvant systemic therapy (e.g., chemotherapy and/or hormone therapy) after breast-conserving surgery (Summary Table 19). Edge et al. assessed data exclusively from women at least 67 years of age and reported an overall rate of 70.7%.[126] White at al. observed a higher rate (84.1%) in a much larger sample of cases.[166]

Summary Table 19: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of adjuvant systemic therapy after breast-conserving surgery[IV]				
Edge, 2002, US	Convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed invasive BC who underwent BCS	464	1995-1997	70.7% (CT: 10.1%; Tamoxifen: 89.9%)/NA
White, 2003, US	Convenience sample women BC node (+) stage I-II diagnosed in 1994	16,643	1994	84.1%/Age: <70 y: 84.9-88.7%; ≥70 y: 72%/Race/ethnicity: White: 85.3%; Black-Hispanic: 78.7%/ Payer: Government: 78.9%; Private: 87.6% S

The appropriate use of tamoxifen was investigated in four studies (Summary Table 20). The two larger ones by Mandelblatt et al.[146] and Guadagnoli et al.[131] observed similar adherence rates of 62% and 59% or 63%, the latter two referring to data from the states of Minnesota and Massachusetts, respectively. In a small sample, Ray-Coquard et al. observed a rate of 94%.[158] A small convenience sample studied by Cheung found adherence to be 28%.[116] Cornfeld et al. used the National Cancer Comprehensive Network guidelines (1999) to assess private practice case data from 11 oncologists, and observed a rate of 100%.[120]

Summary Table 20: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of tamoxifen[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	28%/NA
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	63% (MA) vs. 59% (MN)/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	94%/NA
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II BC	1,833	1994	62%/Race/ethnicity: Black: 58% (S); White: 66%
Cornfeld, 2001, US	Convenience sample women BC node (+) treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA

Palazzi et al. evaluated data regarding the appropriate use of tamoxifen after breast-conserving surgery in premenopausal women with node-negative, intermediate risk, early stage breast cancer (Summary Table 21).[155] Using data from 12 centers, and appraised according to standards established at the St. Gallen Consensus Conference (1995), they noted an adherence rate of 33%. Palazzi et al's corresponding rate of appropriate use of tamoxifen for postmenopausal women with the same breast cancer characteristics was 59%. Guadagnoli et al.'s estimate (51%) was slightly lower in the same type of women.[130]

Summary Table 21: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of tamoxifen in premenopausal women with node (-), intermediate risk, breast cancer[IV]				
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	33%/NA
Appropriate use of tamoxifen in postmenopausal women with node (-), intermediate risk, breast cancer[IV]				
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	59%/NA
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed stage I-II BC, 30 hospitals (MN)	632	1993	51%/Age: 50-59 y: 52%; 60-69 y: 55%; 70-79 y: 51%; >80y: 34% S
Appropriate use of tamoxifen in postmenopausal women with node (-), high risk, estrogen receptor (+), breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	NR/Age: 50-65%: 62.3%; >65 y: 56.5%
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	59%/NA
Appropriate use of tamoxifen in postmenopausal women with node (+), estrogen receptor (+) breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR (Region: 30.1%-61.5%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	40%/NA

The appropriate use of tamoxifen in postmenopausal women with node-negative, high risk, estrogen receptor positive breast cancer was estimated by two groups (Summary Table 21). Palazzi et al. reported a rate of 59%,[155] whereas Sawka et al. noted data stratified by age.[161] Palazzi et al. then examined data from postmenopausal women diagnosed with node-positive, estrogen receptor positive breast cancer.[155] They found a 40% adherence rate. Engel et al. noted that the rate varied between 30.1% and 61.5% across six regions.[127]

The appropriate use of adjuvant chemotherapy and hormone therapy (tamoxifen) was investigated in three studies (Summary Table 22). Engel et al. reported that the rate varied from 9.1% to 32.2% across six regions,[127] whereas Sawka et al. noted a 6.6.% rate.[161] Du et al. primarily evaluated population-based tumor registry data,[125] and found a higher rate of adherence (9.6%) than was observed by Sawka et al.

Summary Table 22: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy and hormone therapy (tamoxifen)[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions Germany; node (+); HR (+); postmenopausal	NR (Total = 8,661)	1996-1998	NR (Region: 9.1%-32.2%)/NA
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	6.6%/NA
Du, 2003, US	Population-based sample women BC ≥20 y stage I-IIIA treated & registered in New Mexico tumor registry	5,101	1991-1997	9.6%/Age: <45 y: 15.8%; 45-49 y: 17%; 50-54 y: 18.5%; 55-59 y: 11.7%; 60-64 y: 8%; 65-69 y: 5.4%; 70-74 y: 4%; ≥75 y: 0.8%
Appropriate use of chemotherapy and hormone therapy (tamoxifen) in premenopausal women, node (+), hormone receptor (+), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 10.3%-57.1%)/NA

Engel et al. reported variations in the rate, from 10.3% to 57.1% across six regions, with respect to the appropriate use of adjuvant chemotherapy and hormone therapy (tamoxifen) in premenopausal women with node-positive, hormone receptor positive breast cancer (Summary Table 22).[127]

Regarding the appropriate use of adjuvant chemotherapy, seven studies were conducted (Summary Table 23). However, Du et al.[125] and Du and Goodwin[124] likely overlap in terms of their population-based cases of breast cancer. The latter studied women at least 65 years of age diagnosed with all stages of breast cancer (I-IV). The former assessed data from women at least 20 years of age diagnosed with stage I-IIIA breast cancer. The adherence rate from the Du et al. study (28.7%),[125] with the wider range of cases defined by age, more than doubled the rate observed with respect to the other study (12.4%).[124] Mandelblatt et al. noted a rate of 9% in women at least 67 years of age.[146] The highest rates were observed in the Guadagnoli et al. study for women from Massachusetts (97%) and Minnesota (94%).[131] DeMichele et al. found that, of 208 chemo-eligible patients, only 74% (n = 156) received a recommendation to receive chemotherapy.[122] Of 132 women who were not eligible to receive chemotherapy, 11% received it.

Summary Table 23: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy[IV]				
Du, 2003, US	Population-based sample women BC ≥20 y stage I-IIIA treated & registered in New Mexico tumor registry	5,101	1991-1997	28.7%/Age: <45 y: 66%; 45-49 y: 54.9%; 50-54 y: 44.2 %; 55-59 y: 31%; 60-64 y: 18.1%; 65-69 y: 12.3%; 70-74 y: 7.1%; >75 y: 3.4%
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	97% (MA) vs. 94% (MN)/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	85%/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	30%/NA
DeMichele, 2003, US	Convenience sample women BC ≥50 y evaluated at UPCC 1993-1997 & eligible for adjuvant CT	Eligible: 208; Non-eligible: 132	1993-1997	74%; Non-eligible received: 11%/Age: 50-59 y: 74%; 60-69 y: 74%; 70-86 y: 70%
Du, 2001, US	Population-based sample women BC ≥65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1991-1996	12.4%/Age: 65-69 y: 20.5%; 70-74 y: 13.9%; 75-79 y: 8.7%; ≥80 y: 3.3%
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I –II BC	1,833	1994	9%/Race/ethnicity: Black: 11% S; White: 7%

Palazzi et al. identified a rate of 59% for the appropriate use of chemotherapy in women with node-negative, high risk, estrogen receptor negative breast cancer (Summary Table 24). Du and Goodwin noted a lower rate of 17.9% for these women,[124] whereas Sawka et al. provided no overall adherence data.[161] Du and Goodwin reported a 2% adherence rate regarding the appropriate use of chemotherapy for women with node-negative, estrogen receptor positive breast cancer.[124] These patients were at least 65 years of age.

Summary Table 24: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in women with node (-), high risk, estrogen receptor (-), breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993-1998	NR/Age: <50 y: 78.6%; 50-65 y: 19.1%
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	59%/NA
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	17.9%/NA
Appropriate use of chemotherapy in women with node (-), estrogen receptor (+), breast cancer[IV]				
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	2%/NA

Palazzi et al. reported an adherence rate of 55% regarding the appropriate use of chemotherapy for premenopausal women with node-negative, high risk, estrogen receptor positive breast cancer (Summary Table 25).[155]

Summary Table 25: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in premenopausal women with node (-), high risk, estrogen receptor (+), breast cancer[IV]				
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	55%/NA
Appropriate use of chemotherapy in premenopausal women with node (+), estrogen receptor (-), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 63.6%-92.3%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	90%/NA

Both Palazzi et al. and Engel et al. evaluated the appropriate use of chemotherapy for premenopausal women with node-positive, estrogen receptor negative breast cancer (Summary Table 25). While Engel et al. reported a range, for six regions, of 63.6% to 92.3%,[127] Palazzi et al. found that 90% of these women received the recommended therapy.[155]

Three studies examined data with respect to the appropriate use of chemotherapy for postmenopausal women with node-positive, estrogen receptor negative breast cancer (Summary Table 26). Engel et al. reported rates of 38.5% to 69.6% across six regions.[127] Palazzi et al.[155]

and Du and Goodwin[124] observed rates of 81% and 61.5%, respectively. Du and Goodwin also noted a rate of 27% concerning the appropriate use of chemotherapy in postmenopausal women with node-positive, estrogen receptor positive breast cancer.[124] The latter group included women who were at least 65 years of age.

Summary Table 26: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in postmenopausal women with node (+), estrogen receptor (-), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 38.5%-69.6%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	81%/NA
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	61.5%/NA
Appropriate use of chemotherapy in postmenopausal women with node (+), estrogen receptor (+), breast cancer[IV]				
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	27%/NA

Craft et al. evaluated data with regards to the appropriate use of chemotherapy for women, under the age of 50 years, with node-positive breast cancer (Summary Table 27).[121] They noted a 100% adherence rate in a very small sample (n = 27).

Summary Table 27: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in women <50 years of age with node (+), breast cancer[IV]				
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	27	1997-1998 (14 mo)	100%/NA
Appropriate use of chemotherapy &/or ovarian ablation in premenopausal women with node (+), estrogen receptor (+), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 42.9%-84.6%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	NR (CT 73%; CT + OA: 18%; OA: 4%)/NA

Palazzi et al.[155] and Engel et al.[127] assessed data regarding the appropriate use of chemotherapy and/or ovarian ablation in premenopausal women with node-positive, estrogen receptor positive breast cancer (Summary Table 27). Palazzi et al provided data by treatment, with 73% of the women receiving chemotherapy, 4% ovarian ablation, and 18% both treatments. Engel et al. provided rates by region (42.9% to 84.6%).

Three studies assessed the adherence to the recommendation not to provide any adjuvant systemic treatment for women with node-negative, low risk breast cancer (Summary Table 28). Palazzi et al.,[155] Sawka et al.,[161] and Harlan et al.[134] reported adherence rates of 69%, 84.9%, and 52.2%, respectively.

Summary Table 28: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate decision not to provide adjuvant systemic therapy for women node (-), low risk, breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	84.9%/Age: 50-65 y: 90.3%; >65 y: 85.9%
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	69%/NA
Harlan, 2002, US	Random sample from population-based databases women stage I, II & IIIA BC diagnosed in 1987-1991 & 1995	7,724	1987-1991 & 1995	52.2% (1995)/NA
Appropriate decision not to provide adjuvant systemic therapy for women > 65 years of age with high risk, estrogen receptor (-), breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	82.1%/NA

Sawka et al. also evaluated the adherence to the standard of not providing adjuvant systemic therapy to women over the age of 65 years and diagnosed with node-negative, high risk, estrogen receptor negative breast cancer (Summary Table 28).[161] A rate of 82.1% was observed.

Ottevanger et al. investigated the quality of the delivery of care involving chemotherapy (Summary Table 29).[154] They reported performance data regarding the use of proper doses of chemotherapy, specifically where what is given is at least 85% of both the recommended dose intensity (DI) and the relative dose intensity (RDI) of the cyclophosphamide/methotrexate/5-fluorouracil (CMF) poly-chemotherapy regimen. The adherence to the DI standard was 78.9% and to the RDI, 58.7%.

Summary Table 29: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of chemotherapy: proper doses administered (≥ 85% dose intensity [DI] & relative dose intensity [RDI]) of CMF[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	254	1993-1998	78.9% (DI); 58.7% (RDI)/NA
Availability of office procedure manual used for chemotherapy administration[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA

Cornfeld et al. investigated a structural variable pertaining to the availability of an office procedure manual to be used to administer chemotherapy (Summary Table 29).[120] They noted that all 11 oncologists' private practice offices had such a resource.

Numerous studies measured the QOL of those undergoing treatment for breast cancer. For example, using the validated Medical Outcomes Scale, short form (SF-36), and the Rotterdam symptom check list, Jansen et al. assessed the impact on QOL of post-operative radiotherapy in early breast cancer patients (Summary Table 30).[139] The SF-36 has been used across numerous healthcare domains, including cancer and breast cancer. However, the researchers were particularly interested in whether the internal (i.e., subjective) standards, values, or conceptualizations of the key domains defining QOL (e.g., fatigue) changed over time; and, whether possible shifts in these standards might render meaningless before and after-treatment comparisons of QOL data. The researchers observed the effects of scale recalibration that would have influenced QOL evaluations, leading to underestimation of the impact of radiotherapy on measures of fatigue and overall QOL.

Summary Table 30: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Overall changes in QOL over time, before & after radiotherapy[lac]				
Jansen, 2000, Netherlands	Convenience sample women ESBC underwent surgery (BCS or mastectomy)	46	1997-1999	38% (worse); 40% (stable); 22% (improved)/NA
Hassey 2000, US	Convenience sample women ESBC beginning a course of RT after BCS at a hospital in Northeast. 21-45 y; newly diagnosed; not undergoing CT or HT	23	6 mo	NR (NS changes over time in QLI scales)/NA

As measures of QOL, Hassey and Lafferty employed the Ferrans QOL Index (QLI), Cancer version (e.g., psychological/spiritual functioning), the Psychosocial Adjustment to Illness Scale (PAIS: e.g., sexual functioning), and the Adaptation to the Survivorship Experience tool (ASE: e.g., adaptation to the meaning of cancer) (Summary Table 30).[123] The first and third instruments have been used to assess possible changes brought about by cancer treatment. Their results suggested certain changes in QOL, psychosocial adjustment, and adaptation to

survivorship experiences over time in a sample of women receiving radiotherapy following breast-conserving surgery.

Health-related QOL was measured over time by Osoba and Burchmore using the validated European Organization for Research and Treatment of Cancer core QOL Questionnaire (EORTC QLQ-C30) (Summary Table 31).[153] It was used to assess the domains of global QOL, physical, role and social functioning, and fatigue. Respondents were women in treatment with trastuzumab for metastatic breast cancer. The results suggested that trastuzumab was not associated with worsening health-related QOL. Perez et al. performed a longitudinal study of health-related QOL and utility measures (time trade-off).[156] The QOL measures were the Spitzer QOL Index and Uniscale, and both had previously demonstrated construct validity in patients with breast cancer. Participants were women presenting with symptomatic, metastatic breast cancer. Results were expressed only in terms of the relationship of the two key constructs of QOL and time trade-off.

Summary Table 31: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Change in QOL in women with metastatic breast cancer[Iac]				
Osoba, 1999, Canada & US	Convenience sample women progressive HER-2-overexpressing metastatic BC had been previously treated with CT (phase II) or had not have previous cytotoxic CT (phase III) received trastuzumab	154	32 wks (NR)	100%/Phase of study: Phase II: no apparent worsening of scores; Phase III: NS changes
Perez, 2001, New Zealand UK	Convenience sample women presenting at Dunedin Hospital, NZ, with metastatic symptoms BC	38	1 y (NR)	NR/NA
Women with a significant improvement in QOL in clinical phases of breast cancer[Iac]				
Chie, 1999, China	Convenience sample women diagnosed or treated for BC in the breast surgery; RT & oncology outpatients departments; or in general surgical wards of National Taiwan University Hospital	115	1997 (2 mo)	NR/NA
Change in QOL by time and treatment arm in postmenopausal, node (-) breast cancer women who underwent adjuvant therapy[Ia]				
Bernhard, 1997, Netherlands	Convenience sample pre- & postmenopausal women with operable BC	312	1993-1995	NS in scales of physical well-being; mood; appetite at 1, 3 & 6 mo/NA

Chie et al. utilized the SF-36, QLQ-C30, questions about utility to be responded to using a visual analogue scale, and other instruments examining constructs such as standard gamble and time trade-off (Summary Table 31).[117] Significant differences were observed for most QOL scores among women across various clinical stages of breast cancer. Bernhard et al. employed the Linear Analogue Self-Assessment (LASA) format to assess indicators of QOL, including physical well-being, mood and appetite.[110] This format has been validated for use in studies with

cancer patients. Results indicated nonsignificant changes over time in the indices of physical well-being, mood, and appetite.

Molenaar et al. employed the Medical Outcomes Study 20 (MOS20) QOL tool as well as the EORTC QLQ-BR23 (Summary Table 32), the latter designed to assess breast cancer-specific functioning and symptoms (i.e., body image, sexual functioning, arm symptoms, breast symptoms, systemic therapy symptoms, and future perspective).[148] The psychometric soundness of the breast cancer specific instrument had been demonstrated previously. On some measures (e.g., arm symptoms), it was found that patients exposed to a CD-ROM decision support fared better than controls.

Summary Table 32: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Change in QOL over time[lac]				
Molenaar, 2001, Netherlands	Convenience sample women newly diagnosed with stage I & II BC eligible for either BCS or mastectomy in 3 Dutch hospitals	167	1996-1998	Generic QOL scale & specific QOL scale: positive effect (CDROM) 0, 3 & 9 mo; ND/NA
Bower, 2000, US	Convenience sample women ESBC (stage 0-II); diagnosed <5 y; completed adjuvant therapy; currently disease-free; only treated with tamoxifen (cancer survivors)	1,957	1994-1997	NR/Energy/fatigue: 60; Physical functioning: 80.35; Role limitation-physical: 75.80; Emotional well-being: 75; Role limitation-emotional: 77; Social functioning: 86; Bodily pain: 78.60; General health: 73
Frazer, 1998, US	Convenience sample women ESBC diagnosed in 1993 and treated by surgery and HT at MDACCO, Orlando, Florida	70	1993-1996	NS changes over time in all the subscales and overall/NA
Mor, 1994, US	Convenience sample women BC from 2 research trials	262	NR	NR/Age: 24-54 y: 67.6%; >55 y: 71%

In addition to the RAND 36-item Health Survey (MOS SF-36) and a few other instruments, Bower et al. included the Breast Cancer Prevention Trial Symptom Checklist (e.g., symptom intensity) in a study of the occurrence of fatigue in a large sample of breast cancer survivors, compared with general population norms (Summary Table 32).[113] The authors found that, although most women did not experience heightened levels of fatigue relative to women in the general population, a subset of women did experience intense fatigue while being treated with tamoxifen. Frazer et al. used the validated, 39-item, Guttman scaled Health Status Questionnaire to assess breast as well as prostate cancer patients' experience over a three year period while being treated with surgery and hormone therapy.[129] They reported no statistically significant intergroup or intragroup differences between responses of patients with breast cancer and prostate cancer.

Mor et al. collected, then aggregated QOL survey data across two studies from breast cancer patients at various stages of the disease process, to assess the effect of age on women's perceptions of the psychosocial impact of their illness (Summary Table 32).[149] They evaluated psychosocial status using a subscale of the MOS short form General Health Survey (SF-36) called the Mental Health Inventory (MHI-5). A treatment Impact Scale was developed by the

investigators to assess the perceived level of difficulty or disruption that treatment caused in their patients' daily routine and functioning. Overall, the results suggested age-related differences where, despite being advantaged relative to older women in terms of socioeconomic status, social support availability and extent of the disease, younger women experienced the impact of their illness more negatively (e.g., higher levels of perceived emotional and financial distress).

Molenaar et al. also evaluated breast cancer patients' satisfaction with their treatment choice (Summary Table 33).[148] Measures were developed, including two multi-item instruments to assess patients' satisfaction with the amount, clarity, and usefulness of the information they had received, and, to indicate their satisfaction with treatment-specific information (e.g., radiotherapy, local recurrence). In addition, using most of the Decisional Conflict Scale in addition to the full Patient Satisfaction Questionnaire, satisfaction with the decision-making process and with care were measured, respectively. Findings indicated that, relative to those patients not receiving information via a CD-ROM resource, those who did were more satisfied with breast cancer-specific information, the decision-making process, and communication.

Summary Table 33: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Satisfaction of women with breast cancer with the treatment choice[Iac]				
Molenaar, 2001, Netherlands	Convenience sample women newly diagnosed with stage I & II BC eligible for either BCS or mastectomy in 3 Dutch hospitals	167	1996-1998	(+) Effect (CDROM) 0, 3 & 9 mo; ND/NA
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	Very satisfied: 80% (MA) vs. 76% (MN)/NA
Participation of women with breast cancer in decision-making as much as they wanted[IV]				
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	83% (MA) vs. 81% (MN)/NA
Received enough information about surgery and radiotherapy[IV]				
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	80% (MA) vs. 80% (MN)/NA

Employing 5-point Likert, as well as other, scales specially developed for their study of women with stage I-II breast cancer in the states of Massachusetts and Minnesota, Keating et al. measured patients' satisfaction with their treatment choice, participation in the decision-making process to the extent they wished, and the amount of information received concerning surgery and radiotherapy (Summary Table 33).[140] The results suggest that collaborative care may benefit early stage breast cancer patients with respect to treatment selection and satisfaction.

Within the general category of quality measurement, Cornfeld et al. assessed adherence to the following structural indicator across the private practices of eleven oncologists: board certified MDs in medical oncology (Summary Table 34).[120] They noted a rate of 100%. These

investigators also performed another measurement concerning structure, observing that all participant oncologists had their documentation of Continuing Medical Education credits for the two-year period preceding an audit.

Summary Table 34: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Board certified medical doctors in medical oncology[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA
Documentation of Continuing Medical Education credits for the 2 years preceding audit[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA

Bickell et al. reported a rate of adherence of 64% to the standard that patients with an established diagnosis of at least stage IB breast cancer be referred to an oncologist for treatment (Summary Table 35).[111] Cheung found that all 100 women with breast cancer <5 cm had been given the opportunity to see a nurse specializing in breast cancer.[116] Bickell et al. found varying evidence in tumor registries and other data sources across four hospitals (65% to 100%), indicating that women with stage I-II breast cancer had had a discussion concerning surgical options (mastectomy vs. breast-conserving surgery).[111] Molenaar et al. noted a 100% adherence rate for this quality indicator in their convenience sample of Dutch women newly diagnosed with stage I-II breast cancer and eligible for breast-conserving surgery or mastectomy.[148]

Summary Table 35: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Referral to oncologist for treatment[IV]				
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	64%/NA
Women with breast cancer given the opportunity to see a breast cancer specialist nurse[IV]				
Cheung, 1999, Hong Kong	Convenience sample women with operable primary BC <5 cm; attended by the author	100	NR	100% (Standard: 100%)/NA
Evidence of discussion about surgical options[IV]				
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	NR (Hospital: 65-100%)/NA
Molenaar, 2001, Netherlands	Convenience sample women newly diagnosed with stage I & II BC eligible for either BCS or mastectomy in 3 Dutch hospitals, patient preference measured	167	1996-1998	100%

Three studies evaluated whether or not women with operable breast cancer were admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes (Summary Table 36). The standard was established as $\geq$90% based on BASO's (1992)

guidelines. McCarthy et al.[147] and Cheung[116] reported adherence rates of 90.4% and 93%, respectively. Sauven et al. only provided data by year, observing that the rate decreased from 82% in 1996/1997, to 77% in 1999/2000.[160]

Summary Table 36: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
≥90% of women admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR/Overall by y (range): 77-82%
Cheung, 1999, Hong Kong	Convenience sample women with operable primary BC <5 cm; attended by the author	100	NR	93%/NA
McCarthy, 1997,UK	Convenience sample women operable BC, <70 y treated at Nottingham City Hospital's	83	1994	90.4%/NA

Four studies assessed adherence to overall treatment sequences according to guidelines, including the initial examination, surgery, radiotherapy, chemotherapy, hormone therapy, and followup (Summary Table 37). Across two random samples, one population-based sample, and one convenience sample, the rates ranged from 36% to 81%.[136,150,158,159] The two random samples drawn by Ray-Coquard et al. provided the lowest rates, at 36% and 54%.[158,159] When Ray-Coquard et al.'s more recent study evaluated data by category of care, they noted that adherence was highest for surgery (94%) and lowest for radiotherapy (77%).

Summary Table 37: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of treatment sequences according to guidelines (including surgery; radiotherapy; chemotherapy; hormone therapy; initial examination; and followup)[IV]				
Mor, 2000, US	Convenience sample women >60 y with BC stage I or II diagnosed between 1992 - 1997 at 6 hospitals in Providence, RI	350	1992-1997	72.9%/Age: 60-69 y: 89%; ≥80 y: 50% S
Ray-Coquard, 2002, France	Random sample women localized BC (in situ or invasive) treated in the cancer network in Rhone-Alpes region	346	1996	36% (Initial examination: 86%; Surgery: 94%; CT: 78%; RT: 77%; HT: 79%; Followup: 81%)/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive BC) in a cancer center in Rhone Alpes Area	99	1995	54%/NA
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia	NR (Total = 1,159)	1995	81% (Extent of disease: LCIS: 78%; DCIS: 71%; Metastatic: 73%; M0 invasive: 83%)/NA

Three studies examined data with respect to the appropriate use of definitive locoregional therapy (i.e., total mastectomy plus axillary lymph node dissection, or, breast-conserving surgery plus axillary lymph node dissection and radiotherapy) (Summary Table 38). Nattinger et al.[152] and Silliman et al.[163] observed similar adherence rates of 77.2% and 78%, respectively, in spite of great size differences in their samples. Hebert-Croteau et al. provided no overall data yet age-related figures are presented in response to Question 2c.[135]

Summary Table 38: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy)[IV]				
Nattinger, 2000, US	National population-based sample women ≥30 y at the time of first diagnosis of invasive local or regional unilateral BC	144,759	1995	78%/NA
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 83.5%; ≥70 y: 48.7%
Silliman, 1999, US	Convenience sample women ≥55 y newly diagnosed stage I or II BC treated 1 center in Boston	303	NR	77.2% (Surgery type: BCS + RT: 56%; Mastectomy: 22%)/ Income: ≤U$14,999: 55%; 15,000-29, 999: 85%; 30,000-49,999: 91%; ≥50,000: 87%/Education: < high school: 55%; high school: 75%; some college: 83%; college: 82%
Appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery + axillary lymph node dissection or adjuvant treatment)[IV]				
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 90.9%; ≥70 y: 60.9%
Silliman, 1999, US	Convenience sample women ≥55 y newly diagnosed stage I or II BC treated 1 center in Boston	303	NR	51.8%/Age: 55-64 y: 50%; 65-74 y: 41%; 75-84 y: 9%
Cases not receiving recommended treatment (radiotherapy after breast-conserving surgery or systemic therapy) due to system failure[IV]				
Bickell, 2003, US	Convenience sample women ESBC who had treatment underuse; not RT or adjuvant therapy recommended when indicated	44	1998-1999	32%/NA
Appropriate use: Women with metastatic cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent, within 6 weeks of the identification of metastases[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	4	1998-2000	82.6%/NA

Hebert-Croteau et al. and Silliman et al. also examined the appropriate use of alternative, definitive therapy (i.e., radiotherapy after breast-conserving surgery plus axillary lymph node dissection, or, adjuvant treatment) (Summary Table 38).[135,163] Only Silliman and colleagues reported an overall rate (51.8%).[163] Bickell et al. evaluated a convenience sample of early stage

breast cancer patients who did not receive physician recommended treatment (radiotherapy after breast-conserving surgery, or, systemic therapy) due to system failure.[112] They noted that, of 44 women, 32% of cases experienced system failure. Finally, McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 82.6% adherence to a process indicator asserting that women with metastatic breast cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent, within 6 weeks of the identification of metastases (Summary Table 38).[5] This indicator was supported by observational study data and expert opinion.

2b: For what treatment-related purposes have these quality measures been used? The evidence is organized according to three broad categories of purpose. The measurements relating to the following quality indicators were undertaken to achieve external quality oversight:

- appropriate use: "Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment" (radiotherapy);[5]

- "quality of radiotherapy after breast-conserving surgery" (radiotherapy);[138]

- "appropriate use of radiotherapy after mastectomy" (radiotherapy);[127,128,138]

- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy);[166]

- "quality of radiotherapy: done five days per week" (radiotherapy);[166]

- "quality of radiotherapy: homogeneous dose distribution of radiotherapy" (radiotherapy);[162,166]

- "quality of radiotherapy: use of wedges on tangent breast fields" (radiotherapy);[162,166]

- "appropriate use of radiotherapy on axilla following axillary lymph node dissection to deal with increased risk of local recurrence (i.e. extracapsular extension; ≥ 4 positive nodes)" (radiotherapy);[114,138,154]

- "appropriate use of parasternal radiotherapy for tumors located in the medial part of breast" (radiotherapy);[154]

- "appropriate use of palliative radiotherapy for women with progression or recurrence" (radiotherapy);[128]

- "quality of radiotherapy: both tangents fields treated daily" (radiotherapy);[162]

- "quality of radiotherapy: receiving 4,500-5,000 cGy total breast dose given in 180-200 cGy fractions" (radiotherapy);[162]

- "quality of radiotherapy: electron beam breast radiation used" (radiotherapy);[162]

- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy);[126,166]

- "appropriate use of any adjuvant systemic therapy in women with node positive breast cancer" (adjuvant systemic therapy);[130,134]

- "appropriate use of any adjuvant systemic therapy in women with node negative breast cancer" (adjuvant systemic therapy);[130,134]

- "appropriate use of tamoxifen in premenopausal women with node negative, intermediate risk, breast cancer" (adjuvant systemic therapy);[155]

- "appropriate use of tamoxifen in postmenopausal women with node negative, intermediate risk, breast cancer" (adjuvant systemic therapy);[130,155]

- "appropriate use of tamoxifen in postmenopausal women with node negative, high risk, estrogen receptor positive, breast cancer" (adjuvant systemic therapy);[155,161]

- "appropriate use of tamoxifen in postmenopausal women with node positive, estrogen receptor positive, breast cancer" (adjuvant systemic therapy);[127,155]

- " appropriate use of chemotherapy and hormone therapy (tamoxifen)" (adjuvant systemic therapy);[125,127,161]

- "appropriate use of chemotherapy and hormone therapy (tamoxifen) in premenopausal women with node positive, hormone receptor positive, breast cancer" (adjuvant systemic therapy);[127]

- "appropriate decision not to provide adjuvant systemic therapy for women with node negative, low risk breast cancer" (adjuvant systemic therapy);[134,155,161]

- "appropriate use of chemotherapy in premenopausal women with node negative, high risk, estrogen receptor positive, breast cancer" (adjuvant systemic therapy);[155]

- "appropriate use of chemotherapy in women with node negative, high risk, estrogen receptor negative, breast cancer" (adjuvant systemic therapy);[124,155,161]

- "appropriate use of chemotherapy in premenopausal women with node positive, estrogen receptor negative, breast cancer" (adjuvant systemic therapy);[127,155]

- "appropriate use of chemotherapy and/or ovarian ablation in premenopausal women with node positive, estrogen receptor positive, breast cancer" (adjuvant systemic therapy);[127,155]

- "appropriate use of chemotherapy in postmenopausal women with node positive, estrogen receptor negative, breast cancer" (adjuvant systemic therapy);[124,127,155]

- "quality of chemotherapy: proper doses administered (≥85% dose intensity [DI] and of relative dose intensity [RDI]) of CMF" (adjuvant systemic therapy);[154]

- "appropriate use of chemotherapy in postmenopausal women with node positive, estrogen receptor positive, breast cancer" (adjuvant systemic therapy);[124]

- "appropriate use of chemotherapy in women with node negative, estrogen receptor positive, breast cancer" (adjuvant systemic therapy);[124]

- "appropriate decision not to provide adjuvant systemic therapy for women older than 65 years of age with high risk, estrogen receptor negative, breast cancer" (adjuvant systemic therapy);[161]

- appropriate use: "Women with invasive breast cancer that is node-positive, or node-negative and primary tumor $\geq$ 1 cm, should be treated with adjuvant systemic therapy to include combination chemotherapy (and/or tamoxifen, 20mg/d)" (adjuvant systemic therapy);[5]

- "appropriate use of definitive locoregional therapy (total mastectomy with ALND, or breast-conserving surgery with ALND and radiotherapy)" (general);[135,152,163]

- "appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery with ALND or adjuvant treatment)" (general);[135,163]

- "referral to oncologist for treatment" (general);[111]

- "evidence of discussion about surgical options" (general);[111,148]

- appropriate use: "Women with metastatic breast cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent within 6 weeks of the identification of metastases" (general);[5]

- "no breast-conserving surgery or mastectomy in metastatic disease" (surgery).[136]

- appropriate use: “Women with stage I or stage II breast cancer should be offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery are present” (surgery);[5]

The measurements relating to the following quality indicators were undertaken to achieve internal quality improvement:

- “women undergoing breast-conserving surgery should have no more than two therapeutic operations” (breast-conserving surgery);[116]

- “availability of office procedure manual used for chemotherapy administration” (adjuvant systemic therapy);[120]

- “appropriate use of chemotherapy in women younger than 50 years of age, with node positive, breast cancer” (adjuvant systemic therapy);[121]

- “overall changes in QOL over time, before and after radiotherapy” (QOL);[123,139]

- “change in QOL in women with metastatic breast cancer” (QOL);[153,156]

- “women with a significant improvement in QOL in clinical phases of breast cancer” (QOL);[117]

- “change in QOL by time and treatment arm in postmenopausal, node negative breast cancer women who underwent adjuvant therapy” (QOL);[110]

- “change in QOL over time” (QOL);[113,129,148,149]

- “satisfaction of women with breast cancer with the treatment choice” (patient satisfaction);[140,148]

- “participation of women with breast cancer in decision-making as much as they wanted” (patient satisfaction);[140]

- “received enough information about surgery and radiotherapy” (patient satisfaction);[140]

- “board certified medical doctors in medical oncology” (general);[120]

- “documentation of Continuing Medical Education credits for the two years preceding each audit” (general);[120]

- “women with breast cancer given the opportunity to see a breast cancer specialist nurse” (general);[116]

- "cases not receiving recommended treatment (radiotherapy after breast-conserving surgery or systemic therapy) due to system failure" (general).[112]

Some studies evaluating the performance of a given quality indicator varied in terms of the treatment-related purposes they were intended to achieve. References to studies designed to achieve each purpose are made explicit:

- "appropriate use of all surgery" (surgery); both internal quality improvement and external quality oversight;[158]

- "appropriate use of breast-conserving surgery" (breast-conserving surgery); internal quality improvement;[116] external quality oversight[111,114,127,132,135,136,140,142-146,151,154,164-166] and both internal quality improvement and external quality oversight;[150,158]

- "appropriate use of mastectomy" (mastectomy); internal quality improvement[116] and external quality oversight;[154]

- "appropriate use axillary lymph node dissection" (axillary lymph node dissection); internal quality improvement[121] and external quality oversight;[111,114,126,131,135,146,152]

- "appropriate use of radiotherapy" (radiotherapy); both internal quality improvement and external quality oversight;[158] and external quality oversight alone;[128,164]

- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy); internal quality improvement;[121] external quality oversight[111,126-128,131,132,135,136,142,143,145,146,151,152,154,164,166]; and both internal quality improvement and external quality oversight;[150]

- "regional recurrence needing further surgery or radiotherapy" (radiotherapy); internal quality improvement[116] and external quality oversight;[128]

- "appropriate use of tamoxifen (hormone therapy)" (adjuvant systemic therapy); internal quality improvement;[116,120] external quality oversight;[131,146] and both internal quality improvement and external quality oversight;[158]

- "appropriate use of any adjuvant systemic therapy (chemotherapy and/or hormone therapy)" (adjuvant systemic therapy); internal quality improvement;[121] external quality oversight;[111,130,135,163] and both internal quality improvement and external quality oversight;[150]

- "appropriate use of chemotherapy" (adjuvant systemic therapy); internal quality improvement[116] and external quality oversight;[122,124,125,131,146] and both internal quality improvement and external quality oversight;[158]

- "appropriate use of treatment sequences according to guidelines (including surgery, radiotherapy, chemotherapy, hormone therapy, initial examination and followup)" (general); both internal quality improvement and external quality oversight;[150,158] and external quality oversight;[136,159]

- "at least 90% of women admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes" (general); internal quality improvement,[116,147] and external quality oversight.[160]

2c: What quality measures, if any, are available to assess differences in the quality of treatment of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? The reader is referred to the summary tables provided in response to Questions 2 and 2a. While quality measures to assess any of the above-noted differences have not been developed scientifically to achieve this goal, a number of treatment-related quality measurements have been conducted which capture such disparities. Results relating to specific quality indicators are reported from studies having conducted tests of significance to highlight possible gaps in care.

Regarding age, a number of studies observed that, relative to older women, younger women with breast cancer were significantly (statistically) more likely to receive the following treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery) (<70 vs. >70 years in MN only)[132];(decreasing trend in older groups);[142,143] (50-69 vs. >70 years);[135]

- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection) (<70 vs. >70 years);[114,131] (50-69 vs. >70 years);[135] (decreasing trend in older groups);[126]

- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy) (<80 vs. >80 years);[143] (MA: <50 vs. 50-59 & >70 years; MN: <50 vs. >80 years);[131] (50-69 vs. >70 years);[135] (<70 vs. >70 years);[151] (60-69 vs. 70-79 vs. >80 years);[150]

- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy) (< 70 vs. > 70 years);[166]

- "appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer" (adjuvant systemic therapy) (decreasing trend in older groups);[130]

- "appropriate use of tamoxifen in postmenopausal women with node (-), intermediate risk, breast cancer" (hormone therapy) (<80 vs. >80 years);[130]

- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy) (60-69 vs. 70-79 vs. >80 years);[150]

- "appropriate use of chemotherapy" (chemotherapy) (decreasing trend in older groups);[122,125]

- "appropriate use of chemotherapy and hormone therapy (tamoxifen)" (adjuvant systemic therapy) (decreasing trend in older groups);[125]

- "appropriate use of treatment sequences according to Guidelines (including surgery; radiotherapy; chemotherapy; hormone therapy; initial examination; and followup)" (general) (60-69 vs. >80 years);[150]

- "appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy)" (general) (50-69 vs. >70 years);[135]

- "appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery + axillary lymph node dissection or adjuvant treatment)" (general) (50-69 vs. >70 years);[135] (decreasing trend in older groups).[163]

No studies were found to demonstrate that, relative to younger women, older women with breast cancer were significantly more likely to receive specific types of treatment-related care. In studies where tests of statistical significance were performed, no differences were observed with respect to age for the following recommended types of treatment-related care:

- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy) (<70 vs. >70 years);[166]

- "quality of radiotherapy: done 5 days/week" (radiotherapy) (<70 vs. >70 years);[166]

- "quality of radiotherapy: homogenous dose distribution of radiotherapy" (radiotherapy) (<70 vs. >70 years);[166]

- "quality radiotherapy: use of wedges on tangent breast fields" (radiotherapy) (<70 vs. >70 years);[166]

- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy) (<70 vs. >70 years);[130]

- "appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer" (adjuvant systemic therapy) (<51 vs. 51-64 vs. >65 years);[134]

- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy) (50-69 vs. >70 years);[135]

- "change (improvement) in scales of QOL over time" (QOL) (24-54 vs. >55 years).[149]

With respect to race or ethnicity, a number of studies observed that, relative to white women, black women were significantly more likely to receive these types of treatment-related care:

- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection);[146]
- "appropriate use of chemotherapy" (chemotherapy).[146]

On the other hand, some studies reported that, relative to black women, white women were significantly more likely to receive these types of treatment-related care.

- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy);[146,151,166]
- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy);[166]
- "appropriate use of tamoxifen" (hormone therapy).[146]

In studies where tests of statistical significance were performed, no differences were observed with respect to race or ethnicity for the following types of care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[143,146,151,166]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection);[126]
- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy);[143]
- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy);[166]
- "quality of radiotherapy: done 5 days/week" (radiotherapy);[166]
- "quality of radiotherapy: homogenous dose distribution of radiotherapy" (radiotherapy);[166]
- "quality of radiotherapy: use of wedges on tangent breast fields" (radiotherapy);[166]
- "appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer" (adjuvant systemic therapy).[134]

Regarding income-related definitions of socioeconomic status, a number of studies observed that, relative to women with lower annual incomes, women with higher annual incomes were significantly more likely to receive the following treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[136]
- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy);[163]
- "appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy)" (general).[163]

No studies were identified wherein, relative to women with higher annual incomes, those with lower annual incomes were significantly more likely to receive specific treatment-related types of care. In studies where tests of statistical significance were performed, no differences were observed with respect to annual income for the "appropriate use of breast-conserving surgery" (breast-conserving surgery).[132]

With respect to education-related definitions of socioeconomic status, a number of studies observed that, relative to women with a lower educational level, women with a higher educational level were significantly more likely to receive treatment-related care.

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[142]
- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy);[163]
- "appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy) (general).[163]

No studies observed the converse, however, where women with lower educational levels were advantaged. In studies where tests of statistical significance were performed, no differences were observed with respect to educational level for the following types of treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[132]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection).[126]

With respect to definitions of socioeconomic status based on healthcare coverage, no studies observed that, relative to women with private insurance, women with governmental coverage were significantly more likely to receive specific treatment-related care. On the other hand, some studies reported that, relative to women with governmental coverage,

women with private insurance were significantly more likely to receive the following types of treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[151,166]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection);[114]
- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy);[151,166]
- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy).[166]

In studies where tests of statistical significance were performed, no differences were observed with respect to healthcare coverage for the following types of care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery) (HMO member vs. other);[132]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection) (HMO vs. private);[126]
- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy);[166]
- "quality of radiotherapy: done 5 days/week" (radiotherapy);[166]
- "quality of radiotherapy: homogenous dose distribution of radiotherapy" (radiotherapy);[166]
- "quality of radiotherapy: use of wedges on tangent breast fields" (radiotherapy).[166]

With respect to residence-related definitions of socioeconomic status, a number of studies observed that, relative to women living in rural areas, women living in urban areas were significantly more likely to receive this treatment-related care: "appropriate use of breast-conserving surgery" (breast-conserving surgery) (Minnesota only).[132] No studies noted an opposite finding or a null result.

2d: What is the evidence supporting the use of quality measures for the treatment of breast cancer in women, exhibited in terms of the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? With regards to the appropriate use of breast-conserving surgery or appropriate use of mastectomy, Ottevanger et al. found that the 5-year overall survival as well as the disease-free survival in patients receiving breast-conserving surgery plus radiotherapy or mastectomy was equivalent, that is, statistically nonsignificant differences were observed.[154] These

investigators also evaluated the locoregional relapse rate in patients who did and did not receive, as indicated, radiotherapy on the axilla following axillary lymph node dissection, to deal with increased risk of local recurrence (i.e. extracapsular extension, ≥4 positive nodes). They observed a statistically nonsignificant difference between the two types of patient. These same investigators also reported a statistically nonsignificant difference in 5-year overall survival for women who did and did not receive radiotherapy on the axilla. Finally, Ottevanger and colleagues assessed the quality of chemotherapy defined in terms of the proper dose of CMF being administered: ≥85% dose intensity and relative dose intensity. They measured the 5-year overall survival and disease-free survival of patients with <65% as opposed to >85% dose intensity, and found that using <65% of the dose intensity was directly correlated with a decrease in each of these outcomes.

2e: What is the evidence supporting the use of quality measures for the treatment of breast cancer in women, exhibited in terms of their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? Psychometric performance data relating to breast cancer treatment were scarce. The only reported data involved instruments validated to assess patient-centered outcomes such as QOL. These tools had a history of validated use with cancer and breast cancer, yet psychometric data were only reported with respect to their use in the studies of pertinence to the present review. Psychometric data obtained in validating these measures with breast cancer patients were not included in the study reports.

Internal consistency data for the QLI in Hassey and Lafferty's study of changes brought about by radiotherapy after breast-conserving surgery were established using Cronbach's alpha, which ranged from 0.73 to 0.93 (Summary Table 30).[123] The PAIS's Cronbach's alpha was 0.76. Finally, Cronbach's alpha values ranged from 0.71 to 0.81 for the ASE and its subscales.

Chie et al.'s on-study SF-36's Cronbach alpha values exceeded 0.83, while the corresponding datum for the QLQ-C30 was 0.86 (Summary Table 31).[117] In Molenaar et al.'s research (Summary Table 32),[148] modest study-based reliability was observed for the QLQ-BR23 across three (arm, breast, systemic therapy) subscales (0.58-0.65). The satisfactory reliability of the other subscales fell between 0.76 and 0.89. Frazer et al. used the validated, 39-item, Guttman scaled Health Status Questionnaire to assess breast, as well as prostate, cancer patients' experience over a 3-year period while being treated with surgery and hormone therapy (Summary Table 32).[129] Across eight subscales, good reliability was established using Cronbach's alpha (0.85), the Guttman split-half method (0.83), and the Spearman-Brown formula (0.85). Molenaar et al. also evaluated breast cancer patients' satisfaction with their treatment choice (Summary Table 33) using the full Patient Satisfaction Questionnaire and the Decision Conflict Scale.[148] These scales demonstrated satisfactory reliability in this study (i.e., 0.76-0.89).

Question 3: What measures of the quality of care are available to assess the appropriate use and quality of followup for breast cancer in women, including patient-reported QOL, and, patient satisfaction?

3a: In what patient population have these quality measures been used? With respect to followup, the performance of five quality indicators was measured. McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 84.6% adherence to a process indicator asserting that women with a history of breast cancer should have a yearly mammography (Summary Table 39).[5] This indicator was supported by randomized controlled trial evidence. Another was a process variable involving the appropriate use of clinical practice guidelines for followup surveillance of breast cancer. Cornfeld et al. selected a convenience sample of women with breast cancer having received treatment in a private setting from eleven clinical oncologists in the United States.[120] Ray-Coquard et al. chose a random sample of women with localized breast cancer, including ductal carcinoma in situ and non-metastatic invasive carcinoma.[158] Both studies abstracted data from medical records, and Cornfeld et al. also utilized a doctor-reported survey. Cornfeld et al. employed the National Comprehensive Cancer Network guidelines (1999), whereas Ray-Coquard et al. employed a regional set of clinical practice guidelines (1993) to define the standard and observed a rate of 80%. Cornfeld et al.'s rates were reported by type of practice, that is, for physical examination (100%), mammography (98%), and gynecology followup (76%).

Summary Table 39: Followup

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use: Women with a history of breast cancer should have a yearly mammography[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	99	1998-2000	84.6%/NA
Appropriate use of guidelines for followup surveillance of breast cancer[IV]				
Cornfeld, 2001, US	Convenience sample women with nonmetastatic BC treated in the private practice of 11 oncologists	110	1999-2000 (9 mo)	NR (Overall by practice: Physical exam: 100%; Mx: 98%; Gynecologic followup: 76% (30%-100%))/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	85	1995	80% (undefined followup)/NA

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant; NS = nonsignificant; Mx = mammography; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Cheung assessed three outcome indicators of quality care using data from his medical records, including the proportion of women with breast cancer who developed a local recurrence within 5 years after breast-conserving surgery (Summary Table 40).[116] In a convenience sample of women with operable breast cancer, and a tumor size of <5 cm, the 0% rate met the standard (<10%). He also reported a lower rate of local recurrence than the standard (<10%) within 5 years after mastectomy (2.6%). Finally, Cheung observed that 2% of women with a high risk of

flap recurrence, including 36% of those having received a mastectomy, appropriately received prophylactic radiotherapy.

Summary Table 40: Followup

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Women with breast cancer developing local recurrence within 5 years after breast-conserving surgery[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	0% (Standard: <10%)/NA
Women with breast cancer developing local recurrence within 5 years after mastectomy[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	2.6% (Standard: <10%)/NA
Appropriate use of prophylactic radiotherapy in women with high risk of flap recurrence[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	2% (36% in mastectomy cases)/NA

3b: For what followup-related purposes have these quality measures been used? The evidence is organized according to three broad categories of purpose. The measurements relating to the following quality indicators were undertaken to achieve external quality oversight:

- appropriate use: "Women with a history of breast cancer should have a yearly mammography" (followup);[5]
- "women with breast cancer developing local recurrence within five years after breast-conserving surgery" (followup);[116]
- "women with breast cancer developing local recurrence within five years after mastectomy" (followup);[116] and,
- "appropriate use of prophylactic radiotherapy in women with high risk of flap recurrence" (followup).[116]

Two studies evaluating the performance of a given quality indicator varied somewhat in terms of the followup-related purposes they were intended to achieve: "appropriate use of guidelines for followup surveillance of breast cancer" (followup): internal quality improvement and external quality oversight;[158] and, internal quality improvement alone.[120]

3c: What quality measures, if any, are available to assess differences in the quality of followup of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? No studies were identified as reporting data addressing this question.

3d: What is the evidence supporting the use of quality measures for the followup of breast cancer in women, exhibited in terms of the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes*?* No studies were identified as reporting data addressing this question.

3e: What is the evidence supporting the use of quality measures for the followup of breast cancer in women, exhibited in terms of: their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? No studies were identified as reporting data addressing this question.

Question 4: What measures are available to assess the adequacy and completeness of documentation of pathology, operative, radiation, and chemotherapy reports?

All of the quality indicators described with respect to the documentation, or reporting, of care of pertinence to the review belong to the process category. Numerous indicators were identified with respect to the adequacy and completeness of the documentation of pathology reports, with Imperato et al. investigating many of these.[137] They randomly selected a retrospective sample of Medicare cases with breast cancer (n = 555) having undergone a mastectomy concomitant with axillary lymph node dissection in four New York State hospitals. Medical records data complemented those from a regional Medicare database, and these were evaluated in terms of standards of care established by CAP and the Association of Directors of Anatomic and Surgical Pathology (ADASP). The standards were developed in 1997 and updated in 2000. Imperato et al. derived adherence rates for the following quality indicators relating to the reporting of the: gross observation of the lesion in mastectomy specimens (60.5%); verification of the tumor size (microscopic: 63%); number of positive lymph nodes (microscopic: 98.6%); nuclear grade (microscopic: 44.3%); mitotic rate (microscopic: 22.5%); and, extent of the tubule formation (microscopic: 19.6%) (Summary Table 41).

Summary Table 41: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting gross observation of lesion[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	60.5%/NA
Reporting verification tumor size (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	63%/NA
Reporting number of positive lymph nodes (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	220	1999	98.6%/NA
Reporting nuclear grade (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	555	1999	44.3%/NA
Reporting mitotic rate (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	555	1999	22.5%/NA
Reporting extent of tubule formation (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	555	1999	19.6%/NA

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant difference; NS = nonsignificant difference; Mx = mammography; H = Hispanic; Bx = biopsy; ALND = axillary lymph node dissection; TNM = tumor;node;metastasis state; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

The frequency of reporting the laterality of the surgical specimen in the gross examination was evaluated in three different studies (Summary Table 42). In addition to Imperato et al.'s work,[137] Appleton et al. selected a convenience sample of pathology reports,[109] and White et al. preferred a convenience sample of cancer registry reports for women with stage I-II breast cancer.[166] They employed the 1997/2000 CAP and ADASP guidelines, NHSBSP guidelines (1991), and the standards for breast-conservation treatment developed jointly in 1992 by ACOS, ACR, CAP and, SSO, respectively. The overall adherence rates obtained by White et al. and Imperato et al. were 98.3% and 99.3%, respectively. Appleton et al. presented results by year of audit, with an increase observed from 1992 (60%) to 1996 (100%).

Summary Table 42: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting laterality of surgical specimen (gross examination) [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, 1999 in NY state hospitals	555	1999	99.3%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range)): 50 – 100%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	98.3%/Age: <70 y: 98.2%; ≥70 y: 98.6%/Race: White: 98.2%; Black-Hispanic: 98.5%/Payer: Government: 98.4%; Private: 98.3%

The reported identification of the affected quadrant in the gross examination was evaluated in four studies (Summary Table 43). Shank et al.[162] and White et al.[166] each employed the ACOS, ACR, CAP and SSO (1992) guidelines, whereas Imperato et al. used the CAP (1997) and ADASP (1997) standards,[137] and Appleton et al. applied the NHSBSP (1991) guidelines.[109] Overall adherence rates obtained by White et al. (21.1%) and Imperato et al. (30.7%) were exceeded by those reported by both Shank et al. (97.8%) and Appleton et al. (80%). The latter's performance data reached 100% by 1996.

Summary Table 43: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting identification of affected quadrant (gross examination) [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	336	1999	30.7%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 60%-100%)/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	97.8%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	21.1%/Age: <70 y: 21.1%; ≥70 y: 21.3%/Race: White: 20.5%; Black-Hispanic: 26.3%/Payer: Government: 22%; Private: 20.4%

Using convenience samples of women with breast cancer stage I-II, two studies measured the frequency of reporting the orientation of the specimen in the gross examination (Summary Table 44). Wilkinson et al.'s sample of pathology reports (n = 83) was selected from one hospital cancer database and included women who had had an excisional biopsy,[167] whereas White et al. (n = 16,643) collected data from the cancer registries of 842 hospitals.[166] The standards were the CAP (1998) guidelines[167] and the 1992 ACOS, ACR, CAP, SSO (1992) standards for breast conservation therapy, respectively.[166] The overall adherence rate was 25% for Wilkinson et al. and 67.1% for White et al.

Summary Table 44: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting the orientation of the pathology specimen (gross examination)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	25%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	67.1%/Age: <70 y: 68%; ≥70 y: 64.9%/Race: White: 67.6%; Black-Hispanic: 64.2%/Payer: Government: 67.5; Private: 67.1%

The frequency with which the size of the pathology specimen obtained in the gross examination is reported was assessed by Wilkinson et al.[167] and Appleton et al. (Summary Table 45).[109] Wilkinson et al. included pathology reports from women with stage I-II breast cancer who had undergone an excisional biopsy, whereas Appleton et al. evaluated the reports relating to specimens obtained via mastectomy. Wilkinson et al.'s overall adherence rate was 91%, whereas Appleton et al.'s figure in both 1992 and 1996 was 100%.

Summary Table 45: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting size of specimen (gross examination)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx. Size in 3 dimensions	83	1998-1999	91%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 90%-100%)/NA

Four studies evaluated how often tumor size, determined through macroscopic examination, was reported (Summary Table 46). The overall adherence rates for Wilkinson et al.,[167] Shank et al.,[162], Imperato et al.,[137] and Appleton et al.[109] were 40%, 45.9%, 93.5%, and 70-100% over the period from 1992 to 1996. With respect to reporting the tumor size ascertained via the microscopic examination, Wilkinson et al. and Shank et al.'s rates were 90% and 95.3%, respectively.

Summary Table 46: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting tumor size (macroscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	40%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	45.9%/NA
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	336	1999	93.5%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 70%-100%)/NA
Reporting tumor size (microscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, 1998-1999 after excisional Bx	83	1998-1999	90%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95.3%/NA

Imperato et al.[137] and Shank et al.[162] found that, in 83.7% and 92% of cases, respectively, the presence or absence of lymph nodes in the gross examination had been documented (Summary Table 47). These same investigators found that, in 93.5% and 100% of cases, respectively, the number of lymph nodes present in the gross examination had been reported. In light of regional guideline standards, Ottevanger et al. assessed national cancer registry data for premenopausal women with stage II to IIIA breast cancer, and found that if at least ten nodes were identified as positive, the rate was 59.2%.[154] The value associated with fewer than ten positive nodes was 40.8%.[154]

Summary Table 47: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting lymph node presence/absence (gross examination)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	83.7%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	92%/NA
Reporting number of lymph nodes present (gross examination)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	93.5%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	100%/NA
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	233	1993-1998	NR (By n nodes: ≥10 nodes: 59.2%; <10 nodes: 40.8%)/NA

Appleton et al. collected adherence data with regards to four quality indicators associated with the documentation of elements of the gross examination in mastectomy cases (Summary Table 48).[109] They reported rates, broken down by year (1992-1996), of 40% to 100%, 30% to 100%, 10% to 80%, and 0% to 20% for the documentation of the nature of the specimen in the gross examination, the distance from the tumor to the nipple, the cut surface of the tumor, and, the description of the skin. However, only with respect to the second last quality indicator did the rate decrease over time, from 80% in both 1992 and 1994, to 10% in 1996. For the three remaining quality indicators, the highest rates were observed in 1996.

Summary Table 48: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting nature of specimen (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 40-100%)/NA
Reporting distance of tumor from nipple (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 30%-100%)/NA
Reporting description of cut surface of the tumor (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 10%-80%)/NA
Reporting description of skin (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 0%-20%)/NA

The same investigators reported rates relating to descriptions again concerning aspects of the gross examination (Summary Table 49).[109] An adherence rate of 100% characterized the reporting of the size of the overlying skin. The rate increased from 50% in 1992 and 1994, to 100% in 1996 regarding descriptions of the nipple. The proportion rose from 0% in 1992 and 1994, to 10% in 1996 for reports of the presence or absence of the fascia or skeletal muscle.

Summary Table 49: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting size of overlying skin (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	100%
Reporting description of nipple (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 50%-100%)/NA
Reporting presence or absence of fascia or skeletal muscle (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 0%-10%)/NA

Appleton et al. evaluated three instances of reports of microscopic examinations (Summary Table 50).[109] They noted an increment in the rate of adherence from 40% in 1992, to 80% in 1994 and 1996 for reporting of the involvement of apical lymph nodes. A decrease from 90% in 1992 and 1994, to 80% in 1996, was observed with respect to the description of the background breast. Reports of the size of the concurrent ductal carcinoma in situ (DCIS) reached 100% in 1996 after observations of 38% in 1992 and 33% in 1994.

Summary Table 50: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting involvement of apical lymph nodes (microscopic) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 40%-80%)/NA
Reporting size of concurrent ductal carcinoma in situ (microscopic) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 33%-100%)/NA
Reporting description of background breast (microscopic) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 80%-90%)/NA

There was wide variation in the reporting of the presence or absence of ductal carcinoma in situ based on the microscopic test (Summary Table 51). Wilkinson et al.'s adherence rate was 71%,[167] White et al.'s 43.2%,[166] Shank et al.'s 8.5%,[162] and Appleton et al.'s ranged from 70% to 100%, organized by year of audit.[109]

Summary Table 51: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting ductal carcinoma in situ (DCIS) present/absent (microscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	71%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	8.5%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	43.2%/Age: <70 y: 44.8%; ≥70 y: 38.6%/Race: White: 43.3%; Black-Hispanic: 40.8%/Payer: Government: 40.2%; Private: 45.7% S
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR/Overall by y (range): 70%-100%

Three groups of investigators evaluated the adherence rates to standards regarding the reporting of the measurements of the macroscopic margins of the carcinoma (Summary Table 52). The largest sample, whose data were examined by White et al., revealed the lowest rate (72.4%)[166] while Cheung[116] and Shank et al.[162] reported percentages of 100% and 96.8%, respectively.

Summary Table 52: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting measurement of macroscopic margins of carcinoma[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	96.8%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	72.4%/Age: <70 y: 72.5%; ≥70 y: 72.1%/Race: White: 72.5%; Black-Hispanic: 73.5%/Payer: Government: 73.1%; Private: 72.3%
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	100%/NA

Evaluations of reports of the assessment of microscopic margins revealed variability in adherence (Summary Table 53), with overall percentages of 69.4% to 95.6%,[137,162,166,167] and Appleton et al. observing a range of 90% to 100% by year of audit in small numbers of cases.[109]

Summary Table 53: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting assessment of microscopic margins [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	94%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95.6%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	89.5%/Age: <70 y: 90%; ≥70 y: 88.7%/Race: White: 89.7%; Black-Hispanic: 86.8%/ Payer: Government: 89%; Private: 90.2%
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	69.4%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 90%-100%)/NA

Imperato et al.[137] and White et al.[166] assessed the frequency of reports of microscopically confirmed carcinoma (Summary Table 54). Their data revealed rates of 100% and 97.8%, respectively.

Summary Table 54: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting carcinoma confirmed microscopically [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	100%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	97.8%/Age: <70 y: 97.7%; ≥70 y: 97.9%/Race: White: 97.9% Black-Hispanic: 96.7%/Payer: Government: 98.1%; Private: 97.7%

Four studies determined how often the histological type revealed by way of microscopic examination was reported (Summary Table 55). The rates were high, ranging from 95.9% to 100%.[109,137,162,166,167]

Summary Table 55: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting histological type (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	100%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	99.7%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	98.8%/Age: <70 y: 98.8%; ≥70 y: 98.7%/Race: White: 98.8%; Black-Hispanic: 99%/Payer: Government: 99%; Private: 98.7%
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	95.9%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	100%

Variability characterized adherence to the standards for the reporting of histological grade via microscopic investigation (Summary Table 56). The overall adherence rates were 59.1% for Imperato et al.,[137] 80.6% for White et al.[166] and 90% for Wilkinson et al.[167] Appleton et al.'s rates were expressed by year, with 90% in 1992, 80% in 1994 and 100% in 1996.[109]

Summary Table 56: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting histological grade (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, 1998-1999 after excisional Bx	83	1998-1999	90%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	80.6%/Age: <70 y: 81.1%; ≥70 y: 79.3%/Race: White: 80.5%; Black-Hispanic: 79.7%/ Payer: Government: 80.1%; Private: 81.2%
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	59.1%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 80%-100%)/NA

Reports of lymph-vascular invasion observed microscopically were assessed in three studies (Summary Table 57), with similar results. Imperato et al.'s rate was 45.6%,[137] Wilkinson et al.'s was 47%,[167] and White et al.'s was 53.5%.[166]

Summary Table 57: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting lymph-vascular invasion (microscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	47%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	53.5%/Age: <70 y: 54.3%; ≥70 y: 51.5%/Race: White: 52.9%; Black-Hispanic: 54.4%/ Payer: Government: 51.3%; Private: 54.9% S
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	45.6%/NA

Shank et al.[162] and White et al.[166] evaluated cases in which the size of the invasive carcinoma, observed microscopically, was reported (Summary Table 58). Shank et al. noted a rate of 8.5% based on a small number of cases, whereas White et al.'s rate was 91.8%.

Summary Table 58: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting size of invasive carcinoma (microscopic)[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	8.5%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	91.8%/Age: <70 y: 91.6%;<70 y: 91.9%/Race: White: 91.7%; Black-Hispanic: 91.2%/Payer: Government: 91.6%; Private: 92%

The same two groups of investigators described similar rates of adherence with regards to reporting estrogen receptor status (Summary Table 59). The figures were 89% in Shank et al.'s study[162] and 91.7% in White et al.'s.[166] Their respective rates of reporting progesterone receptor status were 86.7% and 90.6%.

Summary Table 59: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting estrogen receptor status (microscopic)[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	89%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	91.7%/Age: <70 y: 91.9%; ≥70 y: 91.2%/Race: White: 91.8%; Black-Hispanic: 90.4%/Payer: Government: 91.4%; Private: 92.3%
Reporting progesterone receptor status (microscopic)[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	86.4%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	90.6%/Age: <70 y: 90.9%; ≥70 y: 89.7%/Race: White: 90.7%; Black-Hispanic: 89.6%/Payer: Government: 90.1%; Private: 91.4%

Based on a small number of cases (n = 83), Wilkinson et al. identified three indicators pertaining to documentation (Summary Table 60).[167] They observed a 77% adherence rate for reporting the inking of specimens, 9% for reporting TNM staging, and a 6% rate related to reporting a Bloom Scarf Richardson tumor grade.

Summary Table 60: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting specimen inked (microscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	77%/NA
Reporting Bloom Scarf Richardson scale (tumor grade) (microscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	6%/NA
Reporting TNM staging (microscopic)[IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	9%/NA

Documenting the distance to the closest margin was evaluated twice (Summary Table 61). Overall adherence rates were 69% in Wilkinson et al.,[167] and ranged from 80% to 100%, by audit year, in Appleton et al.;[109] Shank et al.[162] noted a 99.3% adherence rate pertaining to reports of the pathological extent of the primary tumor.

Summary Table 61: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting distance to the closest margin (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	69%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 80%-100%)/NA
Reporting pathological extent of primary tumor (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	99.3%/NA

Shank et al. also collected data showing that, in 95.3% and 98.9% of cases relating to the performance of flow cytometry and cytometry ploidy, respectively, reports had been provided (Summary Table 62).[162] In 99.7% of cases, Shank et al. observed that pathology reports were included on the chart.

Summary Table 62: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting having performed flow cytometry (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95.3%/NA
Reporting cytometry ploidy (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	98.9%/NA
Pathology reports on chart [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	99.7%/NA

Regarding the adequacy and completeness of imaging reports, White et al. noted that, in 47% of cases, the size of the mammographic abnormality had been reported (Summary Table 63).[166]

Summary Table 63: Imaging reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Size of mammographic abnormality[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	47%/Age: <70 y: 45.9%; ≥70 y: 50.7%/Race: White: 47.5%; Black-Hispanic: 46.3%/Payer: Government: 50.3%; Private: 44.8% S
KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant; NS = nonsignificant; Mx = mammography; H = Hispanic; Bx = biopsy; ALND = axillary lymph node dissection; TNM = tumor;node;metastasis state; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data				

Two quality indicators relating to the adequacy and completeness of chemotherapy reports were studied by Cornfeld et al. (Summary Table 64).[120] The first is a structural variable relating to the presence of chemotherapy sheets on the active treatment charts. The second is a process indicator indicating the presence of the body surface area calculations on the chemotherapy flow sheets. The overall adherence rates were 99% and 90%, respectively.

Summary Table 64: Chemotherapy reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Presence of chemotherapy flow sheets in active treatment charts[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	99%/NA
Presence of body surface area calculations on chemotherapy flow sheets[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	90%/NA
KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant; NS = nonsignificant; Mx = mammography; H = Hispanic; Bx = biopsy; ALND = axillary lymph node dissection; TNM = tumor;node;metastasis state; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data				

In the sole study providing data regarding possible linkages to outcomes, Ottevanger et al. noted that reporting the number of affected lymph nodes was linked to overall survival and disease-free survival.[154]

Chapter 4. Discussion

Overview

The goal of this systematic review was to identify, review, catalog, and describe some of the key parameters defining those measures of the quality of breast cancer care for women (e.g., study population). Specifically, this includes diagnosis, treatment (including supportive care), followup, and reporting/documentation of this care. An additional focus established in consultation with our TEP was to review efforts assessing the impact of this care on QOL and patient satisfaction. Screening and prevention were not included in the scope of the review at the request of the Federal Partners—these topics will be addressed elsewhere.

A total of 3,848 bibliographic records were identified and reviewed, from which 60 reports met eligibility criteria. These reports referred to 58 studies, and described quality measurement data for 143 quality indicators. Virtually no formally (i.e., scientifically) developed quality measures were found. As such, one can have little confidence in the reliability and validity of the adherence rates revealed by almost all of the quality indicators. Studies employing unvalidated measures cannot provide empirical evidence showing that their implementation with a given data source (e.g., medical records), by different evaluators, or the same evaluator on different occasions, results in the same, or even consistent, adherence data. The dearth of validated quality measures underscores the decision, made prior to the evaluation of evidence, to downplay any discussion of adherence rates potentially indicative of gaps in care. The implications of these findings are highlighted below, along with some recommendations regarding possible future research.

Key Observations

No validated quality measures relating to breast cancer care constructs, other than patient-reported QOL and patient satisfaction with care, were identified (Questions 1, 1e, 2, 2e, 3, 3e, 4). That is, none of the studies evaluating rates of adherence relating to the receipt or delivery of recommended care for breast cancer employed measures exhibiting even an unsound or inconsistent psychometric foundation established prior to, or during, their study. Of the studies having used validated instruments, one of the QOL or patient satisfaction with care measures assessed the impact of diagnosis, and 11 of the QOL or patient satisfaction with care measures assessed the impact of treatment. None evaluated followup care. Each of these measures assessed, typically with multiple items, patients' perspective on their QOL or satisfaction with care. Often, such an instrument yielded an overall score and subscale scores, reflecting varying facets of QOL (e.g., emotional well-being). All had been adapted for use in studies of breast cancer care in women, with two expressly validated for use with this population: the FACT-B,[115] and the EORTC-QLQ-BR23.[148]

Since validated quality measures were rarely identified, questions relating to the populations in which quality measures had been used (Questions 1a, 2a, 3a), and to their care-related purposes (Questions 1b, 2b, 3b), could only be addressed with respect to quality measurement

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.goc/clinic/epcindex.htm

efforts involving unvalidated instruments. Moreover, while some data were observed that appeared to indicate disparities in care related to four key variables (i.e., age, race, ethnicity, socioeconomic status), no validated quality measures were used to highlight these patterns (Questions 1c, 2c, 3c). Virtually no data were reported that revealed study-observed links to improved clinical outcomes (Questions 1d, 2d, 3d).

Most of the quality measurements involved process (e.g., access) indicators of quality care, a finding that was not unexpected since many of the performance standards came from clinical practice guidelines.[8] Few quality indicators of the structural or outcome variety were identified.

The overwhelming majority of quality measurement efforts focused on determining, retrospectively, *whether or not* recommended care had been delivered or received (i.e., "appropriate use") and, on occasion, the timeliness required for its delivery or receipt. Very few studies, however, evaluated rates of adherence pertaining to the *quality* with which this care was delivered. The distinction between "delivery" and "receipt" is likely non-trivial, since there were various data sources and informants (e.g., patients vs professionals vs cancer registries) from which, and from whom, data were obtained to index adherence to quality care. It also suggests potentially conflicting perspectives, and data, regarding a given healthcare "event." This is a topic the present review did not investigate.

Most of the subcategories of diagnostic care outlined in the request for task order did not receive any attention in the quality measurement studies. That a quality indicator was not identified by this review indicates that no studies were found to assess adherence to this standard of care. Efforts to measure the quality of breast cancer care in women have focused far more often on treatment than on diagnosis. This may be the result of a number of factors, including debate as to whether some types of diagnostic care are needed as often as they are delivered (e.g., bone scans),[169] as well as some of the diagnosis-related strategies (e.g., genetic testing) exhibiting a shorter track record. Only two types of treatment predefined in the request for task order failed to have quality data represented in the review. Followup received even less consideration than diagnosis, and efforts to evaluate documentation fell in between diagnosis and treatment, particularly in terms of the number of identified quality indicators. It is unclear how focusing our search from 1993 onwards might have influenced this distribution of observations. Although the present project established a cut-off date different from the one implemented in Malin et al.'s recent systematic review (i.e., 1985-),[170] our review nonetheless identified all of the same quality indicators for which they reported patterns of breast cancer care data.

Different definitions of recommended care for the same patient type were observed on occasion in our review. For example, two investigations measured adherence to a standard recommending that women with breast cancer be seen in a timely fashion, post-referral, by a specialist, and for diagnostic purposes (Summary Table 5). Based on the BASO (1998) and BASO (1995) standards, Khawaja et al[141] and Cheung[116] specified "timely" as within 2 weeks of referral and within 15 working days of referral, respectively. Of three studies looking at the appropriate use of chemotherapy in postmenopausal women with node-negative, estrogen-receptor negative breast cancer,[124,127,155] only Du and Goodwin specified a time frame (6 months) within which the chemotherapy needed to be delivered (Summary Table 26).[124] One way to explain these differences is that different performance standards had been used. In the first example, the same BASO clinical practice guidelines had been updated. Guidelines can also vary in terms of their recommended care (i.e., quality indicators) for a given population if each employs a different criterion regarding the strength of the evidence required to support its recommendations. Malin et al. have observed that, due to a shifting consensus regarding the

appropriateness of different types of care for specific populations (e.g., adjuvant chemotherapy), it can be very difficult to determine whether care has been consistent with the standard.[170]

Different rates of adherence were often observed in our review with respect to the same quality indicator. For example, regarding the appropriate use of mastectomy (Summary Table 9) for women with operable primary breast cancer less than 5 cm, Cheung again applied the BASO (1995) guidelines to his own medical records, noting a 68% adherence rate. Ottevanger et al.,[154] on the other hand, analyzed data regarding the appropriate use of mastectomy in premenopausal women with stages II-IIIA, node-positive breast cancer. Their population-based data revealed a 44.5% adherence rate based on Dutch regional guidelines (i.e., Comprehensive Cancer Center East). This discrepancy in rates may be attributable to the different definitions of the breast cancer population.

There are, however, reasons other than the definition of the performance standard or the sampled population of breast cancer patients, that can account for differences in rates of adherence to recommended care. These issues are presented below. For now, attention is turned to several other key patterns observed within the present review.

If any of the adherence data reviewed here are considered to be even remotely trustworthy, then there appear to be gaps in care. These gaps invariably reflect problems related to the underuse of care, and not with the overuse or misuse of care. However, with no evidence that reliable and valid measures were used, and compounded by the fact that little or no information was reported to suggest that multiple data abstractors had been used in the included studies (i.e., to minimize bias and errors in data collection), it is the view of the authors that the data likely do not accurately reflect the clinical realities experienced either by healthcare providers and their institutions or systems, or by their patients. Unknown is how discordant the rates actually are. It may be best to proceed with caution before allowing even minor decisions to be guided by these adherence data.

With respect to the topic of diagnosis, considerable variability was observed among the standards used to assess quality. Also apparent was heterogeneity regarding the diagnostic contexts from which some of the sample populations with breast cancer had been drawn. For example, it was noted that some women were diagnosed with breast cancer because they had undergone diagnostic mammography to investigate breast symptoms. Other women were diagnosed as a result of a screening mammography. Patient sampling strategies ranged from a focus on individual physicians' records to national population-based samples.

Overall, the majority of the diagnosis-related quality indicators related to internal quality improvement, and not surprisingly, the data source and measurement purpose covaried. For example, when only a single site was involved (e.g., one hospital, one specialist's office), the purpose tended to be internal quality improvement. However, when data were obtained from a national database (e.g., SEER) or a regional database covering multiple sites, the purpose was likely to be external quality control. However, patterns of measurement purpose data may be misleading for all categories of care, and not just diagnosis, because some studies evaluated many more quality indicators than did others.

Notwithstanding the absence of validated quality measures, the problem with drawing conclusions with respect to the impact of age on adherence rates relating to diagnosis is that the different studies varied in their definitions of "younger" versus "older" women. Relatively speaking, older women were disadvantaged in terms of receipt of a preoperative mammogram when younger meant "under the age of 70 years;"[166] and, younger women were less likely to receive two types of care when, across two studies, "older" referred to at least 40 and at least 50

years of age, respectively (see response to Question 1c.).[119,133] Adherence data stratified by race, ethnicity, or type of healthcare coverage were too scarce to permit the identification of any reliable patterns of association. No studies reported data suggesting linkages to specific clinical outcomes that could have confirmed the relationship between diagnosis-related care and improved outcomes reflected in the performance standard. One study observed sound on-study reliability data for an instrument previously validated as a QOL measure.[115]

For treatment studies, both the breast cancer populations and the performance standards varied greatly. Studies conducted in, as opposed to outside North America, tended to include larger sample populations and use national databases more frequently (e.g., SEER, Medicare claims). Early stage breast cancer was the diagnosis represented most often in treatment studies. Seldom evaluated in any category of care, including treatment, were those women with late-stage breast cancer, as well as those for whom palliative care is indicated. The majority of the quality indicators were identified as having been conducted to afford external quality oversight.

Adherence data suggested that, relative to older women, younger women were significantly more likely to receive 12 types of treatment-related care (see response to Question 2c.). All of these quality indicators referred to the delivery/receipt of this care, where indicated (i.e., "appropriate use"); and, unlike the situation concerning diagnosis, the distinctions between "older" and "younger" were more consistent. No studies observed that older women were significantly advantaged over younger women in terms of care. Evidence for eight quality indicators indicated that neither age group was advantaged over the other in terms of care. Yet, half of the latter pertained to the *quality* of the delivered care, and not to whether the indicated care was delivered. The reader is reminded that a "no difference" with respect to stratification data was determined by a test of statistical significance.

With respect to race, black women were more likely than white women to receive two of the recommended treatments, whereas white women were more likely than black women to receive three of the recommended treatments (see response to Question 2c.). Yet, for eight quality indicators, including four relating to the quality of delivered care, no race-related differences were observed. At least using these data from unvalidated measures, race appears to have had less of an impact on the delivery/receipt of care than might have been expected. While few data are available to comment upon, women with higher incomes, more education, and private (versus governmental) healthcare coverage were somewhat more likely to receive recommended treatment. As was the case with the subject of diagnosis, the latter quality indicators were mostly of the "appropriate use" variety.

As with the variables of age and race, there were no differences associated with the type of healthcare coverage for four quality indicators reflecting the quality of delivered treatments. Four studies employed QOL measures whose data indicated sound reliability, invariably defined in terms of the internal consistency of both overall scores and subscale scores. One study employed a patient satisfaction questionnaire, and reported satisfactory reliability.

Finally, Ottevanger et al. reported data linking care to outcomes: a) equivalent disease-free survival in women receiving breast-conserving surgery plus radiotherapy, and, mastectomy; b) a nonsignificant difference in the locoregional relapse rate for women who did and for those who did not receive indicated radiotherapy on the axilla following axillary lymph node dissection, to specifically deal with increased risk of local recurrence (i.e. extracapsular extension, ≥4 positive nodes); and, c) a statistically nonsignificant difference in 5-year overall survival for women who did and for those who did not receive radiotherapy on the axilla.[154] These investigators also assessed the quality of chemotherapy defined in terms of the proper administered dose of CMF

(≥85% dose intensity and relative dose intensity). They measured the 5-year overall survival and disease-free survival of patients with <65% as opposed to >85% of the dose intensity, noting that using a <65% criterion was directly correlated with a decrease in each of these outcomes.

The few studies of followup tended to focus on the issue of recurrence. Too few data relating to purpose make it inappropriate to draw any conclusions. No other data were available to report. Yet, 45 quality indicators referred to the reporting/documentation of specific, review-relevant types of breast cancer care, 42 of which pertained to pathology reports. In the sole study providing data regarding linkages to outcomes, Ottevanger et al. noted that reporting the number of affected lymph nodes was linked to overall survival and disease-free survival.[154]

Across all categories of care, a few larger patterns emerged. As stated earlier, almost no quality measurements involved validated measures; and, not all types of care represented in the request for task order were investigated in the collection of 58 studies. Diagnosis-related care received little attention in the included literature; for some indicators (e.g., sentinel node biopsy), the lack of any type of standard required them to be excluded from the systematic review.

Most quality indicators reflected *processes* of care, focusing most frequently on whether or not women with breast cancer received indicated care. At the same time, there were very few investigations of the quality of the delivered care. Where gaps in care seemed to exist, they were invariably marked by patterns of underuse. Almost no studies highlighted data regarding overuse of care, suggesting that they might not have been designed to highlight such patterns.

When a subgroup of women (i.e., older, black, lower income, lower education, governmental healthcare coverage) was disadvantaged in terms of treatment, the types of quality indicator were defined in terms of whether or not they had received the indicated care. On the other hand, no subgroup of women for whom adherence data were reported (i.e., older, black, governmental healthcare coverage) was disadvantaged relative to their counterparts (i.e., younger, white, private healthcare coverage) when it came to the *quality* of the delivered care. It must be remembered, however, that these data regarding patterns of care may be somewhat or wholly unreliable and invalid given the paucity of validated quality measures. Little can be said about evidence pertaining to linkages to clinical outcomes.

Critical Analysis

Without validated quality measures with which to collect adherence data, there may always be some doubt about the reliability and validity of these data. Notwithstanding this limitation, in general, the methodologic rigor displayed by the included studies varied. Yet, most reports failed to describe having used multiple reviewers to abstract data, or how the reviewers were trained and calibrated, further diminishing the potential meaningfulness of the adherence data. Using a single data abstractor is a recipe for systematic and unsystematic bias (i.e., errors). One investigator, for example, was the sole assessor of their own practice records.[116]

It was also observed in conducting this review that the often unclear or imprecise way in which some study reports defined their quality indicators would have likely compromised their reliable implementation by multiple data abstractors. The present review's relevance assessors and data abstractors often noted how difficult it was to determine the exact definition, and wording, of the quality indicators. Clear and well-defined wording is necessary for any instrument to reliably measure what it was intended to. McGlynn et al.'s quality indicators likely constituted the most precisely described set identified in any given adherence study.[5] Seven of

their nine indicators specified "timeliness" for delivery or receipt of care (e.g., radiotherapy after breast-conserving surgery).

The reviewers also remarked how difficult it was, in general, to determine whether some reports were describing studies conducted to assess adherence data in ways that met the review's eligibility criteria. In some studies, it was hard to determine whether the quality indicator under investigation reflected a concern with the delivery of appropriate care to a specific type of patient or the quality with which it was delivered (e.g., axillary lymph node dissection).[111] While most of the studies entailed retrospective evaluations, even the few prospective ones were characterized by these problems.

Many of the studies obtained data from just one data source. Although it might be thought that this is less of a problem if the data source is a large, national cancer registry than if it is the medical records of a small clinic, each data source is limited in some fashion. This issue is explored further in the next section.

Research Implications

The research implications of the present findings suggest the need to close the gap between the existing, and likely ideal, scientific way to measure the quality of breast cancer care required to highlight possible gaps in this care. While more research to develop better research methods is clearly indicated, that is, employing principles by which any formal measure is derived, it may be wise to wait until the results of at least one important research undertaking are reported before independently undertaking what ASCO may already be in the process of achieving. Additional detail about this work is presented below.

Overall, it appears to be the case that there are certain factors whose influence on adherence data needs to be taken into consideration when conducting quality measurement studies. These include the specific definitions of recommended care in the reference standard (e.g., clinical practice guideline), in no small measure determined by the criterion defining the strength of evidence required to support the recommendations. Second, the method of case identification associated with a data source defining a cohort of breast cancer patients can result in systematic differences in distributions of baseline health status, processes of care, and outcomes.[6] Each data source is characterized by specific definitions of the breast cancer population(s) (e.g., stage, age, comorbidity). As well, data sources vary in terms of the completeness, reliability, and validity of their data based on the context (e.g., diagnostic setting), method (e.g., patient self-report vs medical record vs. specialists' recall vs administrative data), and timing of their data collection (e.g., immediate vs delayed).[6] For example, it has been pointed out that:

> asymptomatic patients in whom breast cancer is diagnosed after mammography include most patients with ductal carcinoma in situ and patients with invasive cancer. Estimated 5-year survival for this cohort is high (approximately 85%) because diagnosis by screening identifies more ductal carcinoma in situ cases on average than based on a physical finding.[6]

There are likely uneven distributions of patients, for example on the basis of stage, across various diagnostic settings.[6] Thus, knowing the case composition of a data source is required to determine whether it is appropriate to address a specific quality measurement question.

Different data sources have their strengths and weaknesses. For example, medical records reveal clinical characteristics, processes, and outcomes across settings and specialty types.[6] Yet, hospital-based records may not be the best source for information concerning the ambulatory care received by most breast cancer patients.[6] National and state registries can report diagnosis, stage, first treatment, and outcomes. Some experts have suggested that their regulatory authority uniquely situates cancer registries to provide the infrastructure required to measure the quality of care.[170] It is a better strategy to utilize a national cancer registry (e.g., SEER) to identify a population-based cohort of incident cancer cases. As well, especially larger national registries do not exhibit the same problems with referral or selection bias. However, these data sources understandably do not provide a record of all of the minute details considered by some to be essential for the delivery of quality breast cancer care (e.g., discussion of treatment options). Also, they likely do not accurately report all of the details pertaining to treatment received in ambulatory settings.

Administrative data, on the other hand, do provide considerable information about ambulatory care, and services received in general, yet sources such as managed care claims yield data that are not transparent to the reasons a procedure was not used.[6] Claims and encounter data capture the use of services without specific reference to the circumstances in which the care was received.

Any of these data sources nevertheless allow the researcher to select a sample of the available data with which to derive rates of adherence to recommended care, with strategies ranging from assessing data from all candidate cases to a random sample thereof. The nature of a data source (e.g., one physician's records) can limit the size of a possible sample, and this in turn can influence the choice of sampling method. The choice of data source and the sampling method jointly determine not just the nature, reliability, and internal validity of observations, but also their generalizability (i.e., external validity). Researchers typically have to juggle factors such as convenience and cost, or burden, in addition to the need for generalizability in deciding upon their data sources and sampling strategies.

Overall, some of the variation observed in patterns of care may be attributable to variability in the quality of the data obtained from different data sources.[170] Missing or incomplete data often characterize databases. Yet, perhaps as important to the enterprise of measuring healthcare quality is knowing the important types of patient(s) who, in spite of attempts to find them, are likely to remain unidentified using the selected data sources and sampling techniques.[6]

This discussion raises the possibility of collecting quality-of-care data from various data sources that are linked, so that data missing for a set of breast cancer patients with one source can be obtained through another source (e.g., national, state, regional, or hospital registries; pathology laboratories, claims or encounter data [e.g., Medicare], mammogram suites, or, physician or clinic reports of patients diagnosed with breast cancer).[5,6] Such an option is not unreasonable given that breast cancer care typically entails a suite of professionals who interact with the breast cancer patient across various contexts, and time (e.g., breast cancer nurse, diagnostician, surgeon, radiation oncologist, medical oncologist). These interactions provide different perspectives on patient care that can readily be used to complement the patient's own view of the care process.[6] Yet, some sources might overlap in terms of certain data, suggesting that researchers could skip certain ones. Decisions as to which data sources to utilize would be predicated on knowing the level of agreement in the recall of data from different informant sources (e.g., patient recall vs medical record review).[6] Data obtained from breast cancer patients suggest good agreement between patient recall and medical record review on some

details concerning the use of oral contraceptives, for example.[6] Yet, one barrier to integrating patient-level data from various data sources is that these linkages have to be established before this can happen.

Timing is an important influence on adherence rates as well. First, how long it takes for certain types of data to be collected for inclusion in a database can affect its accuracy. Memory for details can dissipate, making recall less reliable.[6] This suggests the need to collect data as soon as possible. Yet, it is also possible that relying on multiple data sources for data can compensate for loss of detail. Timing can also affect adherence rates in a second way. How soon after a recommendation regarding care has been disseminated (e.g., publication of a clinical practice guideline) that quality measurement is conducted may impact rates. From one point of view, the longer the interval of time between the dissemination of the performance standard and the quality measurement effort, the more likely the standard will have been adopted, and the higher the adherence rate. On the other hand, it is likely that much more than time is required for health professionals and systems to adopt new recommendations. They likely need to be actively promoted, with the provision of incentives being one possible option.

Overall, these factors alone or together can influence the picture of the patterns of care delivered and received by women with breast cancer. However, as important a factor in conducting quality measurements is having validated instruments and methods (e.g., two data abstractors) with which to reliably collect these data. This will also permit efforts to continue testing the validity of the links to improved outcomes underpinning the quality indicators.

Future Research

What, then, are the most pressing needs for future research? While the evidence supporting the role of the above-noted influences on adherence rates should continue to be investigated, it is likely that validated quality measures relating to constructs other than QOL need to be developed. A brief discussion of one possible approach follows.

On the basis of the present findings, there appear to be various quality indicators that could serve as candidates for formal development as quality measures. However, there may be some that are more ripe for development than others, given current medical knowledge. One approach to identifying these candidates could combine two methodologies.

First, any quality indicator should likely be evidence-based, where the definition of the "best" or "minimal" empirical evidence supporting the recommendation is determined a priori.[171,172] For treatment, it could be assumed that randomized controlled trial evidence is the gold standard to establish efficacy or effectiveness, followed next by controlled trials in general. The strength of the evidence (i.e., the design types, power, quality/validity, effect sizes, and number of research studies) supporting a quality indicator could then be used to define the clinical "appropriateness" of each standard where, the stronger the evidence (e.g., several well-powered, high quality randomized controlled trials supporting a given treatment), the greater the potential for its scientific development as a measure. Important issues to resolve would include identifying which version of a quality indicator (e.g., care X for patient Y), whose details (e.g., timeliness) vary somewhat (e.g., within 10 vs 15 working days), is supported by the strongest evidence.

Organizations such as Cancer Care Ontario routinely conduct systematic reviews to obtain evidence to inform their clinical practice guidelines. The work by McGlynn and her colleagues

employed a similar approach to identifying and reviewing evidence which was then subjected to a peer consensus process to make sense of the evidence and determine which quality indicators were most ready for use.[5,17,172] This peer consensus process is the second element necessary to identify quality indicators as candidates for development as measures. The ideal model is likely the RAND approach already described in the review, since it encompasses both the systematic identification of evidence and its evaluation by a peer consensus process.

Yet, evidence particularly from evidence-based clinical practice guidelines can also be combined with results obtained through systematic review. This is the approach that was initially proposed in the present review, but had to be abandoned for reasons relating to resources. In brief, the strategy aimed to organize, through juxtaposition in a Recommendations Matrix, the evidence-based quality indicators derived from evidence-based clinical practice guidelines, systematic reviews, as well as from empirical evidence either highlighted in key journal published commentaries or nominated by clinical experts as having the potential to overturn or modify a recommended standard of care.[83] The clinical content or meaning, quality, and up-to-datedness of the evidence would then be assessed.[84-89] It might be useful to include international participation (e.g., Guidelines Internal Network) in this process since developers of clinical practice guidelines often use different (or no) evidence-based criteria to derive recommendations.

A validational process would follow the identification of potential quality measures that, through pilot-testing, would assure the comprehensibility of the wording of the potential measure in addition to its reliable use by various data abstractors. Other psychometric properties such as validity would also need to be established. At minimum, both face and content validity would need to be achieved.[18] Face validity refers to the consensus achieved by employing a group of experts who decide whether the measure is an accurate representation of the standard as they understand it. While, on the surface, many of the quality indicators identified by this review appear to have had good face validity, one needs to establish this in rigorous fashion through the input of independent experts. These experts could also be asked if the measure appears to contain all of the elements defining the standard (i.e., the care; its timeliness). This is content validity.

Yet, while face and content validity are important properties to be established for all measures, other types of validity (e.g., construct validity) may be more essential for measures assessing QOL than for those guiding observers to count numbers of therapeutic operations (e.g., number of biopsy samples obtained). In the latter situation, establishing inter-observer reliability is likely more pertinent. Not all quality measures may need to be held to the same standards regarding validation.

Nonetheless, this validational process would also require evidence demonstrating that this care continues to yield improved clinical outcomes. Unfortunately, some outcomes require a considerable length of time to observe, which may make it difficult to prospectively assess their links to care (e.g., 5-year survival). Appropriate data sources can be selected instead, with which to retrospectively collect data. The feasibility of obtaining these quality data within the normal flow of clinical care, and across various clinical contexts (i.e., adaptability), would also need to be determined. Finally, an appropriate method to update the evidence base would be essential.

At present, ASCO is developing a robust set of potential quality measures relating to both stage I-III breast cancer and stage II-III colorectal cancer (ASCO. National initiative on cancer care quality (NICCQ): a project of the American Society of Clinical Oncology. Unpublished document. Received October 2003 from Dr. Mark Somerfield, ASCO). Their goal is to produce,

based on pilot-testing using multiple data sources (e.g., patient survey, ACOS' National Cancer Database), a detailed profile of their (e.g., inter-rater) reliability, feasibility, and validity. The quality indicators were derived from published clinical practice guidelines and empirical evidence. An expert consensus process helped define potential quality measures, at times identifying indicators for which there was no corresponding reference in the literature. This work is the product of a collaboration involving the ASCO Quality Task Force and its multidisciplinary clinician team.

The seven broad domains assessed with respect to breast cancer care include:

- Data gathering: pathology, evaluation, staging (e.g., adequacy of pathology reporting, adequacy of diagnostic evaluation, documentation of staging);
- Initial management (e.g., surgical management, systemic adjuvant therapy, radiation therapy);
- Management of treatment toxicity (e.g., lymphedema, vaginal bleeding with tamoxifen);
- Referrals and coordination of care;
- Patient preferences and inclusion in decision-making;
- Psychosocial support; and,
- Surveillance after initial therapy.

The items are expressed as a series of "if-then" statements, as in "If a patient has a breast tumor removed, then the pathology report should state that the margins were inked" (ASCO. National initiative on cancer care quality (NICCQ): a project of the American Society of Clinical Oncology. Unpublished document. Received October 2003 from Dr. Mark Somerfield, ASCO).

The results of ASCO's project are widely anticipated since it is possible that they will develop the validated measures required to push forward the field of quality measurement with respect to breast cancer care. What remains to be seen is whether or not these quality measures will also cover those definitions of care (e.g., quality of delivery of care, structural factors) identified by the present review to be mostly absent from the literature. It will also be interesting to observe whether or not their measures replicate any of the tentatively observed findings reported in the present review, for example, that racial differences in the likelihood of receiving recommended care were defined in terms of whether or not indicated care is received, but not in terms of the quality of its delivery. Prospective (e.g. before-after) studies could also evaluate the impact, on patterns of care, of disseminating these quality measures.

Clinical Implications

Given the goal of the present review, and the observation that adherence data were mostly collected using unvalidated measures employed typically by a single data abstractor, gaps in care suggested by these data are de-emphasized. Even McGlynn et al.'s data suggesting that nearly

76% of women received appropriate care of various kinds may be problematic in that it is unclear whether they had fully pilot-tested their well-defined quality indicators as measures.[5] Moreover, in spite of how well their quality indicators pertaining to breast cancer care had been developed, McGlynn et al.'s number of eligible cases was small for each individual quality indicator because their adherence study involved a random sample of the community. Furthermore, six of nine quality indicators were merely supported by observational evidence, and expert opinion. This included two of four indicators relating to treatment, for which randomized controlled trial evidence is considered the gold standard. Together, these observations significantly limit the meaningful interpretability and generalizability of any data obtained in their study concerning gaps in breast cancer care. Some larger questions raised by a few of the observations highlighted in this review are now presented.

To begin with, are we to interpret the volume difference between research efforts relating to the quality of diagnosis, as compared with treatment, as indicating that a concern with the quality of breast cancer diagnosis, or even followup, is substantially less important, or that there are fewer concerns with the quality of diagnosis and, accordingly, there has been less of a need to undertake quality measurement studies pertaining to this category of care? Or, does this picture suggest that there is greater concern regarding possible gaps in care relating to treatment? Likewise, relative to the subject of diagnosis, does the greater number of quality measurement efforts focused on the reporting of care indicate that there is greater concern about a possible gap between the ideal and actual ways in which breast cancer care is documented?

Also, can the observation that, relative to the number of attempts to evaluate whether the indicated care was delivered or received (i.e., the question of "appropriate use"), very few efforts assessed the actual quality of the delivered care, be taken to mean that there are fewer concerns about the quality of the ways in which breast cancer care is delivered? Is there greater concern about making the right decision to deliver care than about the quality of its delivery?

In an even more speculative vein, why might older women be disadvantaged in terms of the delivery or receipt of breast cancer care? Is it because there are fewer specific recommendations, reflecting fewer instances of empirical evidence and investigation that pertain specifically to older women with breast cancer? Some guidelines (e.g., NIH, 1990) do not exclude older women when it comes to recommendations, but is this because it is assumed that care recommended for younger women may as well be applied to older women in the absence of specific quality indicators for the latter? Or, is there less evidence and investigation involving older breast cancer patients because there is some implicit belief that efforts might be better spent caring for younger women for whom a greater medical difference might be made? Likewise, for those women with advanced stage breast cancer, does the scarcity of evidence-based recommendations, not to mention the dearth of quality indicators identified by this review, reflect a bias towards intervening with those women with earlier stages of breast cancer for whom a greater medical difference might be made? The paucity of quality indicators specifically for older women with breast cancer is especially problematic given a relatively recent estimate that about 60% of new breast cancer cases are diagnosed each year in the U.S. in women 60 years of age and older.[173] Finally, to what might any disparity in care relating to race be attributable?

Or, is it possible that the field of scientific inquiry regarding the measurement of the quality of breast cancer care is too early in its development for anyone to meaningfully discern intentions from patterns of study foci relating to patterns of care? Whatever the correct responses to these questions, or the better questions, turn out to be, it is likely that, until possible

gaps in care are demonstrated with reliable and valid quality measures, the above-noted speculations will remain unresolved.

Nevertheless, it must also be acknowledged that there are reasons other than a failure on the part of the healthcare professional or system (e.g., failure to anticipate the temporal evolution of clinical events) for a patient to fail to receive recommended care. Other possibilities include the refusal on the part of the patient to accept the care recommended by the professional, the inability of the patient to make themselves available due to extenuating circumstances (e.g., no clinic nearby), or a decision based on a careful consideration of all key factors by the professional to design care specific to this patient, yet which diverges from the standard.[6] Only an active effort to determine *all* the correct reasons for failed adherence will shed meaningful light on gaps in care. The present collection of studies did not typically make such attempts.

Limitations of the Review

A number of limitations characterized the present systematic review. In having to narrow the review scope, UO-EPC lost the chance to go back to reference standards (e.g., clinical practice guidelines), and their evidence sources (i.e., empirical studies), to determine the clinical appropriateness of quality indicators in terms of the strength of the evidence linking these standards to improved outcomes. No scheme (e.g., US Preventive Services Task Force) could thus be employed to assess the strength of the evidence supporting the standards of care.

The report thus had to rely solely on the descriptions from individual study investigators, to identify the presumably evidence-based reference standards supporting this care (e.g., clinical practice guidelines), a consequence fully understood by our TEP. This meant that some quality indicators were likely allowed entry into the review based on less than optimal empirical evidence. Also, with the virtual lack of data *in the adherence studies* demonstrating links to outcomes, we could not confirm the links to improved outcomes supporting the care highlighted in the reference standards (e.g., clinical practice guidelines). One difficulty associated with prospectively obtaining these data is having the time required to do so (e.g., 5-year survival).

One variation on this theme involves the category of reporting/documentation of care. In spite of concerns that very few of the quality indicators appeared to have any empirical basis other than clearly articulated standards for sound clinical practice, it was decided to allow these to remain in the review. Had we excluded these quality indicators, none from this category of practice would have been represented in the review. On the other hand, it was decided to exclude the few studies evaluating sentinel node biopsy because the evidence substantiating the standard was not indicated in study reports. Although sentinel node biopsy is increasing in popularity as a procedure, this alone was insufficient justification to permit its inclusion in the review.

At the same time, the narrowed scope meant that ad hoc opportunities to explore included data were missed. It became impossible to consider comparing the strengths of the empirical evidence supporting different quality indicators, established in different countries or regions, to see whether this could explain possible differences in breast cancer care.

The “trajectory of scientific development” scheme was designed especially for this study, and without benefit of a formal validational process. Thus, the data obtained through its implementation are not likely to be overly reliable or valid. Almost none of the grades received by quality indicators rose above a Level IV (i.e., no history of formal scientific validation),

confirming what is likely the most unequivocal finding of this review: other than a few QOL or patient satisfaction instruments, no validated quality measures could be identified.

Conclusion

Some have asserted that the exact degree to which healthcare quality in the U.S. is consistent with quality standards is basically unknown; and, that the continuing failure to have a clear and comprehensive view of the level of quality care received by the average American will reinforce the belief that quality care is not a serious national problem.[174] With respect to breast cancer care, the failure to have reliable and valid quality measures with which to confidently point to gaps in care, and thereby promote accountability, improvement, and research,[175] is a situation that, in our view, does nothing to help resolve this important dilemma.

Given that, among oncologic conditions, breast cancer in women has one of the most extensive literatures to support an association between types of care and outcomes, it is not surprising that most of the patterns of care studies in oncology have been focused here.[170] However, the measurement, reporting, and improvement in the quality of the delivery of healthcare, while central to the present day healthcare ethos, are still relatively recent undertakings.[176] Thus, it may indeed be the case that the shortcomings characterizing this field of inquiry are the signs of a fledgling enterprise.

It could be argued that an unvalidated quality measure is no less a quality measure than a validated one. From a non-technical point of view, the authors of this report would not disagree. Yet, from a scientific-technical point of view, the authors would dissent. What is likely important to recognize is that a validated way to observe anything presupposes a manner of calibration based on past testing that permits the reliable (e.g., equally usable by different, trained users) and valid (i.e., it reveals what it was designed to reveal) observation of events. In this sense, quality measurement is no different than determining blood pressure. If the instrument used to assess any "event" were deemed unreliable in some way, then its data would be unlikely to reflect the correct state of affairs. And yet, it should also be pointed out that, without a quality indicator's strong and consistent links to improved outcomes, even perfection in its psychometric performance will not overcome the possibility that the whole scientific-validational exercise was irrelevant. The issue of the strength of the supporting evidence, and thus an indicator's clinical appropriateness, is every bit as important as the requirement of its validation; and, it comes earlier in the process of measuring the quality of care.

That there are virtually no validated quality measures to be used at this time to assess the quality of breast cancer care is cause for developing some. Until then, it will likely be impossible to derive a meaningful overview of gaps in this care that can inform the public about the quality of its healthcare choices.[3] Some promise is attached to ASCO's ongoing enterprise to validate quality measures relating to breast cancer care, yet it will be some time before the results are known. If, on the other hand, the ASCO quality measures turn out to have unsound psychometric properties, any future endeavors to develop such instruments—as well as the evidence-based measurement and reporting systems in which they would be "housed"—will need to weigh the benefits seen in terms of improved patterns of care against the cost of developing and maintaining them.[6,177]

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Wyld L, Reed MW. The need for targeted research into breast cancer in the elderly. [Review] [117 refs]. Br J Surg 2003; 90(4):388-99. Not a quality measure/ment (Systematic review).

Yamada Y, Ackerman I, Franssen E, et al. Does the dose fractionation schedule influence local control of adjuvant radiotherapy for early stage breast cancer? [Review] [42 refs]. Int J Radiat Oncol Biol Phys 1999;44(1):99-104. Not a quality measure/ment (Systematic review).

Yamauchi H, Stearns V, Hayes DF. When is a tumor marker ready for prime time? A case study of c-erbB-2 as a predictive factor in breast cancer. [Review] [138 refs]. J Clin Oncol 2001;19(8):2334-56. Not a quality measure/ment (Systematic review).

Search Strategy 1

1. breast cancer.tw.
2. exp breast neoplasms/
3. breast$.tw.
4. exp breast/
5. exp neoplasms/
6. (3 or 4) and 5
7. ((breast$ or mammar$) adj2 (neoplasm$ or cancer$ or tumour$ or tumor$ or carcinoma$ or adenocarcinoma$ or dcis or ductal or infiltrating or intraductal or lobular or medullary)).tw.
8. or/1-2,6-7
9. quality of health care/
10. Guideline Adherence/
11. Medical Audit/
12. Nursing Audit/
13. "Outcome and Process Assessment (Health Care)"/
14. "Commission on Professional and Hospital Activities"/
15. "Outcome Assessment (Health Care)"/
16. "Process Assessment (Health Care)"/
17. "Peer Review, Health Care"/
18. "Professional Review Organizations"/
19. Program Evaluation/
20. Benchmarking/
21. Quality Assurance, Health Care/
22. Guidelines/
23. Practice Guidelines/
24. "Total Quality Management"/
25. "Quality Indicators, Health Care"/
26. Utilization Review/
27. practice guideline.pt.
28. Consensus Development Conference.pt.
29. ((quality or performance) adj2 (measure$ or indicator$ or assessment$)).tw.
30. "standard of care".tw.
31. ((practice or consensus or position) adj2 (guideline$ or recommendation$ or statement$)).tw.
32. or/9-31
33. 8 and 32
34. limit 33 to yr=1993-2003
35. (diagnos$ or detect$ or treatment$ or therap$ or radiol$ or surg$ or pathol$ or instrument$ or rehab$ or chemoth$).mp.
36. (biops$ or scan or MRI or CT or genet$ or mastectomy or radiation$).mp.
37. (di or dt or ge or is or pa or ra or rt or rh or su or th).fs.
38. 34 and (35 or 36 or 37)
39. limit 38 to english language
40. 38 not 39
41. (20031$ or 20032$ or 20024$ or 20025$).ew.
42. 39 and 41
43. 40 or 42

Appendix A. Search Strategies

Search Strategy 2

1. (Breast$ or mammo$ or mamma$ or mast$).mp.
2. (cancer$ or neoplasm$).mp.
3. quality.mp.
4. 1 and 2 and 3

Search Strategy 3

1. systematic review$.mp.
2. systematic literature review$.mp.
3. meta-analysis.pt.
4. (meta-analysis or metaanalysis or meta-analyses).ti.
5. evidence-based medicine.mp.
6. evidence-based.mp. and ((guideline or guidelines).ti. or recommendations.mp.)
7. evidenced-based.mp. and ((guideline or guidelines).tw. or recommendation$.mp.)
8. consensus development conference.pt.
9. guideline.pt.
10. health planning guidelines.mp.
11. cochrane database of systematic reviews.jn.
12. acp journal club.jn.
13. (health technology assessment reports or health technology assessment rockville md or health technology assessment winchester england).jn.
14. evidence report technology assessment summary.jn.
15. (evidence based mental health or evidence based nursing).jn.
16. clinical evidence.jn.
17. or/1-16
18. systematic.tw. or systematically.mp. or critical.tw.
19. (study and selection).ti,ab.
20. (predetermined or inclusion).mp. and criteri$.tw.
21. exclusion criteri$.mp.
22. main outcome measures.mp.
23. standard of care.mp.
24. or/18-23
25. (Survey or surveys).tw. or overview$.mp. or review.tw. or reviews.mp.
26. (search$ or handsearch).mp.
27. (analysis or critique).tw. or appraisal.mp.
28. (reduction and risk and (death or recurrence)).mp.
29. or/25-28
30. literature.tw. or articles.mp.
31. (publications or publication).tw.
32. bibliography.tw. or bibliographies.mp.
33. (published or unpublished or citation$).mp.
34. Database.mp. or internet.tw. or textbooks.tw. or references.mp.
35. trials.mp.
36. meta-analysis/
37. clinical.tw. and studies.mp.
38. treatment outcome.mp.
39. or/30-38
40. and/24,29,39
41. case report.ti.
42. case report/
43. editorial.ti.
44. (editorial or letter or newspaper article).pt.
45. or/41-44
46. (17 or 40) not 45
47. breast cancer.tw.
48. exp breast neoplasms/
49. breast$.tw.
50. exp breast/
51. exp neoplasms/
52. (49 or 50) and 51

53. ((breast$ or mammar$) adj2 (neoplasm$ or cancer$ or tumour$ or tumor$ or carcinoma$ or adenocarcinoma$ or dcis or lcis or ductal or infiltrating or intraductal or lobular or medullary)).tw.
54. or/47-48,52-53
55. (diagnos$ or detect$ or treatment$ or therap$ or radiol$ or surg$ or pathol$ or instrument$ or rehab$ or chemoth$).mp.
56. (biops$ or scan or MRI or CT or genet$ or mastectomy or radiation$).mp.
57. (di or dt or ge or is or pa or ra or rt or rh or su or th).fs.
58. or/55-57
59. 46 and 54 and 58
60. limit 59 to yr=1994-2003

Letter to American Cancer Society of Clinical Oncology

Mark Somerfield, PhD
Director, Cancer Policy and Clinical Affairs
American Society of Clinical Oncology
1900 Duke Street, Suite 200
Alexandria, VA 22314
October 1, 2003

Dear Mark:

Thanks for speaking with me yesterday. I have copied our AHRQ representative on this email since she, I am certain, will be most pleased that we have been able to speak.

To restate our request, we at the University of Ottawa Evidence-based Practice Center, under contract from AHRQ, are doing a systematic review of quality measures regarding breast cancer diagnosis and treatment (see attached RFTO), and we would like to integrate into our evidence report specific information and data we understand ASCO has been, and is still, collecting:

a. the quality measures exclusively pertaining to our topic (i.e., less than the total of 108), including information/data about:

b. their exact definition;

c. their developmental history (rationale; protocol for development; pilot test data, including psychometric history and specific links to improved outcomes; databases used for case identification) as well as their source(i.e., systematic reviews; guidelines; peer review process; some combination thereof); and,

d. their subsequent performance in the field following their establishment as 'viable' quality measures, including any protocols for their implementation, databases used for case identification, etc. I would welcome any additional opportunity to clarify our work, or to do whatever facilitates this process.

Perhaps you or your representative would like to become involved in our process, for example, as part of an Expert Panel.

I look forward to hearing back from you.

Sincerely,

Howard Schachter PhD
University of Ottawa Evidence-based Practice Center
CC: Stacie Jones, AHRQ

Relevance Screening Forms

INSTRUCTIONS: PLEASE USE REVIEW-SPECIFIC DEFINITIONS IN SELECTING RESPONSES.

LEVEL 1 SCREENING:

1. Does this refer to breast cancer in women? YES NO CAN'T TELL

2. Does this refer to (the reporting/documentation of, or, patient-reported quality of life or patient-reported satisfaction relating to) its diagnosis, treatment (e.g., supportive care), or followup care?
YES NO CAN'T TELL

3. Does this refer to at least one of the following?[1]
- Quality measure/ment(s) made available, published, or conducted beginning in 1993
- Clinical practice guideline (CPG) published beginning in 1996
- Systematic review (SR) published beginning in 1994
- Commentary or editorial in a key general or cancer journal describing important (new) evidence that could alter practice/care recommendations, published beginning in 1994[2]
- Evidence nominated by key informant, describing (new or missed) evidence that could alter practice/care recommendations[3]

YES NO CAN'T TELL

LEVEL 2 SCREENING:[4]

4. To which does it refer? (*select all that apply*)
- o Quality measure/ment(s) made available, published, or conducted beginning in 1993
- o Clinical practice guideline (CPG) published beginning in 1996
- o Systematic review (SR) published beginning in 1994
- o Commentary or editorial in a key general or cancer journal describing important (new) evidence that could alter practice/care recommendations, published beginning in 1994[2]
- o Evidence nominated by key informant, describing (new or missed) evidence that could alter practice/care recommendations[3]

LEVEL 3 SCREENING:[5]

1. Does this refer to a clinical practice guideline or systematic review? YES NO CAN'T TELL

[1]Note that, after the final search update, and directly relating to the narrowed focus whereby CPGs and SRs were now outside the scope of the review, the eForm was modified to allow screeners to flag these two types of report for exclusion (see Modified QUOROM Flow Chart). This precluded having to order articles that, via the initial screening of pre-update bibliographic records, had been allowed to pass on to Level 2 screening.
[2]These literature searches had not yet been conducted before the scope was narrowed.
[3]Active solicitation had not yet begun before the scope was narrowed.
[4]The key difference between Level 1 and Level 2 screening was that, in the latter, the following question was added to the three used in the former.
[5]Only this one question was asked.

Data Abstraction Form

Instructions: ***Please answer each question.*** Selecting response options means clicking on them. A text box requires you to provide specific information. When it is not reported (= NR), the question does not apply (= N/A), you cannot tell what/where it is (= CT), or you have no comment to make (= NC), type the relevant code in the text box. If the research report describes more than one *quality indicator*, answer in this eForm all the questions for the *first reported quality indicator/measure* while at the same time letting the review manager know that a data abstraction form is required for each additional one.

GENERAL INFORMATION:

1. Initials of reviewer: **TEXT BOX (BOX)**

2. Reference identification # (Refid#): **BOX**

3. Author, Year: **BOX**

4. Number of unique, review-relevant studies that this report describes: **BOX**

5. Other Refids that refer to this same research project:

6. Publication status (*select one*):
   - Peer-reviewed journal publication
   - Journal publication
   - Conference abstract/poster
   - Book
   - Book chapter
   - HTA/technical report
   - Thesis
   - Unpublished document
   - Study sponsor's internal report
   - Internet document
   - Other

7. If you answered "Other" to the preceding question, specify what you mean: **BOX**

8. Country in which the study was conducted (*select all that apply*):
   - Australia
   - Canada
   - United States
   - Japan
   - United Kingdom (*not* Ireland)
   - France
   - Germany

Italy
Finland
Russia
Other
Not reported

9. If you answered "Other" to the preceding question, specify what you mean: **BOX**

10. Number of sites: **BOX**

11. Funding source type (*select all that apply*):
Government
Industry
Private (non-industry)
Hospital
Other
Not reported
Can't tell

12. Specify the funding source(s): **BOX**

13. Number of unique quality measures (or measurements) [QMs] this report describes? **BOX**

14. Year(s) in which the QMs were assessed? **BOX**

DEFINITION:

15. Title of QM (the percentage of…): **BOX**

16. Bibliographic source(s) of QM: **BOX**

17. Category of QM = "breast cancer and…" (i.e., primary clinical component[s]) (*select one*):
Diagnosis (e.g., pathology)
Treatment
Follow-up
Supportive care
Reporting/documentation (e.g., pathology)

18. Institute of Medicine care domains (*select all that apply*):
Effectiveness
Patient-centeredness
Safety
Timeliness

19. Specific type of quality measure (*select all that apply*):

- Appropriate use of diagnostic imaging
- Quality of diagnostic imaging
- Appropriate use of breast biopsy
- Quality of diagnostic breast biopsy
- Appropriate use of sentinel lymph node biopsy
- Quality of diagnostic sentinel lymph node biopsy
- Appropriate use of chest x-ray
- Appropriate use of bone scan
- Appropriate use of CT scans
- Appropriate use of MRI
- Appropriate use of blood tests
- Availability of pathological staging
- Accuracy of pathological staging
- Availability of tumor marker status
- Accuracy of tumor marker status
- Availability of genetic testing
- Accuracy of genetic testing
- Appropriate use of genetic testing
- None of the above

20. Specific type of quality measure (*select all that apply*):

- Appropriate use of breast conserving surgery (BCS)
- Quality of BCS
- Appropriate use of mastectomy (including adequacy of surgical margins)
- Quality of mastectomy (including adequacy of surgical margins)
- Appropriate use of lymph node surgery
- Quality of lymph node surgery
- Appropriate use of reconstructive surgery
- Quality of reconstructive surgery
- Appropriate use of radiation therapy (RT) after BCS
- Quality of RT after BCS
- Appropriate use of RT post-mastectomy
- Quality of RT post-mastectomy
- Appropriate use of adjuvant and neo-adjuvant systemic therapy (chemotherapy; hormone therapy)
- Quality of adjuvant and neo-adjuvant systemic therapy (chemotherapy; hormone therapy)
- Appropriate use of hormonal and chemotherapy management of metastatic disease
- Quality of hormonal and chemotherapy management of metastatic disease
- Appropriate dosing of chemotherapy
- Quality of dosing of chemotherapy
- Appropriate use of dosing of radiotherapy
- Quality of dosing of radiotherapy
- None of the above

21. Specific type of quality measure (*select all that apply*):
    - Adequacy of documentation of pathology reports
    - Completeness of documentation of pathology reports
    - Adequacy of documentation of operative reports
    - Completeness of documentation of operative reports
    - Adequacy of documentation of radiation reports
    - Completeness of documentation of radiation reports
    - Adequacy of documentation of chemotherapy reports
    - Completeness of documentation of chemotherapy reports
    - None of the above

22. Specific type of quality measure (*select all that apply*):
    - Quality of follow-up (e.g., timeliness; interventions)
    - Quality of supportive care (e.g., interventions)
    - Quality of life
    - Patient satisfaction

23. Primary measure domain (*select all that apply*):
    - Structure (e.g., accreditation; number of certified specialists)
    - Access (e.g., attainment of timely & appropriate care)
    - Process (e.g., adherence to recommended care)
    - Outcome, including patient experience (e.g., QOL; patient satisfaction)

24. Specify the stated importance of, or need for, the QM (i.e., rationale; purpose: e.g., wide variation in quality of care; substandard care; over-use; under-use): **BOX**

25. Specify the references highlighting the importance of, or need for, the QM: **BOX**

26. Describe the QM's "denominator" (i.e., inclusion/exclusion criteria): **BOX**

27. Describe the QM's "numerator" (i.e., inclusion/exclusion criteria defining specific subset of denominator): **BOX**

PERFORMANCE:

28. Was this quality measure "systematically developed" to any degree? (*select one*)
    - Yes (e.g., pilot-testing: see Development questions)
    - No (a quality indicator whose performance has been merely measured)
    - Can't tell

29. Based on which type(s) of evidence was the criterion/standard defined (*select all that apply*)?
    - Clinical practice guideline: evidence-based
    - Clinical practice guideline: consensus-based
    - Systematic review of evidence

Selective/narrative review (i.e., unsystematic search of literature)
Expert (consensus) panel process
Other

30. If you answered 'Other' to the preceding question, specify what you mean: **BOX**
31. Name the evidence type(s) (e.g., guidelines), including its year of publication: **BOX**

32. Which methods of case identification (e.g., cancer registries; claims databases) were used to evaluate the performance of the QM? Please name them. **BOX**

33. Which data sources (e.g., patient self-report; medical records), per method of case identification, were used to evaluate the performance of the QM? **BOX**

34. Denominator time window (time period in which patients are reviewed for inclusion in the denominator), per method of case identification: **BOX**

35. Numerator time window (time period in which patients are reviewed for inclusion in the numerator), per method of case identification: **BOX**

36. Sample description, per set of identified cases (e.g., national convenience sample of women with…): **BOX**

37. Response rate (cases with complete data/eligible cases), per set of identified cases: **BOX**

38. Specify reasons for exclusion (& sample size), per set of identified cases (NOTE: the need for individualized care that contradicts recommended care would constitute an exclusion yet may not indicate poor/inappropriate care): **BOX**

39. Size of sample(s) analyzed, per set of identified cases: **BOX**

40. Specify tumor characteristics, per set of identified cases: **BOX**

41. Specify family history of breast cancer (first degree members), per set of identified cases: **BOX**

42. Specify proportion of patients in each stage of the disease at the time of study, per set of identified cases: **BOX**

43. Specify duration of the disease since diagnosis, per set of identified cases: **BOX**

44. Year diagnosed, per set of identified cases: **BOX**

45. How diagnosed, per set of identified cases: **BOX**

46. Sample age, per set of identified cases: **BOX**

47. Sample socioeconomic status, per set of identified cases: **BOX**

48. Sample race/ethnicity, per set of identified cases: **BOX**

49. Other demographic factors (e.g., location of permanent residence), per set of identified cases: **BOX**

50. Specify population's treatments (including surgery, radiotherapy, & systemic therapy), per set of identified cases: **BOX**

51. Specify type(s) of surgery (breast conserving surgery, mastectomy with or without reconstructive surgery, etc.), per set of identified cases: **BOX**

52. Overall concordance rate, per set of identified cases: **BOX**

53. Variations in rate of concordance according to stratification(s) of the population (e.g., age; vulnerable populations; hospitals; regions), per set of identified cases: **BOX**

54. Results re possible differences between groups (e.g., odds ratio) identified by stratification: **BOX**

55. Additional data (e.g., specificity; sensitivity; adaptability), per set of identified cases: **BOX**

56. Specify the evidence regarding the nature and adequacy of the (e.g., risk) adjustment(s) when cross-population or -database comparisons are made: **BOX**

57. Specify scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes, per set of identified cases: **BOX**

58. Results involving scores (e.g., QOL), per set of identified cases (i.e., overall score, with interpretation; scores per group identified by stratification; results reflecting possible differences between groups identified by stratification: e.g., differences in outcome [e.g., survival] associated with receipt/non-receipt of care 'X'): **BOX**

CURRENT STATUS:

59. Describe the state of use (i.e., over the past 3 years: e.g., pilot testing; used by organizations yet discontinued by developer): **BOX**

60. Describe the current use (*select all that apply*):
    Accreditation (accountability)
    Internal quality improvement
    Decision-making (accountability)
    External quality oversight (accountability)

Quality of care reporting
Research
Not being used
Other

61. If you answered "Other" to the preceding question, specify what you mean: **BOX**
62. If not in use, specify the reason(s): **BOX**

63. Describe the care setting(s) in which the QM is employed: **BOX**

64. Who are the professional(s) most likely to use this QM? **BOX**

65. Additional comments: **BOX**

DEVELOPMENT:

66. Who developed this QM? **BOX**

67. How was the search for evidence performed to support the QM? **BOX**

68. Type of evidence supporting the measure (*select all that apply*):
    Clinical practice guideline: evidence-based
    Clinical practice guideline: consensus-based
    Systematic review
    Selective/narrative review (e.g., manual search of literature)
    Expert (consensus) panel process
    Other

69. If you answered "Other" to the preceding question, specify what you mean: **BOX**

70. Bibliographic databases searched: **BOX**

71. How was the evidence appraised (e.g., grading quality or level of evidence) **BOX**

72. How was the wording/phrasing of the QM initially formulated (e.g., expert consensus)? **BOX**

73. How was the wording/phrasing of the QM refined? **BOX**

74. How was the QM pilot-tested? **BOX**

75. Which methods of case identification (e.g., cancer registries; claims databases) were used to pilot test the QM? Please name them. **BOX**

76. Which data sources (e.g., patient self-report; medical records), per method of case identification, were used to pilot test the QM? **BOX**

77. Denominator time window (time period in which patients are reviewed for inclusion in the denominator), per method of case identification: **BOX**

78. Numerator time window (time period in which patients are reviewed for inclusion in the numerator), per method of case identification: **BOX**

79. Sample description, per set of identified cases (e.g., national convenience sample of women with…): **BOX**

80. Response rate (cases with complete data/eligible cases), per set of identified cases: **BOX**

81. Specify reasons for exclusion (& sample size), per set of identified cases (NOTE: the need for individualized care that contradicts recommended care would constitute an exclusion yet may not indicate poor/inappropriate care): **BOX**

82. Size of sample(s) analyzed, per set of identified cases: **BOX**

83. Specify tumor characteristics: **BOX**

84. Specify family history of breast cancer (first degree members), per set of identified cases: **BOX**

85. Specify proportion of patients in each stage of the disease at the time of study, per set of identified cases: **BOX**

86. Specify duration of the disease since diagnosis, per set of identified cases: **BOX**

87. Year diagnosed, per set of identified cases: **BOX**

88. How diagnosed, per set of identified cases: **BOX**

89. Sample age, per set of identified cases: **BOX**

90. Sample socioeconomic status, per set of identified cases: **BOX**

91. Sample race/ethnicity, per set of identified cases: **BOX**

92. Other demographic factors (e.g., location of permanent residence), per set of identified cases: **BOX**

93. Specify population's treatments (including surgery, radiotherapy, & systemic therapy), per set of identified cases: **BOX**

94. Specify type(s) of surgery (breast conserving surgery, mastectomy with or without reconstructive surgery, etc.), per set of identified cases: **BOX**

95. Specify the psychometric properties of the QM established through pilot-testing (e.g., reliability; validity; sensitivity; specificity), per set of identified cases: **BOX**

96. Specify the psychometric properties of the QM established through pilot-testing (e.g., reliability; validity; sensitivity; specificity), per stratification, per set of identified cases: **BOX**

97. Specify the evidence regarding the adaptability of the QM (e.g., its applicability in different contexts/settings re breast cancer): **BOX**

98. Specify the evidence regarding the nature and adequacy of the (e.g., risk) adjustment(s) when cross-population or -database comparisons are made: **BOX**

99. What additional explicit conditions of use are specified for this QM (e.g., sample size, settings)? **BOX**

100. Specify any changes made to the QM following pilot-testing? **BOX**

101. Overall concordance rate, per set of identified cases: **BOX**

102. Variations in rate of concordance according to stratification(s) of the population (e.g., age; vulnerable populations), per set of identified cases: **BOX**

103. Specify scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes, per set of identified cases: **BOX**

104. Results involving scores (e.g., QOL), per set of identified cases (i.e., overall score, with interpretation; scores per group identified by stratification; results reflecting possible differences between groups identified by stratification: e.g., differences in outcome [e.g., survival] associated with receipt/non-receipt of care "X"): **BOX**

105. Additional comments: **BOX**

106. COMMENTS BOX

Trajectory of Scientific Development of Quality Indicators Used in Quality Measurement

INSTRUCTIONS: Select a level, then all sub-levels that apply from within it (e.g., I-ac).

Level I. Information/data are reported indicating that the quality indicator used in the present study to measure quality was developed *prior to its implementation in the present study*, according to the scientific principles by which any measure is formally developed (e.g., pilot testing, with appropriate rigor and data sources, its feasibility and ease of use, reliability, internal validity, etc.) ***AND***:

a. (reference to) data from the pre-study developmental process indicate *consistently sound*[1] psychometric properties (e.g., reliability; internal validity);
b. (reference to) data from the pre-study developmental process indicate *consistently or inconsistently unsound* psychometric properties;
c. data obtained/reported in the present study indicate *consistently sound* psychometric properties;
d. data obtained/reported in the present study indicate *consistently or inconsistently unsound* psychometric properties; or,
e. no pre-study developmental or study-related psychometric data are referred to or reported.

Level II. Information/data are reported indicating that the quality indicator used in the present study to measure quality was being *actively developed in the present study*, according to the scientific principles by which any measure is formally developed, ***AND***:

a. data obtained/reported in the present study indicate *consistently sound* psychometric properties;
b. data obtained/reported in the present study indicate *consistently or inconsistently unsound* psychometric properties;
c. no study-related psychometric data are reported.

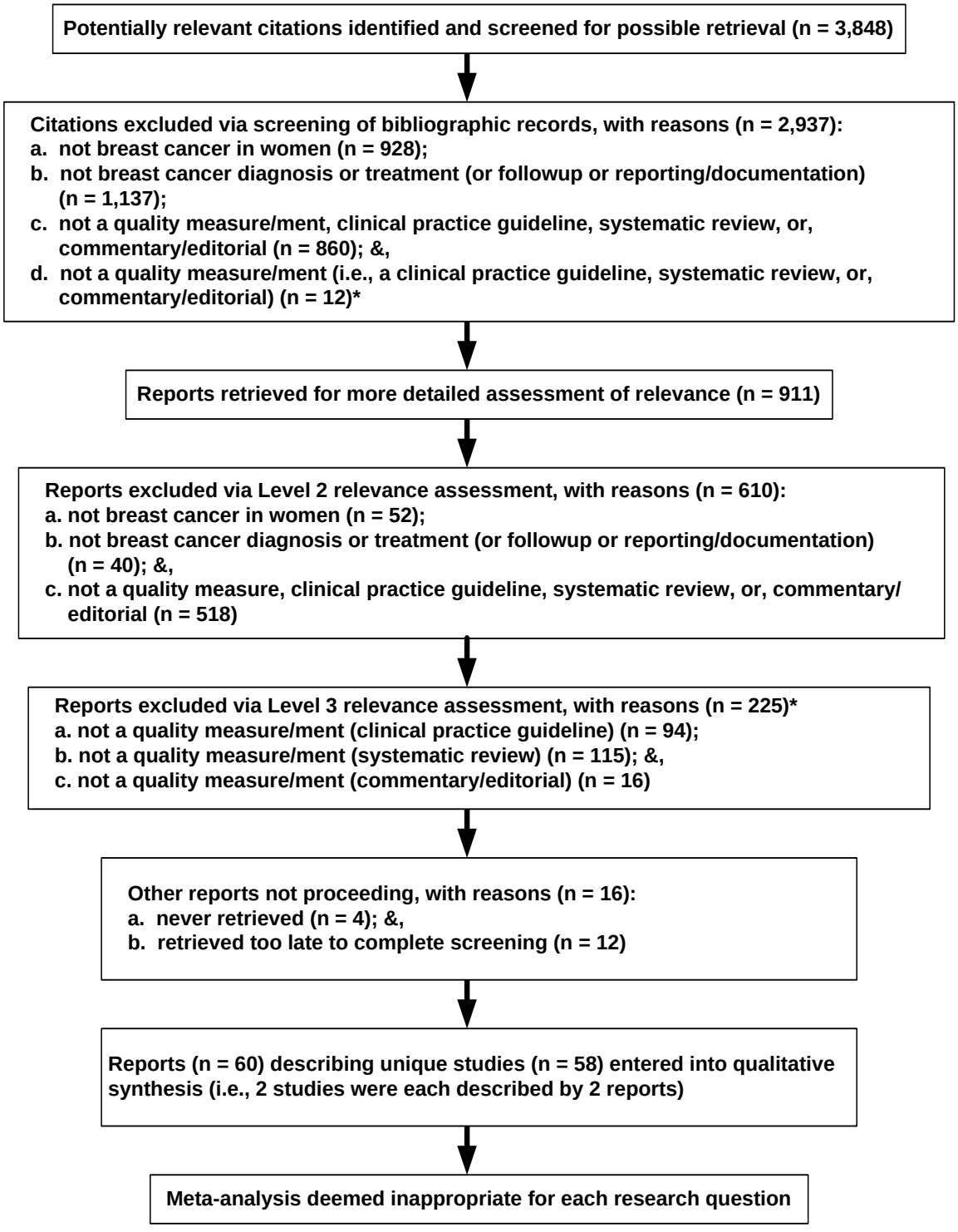
Level III. No information/data are reported indicating that the quality indicator used in the present study to measure quality has been, or in this study was being, developed according to the scientific principles by which any measure is formally developed, ***YET***:

a. data obtained/reported in the present study indicate *consistently sound* psychometric properties;
b. data obtained/reported in the present study indicate *consistently or inconsistently unsound* psychometric properties;
c. no study-related psychometric data are reported.

Level IV. There is no (reference to) pre-study developmental or study-related evidence indicating that the quality indicator used in the present study to measure quality was ever developed according to the scientific principles by which any measure is formally developed.

[1]*Consistently sound* describes a situation involving a given psychometric property (e.g., inter-observer reliability; construct validity) observed across more than one study (e.g., two studies report sound reliability) ***and/or*** to different psychometric properties observed either within one study or across more than one study (e.g., sound reliability; sound construct validity). *Consistently unsound* refers to a situation involving a given psychometric property observed across more than one study (e.g., both report unsound reliability) ***and/or*** to different psychometric properties observed either within one study or across more than one study (e.g., unsound reliability; unsound construct validity). *Inconsistently unsound* points to a situation involving a given psychometric property observed across more than one study (e.g., one reports sound reliability while another reports unsound reliability) ***and/or*** to different psychometric properties observed either within one study or across more than one study (e.g., sound reliability; unsound construct validity).

Appendix D. Modified QUOROM Flow Chart



*Due to narrowed scope of review.

Appendix E. Evidence Tables

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Appleton, 1998, UK	**Process:** • % reporting nature of specimen[IV]	• Overall: NR • By y: 1992: 60% 1994: 40% 1996: 100% • Links: NA	• Standard: NHSBSP guidelines, 1991-1992 • Data sources: pathology reports • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: research; internal quality improvement; quality of care reporting • Care setting: pathology centers • Professionals: pathologists	• Inclusion: convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists, 1992, 1994, & 1996 • Exclusion: NR • Period: 4 y (1992-1996) • n specimens (enrolled/ evaluated): 40/30 (10 for each y) • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR
	• % reporting type of tumor[IV]	• Overall: NR • By y: 1992: 100% 1994: 100% 1996: 100% • Links: NA		
	• % reporting grade of tumor[IV]	• Overall: NR • By y: 1992: 90% 1994: 80% 1996: 100% • Links: NA		
	• % reporting size of tumor[IV]	• Overall: NR • By y: 1992: 80% 1994: 70% 1996: 100% • Links: NA		
	• % reporting number of involved & sampled LN[IV]	• Overall: NR • By y: 1992: 100% 1994: 100% 1996: 100% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patient; enrolled = n qualified; evaluated = n analyzed; NHSBSP = National Health Service Breast Screening Programme; LN = lymph nodes; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Appleton, 1998, UK (cont'd)	• % reporting involvement of resection margins[IV]	• Overall: NR • By y: 1992: 90% 1994: 90% 1996: 100% • Links: NA	• See above.	• See above.
	• % reporting side of mastectomy[IV]	• Overall: NR • By y: 1992: 60% 1994: 50% 1996: 100% • Links: NA		
	• % reporting size of specimen (macroscopic) [IV]	• Overall: NR • By y: 1992: 100% 1994: 90% 1996: 100% • Links: NA		
	• % reporting of affected quandrant (gross exam) [IV]	• Overall: NR • By y: 1992: 80% 1994: 60% 1996: 100% • Links: NA		
	• % reporting size of overlying skin[IV]	• Overall: NR • By y: 1992: 100% 1994: 100% 1996: 100% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; NHSBSP = National Health Service Breast Screening Programme; LN = lymph nodes; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Appleton, 1998, UK (cont'd)	• % reporting distance of tumor from nipple[IV]	• Overall: NR • By y: 1992: 50% 1994: 30% 1996: 100% • Links: NA	• See above.	• See above.
	• % reporting description of cut surface of tumor[IV]	• Overall: NR • By y: 1992: 80% 1994: 80% 1996: 10% • Links: NA		
	• % reporting description of skin[IV]	• Overall: NR • By y: 1992: 0% 1994: 20% 1996: 0% • Links: NA		
	• % reporting description of nipple[IV]	• Overall: NR • By y: 1992: 50% 1994: 50% 1996: 100% • Links: NA		
	• % reporting presence or absence of fascia or skeletal muscle[IV]	• Overall: NR • By y: 1992: 0% 1994: 0% 1996: 10% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; NHSBSP = National Health Service Breast Screening Programme; LN = lymph nodes; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Appleton, 1998, UK (cont'd)	• % reporting presence or absence of vascular invasion[IV]	• Overall: NR • By y: 1992: 90% 1994: 60% 1996: 100% • Links: NA	• See above.	• See above.
	• % reporting involvement of apical LN[IV]	• Overall: NR • By y: 1992: 40% 1994: 80% 1996: 80% • Links: NA		
	• % reporting distance of tumor to resection margins[IV]	• Overall: NR • By y: 1992: 100% 1994: 80% 1996: 100% • Links: NA		
	• % reporting presence or absence of concurrent DCIS[IV]	• Overall: NR • By y: 1992: 100% 1994: 70% 1996: 100% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; NHSBSP = National Health Service Breast Screening Programme; LN = lymph nodes; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Appleton, 1998, UK (cont'd)	• % reporting size of concurrent DCIS[IV]	• Overall: NR • By y: 1992: 38% 1994: 33% 1996: 100% • Links: NA	• See above.	• See above.
	• % reporting description of background breast[IV]	• Overall: NR • By y: 1992: 90% 1994: 90% 1996: 80% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; NHSBSP = National Health Service Breast Screening Programme; LN = lymph nodes; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Bernhard, 1997, Netherlands	**Process:** • Change in QOL by time & treatment arm; postmenopausal women, node(-) BC who underwent adjuvant therapy[Ia]	• Overall: NR • Physical well-being: Tamoxifen: 83.4 (1 mo) Tmx + CM: 83.2 (1 mo) Tamoxifen: 85.5 (3 mo) Tmx + CMF: 78.2 (3 mo) Tamoxifen: 86.5 (6 mo) Tmx + CMF: 85.3 (6 mo) • Mood: Tamoxifen: 78.8 (1 mo) Tmx + CMF: 78.2 (1mo) Tamoxifen: 80.7 (3 mo) Tmx + CMF: 76.8 (3 mo) Tamoxifen: 81.8 (6 mo) Tmx +CMF: 82.0 (6 mo) • PACIS: Tamoxifen: 78.1(1 mo) Tmx + CMF: 71.2 (1 mo) Tamoxifen: 81.0 (3 mo) Tmx + CMF: 69.5 (3 mo) Tamoxifen: 80.8 (6 mo) Tmx + CMF: 78.7 (6 mo) • Links: NA	• Standard: IBCSG form for assessing impact of adjuvant therapy on QOL; LASA scales (physical well-being; mood; appetite) • Data sources: pts self-reported status using IBCSG form • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: research • Care setting: hospitals; cancer centers; • Professionals: oncologists	• Inclusion: convenience sample pre- & postmenopausal women with operable BC • Exclusion: pts who completed no 1993 version QOL forms; completed forms in multiple languages • Period: 2 y (1993-1995) • n patients (enrolled/ evaluated): 345/312 • Age (mean & range): (NR) • Race/ethnicity: NR • Case characteristics: women with operable BC • Socioeconomic status: NR • Funding: ACS; NHMRC of Australia grants

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; PACIS = Perceived Adjustment to Chronic Illness Scale; ACS = American Cancer Society; NHMRC = National Health and Medical Research Council; state of use = last 3 y; LASA = Linear analogue self-assessment; Higher scores in scale = better quality of life; QOL = quality of life; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Bickell, 2000, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 59% • By hospital: 49-69% • Links: NA	• Standard: Mount Sinai Health Final Guidelines for Stage I & II BC treatment, 1994-1995 • Data sources: tumor registries; hospital discharge & pathology databases from 4 teaching hospitals NY area • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement; external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women BC receiving definitive surgical treatment of primary stage I or II in 4 hospitals in NY • Exclusion: treatment in other hospital; recurrent cancers; males; DCIS • Period: 2 y (1995-1996) • n patients (enrolled/ evaluated): 1,258/723 • Age (mean & range): 65 (NR) y • Race/ethnicity: Black (5-12%) • Case characteristics: stage I or II BC • Socioeconomic status: Medicaid 4-23% • Funding: United Hospital Fund
	• % appropriate use of RT after BCS[IV]	• Overall: 81% • By hospital: 69-87% • Links: NA		
	• % appropriate use of adjuvant systemic treatment , stage ≥ 1B[IV]	• Overall: 78% • By hospital: 71-86 % • By age: <50 y: 59-87% ≥50 y: 65-85% • Links: NA		
	• % appropriate use of ALND[IV]	• Overall: 87% • By hospital: 79-92% • Links: NA		
	• % quality of hormone receptor assay[IV]	• Overall: 85% • By hospital: 56-99% • Links: NA		
	Access: • % referral to oncologist[IV]	• Overall: 64% • By hospital: 50-81% • Links: NA		
	• % evidence of surgical options discussion[IV]	• Overall: NR • By hospital: 65-100% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast- conserving surgery; RT = radiotherapy; GP = general practitioner; NY = New York; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Bickell, 2003, US	**Structure:** • % cases not receiving recommended treatment (RT after BCS or systemic therapy) due to system failure[IV]	• Overall: 32% (14/44) • Links: NA	• Standard: Mount Sinai Health Final Guidelines for Stage I-II BC treatment, 1994-1995 • Data sources: Interview of 13 surgeons who treated pts • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women ESBC who had under-use of treatment; RT or adjuvant therapy not recommended when indicated • Exclusion: NR • Period: 2 y (1998-1999) • n patients (enrolled/ evaluated): NR/44 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: stage I or II BC • Socioeconomic status: NR • Funding: Department of Health Policy, Mount Sinai School of Medicine & the Mount Sinai NYU Health System

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast-conserving surgery; RT = radiotherapy; GP = general practitioner; state of use = last 3 y; BC = breast cancer; MD = medical doctor; NYU = New York University; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Bower, 2000, US	**Outcome**: • % change in QOL over time[Iac]	• Overall: NR • Energy/fatigue: 60 • Physical functioning: 80.35 • Role limitation- physical: 75.80 • Emotional well-being: 75 • Role limitation- emotional: 77 • Social functioning: 86 • Bodily pain: 78.60 • General health: 73 • Links: NA	• Instrument(s): RAND 36-item Health Survey 1.0 (physical; role function-physical; body pain; social functioning; emotional well-being; role function-emotional; energy/fatigue; general health perceptions) • Data sources: tumor registry; medical records; self-reported questionnaires • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women ESBC (stage 0-II); diagnosed <5 y; completed adjuvant therapy; currently disease-free; only treated with tamoxifen (cancer survivors) • Exclusion: no English-spoken • Period: 3 y (1994-1997) • n patients (enrolled/ evaluated): NR/1,957 • Age (mean & range): 55 (NR) y • Race/ethnicity: White (80%); Black (12.5%) • Case characteristics: BC survivors; currently tamoxifen (47.5%) • Socioeconomic status: married (70%); employed (45%); income/ y > U$ 75,000 (36.5%) • Funding: NCI

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; QOL = quality of life; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; ESBC = early stage breast cancer; RT = radiotherapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Brenin, 1999, US	• % appropriate use of axillary lymph node dissection[IV]	• Overall: 93.2% (n = 15,992) • By age (y): <70: 97% >70: 86% • By payer: Private vs. Government: OR 1.4 S • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: National Cancer Data Base • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research; decision-making • Care setting: hospitals; cancer centers; RT centers • Professionals: clinicians; oncologists; RT oncologists; surgeons	• Inclusion: national convenience sample women BC, stage I or II treated in US hospitals, 1994 • Exclusion: not eligible; stage III or IV; subcutaneous mastectomy; not lymph nodes examined undergoing ALND • Period: 1 y (1994) • n patients (enrolled/ evaluated): 17,931/17,151 • Age (mean & range): 61.3 (22 -103) y • Race/ethnicity: NR • Case characteristics: women BC stage I or II; node (+) 5.2%; • Socioeconomic status: NR • Funding: CCACS; ACR
	• % appropriate use of BCS[IV]	• Overall: 44.5% • Links: NA		
	• % appropriate use of RT on axilla[IV]	• Overall: 5.2% (n = 899) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; RT = radiotherapy; DCIS = ductal carcinoma in situ; BC = breast cancer; CCACS = Commission on Cancer of the American College of Surgeons; ACR = American College of Radiology; BCS = breast-conserving surgery; NIH = National Institute of Health; ALND = axillary lymph node dissection; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Cheung, 1999, Hong Kong	**Process:** • % appropriate use of BCS[IV]	• Overall: 32% • Links: NA	• Standard: BASO guidelines, 1995 • Data sources: medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement; research • Care setting: hospitals; cancer centers; RT centers • Professionals: GPs; oncologists; surgeons	• Inclusion: convenience sample women on whom author operated post CPG; women operable primary BC <5 cm; for BCS only tumor size, 3 cm • Exclusion: NR • Period: NR • n patients (enrolled/ evaluated): 100/100 • Age (mean & range): 53 (25-83) y • Race/ethnicity: NR • Case characteristics: BC Grade I-III; node (-) (57%); invasive ductal (72%); vascular invasion (34%); ER (+) (58%) • Socioeconomic status: NR • Funding: NR
	• % appropriate use of mastectomy[IV]	• Overall: 68% • Links: NA		
	• % appropriate use of CT[IV]	• Overall: 30% • Links: NA		
	• % appropriate use of tamoxifen[IV]	• Overall: 28% • Links: NA		
	• % (>90%) quality of FNA samples from lesions which subsequently prove to be BC should be adequate as deemed by the breast pathologist[IV]	• Overall: 99% • Links: NA		
	• % (90%) appropriate use of cytology or needle histology in palpable BC diagnosed pre-operatively [IV]	• Overall: 82% • Links: NA		
	• % (<10%) quality of breast biopsy: primary operable BC receives frozen section[IV]	• Overall: 0% • Links: NA		
	• % gross margins identified without incision into de specimen; & carefully orientated for the pathologist[IV]	• Overall: 100% • Links: NA		
	• % (90%) appropriate number of therapeutic operations (≤2) for women having BCS[IV]	• Overall: 100% • Links: NA		
	• % quality of technique to determine histological node status for all invasive tumors, by sampling or clearance[IV]	• Overall: 100% • Links: NA		
	Access: • % (>80%) urgent referrals seen within 5 working d of referral receipt[IV]	• Overall: 95% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; CT: chemotherapy; RT: radiotherapy; HT: hormone therapy; GP = general practitioner; ER: estrogen receptor; PR: progesterone receptor; CPG: clinical practice guidelines; DCIS: ductal carcinoma in situ; BC: breast cancer; BASO: British Association of Surgical Oncology; FNA: fine-needle aspiration; state of use: last 3 y; BCS = breast-conserving surgery; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Cheung, 1999, Hong Kong (cont'd)	• % (70%) all other new referrals seen within 15 working d[IV]	• Overall: 50% • Links: NA	• See above.	• See above.
	• % appropriate use of imaging &/or cytology or needle biopsy, if required; to be performed at the initial visit[IV]	• Overall: 0% • Links: NA		
	• % (<10%) all new women BC should attend the clinic/hospital on >2 occasions for diagnostic purposes[IV]	• Overall: 41% • Links: NA		
	• % pts attending for diagnostic purposes seen at least on 1 occasion by breast specialist surgeon[IV]	• Overall: 100% • Links: NA		
	• %(>90%) women requiring an operation for diagnostic purposes should be admitted 14 d of investigations leading to surgical decision[IV]	• Overall: 68% • Links: NA		
	• %(>90%): BC pts or an abnormality requiring diagnostic operation; told within 5 working d leading diagnosis[IV]	• Overall: 67% • Links: NA		
	• % (100%) BC pts given opportunity to see a BC nurse[IV]	• Overall: 100% • Links: NA		
	• % (90%) women admitted for operation within 21 d of surgical decision to operate for therapeutic purposes[IV]	• Overall: 93% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; CT = chemotherapy; RT = radiotherapy; HT = hormone therapy; GP = general practitioner; ER = estrogen receptor; PR = progesterone receptor; CPG = clinical practice guidelines; DCIS = ductal carcinoma in situ; BC = breast cancer; BASO = British Association of Surgical Oncology; FN = fine-needle aspiration; state of use = last 3 y; BCS = breast-conserving surgery; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Cheung, 1999, Hong Kong (cont'd)	**Outcome:** • % (<10%) pts developing local recurrence after BCS within 5 y[IV]	• Overall: 0% • Links: NA	• See above.	• See above.
	• % (<10%) pts developing local recurrence after mastectomy within 5 y[IV]	• Overall: 2.6% • Mastectomy cases: 36% • Links: NA		
	• % appropriate use of prophylactic RT employed in women with high risk of flap recurrence[IV]	• Overall: 2% (36% of mastectomies 7) • Links: NA		
	• % (<10%) regional recurrence needing further surgery or RT; at 5 y[IV]	• Overall: 0% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; CT = chemotherapy; RT = radiotherapy; HT = hormone therapy; GP = general practitioner; ER = estrogen receptor; PR = progesterone receptor; CPG = clinical practice guidelines; DCIS = ductal carcinoma in situ; BC = breast cancer; BASO = British Association of Surgical Oncology; FN = fine-needle aspiration; state of use = last 3 y; BCS = breast-conserving surgery; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Chie, 1999, China	**Outcome:** • % women with significant improvement in QOL scores in clinical phases of BC: diagnosis; surgery; initial CT; initial RT; follow-up; recurrence**[lac]	• Overall: NR • Links: NA	• Instrument(s): SF-36 Chinese version; EORTC-QLQ-C30* • Data sources: self- reported questionnaires to pts before RT (pretest); after RT (post-test) & recall of pretest; cancer registry • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women diagnosed or treated for BC in breast surgery; RT & oncology outpatients departments; or in general surgical wards of National Taiwan University Hospital • Exclusion: high-dose regimens that necessitated hospitalization & terminal pts in palliative care unit • Period: 2 mo (1997) • n patients (enrolled/ evaluated): 115/115 • Age (mean & range): NR (<40->65) y • Race/ethnicity: NR • Case characteristics: clinical phases: diagnosis (35.7%); surgery (9.6%); initial CT (13%); initial RT (7%); follow-up after treatment (27.8%); recurrence (7%) • Socioeconomic status: married (73.9%); employed (50.4%%) • Funding: NR

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast-conserving surgery; RT = radiotherapy; CT = chemotherapy; QOL = quality of life; EORTC-QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - cancer 30; SF-36 = medical outcome survey 36-item short form health surveys; state of use = last 3 y; * Validated for BC patients; **Includes: Role functioning; emotional functioning; cognitive functioning; global quality of life; nausea & vomiting; loss of appetite; constipation; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Christensen, 2002, Denmark	**Process**: • % appropriate use of preoperative diagnosis by FNA cytology, needle histology or biopsy[IV]	• Overall: 100% • Links: NA	• Standard: European Guidelines for Quality Assurance in Mammography screening, 1996; Guidelines for cytology procedures and reporting in BC screening, 1993 • Data sources: hospital registries of Copenhagen (pathology & mammography screening program) • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement; external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists; pathologists	• Inclusion: women with (+) mammography screening followed by surgery • Exclusion: data missing; lymphoma • Period: 6 y (1991-1997) • n patients (enrolled/ evaluated): 4,111/4,111 • Age (mean & range): 61 (50-72) y • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; NCI = National Cancer Institute; state of use = last 3 y; FNA = fine- needle aspiration; FP = false positive; FN = false negative; BC = breast cancer; (+) = positive; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures - Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Cochrane, 1997, UK	**Process:** • % appropriate use of referrals to surgeon by GP according to breast referral guidelines[IV]	• Overall: 60% • By age: <40 y: 54% >40 y: 64% S • Links: NA	• Standard: NHSBSP breast referral guidelines, 1995 • Data sources: referral database • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers • Professionals: surgeons; oncologists; RT oncologists; GPs	• Inclusion: random sample women > 35 y with breast problems referred to surgeon by GP in Rapid Access Breast Clinic in Cardiff, UK • Exclusion: screening cases; tertiary referrals; abnormal Mx • Period: 8 mo (1995) • n patients (enrolled/ evaluated): 2,332/2,332 • Age (mean & range): 44 (11-90) y • Race/ethnicity: NR • Case characteristics: women with BC symptoms: lumps (60%); pain (32%); nipple discharge (8%); skin change (5.2%) • Socioeconomic status: NR • Funding: Patterns of Care Study

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; enrolled = n qualified; evaluated = n analyzed; RT = radiotherapy; state of use = last 3 y; Mx = mammogram; NHSBSP = NHS Breast Screening Programme; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Cornfeld, 2001, US	**Structure**: • % board certified MDs in medical oncology[IV]	• Overall: 100% • Links: NA	• Standard: NCCN Guidelines, 1999 • Data sources: survey delivered to private practice oncologists (n = 11); medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers • Professionals: oncologists; surgeons	• Inclusion: convenience sample women with nonmetastatic BC treated in private practice of 11 oncologists surveyed • Exclusion: NR • Period: 9 mo (1999-2000) • n participants (enrolled/ evaluated): NR/220 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR
	• % availability of office procedure manual used for CT administration[IV]	• Overall: 100% • Links: NA		
	• % documentation of CME credits 2 y preceding each audit[IV]	• Overall: 100% • Links: NA		
	• % present CT flow sheets on active treatment charts[IV]	• Overall: 99% • Links: NA		
	Process: • % present body surface area calculations on CT flow sheets[IV]	• Overall: 90% • Links: NA		
	• % appropriate use of tamoxifen BC ER (+)[IV]	• Overall: 100% • Links: NA		
	• % appropriate use of guidelines for follow-up surveillance of BC[IV]	• Overall: NR • By practice: PE: 100% Mammography: 98% Gynecologic follow-up: 76% • Links: NA		
	Outcome: • % participation of oncologists in pts satisfaction survey[IV]	• Overall: 4.91[*] • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; CT = chemotherapy; CME = continuing medical education; BC = breast cancer; HT = hormone therapy; ER (+) = estrogen receptor positive; SD = standard deviation; [*] = number of participants were 3; state of use = last 3 y; NCCN = National Comprehensive Cancer Network; PE = physical examination; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Craft, 2000, Australia	**Process:** • % appropriate use of RT after BCS[IV]	• Overall: 98% (85/87) • Links: NA	• Standard: NHMRC CPG for the management of early BC, 1995 • Data sources: dataset of survey conducted by the Provincial Surgeons of Australia; pathology reports; treatment facility records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers; RT centers • Professionals: surgeons; RT oncologists; oncologists; pathologists; nurses	• Inclusion: convenience sample women newly diagnosed primary localized invasive BC treated in ACT, 1997-1998 • Exclusion: males; distant metastases; in situ • Period: 14 mo (1997-1998) • n patients (enrolled/ evaluated): 217/191 • Age (mean & range): 57 (25-88) y • Race/ethnicity: NR • Case characteristics: women premenopausal (29%); postmenopausal (57%); invasive BC (93%); HR (+) (81%); tumor size 1.1-2 cm (43%); node (-) (56%); tumor type (invasive ductal) grade 2 (35%) • Socioeconomic status: urban (67%) • Funding: Commonwealth Department of Health and Aged Care Cancer Screening Unit
	• % appropriate use of ALND for invasive BC[IV]	• Overall: 91% (173/190) • Links: NA		
	• % appropriate use of some form of adjuvant systemic therapy in node (+) or tumor >2 cm[IV]	• Overall: 96% (95/99) • Links: NA		
	• % appropriate use of adjuvant CT in <50 y; node (+)[IV]	• Overall: 100% (27/27) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; BCS = breast-conserving surgery; ALND = axillary lymph node dissection; ACT = Australian capitol territory; enrolled = n qualified; evaluated = n analyzed; NHMRC = National Health and Medical Research Council; CPG = clinical practice guideline; CT = chemotherapy; RT = radiotherapy; state of use = last 3 y; HR = hormone receptor; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
DeMichele, 2003, US	**Process**: • % appropriate use of CT (recommended)[IV]	• Overall: 74% (156/208) • By age: 50-54 y: 98% (57/58) 55-60 y: 85% (47/55) 61-69 y: 52% (40/52) 70+: 23% (10/43) • Links: NA	• Standard: St. Gallen Consensus Conference, 1992-1995 (update)* • Data sources: University of Pennsylvania pt information system database • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: cancer centers; hospitals; RT centers • Professionals: oncologists; surgeons; RT oncologists	• Inclusion: convenience sample women BC ≥ 50 y evaluated at UPCC 1993-1997 & eligible for adjuvant chemotherapy • Exclusion: missing data • Period: 5 y (1993-1997) • n patients (enrolled/ evaluated): 367/208 • Age (mean & range): 59(50-86) y • Race/ethnicity: NR • Case characteristics: women BC node (+) (61%); ER&PR (+) (46%); tumor size T1 (47%) • Socioeconomic status: NR • Funding: NR
	• % non–eligible pts receiving CT (over treatment)[IV]	• Overall: 11% (23/132) • Links: NA		
	• % appropriate use of CT (received) (patient acceptance) [IV]	• Overall: 74% (154/208) • By age: 50-59 y: 74% (72/97) 60-69 y: 74% (36/47) 70-86 y: 70% (7/10) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; RT = radiotherapy; HR = hormone receptor; state of use = last 3 y; UPCC = University of Pennsylvania Cancer Center; ER = estrogen receptor; PR = progesterone receptor; BC = breast cancer; *Recommendations for women <65 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Du, 2001, US	**Process:** • % appropriate use of CT within 6 mo of diagnosis[IV]	• Overall: 12.4% (708/5,697) • By Stage (1996): I: 3% II: 19.5% III: 43.7% IV: 40.9% • By age: 65-69 y: 20.5% 70-74 y: 13.9% 75-79 y: 8.7% >80 y: 3.3% • Links: NA	• Standard: NIH Consensus Conference Development, 1990 • Data sources: SEER registry; Medicare claim data • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers • Professionals: oncologists; surgeons; GPs	• Inclusion: population-based sample women ≥ 65 y diagnosed BC, 1991-1996 • Exclusion: women with no full coverage of Medicare; members of HMO • Period: 6 y (1991-1996) • n patients (enrolled/ evaluated): 35,060/5,697 • Age (mean & range): NR (>65) y • Race/ethnicity: NR • Case characteristics: women BC stage I-IV; > 65 y • Socioeconomic status: Medicare 100% • Funding: Department of Defense; NCI; Sealy & Smith Foundation
	• % appropriate use CT in node (+); ER (+); within 6 mo of diagnosis[IV]	• Overall: 27% (1996) • Links: NA		
	• % appropriate use CT in node (+); ER (-); within 6 mo of diagnosis[IV]	• Overall: 61.5% (1996) • Links: NA		
	• % appropriate use CT in node (-); ER (+); within 6 mo of diagnosis[IV]	• Overall: 2% (1996) • Links: NA		
	• % appropriate use CT in node (-); ER (-); within 6 mo of diagnosis[IV]	• Overall: 17.9% (1996) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; SEER = Surveillance, Epidemiology, and End Results; CT = chemotherapy; HMO = Health Maintenance Organization; ER = estrogen receptor; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Du, 2003, US	**Process:** • % appropriate use of CT[IV]	• Overall: 28.7% • By stage: I: 11.3% II: 47% IIIA: 68% • By age: <45 y: 66% 45-49 y: 54.9% 50-54 y: 44.2 % 55-59 y: 31% 60-64 y: 18.1% 65-69 y: 12.3% 70-74 y: 7.1% > 75 y: 3.4% • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: New Mexico tumor registry; pathology laboratories & hospitals in New Mexico • Developmental period: NR • Reference Standard(s) (Publication Date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers • Professionals: oncologists	• Inclusion: population-based sample women ≥20 y stage I-IIIA BC treated & registered in New Mexico tumor registry, 1991-1997 • Exclusion: stage other than I-IIIA, <20 y • Period: 7 y (1991-1997) • n patients (enrolled/evaluated): NR/5,101 • Age (mean & range): 61(20-98) y • Race/Ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NCI, NIH, Smyth Foundation
	• % appropriate use of CT + HT (tamoxifen) [IV]	• Overall: 9.6% • By age: <45 y: 15.8% 45-49 y: 17% 50-54 y: 18.5 % 55-59 y: 11.7% 60-64 y: 8% 65-69 y: 5.4% 70-74 y: 4.0% > 75 y: 0.8% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; NCI = National Cancer Institute; NIH = National Institute of Health; CT = chemotherapy; BC = breast cancer; CPG = clinical practice guideline; state of use = last 3 y; HT = hormone therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Edge, 2002, US	**Process:** • % appropriate use of ALND after BCS[IV]	• Overall: 63.4% (294/464) • By age: 67-69 y: 84% 70-74 y: 73% 75-79 y: 62% > 80 y: 33% S • By race/ethnicity: White: 64% Black: 60 % NS • By education: < High school: 60% ≥ High school: 66% • By Payer: HMO: 64% Private: 65% • Links: NA	• Standard: NIH Consensus Development Conference 1990; Steering committee on CPGs for the care & treatment of BC, CARO • Data sources: pt interviews; medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: decision-making; external quality oversight • Care setting: hospitals; pathology centers • Professionals: oncologists; surgeons; RT oncologists; GPs	• Inclusion: convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed histologically confirmed invasive BC who underwent BCS • Exclusion: DCIS; bilateral, multicentric, locally advanced disease; incomplete data; history of prior or secondary BC; surgery other than BCS • Period: 2 y (1995-1997) • n patients (enrolled/ evaluated): 1,377/464 • Age (mean & range): NR • Race/ethnicity: White (91%); Black (9%) • Case characteristics: stage I (84.9%); stage IIA (9%); stage IIB (1.7%); HR (+) (69.4%) • Socioeconomic status: education: < High school (66.4%); HMO (73.2%) • Funding: AHRQ & Department of the Army grants
	• % appropriate use of RT after BCS[IV]	• Overall: 77.8% (361/464) • With ALND 54.7% • Links: NA		
	• % appropriate use of adjuvant systemic therapy after BCS[IV]	• Overall: 70.7% (328/464) • By treatment: CT: 10.1% Tamoxifen: 89.9% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; BCS = breast-conserving surgery; ALND = axillary lymph node dissection; NIH = National Institute of Health; CARO = Canadian Association of Radiation Oncologists; GP = general practitioner; MO = non-metastatic; DCIS = ductal carcinoma in situ; RT = radiotherapy; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Engel, 2002, Germany	**Process:** • % appropriate use of BCS[IV]	• Overall: NR • By region: 39.3%-57.7% • Links: NA	• Standard: NIH Consensus Development Conference, 1990; St. Gallen's Consensus for adjuvant systemic therapy, 1995-1998 (update) • Data sources: data submitted by pathologists, gynecologists, surgeons & radiologists, 6 regions in Germany • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; decision-making; quality of care reporting; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; RT oncologists; surgeons; GPs	• Inclusion: convenience sample women any stage BC residing in one of 6 regions*, Germany • Exclusion: NR • Period: 3 y (1996-1998) • n patients (enrolled/ evaluated): 9,210/8,661 • Age (mean & range): NR (<50->70) y • Race/ethnicity: NR • Case characteristics: HR (+) 80%; stage 0-IV; LN status known • Socioeconomic status: NR • Funding: German Federal Ministry of Health
	• % appropriate use of RT after BCS[IV]	• Overall: NR • By region: 80.6%-85.0% • Links: NA		
	• % appropriate use of RT after mastectomy[IV]	• Overall: NR • By region: 10.4%-32.2% • Links: NA		
	• % appropriate use of CT in premenopausal; node (+); HR (+) (1995) [IV]	• Overall: NR • By region: 42.9%-84.6% • Links: NA		
	• % appropriate use of CT & HT in premenopausal; node (+); HR (+) (1995-1998) [IV]	• Overall: NR • By region: 10.3%-57.1% • Links: NA		
	• % appropriate use of CT in premenopausal; node (+); HR (-) (1995/1998) [IV]	• Overall: NR • By region: 63.6%-92.3% • Links: NA		
	• % appropriate use of tamoxifen in postmenopausal; node (+); HR (+) (1995) [IV]	• Overall: NR • By region: 30.1%-61.5% • Links: NA		
	• % appropriate use of CT & HT in postmenopausal; node (+); HR (+) (1995/1998) [IV]	• Overall: NR • By region: 9.1%-32.2% • Links: NA		
	• % appropriate use of CT in postmenopausal; node (+); HR (-) (1995/1998) [IV]	• Overall: NR • By region: 38.5%-69.6% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; HR (+) = hormone receptor positive; ER (-) = hormone receptor negative; FI = family income; BCS = breast-conserving surgery; RT = radiotherapy; CT = chemotherapy; HT = hormone therapy; node (+) = lymph node positive; NIH = national health institute; state of use = last 3 y; GP = general practitioner; *6 regions = Aachen; Dresden; Jena; Marburg; Munich; Stuttgart; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Foroudi, 2002, Canada	• % appropriate use of RT[IV]	• Overall: 56.3%-72.4%* • Initial: 50%-59.2%* • Later: 6.3%-13.3%* • Links: NA	• Standard: North American CPG (n = 12); others • Data sources: North American population-based cancer registries (SEER & Ontario Cancer registry); National Cancer database; single institutions; multi-institution databases • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR	• Inclusion: population-based sample women with BC eligible for RT from North American population • Exclusion: NR • Period: NR • n patients (enrolled/ evaluated): NR • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR
	• % appropriate use of RT; in situ; moderate risk, prefer BCT (i) [IV]	• Overall: 37.7%* • Links: NA		
	• % appropriate use of RT: stage I & II (pN0), prefer BCT ; receiving BI (i) [IV]	• Overall: NR • Stage I: 57%* • Stage II: 52.2%* • Links: NA		
	• % appropriate use of RT: stage I &II (pN0), postmastectomy, R1 or 2, receiving RI (i) [IV]	• Overall: NR • Stage I: 0.6-0.8%* • Stage II:0. 77-0.83%* • Links: NA		
	• % appropriate use of RT: stage II (pN1); <4N(+); postmastectomy, R1 or 2, receiving RI (i) [IV]	• Overall: 0.3%* • Links: NA		
	• % appropriate use of RT: stage II (pN1); <4N(+); postmastectomy, R0, receiving RI (i) [IV]	• Overall: 3.9-4.2%* • Links: NA		
	• % appropriate use of RT: stage II (pN1); >3N(+); postmastectomy, receiving RI (i) [IV]	• Overall: 5.7-6.1%* • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; BCS = breast conserving surgery; RT = radiotherapy; HR = Hormone receptor; CI = contraindication; CT = chemotherapy; HT = hormone therapy; CPG = clinical practice guidelines; BI = breast irradiation; BCT = breast-conserving therapy; R0 = no residual tumor; R1 = microscopic residual tumor; R2 = macroscopic residual tumor; RI = radiation therapy; (i) = initial treatment; PRT = any palliative RT; LCIS = lobular carcinoma in situ; (r) = progression or relapse; state of use = last 3 y; GP = general practitioner; * Estimates of the rate in a decision-making tree analysis; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Foroudi, 2002, Canada (cont'd)	• % appropriate use of RT: stage II (pN1), prefer BCT, receiving BI (i) IV	• Overall: 31.1%* • Links: NA	• State of use: NR • Current use: internal quality improvement; external quality oversight, decision-making; research • Care setting: hospitals; cancer centers; RT centers • Professionals: surgeons; oncologists; RT oncologists; GPs	• See above.
	• % appropriate use of RT: stage IIIB (pT4 or pN3),w/wo mastectomy, receiving RI (i) IV	• Overall: 42%* • Links: NA		
	• % appropriate use of RT stage IIIA, < 4N(+), postmastectomy, R1 or 2; receiving RI (i) IV	• Overall: 0.24-0.35%* • Links: NA		
	• % appropriate use of RT: stage IIIA; < 4N(+), postmastectomy; R0, prefer BCT; receiving RI (i) IV	• Overall: 3.5-5.1%* • Links: NA		
	• % appropriate use of RT: stage IIIA; >3N(+), postmastectomy, receiving RI (i) IV	• Overall: 5.1-7.4%* • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; BCS = breast conserving surgery; RT = radiotherapy; HR = Hormone receptor; CI = contraindication; CT = chemotherapy; HT = hormone therapy; CPG = clinical practice guidelines; BI = breast irradiation; BCT = breast-conserving therapy; R0 = no residual tumor; R1 = microscopic residual tumor; R2 = macroscopic residual tumor; RI = radiation therapy; (i) = initial treatment; PRT = any palliative RT; LCIS = lobular carcinoma in situ; (r) = progression or relapse; state of use = last 3 y; GP = general practitioner; * Estimates of the rate in a decision-making tree analysis; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Foroudi, 2002, Canada (cont'd)	• % appropriate use of RT: stage IIIA; prefer BCT, receiving BI (i) IV	• Overall: 27.8%* • Links: NA	• See above.	• See above.
	• % appropriate use of RT: stage IV, brain metastases at diagnosis, receiving PRT (i) IV	• Overall: 1.8%* • Links: NA		
	• % appropriate use of RT: stage IV; symptomatic bone metastasis at diagnosis; receiving PRT (i) IV	• Overall: 10%* • Links: NA		
	• % appropriate use of RT: LCIS; recur with DCIS or invasive carcinoma; receiving BI (r) IV	• Overall: 0.7%* • Links: NA		
	• % appropriate use of RT: DCIS, post-BCS, recur with DCIS or invasive carcinoma; receiving BI (r) IV	• Overall: 1.2%* • Links: NA		
	• % appropriate use of RT: DCIS, postmastectomy; locoregional relapse, receiving RI (r) IV	• Overall: 0. 02-0.1%* • Links: NA		
	• % appropriate use of RT: stage I & II (pN0), postmastectomy, receiving PRT (r) IV	• Overall: 2.9-4.2%* • Links: NA		
	• % appropriate use of RT: stage I & II (pN0), postmastectomy, locoregional relapse; receiving RI (r) IV	• Overall: NR • Stage I: 1.3-1.9%* • Stage II: 1.7-1.9%* • Links: NA		
	• % appropriate use of RT: stage II (pN1); postmastectomy; receiving PRT IV	• Overall: 0.5%* • Links: NA		
	• % appropriate use of RT: stage II (pN1); postmastectomy (locoregional relapse); receiving RI (r) IV	• Overall: 1.35%* • Links: NA		
	• % appropriate use of RT: stage III; postmastectomy; receiving PRT (r) IV	• Overall: 0.39-0.57%* • Links: NA		
	• % appropriate use of RT: stage III; postmastectomy; locoregional relapse; receiving RI (r) IV	• Overall: 1.2-1.7%* • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; BCS = breast conserving surgery; RT = radiotherapy; HR = Hormone receptor; CI = contraindication; CT = chemotherapy; HT = hormone therapy; CPG = clinical practice guidelines; BI = breast irradiation; BCT = breast-conserving therapy; R0 = no residual tumor; R1 = microscopic residual tumor; R2 = macroscopic residual tumor; RI = radiation therapy; (i) = initial treatment; PRT = any palliative RT; LCIS = lobular carcinoma in situ; (r) = progression or relapse; state of use = last 3 y; GP = general practitioner; * Estimates of the rate in a decision-making tree analysis; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Foroudi, 2002, Canada (cont'd)	• % appropriate use of RT: stage IV, delayed symptoms from bone metastasis; receiving PRT (r) [IV]	• Overall: 10.4-21.7%* • Links: NA	• See above.	• See above.
	• % appropriate use of RT: stage IV, delayed brain metastasis; receiving PRT (r) [IV]	• Overall: 4.8-10%* • Links: NA		
	• % appropriate use of RT: stage IV, delayed cord compression; receiving PRT (r) [IV]	• Overall: 0.4-0.8%* • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; BCS = breast conserving surgery; RT = radiotherapy; HR = Hormone receptor; CI = contraindication; CT = chemotherapy; HT = hormone therapy; CPG = clinical practice guidelines; BI = breast irradiation; BCT = breast-conserving therapy; R0 = no residual tumor; R1 = microscopic residual tumor; R2 = macroscopic residual tumor; RI = radiation therapy; (i) = initial treatment; PRT = any palliative RT; LCIS = lobular carcinoma in situ; (r) = progression or relapse; state of use = last 3 y; GP = general practitioner; * Estimates of the rate in a decision-making tree analysis; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Frazer, 1998, US	**Outcome:** • % change (improvement) in QOL over time[Iac]	• Overall: NS changes over time in all subscales & overall. • Links: NA	• Instrument: 39-item Guttman scaled HSQ Questionnaire form (health perception; social & physical functioning; physical & emotional role limitations; mental health; bodily pain; energy-fatigue) • Data sources: pts self-reported status using Guttman scaled HSQ questionnaire form • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers • Professionals: oncologists; surgeons	• Inclusion: convenience sample women ESBC diagnosed, 1993, & treated by surgery & HT at MDACCO, Orlando, Florida • Exclusion: non-responders • Period: 3 y (1993-1996) • n patients (enrolled/ evaluated): NR/70 • Age (mean & range): 61.4 (37-80) y • Race/ethnicity: NR • Case characteristics: ESBC women with operable BC; treated by surgery & HT • Socioeconomic status: married; not employed; HMO • Funding: NR

NR = not reported; NA = not assessed**;** S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; HSQ = Health Status Questionnaire; MDACCO = M.D. Anderson Cancer Center Orlando; state of use = last 3 y; HT = hormone therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Guadagnoli, 1997, US	**Process:** • % appropriate use of any adjuvant systemic therapy in node (-)[IV]	• Overall: 62% • By age: 50-59 y: 73% 60-69 y: 67% 70-79 y: 56% >80 y: 36% S • Links: NA	• Standard: EBCTCG meta-analysis, 1992 • Data sources: medical records; interviews • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals • Professionals: medical oncologists; oncological radiologists	• Inclusion: convenience sample postmenopausal women newly diagnosed invasive ESBC; stage I-II at 30 hospitals, Minnesota, 1993 • Exclusion: diagnosis of carcinoma in situ; inflammatory cancer; bilateral synchronous carcinoma; premenopausal women • Period: 1 y (1993) • n patients (enrolled/ evaluated): 746/632 • Age (mean & range): NR (50->80) y • Race/ethnicity: NR • Case characteristics: tumor size >1 cm (67%); node (+) (25%); LVN (9%); ER (+) (64%) • Socioeconomic status: married (54%); income > $30,000 (70%); HMO (37%) • Funding: NCI
	• % appropriate use of tamoxifen in node (-)[IV]	• Overall: 51% • By age: 50-59 y: 52% 60-69 y: 55% 70-79 y: 51% >80 y: 34% S • Links: NA		
	• % appropriate use any adjuvant systemic therapy in node (+)[IV]	• Overall: 92% • By age: 50-59 y: 93% 60-69 y: 96% 70-79 y: 89% >80 y: 85% NS • Links: NA		
	• % appropriate use any adjuvant systemic therapy in node (+) BC[IV]	• Overall: 71% • By age 50-59 y: 61% 60-69 y: 70% 70-79 y: 81% >80 y: 74% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NCI = National Cancer Institute; EBCTCG = early breast cancer trialists' collaborative group; HT = hormone therapy; CT = chemotherapy; state of use = last 3 y; ESBC = early-stage BC; LVN = lymphatic- vessel invasion; ER = estrogen receptor; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Guadagnoli, 1998a, US	**Process:** • % appropriate use of RT after BCS[IV]	• Overall: 84% (MA) 86% (MN) • By age (OR): 50-59 y: 0.4 S (MA); 4.2 NS (MN) 60-69 y: 0.5 NS (MA); 2.6 NS (MN) 70-79 y: 0.3 S (MA); 0.3 NS (MN) >80 y: 0.05 S (MA); 0.03 S (MN) • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: hospital tumor registries; medical records; patient survey; patient income & education US census data; physician survey • Developmental period: NR • Reference standard(s) (publication sate): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: clinicians; oncologists; surgeons; RT oncologists	• Inclusion: convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN), 1993-1995 • Exclusion: DCIS; bilateral synchronous BC; inflammatory carcinoma • Period: 2 y (1993-1995) • n patients (enrolled/ evaluated): 2,575/2,575 (MA = 1,514; MN = 1,061) • Age (mean & range): NR (<50 - > 80) y • Race/ethnicity: White 96% (MA); 99% (MN); Black 4% (MA); 1% (MN) • Case characteristics: women > 60 y; stage I-II BC • Socioeconomic status: income <$40,000 54%(MA); 67% (MN); urban 95% • Funding: NCI grants
	• % appropriate use of axillary lymph node dissection[IV]	• Overall: 81% (MA); 94% (MN) • By age (OR) 50-59 y: 0.8 NS (MA); 5.3 NS (MN) 60-69 y: 0.3 NS (MA); 0.9 NS (MN) 70-79 y: 0.1 S (MA); 0.2 S (MN) >80 y: 0.03 S (MA); 0.1S (MN) • Links: NA		
	• % appropriate use of CT*[IV]	• Overall: 97% (MA); 94% (MN) • Links: NA		
	• % appropriate use of tamoxifen[IV]	• Overall: 63% (MA); 59% (MN) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; CT = chemotherapy; RT = radiotherapy; HT = hormone therapy; ER = estrogen receptor; PR = progesterone receptor; CPG = clinical practice guidelines; DCIS = ductal carcinoma in situ; BC = breast cancer; NCI = National Cancer Institute; MA = Massachusetts; MN = Minnesota; OR = odds ratio; state of use = last 3 y; GP = general practitioner; * premenopausal; node (+); ** postmenopausal nodes (+) & ER (+); BCS = breast-conserving surgery; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Guadagnoli, 1998b, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 74%(MA); 48% (MN) • By age (OR): 50-59 y: 0.9 NS (MA); 0.9 NS (MN) 60-69 y: 0.9 NS (MA); 0.7 NS (MN) 70-79 y: 0.6 NS (MA); 0.6 S (MN) ≥80 y: 0.8 NS (MA); 0.4 S (MN) • By residence: Urban: 1.5 NS (MA); 2.2 S (MN) • By income (OR): <$40,000: 0.7 NS (MA); 1.4 NS (MN) By HMO member: 1.4 NS (MA); 0.9 NS (MN) • By education (% High school) (OR): 70-79: 0.9 NS (MA); 1.5 NS (MN) 80-89: 0.9 NS (MA); 1.4 NS (MN) ≥ 90: 1.4 NS (MA); 2.6 NS (MN) • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: medical records; patient survey • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women BC stage I or II in hospitals of 2 US states (MA & MN), 1993-1995 • Exclusion: bilateral disease; prior BCS in same breast; prior RT; pregnancy; central tumor; multifocal; etc • Period: 2 y (1993-1995) • n patients (enrolled/ evaluated): MA: 1,514/1,299; MN: 1,061/836 • Age (mean & range): NR (<50->80) y • Race: White (96%); Black (4%) • Case characteristics: mostly women > 60 y, stage I disease • Socioeconomic status: income < U$ 40,000 (MA: 55%; MN: 67%); urban (MA: 95%; MN: 91%); comorbid disease (MA: 63%; MN: 67%) • Funding: NCI
	• % appropriate use of RT after BCS[IV]	• Overall: 84% (MA); 86% (MN) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast-conserving surgery; RT = radiotherapy; NCI = National Cancer Institute; MA = Massachusetts; MN = Minnesota; NIH = National Institute of Health; state of use = last 3 y; GP = general practitioner; OR = odds ratio; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Haas, 2000, US	**Process:** • % appropriate use of evaluation in compliance with guidelines (biopsy; imaging evaluation; breast exam) [IV]	• Overall: 69.1% • By consultation: Abnormal Mx: 74% Clinical breast complaint: 58.8% • By age: <50 y: 63.8% ≥50 y: 74.5 % • By race/ethnicity: White: 71% Black: 59.5% Hispanic: 75.8% • By payer: HMO: 73.3% Other: 62% • Links: NA	• Standard: Harvard Risk Management Foundation guidelines, 1995 • Data sources: medical records; baseline & follow-up telephone surveys • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers • Professionals: GPs; oncologists; surgeons	• Inclusion: convenience sample women referred for at least 1 visit to GP, 1 y prior to Mx; abnormal screening Mx or underwent Mx for clinical breast concern (lump, thickening, breast pain) regardless of result, Greater Boston area • Exclusion: previously diagnosed BC; evaluated for abnormal Mx or breast complaint within preceding y • Period: 1 y (1996 -1997) • n patients (enrolled/ evaluated): 751/579 • Age (mean & range): NR • Race/ethnicity: White (74.4%); Black (14.5%); Hispanic (5.7%) • Case characteristics: NR • Socioeconomic status: ≥ high school (50%); HMO (60%) • Funding: Harvard Risk Management Foundation
	Outcome: • % women reporting overall satisfaction with quality of breast care [IV]	• Overall: excellent care 46.8% (baseline) 45.8% (follow-up survey) • By age: <50 y: 44.4% (b)- 46.6%(F) ≥ 50 y: 49.3% (b)- 44.9% (F) • By Race/ethnicity: White: 51.9% (b)- 49.8% (F) Black: 35.9% (b)- 35.6% (F) Hispanic: 33.3% (b)-25% (F) • By payer: HMO: 42.9% (b) - 42.4% (F) Other: 52.8% (b) – 50.7% (F) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; Mx = mammogram; state of use = last 3 y; GP = general practitioner; HMO = health maintenance organization; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Harlan, 2002, US	**Process:** • % appropriate use of any adjuvant systemic therapy in node (+)[IV]	• Overall: 70% • By age: <51y: 82% 51-64 y: 73% ≥65 y: 63% S • By race/ethnicity: White: 72% Black: 69% Other: 72% NS • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: NCI-SEER cancer registries • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers • Professionals: oncologists; GPs	• Inclusion: population-based sample women stage I, II & IIIA BC diagnosed, 1987-1991 & 1995 • Exclusion: pts who did not undergo surgery; participation in clinical trials • Period: 5 y (1987-1991 & 1995) • n patients (enrolled/ evaluated): 8,106/7,724 • Age (mean & range): NR • Race/ethnicity: White (83.2%); Black (9.3%); other (7.5%) • Case characteristics: women stage I-IIIA BC; ER (+) (59.2%); tumor size 1-2 cm (47.7%); node (-) (63.4%) • Socioeconomic status: NR • Funding: NCI
	• % appropriate use of any adjuvant systemic therapy in node (-)[IV]	• Overall: NR • By age: <51 y: 45% <65 y: 46% ≥65 y: 41% • By race/ethnicity: White: 44% Black: 40% Other 45% NS • Links: NA		
	• % appropriate decision not to provide adjuvant systemic therapy in node(-); tumor <1cm[IV]	• Overall: 52.2% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; node (+) = lymph node positive; node (-) = lymph node negative; NIH = National Health Institute; NCI SEER = National Cancer Institute Surveillance, Epidemiology, and End-Results; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Hassey Dow, 2000, US	**Outcome:** • % women reporting changes in QOL overtime (from start of RT; during RT & 6 mo post)[Ia]	• Overall: NR; NS changes over time in QLI scales • Links: NA	• Instrument(s): Ferrans Quality-of-Life Index- cancer version (QLI) 1990 • Data sources: questionnaires; demographic data form • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women ESBC beginning course of RT after BCS at a major urban teaching hospital in US Northeast. 21-45 y; newly diagnosed stage I or II BC; not undergoing CT or HT • Exclusion: no previous diagnosis or treatment for any cancer • Period: 6 mo • n patients (enrolled/ evaluated): 28/23 • Age (mean & range): 37.8 (25-45) y • Race/ ethnicity: White (91%); Hispanic & Russian (4%) • Case characteristics: women BC stage I or II; BCS & RT; <45 y • Socioeconomic status: single (40%) • Funding: ONS Foundation/ Laderle Research

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast-conserving surgery; RT = radiotherapy; CT = chemotherapy; HT = hormone therapy; QOL = quality of life; QLI = Ferrans Quality-of-Life Index – Cancer version; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Hebert-Croteau, 1999, Canada	**Process:** • % appropriate use of definitive locoregional therapy (total mastectomy + ALND or BCS + ALND + RT) [IV]	• Overall: NR • By age: 50-69 y: 83.5% ≥70 y: 48.7% S • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: Quebec tumor registry (1988-89); Quebec hospital admission/discharge database (1993-1994) • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: research; external quality oversight • Care setting: hospitals; cancer centers • Professionals: oncologists; GPs; RT oncologists; surgeons	• Inclusion: random sample newly diagnosed stage I-II BC women ≥50 y receiving treatment in 5 sanitary regions of Quebec: Montreal, Quebec, Laval, Monteregie & Chadiere/Appalaches • Exclusion: pts in long term or convalescent hospitals; diagnostic errors; multiple primary tumors; recurrent BC; regional or distant extension; multicentric, inflammatory, Stage III-IV; no pathological confirmation of disease; tumor not originated in mammary gland; phyllodes tumor or lobular carcinoma • Period: 2 y (1993-1994) • n patients (enrolled/ evaluated): 1,732/1,174 • Age (mean & range): NR (50->70) y • Race/ethnicity: NR • Case characteristics: Stage I-II BC node (-); ER (+) (70-79%); tumor size 1-2 cm (41-48%) • Socioeconomic status: NR • Funding: Research in Health Quebec
	• % appropriate use of alternative definitive therapy (RT after BCS + ALND or adjuvant treatment) [IV]	• Overall: NR • By age: 50-69 y: 90.9% ≥70 y: 60.9% S • Links: NA		
	• % appropriate of use of BCS[IV]	• Overall: NR • By age: 50-69 y: 90.9% ≥70 y: 80.1% S • Links: NA		
	• % appropriate use of RT after BCS[IV]	• Overall: NR • By age: 50-69 y: 89.6% ≥70 y: 59% S • Links: NA		
	• % appropriate use of ALND[IV]	• Overall: NR • By age: 50-69 y: 82.4% ≥70 y: 46.9% S • Links: NA		
	• % appropriate use of any adjuvant systemic therapy[IV]	• Overall: NR • By age: 50-69 y: 74.2% ≥70 y: 72.1% NS • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; LN = lymph nodes; LND = lymph node dissection; ALND = axillary lymph node dissection; RT = radiotherapy; enrolled = n qualified; evaluated = n analyzed; completed = n completing the study; GP = general practitioner; state of use = last 3 y; BCS = breast -conserving surgery; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Hislop, 2003, Canada	**Process:** • % appropriate use of BCS[IV]	• Overall: NR • By extent of disease: LCIS: 56% DCIS: 39% Metastatic: 8% M0 invasive: 57% Node (-): 60% • By age: <40 y: 42% 40-49 y: 51% 50-59 y: 58% 60-69 y: 50% 70-79 y: 42% • > 80 y: 41% • By family income: <$35,000: 44% $35,000-44,999: 46% $45,000-54,999: 46% ≥$55,000: 55% • Links: NA	• Standard: BCCA cancer treatment policy manual, 1995 • Data sources: British Columbia cancer registry; medical records; interviews of MDs • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; RT oncologists; GPs	• Inclusion: Population-based sample women histologically confirmed BC diagnosed, British Columbia, 1995 • Exclusion: diagnosed out of province; at death; previous synchronous cancer • Period: 1 y (1995) • n patients (enrolled/ evaluated): 2,563/1,159 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: DCIS or LCIS (n = 152); invasive non metastatic (n = 967); node (-) (n = 496); metastatic (n = 40) • Socioeconomic status: NR • Funding: British Columbia Health Research
	• % appropriate use of RT after BCS + ALND in M0 invasive BC[IV]	• Overall: 38% • By family income: <$35,000: 100% $35,000-44,999: 80% $45,000-54,999: 89% ≥$55,000: 82% • Links: NA		
	• % appropriate use of RT after BCS in DCIS[IV]	• Overall: 38% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; state of use = last 3 y; GP = general practitioner; BCCA = British Columbia Cancer Agency; DCIS = ductal carcinoma in situ; LCIS = lobular carcinoma in situ; BCS = breast-conserving surgery; RT = radiotherapy; ALND = axillary lymph node dissection; M0 = non-metastatic; MD = medical doctor; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Hislop, 2003, Canada (cont'd)	• % appropriate use of mastectomy ± RT + ALDN in M0 invasive[IV]	• Overall: 46% • Links: NA	• See above.	• See above.
	• % appropriate use of mastectomy ± RT in LCIS or DCIS[IV]	• Overall: 21% • Links: NA		
	• % no BCS or mastectomy in metastatic disease[IV]	• Overall: 65% • Links: NA		
	• % appropriate use of treatment sequences according to guidelines[IV]	• Overall: 81% • By extent of disease: LCIS: 78% DCIS: 71% Metastatic: 73% M0 invasive: 83% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; state of use = last 3 y; GP = general practitioner; BCCA = British Columbia Cancer Agency; DCIS = ductal carcinoma in situ; LCIS = lobular carcinoma in situ; BCS = breast-conserving surgery; RT = radiotherapy; ALND = axillary lymph node dissection; M0 = non-metastatic; MD = medical doctor; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Imperato, 2002, US	**Process:** • % reporting laterality of specimen (right or left breast) [IV]	• Overall: 99.3% (551/555) • Links: NA	• Standard: CAP & ADASP guidelines 1997/2000 (update) • Data sources: Medicare pts, NY State acute care hospitals, 1999 (n=1,718); medical records • Developmental period: NR • Reference standard(s) (Publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; quality of care reporting • Care setting: hospitals; pathology centers • Professionals: pathologists; oncologists; surgeons	• Inclusion: random sample Medicare Individuals BC who underwent total mastectomy with LND, NY State hospitals, 1999 • Exclusion: other type of surgery, missing data from records, no residual cancer present in individuals with prior lumpectomy or excisional biopsy • Period: 1 y (1999) • n patients (enrolled/ evaluated): 1718/555* • Age (mean & range): 73.7 (NR) y • Race/ethnicity: White (80.9%); Black (8.5%) Asian (1.1%); unknown (9.5%) • Case characteristics: NR • Socioeconomic status: NR • Funding: Health Care Financing Administration
	• % reporting gross observation of lesion [IV]	• Overall: 60.5% (336/555) • Links: NA		
	• % reporting dimension of tumor (largest) [IV]	• Overall: 93.5% (314/336)\ • Links: NA		
	• % reporting identification of affected quadrant [IV]	• Overall: 30.7% (103/336) • Links: NA		
	• % reporting LN (presence/absence) [IV]	• Overall: 83.7% (465/555) • Links: NA		
	• % reporting presence of carcinoma [IV]	• Overall: 100% (555/555) • Links: NA		
	• % reporting histological type [IV]	• Overall: 95.9% (532/555) • Links: NA		
	• % reporting histological grade [IV]	• Overall: 59.1% (328/555) • Links: NA		
	• % reporting nuclear grade [IV]	• Overall: 44.3% (246/555) • Links: NA		
	• % reporting mitotic rate [IV]	• Overall: 22.5% (125/555) • Links: NA		
	• % reporting extent of tubule formation [IV]	• Overall: 19.6% (109/555) • Links: NA		
	• % reporting verification tumor size [IV]	• Overall: 63.0% (349/555) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; LND = lymph node dissection; (+) = positive; CAP = College of American Pathology; ADASP = Association of Directors of Anatomic and Surgical Pathology; state of use = last 3 y; NY = New York; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Imperato, 2002, US (cont'd)	• % reporting angiolymphatic invasion[IV]	• Overall: 45.6% (253/555) • Links: NA	• See above.	• See above.
	• % reporting resection margin status[IV]	• Overall: 69.4% (385/555) • Links: NA		
	• % reporting n LN present[IV]	• Overall: 93.5% (519/555) • Links: NA		
	• % reporting n node (+)[IV]	• Overall: 98.6% (217/220) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; LND = lymph node dissection; (+) = positive; CAP = College of American Pathology; ADASP = Association of Directors of Anatomic and Surgical Pathology; state of use = last 3 y; NY = New York; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Jackson, 1999, Canada	**Process:** • % appropriate use of RT post-mastectomy on chest wall[IV]	• Overall: 82.5% (4%-95.5%) • Links: NA	• Standard: BCCA guidelines, 1986, update in 1989 & 1993 • Data sources: CAIS, Radiation Therapy Warehouse Table • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: RT oncologists; oncologists; surgeons; GPs	• Inclusion: population-based sample women receiving "radical" or "adjuvant" postoperative RT treatments for BC in 3 clinics in British Columbia inclusive, 1985-1996 • Exclusion: pts receiving palliative treatment or treatment for other disease sites; referrals to other hospitals • Period: 12 y (1985-1996) • n patients (enrolled/ evaluated): 9,748/9,351 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR
	• % appropriate use of RT on regional LN[IV]	• Overall: 75% (3%-92%) • Links: NA		
	• % quality of RT after BCS[IV]	• Overall: 95% (69%-99.5%) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; RT = radiotherapy; CAIS = Cancer Agency Information System; LN = lymph nodes; BCS = breast-conserving surgery; state of use = last 3 y; GP = general practitioner BCCA = British Columbia Cancer Agency; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Jansen, 2000, Netherlands	**Outcome:** • Overall changes in QOL overtime; before & after RT[Iac]	• Overall: QOL scale: 38% (worse); 40% (stable); 22% (improvement) • Links: NA	• Instrument(s): Rotterdam Symptom Checklist (RSCL); SF-36 • Data sources: pt self-report questionnaires before RT (pretest); after RT (post-test) & recall of pretest • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women ESBC who underwent surgery (BCS or mastectomy) • Exclusion: previous CT or RT; DCIS; no speak Dutch • Period: 2 y (1997-1999) • n patients (enrolled/ evaluated): 76/46 • Age (mean & range): 55 (28-77) y • Race/ethnicity: NR • Case characteristics: women BC stage I or II; BCS (n=37); mastectomy (n=9) • Socioeconomic status: married (72%); full-time employment (17%) • Funding: Dutch Cancer Society

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC: early stage breast cancer; BCS: breast-conserving surgery; RT: radiotherapy; CT: chemotherapy; QOL: Quality of life; DCIS: ductal in situ carcinoma; state of use: last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Keating, 2001, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 73.8% (MA); 48% (MN) • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: medical records; telephone interview with pts • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; pathology centers • Professionals: pathologists; oncologists; surgeons	• Inclusion: convenience sample women diagnosed stage I & II BC at 17 hospitals in MA & 30 hospitals in MN • Exclusion: women BC DCIS; bilateral synchronous carcinoma; inflammatory carcinoma; women interview non-responders (no permission by surgeon, not located, unavailable) • Period: 2 y (1993-1995) • n patients (enrolled/evaluated): 1,498/ 792 (MA); 2,330/1,634 (MN) • Age (mean & range): 56.6 y (SD 13.5) MA; 59.4 y (SD 13.6) MN • Race/ethnicity: White 94% (MA); 98% (MN) S • Case characteristics: women BC stage I 58% MA; 60% MN; stage II 42% MA; 40% MN • Socioeconomic status: income < U$20,000/y: 17% MA; 22% MN; U$20,000-40,000/y: 29% MA; 34% MN; >U$40,000/y: 54% MA; 44% MN (p<0.05); HMO insurance 33% MA; 43% MN (p<0.05) • Funding: NCI; Doris Duke Charitable Foundation
	Outcome: • % satisfaction of women with treatment choice after discussing with oncologist or surgeon[IV]	• Overall: Very satisfied: 80% (MA); 76% (MN) • Links: NA		
	• % participation of women with BC in decision-making as much as they wanted[IV]	• Overall: 83% (MA); 81% (MN) • Links: NA		
	• % received enough information about surgery & RT[IV]	• Overall: 80% (MA); 80% (MN) appropriate • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; MA = Massachusetts; MN = Minnesota LN = lymph nodes; BCS = breast-conserving surgery; RT = radiotherapy; n = number; HR = hormone receptor; DCIS = ductal carcinoma in situ; BC = breast cancer; NIH = National Institute of Health; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Khawaja, 2001, UK	**Access:** • % women BC to be seen by specialist within 2 wks of referral (standard: ≥80%) for diagnostic purposes[IV]	• Overall: 100% (22/22) • Soon (<10 d): >65 y: 18.2% (4/22) • Links: NA	• Standard: BASO breast group recommendations 1995/1998 (update) • Data sources: referrals faxed to breast clinic • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: research; internal quality improvement; external quality oversight • Care setting: hospitals; cancer centers • Professionals: GPs; oncologists; surgeons	• Inclusion: convenience sample women BC referred by GP to specialist to diagnose: breast lump; suspicion of malignant change; other breast symptoms • Exclusion: benign disease • Period: 3 mo (1998) • n patients (enrolled/ evaluated): 100/22 • Age (mean & range): 50 (22-90) y • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR
	• % urgent referrals seen within 5 working d (standard: ≥80%)[IV]	• Overall: 82% • By age: 41-65 y: 27.3% (6/22) >65 y: 54.5% (12/22) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC: breast cancer; BASO: British Association of Surgical Oncology; state of use: last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Lagorreta, 2000, US	**Process:** • % appropriate use of BCS when indicated[IV]	• Overall: 63% (474/748) • By stage: Stage 0 & I were 16% (OR: 1.16; S)& 21 % (OR: 1.21; S) respectively, more likely to receive BCS vs stage II pts • By race/ethnicity: Hispanic women 36% less likely to receive BCS vs White women (OR: 0.36; S) By Marital Status (OR): Married: 0.93 Not married/widowed: 1.00 • Links: NA	• Standard: NIH Consensus Conference recommendations, 1990 • Data sources: claims data of Health Net (~1.3 million member); HMO of California; medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: current • Current use: external quality oversight • Care setting: hospitals; cancer centers • Professionals: oncologists; surgeons; GPs	• Inclusion: convenience sample women ≥ 21 y ESBC detected, 1994-1996, with invasive carcinoma (any histological subtype); DCIS; stages 0-II; primary tumor ≤ 5 cm; no evidence multicentricity of tumor; no CI to RT; Paget's disease of breast; eligible for BCS • Exclusion: lobular carcinoma in situ; phyllodes tumor, or sarcoma; primary tumor > 5 cm &/or stage III or IV • Period: 2 y (1994-1996) • n patients (enrolled/ evaluated): 1,017/753 • Age (mean & range): NR (≤ 39- ≥ 65) y • Race/ethnicity: White (72.6%); Hispanic (6.8%); Black (5.2%); unknown (8.5%) • Case characteristics: ESBC stage 0 (8.2%); I (50.1%; II (41.7%), tumor size 1.1-2 cm (45.3%) • Socioeconomic status: Married (61.8%) • Funding: NR

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BCS = breast-conserving surgery; CI = contraindication; CT = chemotherapy; NIH =National Health Institute; ESBC = early stage breast cancer; DCIS = ductal carcinoma in situ; RT = radiotherapy; OR = odds ratio; HMO = Health Maintenance Organization; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Lazovich, 1997, US	**Process:** • % appropriate use of BCS[IV]	• Overall: NR • By stage: Stage I: 54.9% Stage II: 35.2% • By age: <50 y: 52.1% 50-59 y: 54.9% 60-69 y: 47.4% 70-79 y: 39.1% > 80 y: 31.7% S • By payer: Private: 46.2% HMO: 69.9% S • By education: Lowest tertile: 44.9% Middle tertile: 49.9% Highest tertile: 50.9% S • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: SEER cancer registries; medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: national population-based sample women ESBC stage I or II diagnosed in 13 western, Washington counties, 1983-1993 • Exclusion: locally advanced BC; distant metastases; no measurable breast mass; data missing • Period: 3 y (1990-1993) • n patients (enrolled/ evaluated): 18,664/13,541 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: women BC stage I or II; <5 cm • Socioeconomic status: NR • Funding: NCI
	• % appropriate use of RT after BCS[IV]	• Overall: 94.1% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast-conserving surgery; RT = radiotherapy; NIH = National Institute of Health; SEER = Surveillance, Epidemiology and End Results; NCI = National Cancer Institute; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Lazovich, 1999, US	**Process:** • % appropriate use of BCS[IV]	• Overall: NR • By Stage: Stage I: 53.4% (29,234/55,984) Stage II: 32.7% (22,746/53,896) • By Age: <50 y: 48% 50-59 y: 49% 60-69 y: 44.6% 70-79 y: 39.2% ≥80 y: 34.7% • By Race/ethnicity: White: 44.5% Non-White: 43.1% • Per Registry: Iowa: 26.7% Atlanta: 42.1% Utah: 35% New Mexico: 40.1% Hawaii: 46.9% Detroit: 41.2% Connecticut: 55.6% SanFrancisco/Oakland: 50.8% Seattle/Puget Sound: 50% • Links: NA	• Standard: NIH Consensus Conference recommendations, 1990 • Data sources: SEER cancer registries (9 US regions) • Developmental period: NR • Reference Standard(s) (Publication Date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: national population-based sample women ESBC diagnosed in 9 US regions, 1983-1995 • Exclusion: DCIS; Paget's disease; non measurable tumor; tumor > 5 cm; stages III or IV; data missing • Period: 5 y (1990-1995) • n patients (enrolled/ evaluated): 110,235/109,880 • Age (mean & range): NR • Race/ethnicity: White; non-white • Case characteristics: women BC stage I or II; <5 cm • Socioeconomic status: NR • Funding: NIH

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BCS = breast-conserving surgery; RT = radiotherapy; NIH = National Institute of Health; SEER = surveillance, epidemiology and end results; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Lazovich, 1999, US (cont'd)	• % appropriate use RT after BCS[IV]	• Overall: 81.5% (23,042/37,196) • By Stage: Stage I: 83.5% Stage II: 77.4% S • By Age: <50 y: 82.4% 50-59 y: 86.1% 60-69 y: 86.6% 70-79 y: 80.2% ≥80 y: 48.5% S • By Race/ethnicity: White: 81.7% Non-White: 80.7% NS • Links: NA	• See above.	• See above.

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BCS = breast-conserving surgery; RT = radiotherapy; NIH = National Institute of Health; SEER = surveillance, epidemiology and end results; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Mandelblatt, 2001, US	**Process**: • % appropriate use of BCS[IV]	• Overall: 35.5% • By surgeon profile: surgeons with BCS propensity: 44.4% surgeons with mastectomy propensity: 26.8% S • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: claims data from FFS Medicare sector; surveys sent to treating surgeons; telephone surveys with surgeons • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: research • Care setting: hospitals; cancer centers • Professionals: surgeons; oncologists; RT oncologists; GPs	• Inclusion: national random sample, Medicare beneficiaries, ≥ 67 y, newly diagnosed ESBC, 1992-1994; surgeons treating above mentioned group of pts • Exclusion: women ≥ 67 y Stage I, IIA, or IIB BC; bilateral BC; multicentricity of cancer • Period: 6 y (1992-1998) • n patients (enrolled/ evaluated): 3,851/3,851 • n surgeons (enrolled/ evaluated): 1,531/1,000 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: grants: AHRQ & Department of the Army grants
	• % appropriate use of RT after BCS[IV]	• Overall: 72.1% By surgeon profile: surgeons with BCS+ RT propensity: 75.1% surgeons with no RT propensity: 63.2% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NIH = National Institute of Health; FFS = fee-for-service; BCS = breast-conserving surgery; RT = radiotherapy; AHRQ = Agency for Healthcare Research and Quality; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measure - Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Mandelblatt, 2002, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 33% (599/1,833) • By race/ethnicity: Black: 31% (300/984) White: 35% (299/849) NS • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: Medicare data; surgeon contacts; surviving women contacts; 1990 Census File; 1993 & 1995 data from Area Resource File • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; RT oncologists; surgeons; GPs	• Inclusion: national random sample, fee-for service Medicare beneficiary women ≥67 y newly diagnosed primary, unilateral, histologically confirmed stage I-II BC treated, 1994 • Exclusion: previous BC; DCIS without invasive disease; metastatic or multicentric BC; bilateral breast procedures; women BC without surgical procedure; breast surgery not 1st procedure; BC not primary diagnosis; missing data • Period: 1 y (1994) • n patients (enrolled/ evaluated): 6,998/1,833 • Age (mean & range): 74.4 (68.1-80.7) y • Race/ethnicity: Black (53.7%); White (46.3%) • Case characteristics: stage I: Black (53%); White (60%); stage IIA: Black (35%); White (33%); stage IIB: Black (12%); White (7%) • Socioeconomic status: women < poverty level: Black (15.2±7.3%); White (11.8±5.8%); monthly income <U$1,000: Black (54%); White (24%); ≥U$1,000: Black (27%); White (56%); ≤ High school: Black (76%); White (64%); married: Black (32%); White (46%); Medicaid: Black (25%); White (6%); private insurance: Black (43%); White (84%) • Funding: AHRQ; FCCBC; Department of the Army; & NCI grants
	• % appropriate use of RT after BCS[IV]	• Overall: 66.6% (399/599) • By race/ethnicity: Black: 61% (183/300) White: 72.2% (216/299) S • Links: NA		
	• % appropriate use of ALND after BCS or mastectomy[IV]	• Overall: 86% (1,579/1,833) • By race/ethnicity: Black: 88% (867/984) White: 84% (712/849) S • Links: NA		
	• % appropriate use of CT[IV]	• Overall: 9% (172/1,833) • By race/ethnicity: Black: 11% (112/984) S White: 7% (60/849) • Links: NA		
	• % appropriate use of tamoxifen[IV]	• Overall: 62% • By race/ethnicity: Black: 58% (193/331) S White: 66% (263/401) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; DCIS = ductal carcinoma in situ; BCS = breast-conserving surgery; RT = radiotherapy; ALND = axillary lymph node dissection; NIH = National Institute of Health; NCI = National Cancer Institute; AHRQ = Agency for Healthcare Research and Quality; FCCBC = Federal Coordinating Committee on Breast Cancer; state of use = last 3 y; GP = general practitioner; CT = chemotherapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
McCarthy, 1997, UK	**Access:** • %(>90%) of women requiring operation for diagnostic purposes should be admitted within 14 d of surgical decision[IV]	• Overall: 45.5% (5/11) • Links: NA	• Standard: quality assurance guidelines (NHSBSP), 1994 • Data sources: Professional Unit of Surgery's database of Primary Breast Cancers; the Helen Garrod Breast Screening Unit's computerized database; pathology department's computerized histology database; individual hospital case notes • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research; internal quality improvement • Care setting: hospitals; cancer centers • Professionals: oncologists; GPs; surgeons	• Inclusion: convenience sample women operable BC <70 y treated at Nottingham City Hospital's, 1994 Professional Unit of Surgery • Exclusion: NR • Period: 1 y (1994) • n patients (enrolled/ evaluated): 251/251 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NR
	• % (90%) of women admitted for operation within 21 d of surgical decision to operate for therapeutic purposes[IV]	• Overall: 90.4% (75/83) • Links: NA		
	Process: • % (>90%) women BC detected by screening should attend assessment center within 3 wks of mammography[IV]	• Overall: 42.7% (32/75) • Links: NA		
	• % (>70%) appropriate use of pre-operative diagnosis of cancer by cytology or needle histology[IV]	• Overall: 86.7% (72/83) • Links: NA		
	• % (>95%) appropriate use of first localization biopsy operation to correctly identify impalpable lesions[IV]	• Overall: 100% (11/11) • Links: NA		
	• % (90%) appropriate use of operations carried out with proven pre-operative diagnosis of cancer (in situ or invasive) should not require a further operation for incomplete excision[IV]	• Overall: 80.3% (49/61) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; BCS = breast-conserving surgery; n = number of participants; enrolled = n qualified; evaluated = n analyzed; NHSBSP = national coordination group for surgeons working in breast cancer screening; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
McGlynn, 2003, US	**Process:** • % (Appropriate use): If a palpable breast mass has been detected, at least one of the following procedures should be completed within 3 months: fine-needle aspiration, mammography, ultrasound, biopsy and/or a followup visit[IV]	• Overall: 89.1% (n = 77) • Links: NA	• Standard: from observational studies and expert opinion, to randomized controlled trials • Data sources: telephone survey; medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; pathology centers • Professionals: oncologists; surgeons GPs; RT oncologists	• Inclusion: random sample women living in 12 US metropolitan areas • Exclusion: leaving the area; refusal to be interviewed • Period: 2 y (1998-2000) • n patients (enrolled/ evaluated): 192/192 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: Robert Wood Johnson Foundation
	Process: • % (Appropriate use): If a breast mass has been detected on two separate occasions, then either a biopsy, fine-needle aspiration or ultrasound should be performed within 3 months of the second visit[IV]	• Overall: 81.6% (n = 13) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; QI = quality indicator; CI = confidence interval; state of use = last 3 y; RT = radiotherapy; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
McGlynn, 2003, US (cont'd)	**Process:** • % (Appropriate use): A biopsy or fine-needle aspiration should be performed within 6 weeks either when the mammography suggests malignancy or the persistent palpable mass is not cystic on ultrasound[IV]	• Overall: 50.2% (n = 33) • Links: NA	See above.	See above.
	Process: • % (Appropriate use): A biopsy should be performed within 6 weeks if fine needle aspiration cannot rule out malignancy[IV]	• Overall: 100% (n = 2) • Links: NA		
	Process: • % (Appropriate use): Women with stage I or stage II breast cancer should be offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery are present[IV]	• Overall: 50.2% (n = 13) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; QI = quality indicator; CI = confidence interval; state of use = last 3 y; RT = radiotherapy; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
McGlynn, 2003, US (cont'd)	**Process:** • % (Appropriate use): Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 wks of primary resection) or chemotherapy, if patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment[IV]	• Overall: 45.3% (n = 10) • Links: NA	See above.	See above.
	Process: • % (Appropriate use): Women with invasive breast cancer that is node-positive, or node-negative and primary tumor ≥ 1 cm, should be treated with adjuvant systemic therapy to include combination chemotherapy (and/or tamoxifen, 20mg/d) [IV]	• Overall: 85.1% (n = 13) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; QI = quality indicator; CI = confidence interval; state of use = last 3 y; RT = radiotherapy; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
McGlynn, 2003, US (cont'd)	**Process:** • % (Appropriate use): Women with a history of breast cancer should have a yearly mammography[IV]	• Overall: 84.6% (n = 99) • Links: NA	See above.	See above.
	Process: • % (Appropriate use): Women with metastatic breast cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent within 6 wks of the identification of metastases[IV]	• Overall: 82.6% (n = 4) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; QI = quality indicator; CI = confidence interval; state of use = last 3 y; RT = radiotherapy; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Molenaar, 2001, Netherlands	**Outcome**: • % satisfaction of women BC with treatment choice[Iac]	• Overall: positive effect (CDROM) 0, 3 & 9 mo; no data • Links: NA	• Standard: IKA/IKST: Working group on Mamma Carcinoma; treatment guidelines; the Netherlands; Comprehensive Cancer Center, 1995 • Instrument(s): MOS20; EORTC QLQ-BR23 • Data sources: pt self-reported questionnaires; 3 hospitals, Netherlands • Developmental period: NR • Reference standard(s) (Publication Date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; surgeons; GPs; RT oncologists	• Inclusion: convenience sample women, newly diagnosed stage I & II BC eligible for BCS or mastectomy • Exclusion: no Dutch spoken • Period: 2 y (1996-1998) • n patients (enrolled/ evaluated): 180/167 • Age (mean & range): 55.4 (44.6-66.2) y (CDROM group); 54.6 (44-65.2) y (standard care) • Race/ethnicity: NR • Case characteristics: ESBC node (-) (52-57%) • Socioeconomic status: married (53-66%); employed (45-52%) • Funding: Dutch Cancer Society
	• % change in QOL over time; generic QOL scales (higher scores = better QOL; except for pain scores)][Iac]	• Overall: positive effect (CDROM) 0, 3 & 9 mo; no data • Links: NA		
	• % change in QOL over time; BC-specific QOL scales (higher scores = better functioning; except for symptoms scales)[Iac]	• Overall: positive effect (CDROM) 0, 3 & 9 mo; no data • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; ESBC = early stage breast cancer; BCS = breast-conserving surgery; QOL = quality of life; MOS20 = medical outcomes study 20 (general health; physical functioning; pain; role functioning; social & psychosocial functioning); EORTC QLQ-BR23: European Organization for Research and Treatment of Cancer Quality of Life-specific for BC pts (body image; sexual functioning; arm symptoms; breast symptoms; systemic therapy symptoms; & future perspective); state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Mor, 1994, US	**Outcome:** • %change in QOL over time[Ia]	• Overall: NR • By age: 24-54 y: 67.6% >55 y: 71% • Links: NA	• Instrument(s): MHI-5 • Data sources: medical records; telephone interview with pts • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: decision-making; research • Care setting: hospitals; cancer centers • Professionals: oncologists; surgeons; GPs	• Inclusion: convenience sample women BC from 2 research samples • Exclusion: NR • Period: NR • n patients (enrolled/ evaluated): 262/262 • Age (mean & range): NR (24->55) y • Race/ethnicity: White 92.4% • Case characteristics: women BC; local/regional disease; CT (80%) • Socioeconomic status: employed (14.3-51.8%); married (52.9-67.7%); family income > U$ 30,000 (17.6-49.7%) • Funding: NCI

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; QOL = quality of life; BC = breast cancer; state of use = last 3 y; NCI = National Cancer Institute; CT = chemotherapy; MHI-5 = Mental Health inventory (5-item scale for medically ill population); GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Mor, 2000, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 64.1% • Links: NA	• Standard: NCI Consensus Conference for surgeons, 1993 • Data sources: hospital cancer registry (6 hospitals in Rhode Island, US); pathology reports; medical records; pt interviews • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement; external quality oversight, research • Care setting: hospitals; cancer centers • Professionals: surgeons; oncologists	• Inclusion: random sample women > 60 y BC stage I or II diagnosed at 6 hospitals, Providence, RI, Nov 1992 & Feb 1997 • Exclusion: women with BC <60 y; not eligible patients for intervention (low-volume surgeons) • Period: 5 y (1992-1997) • n patients (enrolled/ evaluated): 1,144/350 • Age (mean & range): NR (60->80 y) • Race/ethnicity: NR • Case characteristics: women BC stage I, II or DCIS; >1cm (74.9%); ER/PR known (94.7%); node (-) (38.6%), node (+) (13.1%) • Socioeconomic status: NR • Funding: NCI
	• % appropriate use of RT after BCS[IV]	• Overall: 70.4 % • By age: 60-69 y: 94% 70-79 y: 83% > 80 y: 34% S • Links: NA		
	• % appropriate use of any adjuvant systemic therapy (CT &/or HT); tumor ≥ 1 cm[IV]	• Overall: 81.9% • By age: 60-69 y: 88% 70-79 y: 82% >80 y: 77% S • Links: NA		
	• % appropriate use of treatment sequences recommended or received (if tumor <1 cm, then mastectomy or BCS + RT. If tumor ≥ 1 cm then mastectomy or BCS + RT & CT &/or HT) [IV]	• Overall: 72.9% • By age: 60-69 y: 89% >80 y: 50% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BCS = breast -conserving surgery; CT = chemotherapy; RT = radiotherapy; HT = hormone therapy; ER = estrogen receptor; PR = progesterone receptor; CPG = clinical practice guidelines; NCI = National Cancer Institute; state of use = last 3 y; DCIS = ductal carcinoma in situ; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Morrow, 2001, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 42.6% (7,097/16,643) • By age: 21-49 y: 48.2% 50-69 y: 45% > 70 y: 34% S • By race/ethnicity: White: 42.5% Black -H: 43.7% • By payer: Government: 36.9% Private: 48.4% S • Links: NA	• Standard: ACOS, ACR, CAP, SSO guidelines, 1992 • Data sources: Medicare patients, NY State acute care hospitals, 1999 (n=1,718); medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: current • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: surgeons; RT oncologists; oncologists	• Inclusion: population-based sample women stage I-II BC receiving diagnosis & initial course of treatment at participating institution, 1994 • Exclusion: staging not performed or incomplete; pT3 tumours; surgery other than BCS or mastectomy • Period: 1 y (1994) • n patients (enrolled/ evaluated): 17,931/16,643 • Age (mean & range): 60.8 (21->70) y • Race/ethnicity: White (85.9%); Black (7.8%); Hispanic (2.9%) • Case characteristics: clinical stage I (41.5%); stage II (20.8%); pT1 (68%); pT2 (32%); pN0 (75.5%); pN1 (24.5%); ER (+) (65.6%); PR (+) (56.7%); infiltrating ductal, lobular (92.6%); postmenopausal (70.9%) • Socioeconomic status: Medicare (42.1%) • Funding: Patterns of Care Study
	• % appropriate use of RT after BCS[IV]	• Overall: 86% (6,099/7,097) • By age: <70 y: 88.4% ≥70 y: 78.9% • By race/ethnicity: White: 86.3% Black -H: 83.2% Other: 81.9% • By payer: Government: 83.3% Private: 88.5% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; enrolled = n qualified; evaluated = n analyzed; ACOS = American College of Surgeons; ACR = American College of Radiology; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; BCS = breast-conserving surgery; pT = pathologic tumour size; pN = pathologic nodal status; RT = radiotherapy; state of use = last 3 y; *BCT = tumor excision; axillary dissection & breast irradiation for stage I & II BC; NY = New York; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre-*and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures - Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Nattinger, 2000, US	**Process:** • % appropriate use of definitive locoregional therapy (total mastectomy + ALND, or BCS + ALND + RT) [IV]	• Overall: 78% (1995) • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: NCI SEER registry; federal ARF information • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: surgeons; oncologists; RT oncologists; GPs	• Inclusion: national population-based sample women aged ≥30 y at time of first diagnosis of invasive local or regional unilateral BC, 1983-1995 • Exclusion: no primary BCS or mastectomy, or type of surgery unknown; date of diagnosis unknown; delivery of RT unknown • Period: 13 y (1983-1995) • n patients (enrolled/ evaluated): 147,432/144,759 • Age (mean & range): NR (30->80) y • Race/ethnicity: White (87.3%); Black (7.1%) • Case characteristics: BC local (65%); regional (35%) • Socioeconomic status: NR • Funding: Department of Defence
	• % appropriate use of mastectomy with ALND [IV]	• Overall: 97.3% • Links: NA		
	• % appropriate use of BCS with ALND & RT [IV]	• Overall: 65% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; enrolled = n qualified; evaluated = n analyzed; NCI = National Cancer Institute; SEER = Surveillance, Epidemiology, and End Results; ALDN = axillary lymph node dissection; BCS = breast-conserving surgery; RT = radiotherapy; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Northouse, 1999, US	**Outcome:** • % change in QOL after diagnosis of BC*[Iac]	• Overall: QOL (FACT-B): Mean: 116.5 (SD 20.7); (range 44-145) In average: fairly high QOL scale • By variables: Node (+): lower QOL (mean: 110.8) than node (-) (mean: 120.7) Recurrence of cancer: lower QOL (mean: 107.1) vs no recurrence (mean: 118.2) • Links: NA	• Standard: BC specific version of 37-item scale FACT-B, 1993 (physical & family well-being; relationship with MD; emotional & functional well-being) • Data sources: medical oncology offices, Southeastern region, Michigan, pts self-reported status using Questionnaire forms • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers; • Professionals: oncologists	• Inclusion: convenience sample of black women confirmed diagnosis of BC at least 1 mo post-diagnosis, Southeastern region, Michigan • Exclusion: pts refusal to participate in study • Period: NR • n patients (enrolled/ evaluated): 140/98 • Age (mean & range): 55 (29-81) y • Race/ethnicity: Black (100%) • Case characteristics: BC radical mastectomy (70%); node (-) (57.4%) • Socioeconomic status: working (54.2%); retired (38.6%); unemployed (7.2%); Income < U$15,000 29.7%); married (41%) • Funding: Dean's discretionary fund grant; Wayne State University

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; enrolled = n qualified; evaluated = n analyzed; QOL = quality of life; FACT-B = functional assessment of cancer therapy scale (version 3); state of use = last 3 y; *Higher scores = better QOL; MD = medical doctor; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Osoba, 1999, Canada & US	**Outcome:** • change in QOL in women with metastatic BC treated with trastuzumab assessed by self-administered EORTC core QOLQ – C30 baseline & wks 12; 24; 36[Ia]	• Overall: NR By phase of study: Phase II: no apparent worsening of scores Phase III: NS changes • Links: NA	• Instrument: self-administered EORTC core QOLQ- C30 (30 items) (global score; physical; social; role functions & fatigue in phase II & III of clinical trial) scale 0-100* • Data sources: pts self-reported status using EORTC QOL questionnaire C30 • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers; • Professionals: oncologists	• Inclusion: convenience sample women progressive HER-2- overexpressing metastatic BC previously treated with CT (phase II), or who had not had previous cytotoxic CT (phase III) received trastuzumab • Exclusion: NR • Period: 32 wks • n patients (enrolled/ evaluated): 207/154 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: women with metastatic BC with or without previous CT • Socioeconomic status: NR • Funding: Genentech, Inc.

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; EORTC = European Organization for Research and Treatment of Cancer; QOL = quality of life; QOLQ = quality of life questionnaire; state of use = last 3 y; * Higher scores = better QOL (except in fatigue); Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Ottevanger, 2002, Netherlands	**Process:** • % appropriate use of BCS[IV]	• Overall: 55.5% (141/254) • Links: 5-y OS BCS 77% vs. mastectomy 77 % NS 5-y DFS: BCS 59% vs. mastectomy 65% NS	• Standard: Regional Guidelines (CCCE) (year: NR) • Data sources: Regional Cancer Registry & PALGA (Dutch National Pathology Registration System) • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; quality of care reporting; research • Care setting: hospitals; pathology centers • Professionals: pathologists; oncologists; surgeons	• Inclusion: population-based sample premenopausal women, node (+) BC stages II-IIIA treated in 9 hospitals using the guidelines, 1988-1992 • Exclusion: 1 hospital opposed to CT treatment of the CPG • Period: 5 y (1993-1998) • n patients (enrolled/ evaluated): 254/254 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: premenopausal women, node (+) BC stages II-IIIA • Socioeconomic status: NR • Funding: Comprehensive Cancer Centre East (CCCE)
	• % appropriate use of mastectomy in large or multifocal tumors, tumor fixed to pectoral muscle or fascia or skin[IV]	• Overall: 44.5% (113/254) • Links: 5-y OS BCS 77% vs. mastectomy 77% NS 5-y DFS: BCS 59% vs. mastectomy 65% NS		
	• % appropriate use of RT after BCS[IV]	• Overall: 100% (141/141) • Links: NA		
	• % appropriate use of RT in axilla for extracapsular extension of ALN metastases[IV]	• Overall: 84.7% (72/85) • Links: locoregional relapse rate: 9.4% (received) vs. 14.3% (not) NS 5-y OS: 76% (received) vs. 77% (not) NS		
	• % appropriate use of parasternal RT for tumors located medial part of breast[IV]	• Overall: 49.1% (56/114) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; LN = lymph nodes; BCS = breast -conserving surgery; RT = radiotherapy; CPG = clinical practice guideline; ER = estrogen receptor; PR = progesterone receptor; BC = breast cancer; ALN = axillary lymph nodes; CMF= cyclophosphamide/methotrexate/5-fluorouracil; CT = chemotherapy; state of use = last 3 y; CCCE = Comprehensive Cancer Center East; DFS = disease-free survival; OS = overall survival; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Ottevanger, 2002, Netherlands (cont'd)	• % quality of CT: proper doses administered (≥85% DI & RDI) of CMF[IV]	• Overall: 78.9% (DI); 58.7% (RDI) • Links: 5-y OS <65% DI: 50% vs. >85%: 77% S 5-y DFS: <65% DI: 44% vs. >85%: 61% S	• See above.	• See above.
	• % reporting n axillary LN investigated[IV]	• Overall: • By n nodes: ≥10: 59.2% (138/233) <10: 40.8% (95/233) • Links: 5-y OS: <10 nodes 72% vs. ≥10 nodes 81% NS 5-y DFS: <10 nodes 59% vs. ≥10 nodes 64% NS		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; LN = lymph nodes; BCS = breast -conserving surgery; RT = radiotherapy; CPG = clinical practice guideline; ER = estrogen receptor; PR = progesterone receptor; BC = breast cancer; ALN = axillary lymph nodes; CMF= cyclophosphamide/methotrexate/5-fluorouracil; CT = chemotherapy; state of use = last 3 y; CCCE = Comprehensive Cancer Center East; DFS = disease-free survival; OS = overall survival; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Palazzi, 2002, Italy	**Process:** • % appropriate decision not to provide adjuvant systemic therapy for women node (-), low risk BC[IV]	• Overall: 69% (59/85) • Links: NA	• Standard: SGCC, 1995 • Data sources: database of 12 centers participating • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: RT centers • Professionals: RT oncologists; oncologists; surgeons; clinicians	• Inclusion: convenience sample women with prescription of RT to breast after BCS for infiltrating carcinoma & known ALN status • Exclusion: previous or synchronous surgery for cancer in contralateral breast • Period: 1 y (1997) • n patients (enrolled/ evaluated): 1,610/ 1,547 • Age (mean & range): 55 (25-82) y • Race/ethnicity: NR • Case characteristics: women ESBC; premenopausal (31%); T1 stage (81%); ER (+) (65%); node (+) (31%) • Socioeconomic status: NR • Funding: NR
	• % appropriate use of tamoxifen in premenopausal women BC; node (-); intermediate risk[IV]	• Overall: 33% • Links: NA		
	• % appropriate use of tamoxifen postmenopausal women BC; node (-); intermediate risk[IV]	• Overall: 59% • Links: NA		
	• % appropriate use of CT premenopausal women BC; node (-); high risk; ER (+)[IV]	• Overall: 55% • Links: NA		
	• % appropriate use of tamoxifen postmenopausal women BC; node (-); high risk; ER (+)[IV]	• Overall: 59% • Links: NA		
	• % appropriate use of CT women BC node (-); high risk; ER (-)[IV]	• Overall: 59% • Links: NA		
	• % appropriate use of CT premenopausal women BC node (+); ER (-)[IV]	• Overall: 90% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; SGCC = St Gallen consensus conference; RT = radiotherapy; ESBC = early stage breast cancer; BCS = breast-conserving surgery; ER = estrogen receptor; CT = chemotherapy, OA = ovarian ablation; (+) = positive; (-) = negative; state of use = last 3 y; ALN = axillary lymph node; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Palazzi, 2002, Italy (cont'd)	• % appropriate use of CT &/or OA premenopausal women BC node (+); ER (+)[IV]	• Overall: NR • By treatment: CT: 73% CT+ OA: 18% OA: 4% • Links: NA	See above.	See above.
	• % appropriate use of CT postmenopausal women BC node (+); ER (-)[IV]	• Overall: 81% • Links: NA		
	• % appropriate use of tamoxifen postmenopausal women BC node (+);ER (+)[IV]	• Overall: 40% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; SGCC = St Gallen consensus conference; RT = radiotherapy; ESBC = early stage breast cancer; BCS = breast-conserving surgery; ER = estrogen receptor; CT = chemotherapy, OA = ovarian ablation; (+) = positive; (-) = negative; state of use = last 3 y; ALN = axillary lymph node; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Perez, 2001, New Zealand UK	**Outcome:** • % change in QOL & TTO scales during 1 y in metastatic disease*[Iac]	• Overall: NR • Links: NA	• Instrument: HRQOL scale: Spitzer QLI & uniscale questionnaire (scale 0-100); TTO • Data Sources: pts self-reported status (questionnaires) • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement • Care setting: hospitals; cancer centers • Professionals: oncologists	• Inclusion: Convenience sample women presenting at Dunedin Hospital, NZ, with metastatic symptoms BC • Exclusion: refused to complete TTO scale • Period: 1 y (NR) • n patients (enrolled/ evaluated): 64/38 • Age (mean & range): 58.7 (30-80) y • Race/ethnicity: NR • Case characteristics: women advanced metastatic symptomatic BC • Socioeconomic status: NR • Funding: Cancer Society of NZ

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; QLI = quality of life index; BC = breast cancer; state of use = last 3 y; HRQOL = health related quality of life; QOL = quality of life; * Higher scores = better QOL; NZ = New Zealand; TTO = time trade-off; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Ray-Coquard, 1997, France	• % appropriate use of treatment sequences according to guidelines (including all medical decisions on surgery; RT; CT; HT; initial examination & follow-up) [IV]	• Overall: 54% (53/99) • Links: NA	• Standard: regional CPG, 1993; implemented, 1994 • Data sources: medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement; external quality oversight, decision-making; research • Care setting: hospitals; cancer centers; RT centers • Professionals: surgeons; oncologists; RT oncologists	• Inclusion: random sample women newly diagnosed localized BC (DCIS to nonmetastatic invasive carcinoma) in cancer center, Rhone Alpes area, France • Exclusion: concomitant health care (e.g. genetic counselling; pain treatment; plastic surgery); early death; missing data in records; tumor size not recorded • Period: 1 y (1995) • n patients (enrolled/ evaluated): 701/99 • Age (mean & range): 51 (26-90) y • Race/ethnicity: NR • Case characteristics: localized ESBC; node (-) 66%; ER (+) 57%, DCIS 18% • Socioeconomic status: NR • Funding: NR
	• % appropriate use of initial examination [IV]	• Overall: 86% (61/71) • Links: NA		
	• % appropriate use of surgery [IV]	• Overall: 92% (91/99) • Links: NA		
	• % appropriate use of CT [IV]	• Overall: 85% (84/99) • Links: NA		
	• % appropriate use of RT [IV]	• Overall: 93% (92/99) • Links: NA		
	• % appropriate use of HT (tamoxifen) [IV]	• Overall: 94% (93/99) • Links: NA		
	• % appropriate use of follow-up [IV]	• Overall: 80% (68/85) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; CT = chemotherapy; RT = radiotherapy; HT = hormone therapy; ER = estrogen receptor; PR = progesterone receptor; CPG = clinical practice guidelines; DCIS = ductal carcinoma in situ; BC = breast cancer; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Ray-Coquard, 2002, France	**Process:** • % appropriate use of treatment sequences according to CPG (including surgery; RT; CT; HT; initial examination; follow-up) [IV]	• Overall: 36% • By intervention: Initial examination: 86% Surgery: 94% CT: 78% RT: 77% HT: 79% Follow-up: 81% • Links: NA	• Standard: Regional (ONCORA) CPG, 1995 • Data sources: institutional records • Developmental period: NR • Reference standard(s) (Publication Date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers • Professionals: oncologists; surgeons; GPs	• Inclusion: random sample women newly referred localized BC (in situ or invasive) treated in cancer network, Rhone-Alpes Area, France, 1996 • Exclusion: record with data missing (surgical biopsy), metastases, patients refused surgery, no axillary dissection, treatment CI • Period: 1 y (1996) • n patients (enrolled/ evaluated): 367/ 346 • Age (mean & range): 60 (30-91) y • Race/ethnicity: NR • Case characteristics: women localized BC, T1-T3 or In situ, 17 mm, HR (+) 61% • Socioeconomic status: NR • Funding: Ministry of Health (France)

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; BCS = breast-conserving surgery; RT = radiotherapy; HR = Hormone receptor; CI = contraindication; CT = chemotherapy; HT = hormone therapy; CPG = clinical practice guidelines; state of use = last 3 y; GP = general practitioner; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Sauven, 2003, UK	**Process:** • % appropriate use of preoperative diagnosis by FNA cytology, needle histology or biopsy (minimum: ≥70%; target standard: ≥90%)[IV]	• Overall: NR • By y: 1996/97: 63% 1997/98: 71% 1998/99: 81% 1999/2000: 85% 2000/01: 87% • Links: NA	• Standard: NHSBSP surgical standards, 1992 • Data sources: regional boundaries; KC62 Korner returns; breast screening unit records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: surgeons; oncologists; pathologists	• Inclusion: population-based sample BC women detected by screening UK, Wales, Scotland & Northern Ireland, 1996-2001 • Exclusion: NR • Period: 5 y (1996-2001) • n patients (enrolled/ evaluated): 43,500/43,500 • n surgeons (enrolled/ evaluated): 1,531/1,000 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: NR • Socioeconomic status: NR • Funding: NHSBSP
	• % quality of technique to determine histological node status obtained for all invasive tumors by sampling or clearance[IV]	• Overall: NR • By y: 1996/97: 81% 1997/98: 87% 1998/99: 90% 1999/2000: 93% 2000/01: 93% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NHSBSP = national health service breast screening program; FNA = fine-needle aspiration; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Sauven, 2003, UK (cont'd)	• % quality of sampling for invasive cancer: to include ≥ 4 nodes[IV]	• Overall: NR • By y: 1996/97: 89% 1997/98: 91% 1998/99: 93% 1999/2000: 94% 2000/01: 95% • Links: NA	• See above.	• See above.
	Structure: • % management of cases coming to surgery from screening program carried out by surgeons who have acquired necessary specialist knowledge[IV]	• Overall: NR • By y & case load: > 30 pts/y, high*: 1996/97: 63% 1997/98: 67% 1998/99: 66% 1999/2000: 71% 2000/01: 72% < 10 pts/y, low: 1996/97: 8% 1997/98: 7% 1998/99: 7% 1999/2000: 6% 2000/01: 5% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NHSBSP = national health service breast screening program; FNA = fine-needle aspiration; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Sauven, 2003, UK (cont'd)	**Access:** • % (≥90%) women requiring an operation for diagnostic purposes should be admitted within 14 d of surgical decision [IV]	• Overall: NR • By y: 1996/97: 60% 1997/98: 52% 1998/99: 52% 1999/2000: 60% • Links: NA	• See above.	• See above.
	• % (≥90%) women admitted for operation within 21 d of surgical decision to operate for therapeutic purposes[IV]	• Overall: NR • By y: 1996/97: 82% 1997/98: 81% 1998/99: 80% 1999/2000: 77% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NHSBSP = national health service breast screening program; FNA = fine-needle aspiration; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Sawka, 1997, Canada	**Process**: • % appropriate decision not to provide adjuvant systemic therapy in <50 y; low risk[IV]	• Overall: 84.9% • Links: NA	• Standard: Guidelines of British Columbia, 1991 • Data Sources: Provincial Cancer Registry; medical records; other databases (e.g. drug data) • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; oncology centers; RT centers • Professionals: oncologists; surgeons; RT oncologists	• Inclusion: population-based sample women BC node (-) diagnosed, British Columbia, 1991 • Exclusion: age> 90 y; diagnosis by death certificate; death within 30 days of diagnosis; stage III or IV; in situ disease; non-epithelial malignancies & any previous invasive cancer or history of DCIS; node (+) or unknown nodal status • Period: 5 y (1993- 1998) • n patients (enrolled/evaluated): 2,317/932 • Age (mean & range): NR (<50->65) y • Race/ethnicity: NR • Case characteristics: women BC node (-); tumor <2 cm (62.1%); LVN invasion (68.8%); ER (+) (60.4%); PR (+) (38.9%) • Socioeconomic status: income >U$ 50,000/ y (26.1%); rural residence (15.4%) • Funding: NCI of Canada (Canadian Cancer Society) & National Health Scholar Award from Health Canada
	• % appropriate use of CT in <50 y; high risk; presence of LVN invasion; or tumor > 2 cm; if ER (-)[IV]	• Overall: 78.6% • Links: NA		
	• % appropriate decision not to provide adjuvant systemic therapy in 50-65 y low risk[IV]	• Overall: 90.3% • Links: NA		
	• % appropriate use of tamoxifen & CT or tamoxifen in 50-65 y; high risk; ER (+)[IV]	• Overall: 6.6% (tamoxifen & CT) 62.3% (tamoxifen) • Links: NA		
	• % appropriate use of CT in 50-65 y; high risk; ER (-)[IV]	• Overall: 19.1% • Links: NA		
	• % appropriate use of adjuvant systemic therapy in >65 y; low risk[IV]	• Overall: 85.9% • Links: NA		
	• % appropriate use of tamoxifen in >65 y; high risk; ER (+)[IV]	• Overall: 56.5% • Links: NA		
	• % appropriate decision not to provide adjuvant systemic therapy in > 65 y; high risk; ER (-)[IV]	• Overall: 82.1% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; LN = lymph nodes; LVN = lymph, vessels or nerves invasion; RT= radiotherapy; ER = estrogen receptor; PR = progesterone receptor; BC = breast cancer; CT = chemotherapy; NCI = National Cancer Institute; DCIS = ductal carcinoma in situ; state of use = last 3 y; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Shank, 2000, US	**Structure:** • % pathology reports on chart[IV]	• Overall: 99.7% (725/727) • Links: NA	• Standard: ACR, ACS, CAP & SSO standards for breast conservation treatment, 1992 • Data sources: survey; medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: quality of care reporting; internal quality improvement • Care setting: hospitals; cancer centers; pathology centers • Professionals: RT oncologists, surgeons; pathologists; oncologists	• Inclusion: random sample women stage I-II invasive BC treated, 1993-1994 • Exclusion: pts not treated 1993-1994; males; purely non-invasive carcinoma; not stage I-II BC; gross multicentric disease; bilateral lesion; prior or concurrent malignancies; mastectomy as primary treatment • Period: 2 y (1995-1996) • n patients (enrolled/ evaluated): 993/727 • Age (mean & range): NR (20->80) y • Race/ethnicity: White (84.2%); Black (7.3%); Hispanic (4.4%); Asian (2.8%) • Case characteristics: age >50 y (70%); stage I or II invasive BC; postmenopausal (68.6%) • Socioeconomic status: NR • Funding: NCI
	Process: • % appropriate use of preoperative mammographic evaluation (performed ≤3 mo) [IV]	• Overall: 91.5% (665/727) • Links: NA		
	• % reporting identification of affected quadrant[IV]	• Overall: 97.8% (711/727) • Links: NA		
	• % reporting clinical size of primary tumor[IV]	• Overall: 45.9% (334/727) • Links: NA		
	• % reporting final gross surgical margins[IV]	• Overall: 96.8% (704/727) • Links: NA		
	• % reporting final microscopic surgical margins[IV]	• Overall: 95.6% (695/727) • Links: NA		
	• % reporting histopathological type	• Overall: 99.7% (725/727) • Links: NA		
	• % reporting intraductal carcinoma quantification[IV]	• Overall: 8.5% (62/727) • Links: NA		
	• % reporting of extent of primary tumor[IV]	• Overall: 99.3% (722/727) • Links: NA		
	• % reporting size of invasive component[IV]	• Overall: 8.5% (62/727) • Links: NA		
	• % reporting total pathological tumour size[IV]	• Overall: 95.3% (693/727) • Links: NA		
	• % reporting ER status[IV]	• Overall: 89% (647/727) • Links: NA		
	• % reporting PR status[IV]	• Overall: 86.4% (628/727) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; enrolled = n qualified; evaluated = n analyzed; ACR = American College of Radiology; ACS = American College of Surgeons; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ER = estrogen receptors; PR = progesterone receptors; state of use = last 3 y; RT = radiotherapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Shank, 2000, US (cont'd)	• % reporting performing flow cytometry [IV]	• Overall: 95.3% (693/727) • Links: NA	• See above.	• See above.
	• % reporting cytometry ploidity[IV]	• Overall: 98.9% (719/727) • Links: NA		
	• % reporting pathological node status [IV]	• Overall: 92% (670/727) • Links: NA		
	• % quality of RT: wedges on tangent breast fields[IV]	• Overall: 92.8% (671/723) • Links: NA		
	• % quality of RT: both tangent fields treated daily [IV]	• Overall: 99.9% (724/725) • Links: NA		
	• % quality of RT: 4,500-5,000 cGy total breast dose given to 180-200 cGy fractions[IV]	• Overall: 99% (723/725) • Links: NA		
	• % quality of RT: electron beam breast radiation used[IV]	• Overall: 94% (681/725) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BC = breast cancer; enrolled = n qualified; evaluated = n analyzed; ACR = American College of Radiology; ACS = American College of Surgeons; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ER = estrogen receptors; PR = progesterone receptors; state of use = last 3 y; RT = radiotherapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Silliman, 1999, US	**Process:** • % appropriate use of definitive locoregional therapy (total mastectomy + ALND or BCS with ALND + RT) [IV]	• Overall: 77.2% (234/303) • By surgery type: BCS + RT: 56% Mastectomy: 22% • By income: ≤U$14,999: 55% $15,000-29, 999: 85% $30,000-49,999: 91% ≥$50,000: 87% • By education: <High school: 55% High school: 75% Some College: 83% College: 82% • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: medical records; 35-minute computer-assisted telephone interview with pts; Physicians Profiles database of the Board of Registration in Medicine of the Commonwealth of MA • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight • Care setting: hospitals; cancer centers; RT centers • Professionals: oncologists; RT oncologists; GPs	• Inclusion: convenience sample women ≥55 y newly diagnosed stage I or II BC treated in 1/5 academic centers, Boston • Exclusion: NR • Period: NR • n patients (enrolled/ evaluated): 303/303 • Age (mean & range): 67.7 (55-97) y • Race: White (93%) • Case characteristics: stage I (64%) • Socioeconomic status: income: ≤ U$14,999 (17.5%); $15,000-$29,999 (19.8%); $30,000-$49,999 (21.1%); >$50,000 (17.5%); married (48.8%); ≥ High school (83%) • Funding: NCI, NHI; US ARDALC
	• % appropriate use of any adjuvant systemic therapy (CT &/or HT) [IV]	• Overall: 67.3% (204/303) • By adjuvant therapy: HT alone: 76% CT alone: 13% HT + CT: 11% • By income: ≤U$14,999: 64% $15,000-29,999: 60% $30,000-49,999: 77% ≥$50,000: 73% • By education: < High school: 60% High school: 68% Some College: 64% College: 72% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NCI = National Cancer Centre; NIH = National Health Institute; ARDALC = Army Research, Development, Acquisition and Logistic Command; MA = Massachusetts; state of use = last 3 y; GP = general practitioner; RT = radiotherapy; CT = chemotherapy; HT = hormone therapy; BCS = breast-conserving surgery; ALND = axillary lymph node dissection; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Silliman, 1999, US (cont'd)	• % appropriate use of alternative definitive therapy (both tumor therapy & adjuvant systemic therapy) [IV]	• Overall: 51.8% (157/303) • By age: 55-64 y: 50% (78/157) 65-74 y: 41% (65/157) 75-84 y: 9% • Links: NA	• See above.	• See above.

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; NCI = National Cancer Centre; NIH = National Health Institute; ARDALC = Army Research, Development, Acquisition and Logistic Command; MA = Massachusetts; state of use = last 3 y; GP = general practitioner RT = radiotherapy; CT = chemotherapy; HT = hormone therapy; BCS = breast-conserving surgery; ALND = axillary lymph node dissection; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/ Developmental History/Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Solin, 1999, US	**Process:** • % appropriate use of BCS[IV]	• Overall: 65% (62/95) • Links: NA	• Standard: NIH Consensus Development Conference, 1990 • Data sources: HMO claim database; medical records • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: hospitals; pathology centers; RT centers; cancer centers • Professionals: pathologists; oncologists; surgeons; GPs	• Inclusion: convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC <5cm in diameter • Exclusion: LCIS; bilateral carcinoma • Period: 2 y (1993-1994) • n patients (enrolled/ evaluated): 130/130 • Age (mean & range): 72 (65-91) y • Race/ethnicity: White (83%); Black (5%) • Case characteristics: DCIS (6%); invasive BC (94%); tumor size (<1cm 23%; 1.1-2 cm 26%; 2.1-3 cm 12%); stages 0-IV; node (-) (73%) • Socioeconomic status: NR • Funding: NR
	• % appropriate use of RT after BCS[IV]	• Overall: 89% (55/62) • Links: NA		
	• % appropriate use of definite breast irradiation in DCIS[IV]	• Overall: 60% (3/5) • Links: NA		
	• % appropriate use of definite breast irradiation in stage I-II [IV]	• Overall: 91% (52/57) • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; BCS = breast-conserving surgery; RT = radiotherapy; DCIS = ductal carcinoma in situ; BC = breast cancer; NIH = National Institute of Health; state of use = last 3 y; GP = general practitioner; HMO = health maintenance organization; LCIS = lobular carcinoma in situ; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
Tyldesley, 2003, Canada	**Process**: • % appropriate use of BCS in DCIS; eligible & preferred*[IV]	• Overall: 63% • Links: NA	• Standard: systematic review; evidence based recommendations for BCS in North America (US & Canada); CPG (n = 12); 1991-2001 • Data sources: several databases (SEER; OCR) • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: external quality oversight; research • Care setting: cancer centers; hospitals; RT centers • Professionals: oncologists; surgeons; RT oncologists	• Inclusion: population-based samples women ESBC eligible for BCS in North American population • Exclusion: NR • Period: NR • n patients (enrolled/ evaluated): NR • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: ESBC including DCIS; stage I-IIIA • Socioeconomic status: NR • Funding: Cancer Care Ontario; NCI of Canada
	• % appropriate use of BCS in stage; eligible & preferred**[IV]	• Overall: 57% • Links: NA		
	• % appropriate use of BCS in stage II; eligible & preferred**[IV]	• Overall: 52% • Links: NA		
	• % appropriate use of BCS in stage IIIA; eligible & preferred***[IV]	• Overall: 27% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; RT = radiotherapy; CT = chemotherapy; HR = hormone receptor; state of use = last 3; ER = estrogen receptor; PR = progesterone receptor; BC = breast cancer; NCI = National Cancer Institute; SEER = surveillance epidemiology end results; OCR = Ontario cancer registry; BCS = breast-conserving surgery; DCIS = ductal carcinoma in situ; SLE = systemic lupus erithematous; SS = systemic sclerosis; *DCIS: low/moderate risk; not pregnant; no prior RT; no SLE/SS; **Stage I: not pregnant; no prior RT; solitary primary; no SLE/SS; negative margins; low tumor/breast size rate; *** Stage IIIA: not pregnant; no prior RT; solitary primary tumor; no SLE/SS; CR/PR (complete or partial response to neo-adjuvant CT that eliminates the need for mastectomy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US	**Process:** • % appropriate use of preoperative mammographic evaluation[IV]	• Overall: 88% • By age: <70 y: 88.5% ≥70 y: 86.2% • By race/ethnicity: White: 88.4% Black-H: 86.5% Other: 87.5% • By payer: Government: 87.7% Private: 88.7% • Links: NA	• Standard: ACOS; ACR; CAP; SSO standards for BCT, 1992 • Data sources: cancer registries of 842 US hospitals • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: quality of care reporting; external quality oversight; research • Care setting: hospitals; RT centers; cancer centers • Professionals: RT oncologists; oncologists; surgeons; GPs	• Inclusion: convenience sample women BC Stage I-II diagnosed, 1994 • Exclusion: incomplete pathologic reporting; not appropriate candidates for BCT based on standards; stage III-IV • Period: 1 y (1994) • n patients (enrolled/ evaluated): 17,931/16,643 • Age (mean & range): 62 (21->70) y • Race/ethnicity: White (85.9%), Black (7.8%), Hispanic (2.9%), Asian (2%), other (1.3%) • Case characteristics: NR • Socioeconomic status: private insurance (34.5%); HMO (14.7%); Medicare (42.1%); Medicaid (7%) • Funding: NCI
	• % reporting size of mammographic abnormality [IV]	• Overall: 47% • By age: <70 y: 45.9% ≥70 y: 50.7% • By race/ethnicity: White: 47.5% Black-H: 46.3% Other: 39.6% • By payer: Government: 50.3% Private: 44.8% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = college of American pathologists; SSO = society of surgical oncology; ACR = American Collage of radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % appropriate use of BCS[IV]	• Overall: 42.6% • By age: <70 y: 46% ≥70 y: 34% • By race/ethnicity: White: 43% Black-H: 44% Other: 36% • By payer: Government: 37% Private: 48% S • Links: NA	• See above.	• See above.
	• % reporting laterality of surgical specimen[IV]	• Overall: 98.3% • By age: <70 y: 98.2% ≥70 y: 98.6% • By race/ethnicity: White: 98.2% Black-H: 98.5% Other: 99.3% • By payer: Government: 98.4% Private: 98.3% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American Collage of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = Collage of American pathologists; SSO = Society of Surgical Oncology; ACR = American Collage of radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % reporting identification of affected quadrant[IV]	• Overall: 21.1% • By age: <70 y: 21.1% ≥70 y: 21.3% • By race/ethnicity: White: 20.5% Black-H: 26.3% Other: 21.5% • By payer: Government: 22% Private: 20.4% • Links: NA	• See above.	• See above.
	• % reporting pathological specimen oriented[IV]	• Overall: 67.1% • By age: <70 y: 68% ≥70 y: 64.9% • By race/ethnicity: White: 67.6% Black-H: 64.2% Other: 71.5% • By payer: Government: 67.5% Private: 67.1% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American Collage of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = Collage of American pathologists; SSO = Society of Surgical Oncology; ACR = American Collage of radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % reporting carcinoma microscopically confirmed[IV]	• Overall: 97.8% • By age: <70 y: 97.7% ≥70 y: 97.9% • By race/ethnicity: White: 97.9% Black -H: 96.7% Other: 99.3% • By payer: Government: 98.1% Private: 97.7% • Links: NA	• See above.	• See above.
	• % reporting histological type[IV]	• Overall: 98.8% • By age: <70 y: 98.8% ≥70 y: 98.7% • By race/ethnicity: White: 98.8% Black -H: 99% Other: 99.3% • By payer: Government: 99% Private: 98.7% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American Collage of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % reporting histological grade[IV]	• Overall: 80.6% • By age: <70 y: 81.1% ≥70 y: 79.3% • By race/ethnicity: White: 80.5% Black -H: 79.7% Other: 88.9% • By payer: Government: 80.1% Private: 81.2% • Links: NA	• See above.	• See above.
	• % reporting LV invasion[IV]	• Overall: 53.5% • By age: <70 y: 54.3% ≥70 y: 51.5% • By race/ethnicity: White: 52.9% Black -H: 54.4% Other: 70.8% • By payer: Government: 51.3% Private: 54.9% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % reporting size invasive carcinoma [IV]	• Overall: 91.8% • By age: <70 y: 91.6% ≥70 y: 91.9% • By race/ethnicity: White: 91.7% Black -H: 91.2% Other: 96.5% • By payer: Government: 91.6% Private: 92% • Links: NA	• See above.	• See above.
	• % reporting macroscopic margins of carcinoma measured[IV]	• Overall: 72.4% • By age: <70 y: 72.5% ≥70 y: 72.1% • By race/ethnicity: White: 72.5% Black -H: 73.5% Other: 61.8% • By payer: Government: 73.1% Private: 72.3% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % reporting microscopic margins assessment[IV]	• Overall: 89.5% • By age: <70 y: 90% ≥70 y: 88.7% • By race/ethnicity: White: 89.7% Black -H: 86.8% Other: 95.8% • By payer: Government: 89% Private: 90.2% • Links: NA	• See above.	• See above.
	• % reporting DCIS present/absent[IV]	• Overall: 43.2% • By age: <70 y: 44.8% ≥70 y: 38.6% • By race/ethnicity: White: 43.3% Black -H: 40.8% Other: 49.3% • By payer: Government: 40.2% Private: 45.7% S • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % reporting ER status[IV]	• Overall: 91.7% • By age: <70 y: 91.9% ≥70 y: 91.2% • By race/ethnicity: White: 91.8% Black -H: 90.4% Other: 96.5% • By payer: Government: 91.4% Private: 92.3% • Links: NA	• See above.	• See above.
	• % reporting PR status[IV]	• Overall: 90.6% • By age: <70 y: 90.9% ≥70 y: 89.7% • By race/ethnicity: White: 90.7% Black -H: 89.6% Other: 95.1% • By payer: Government: 90.1% Private: 91.4% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % appropriate use of RT after BCS[IV]	• Overall: 85.9% • By age: <70 y: 88.4% ≥70 y: 78.9% • By race/ethnicity: White: 86.3% Black -H: 83.2% Other: 81.9% • By payer: Government: 83.3% Private: 88.6% S • Links: NA	• See above.	• See above.
	• % quality of RT: planning on a dedicated simulator[IV]	• Overall: 88.9% • By age: <70 y: 89% ≥70 y: 88.8% • By race/ethnicity: White: 89% Black -H: 87.7% Other: 87.3% • By payer: Government: 89.1% Private: 88.8% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % quality of RT: homogenous dose distribution[IV]	• Overall: 96.6% • By age: <70 y: 96.6% ≥70 y: 96.8% • By race/ethnicity: White: 96.6% Black -H: 96.5% Other: 97.5% • By payer: Government: 96.7% Private: 96.7% • Links: NA	• See above.	• See above.
	• % quality of RT: done 5 d/wk[IV]	• Overall: 97.4% • By age: <70 y: 97.4% ≥70 y: 97.4% • By race/ethnicity: White: 97.5% Black -H: 97.5% • By payer: Government: 97.1% Private: 97.1% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % quality of RT: use of wedges on tangent breast fields[IV]	• Overall: 93.4% • By age: <70 y: 93.3% ≥70 y: 93.8% • By race/ethnicity: White: 93.5% Black -H: 92.1% Other: 97.5% • By payer: Government: 93% Private: 93.8% • Links: NA	• See above.	• See above.

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Evidence Table 1. Definition, developmental history, and adherence data revealed by quality measures/measurements (continued)

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/ Data Source(s)/ Developmental History/ Status	Use Parameters: Eligibility Criteria/ Measurement Period/ Sample(s) Characteristics/ Funding Source
White, 2003, US (cont'd)	• % appropriate use of adjuvant systemic therapy in node (+) after BCT[IV]	• Overall: 84.1% • By age: <70 y: 84.9-88.7% ≥70 y: 72% • By race/ethnicity: White: 85.3% Black -H: 78.7% Other: 78.3% • By payer: Government: 78.9% Private: 87.6% S • Links: NA	• See above.	• See above.

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; LV = Lymphatic/Vascular; ER = estrogen receptor; PR = progesterone receptor; RT = radiotherapy; BCS = breast-conserving surgery; ACOS = American College of Surgeons; node (+) = lymph node positive; state of use = last 3 y; GP = general practitioner; NCI = National Cancer Institute; CAP = College of American Pathologists; SSO = Society of Surgical Oncology; ACR = American College of Radiology; BCT = breast-conservation therapy; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Table 1 (continued). Definition, Developmental History, and Adherence Data Revealed by Quality Measures/Measurements

Author, Year, Location	Title of Quality Measures-Measurements (Organized by Domain)	Performance Data: Overall/ By Stratification(s)/ Other Data/ Links to Outcome	Reference Standard(s) (Publication Date)/Data Source(s)/Developmental History/Status	Use Parameters: Eligibility Criteria/Measurement Period/ Sample(s) Characteristics/ Funding Source
Wilkinson, 2003, US	**Process:** • % reporting of size specimen in 3 dimensions[IV]	• Overall: 91% • Links: NA	• Standard: CAP guideline, 1998 • Data sources: cancer database of Department of Surgery at Roswell Park Cancer Institute • Developmental period: NR • Reference standard(s) (publication date): NR • Data sources: NR • Psychometric properties: NR • Links to outcomes: NR • Funding source: NR • State of use: NR • Current use: internal quality improvement; quality of care reporting • Care setting: hospitals; cancer centers; pathology centers • Professionals: oncologists; pathologists; surgeons	• Inclusion: convenience sample women stage I-II breast infiltrative carcinoma referred to RPCI after excisional biopsy, 1998-1999 • Exclusion: simultaneous axillary staging or mastectomy performed; preceding FNA or CNB performed; carcinoma in situ • Period: 2 y (1998-1999) • n patients: (enrolled/evaluated): 100/83 • Age (mean & range): NR • Race/ethnicity: NR • Case characteristics: infiltrating carcinoma; stage I-II • Socioeconomic status: NR • Funding: NR
	• % reporting tumor size[IV]	• Overall: 40% • Links: NA		
	• % reporting orientation of specimen (for margin analysis) [IV]	• Overall: 25% • Links: NA		
	• % reporting microscopic margin status[IV]	• Overall: 94% • Links: NA		
	• % reporting distance to closest margin[IV]	• Overall: 69% • Links: NA		
	• % reporting specimen inked[IV]	• Overall: 77% • Links: NA		
	• % reporting histology type[IV]	• Overall: 100% • Links: NA		
	• % reporting histology grade[IV]	• Overall: 90% • Links: NA		
	• % reporting tumor size (microscopic) [IV]	• Overall: 90% • Links: NA		
	• % reporting lymphovascular invasion (presence/absence) [IV]	• Overall: 47% • Links: NA		
	• % reporting presence of in situ component[IV]	• Overall: 71% • Links: NA		
	• % reporting BSR scale (tumor grade) [IV]	• Overall: 6% • Links: NA		
	• % reporting TNM staging[IV]	• Overall: 9% • Links: NA		

NR = not reported; NA = not assessed; S = significant difference/trend; NS = nonsignificant difference/trend; n = number of patients; pts = patients; enrolled = n qualified; evaluated = n analyzed; BC = breast cancer; RPCI = Roswell Park Cancer Institute; FNA = fine-needle aspiration; CNB = core-needle biopsy; CAP = College of American Pathologists; CPG = clinical practice guideline; state of use = last 3 y; BSR = Bloom Scarf Richardson Scale; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

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Listing of Quality Indicators Used to Measure Adherence to Standards of Breast Cancer Care

1. DIAGNOSIS
1.1 Preoperative diagnosis
• Appropriate use: If a palpable breast mass has been detected, at least one of the following procedures should be completed within 3 months: fine-needle aspiration, mammography, ultrasound, biopsy and/or a followup visit[IV]
• Appropriate use of preoperative mammographic evaluation[IV]
• Appropriate use of imaging &/or cytology or needle biopsy, if required, to be performed at the initial visit[IV]
• Appropriate use of preoperative diagnosis by fine-needle aspiration cytology, needle histology or biopsy[IV]
• Appropriate use: A biopsy or fine-needle aspiration should be performed within 6 weeks either when the mammography suggests malignancy or the persistent palpable mass is not cystic on ultrasound[IV]
• Appropriate use: If a breast mass has been detected on two separate occasions, then either a biopsy, fine-needle aspiration or ultrasound should be performed within 3 months of the second visit[IV]
• Quality of fine-needle aspiration samples from lesions, which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist[IV]
1.2 Surgical procedures
• Appropriate use: A biopsy should be performed within 6 weeks if fine-needle aspiration cannot rule out malignancy[IV]
• Appropriate use of first localization biopsy operation to correctly identify impalpable lesions[IV]
• Quality of breast biopsy: primary operable breast cancer receives a frozen section[IV]
• Quality of technique to determine histological node status for all invasive tumors, either by sampling or clearance[IV]
• Quality of sampling nodes for invasive breast cancer, to include ≥ 4 nodes[IV]
• Quality of hormone receptor assay[IV]
1.3 QOL and patient satisfaction relating to diagnosis
• Change in QOL after diagnosis of breast cancer[Iac]
• Women reporting an overall satisfaction with the quality of breast care[Iac]
1.4 General category
• Appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines[IV]
• >90% of women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography[IV]
• Patients attending for diagnostic purposes seen on at least 1 occasion by a breast specialist surgeon[IV]
• <10% of all new cases of women with breast cancer should attend the clinic/hospital on > 2 occasions for diagnostic purposes[IV]
• Urgent referrals of women with breast cancer to be seen within 5 working days[IV]
• Women with breast cancer to be seen by specialist in timely fashion post referral for diagnostic purposes[IV]
• Management of cases coming to surgery from the screening program carried out by surgeons who have acquired the necessary specialist knowledge[IV]
• ≥90% of women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision[IV]
• ≥90% of women with breast cancer or with an abnormality requiring diagnostic operation need to be told of this within 5 working days of investigations leading to this diagnosis[IV]
• Appropriate use of an evaluation in compliance with guidelines[IV]
• Appropriate use of initial examination[IV]

2. TREATMENT
2.1 Surgery
• Appropriate use: Women with stage I or stage II breast cancer should be offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery are present[IV]
• Appropriate use of all surgery[IV]
• No breast-conserving surgery or mastectomy in metastatic disease[IV]
• Appropriate use of breast-conserving surgery[IV]
• Appropriate number of therapeutic operations (≤ 2) for women having breast-conserving surgery[IV]
• Appropriate use of mastectomy[IV]
• Appropriate use of axillary lymph node dissection[IV]
2.2 Radiotherapy
• Appropriate use of radiotherapy[IV]
• Appropriate use: Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment[IV]
• Appropriate use of radiotherapy after breast-conserving surgery[IV]
• Quality of radiotherapy after breast-conserving surgery (following guidelines)[IV]
• Appropriate use of radiotherapy after mastectomy[IV]
• Quality of radiotherapy via planning on a dedicated simulator[IV]
• Quality of radiotherapy: done 5 days/week[IV]
• Quality of radiotherapy: homogenous dose distribution of radiotherapy[IV]
• Quality of radiotherapy: use of wedges on tangent breast fields[IV]
• Appropriate use of radiotherapy on axilla following axillary lymph node dissection, to deal with increased risk of local recurrence (i.e. extracapsular extension; ≥ 4 positive nodes) [IV]
• Appropriate use of parasternal radiotherapy for tumors located in the medial part of breast[IV]
• Appropriate use of palliative radiotherapy for women with progression or recurrence[IV]
• Regional recurrence needing further surgery or radiotherapy[IV]
• Quality of radiotherapy: both tangent fields treated daily[IV]
• Quality of radiotherapy: receiving 4,500-5,000 cGy total breast dose given in 180-200 cGy fractions[IV]
• Quality of radiotherapy: electron beam breast radiation used[IV]
2.3 Adjuvant systemic therapy
• Appropriate use of any adjuvant systemic therapy[IV]
• Appropriate use: Women with invasive breast cancer that is node-positive, or node-negative and primary tumor ≥ 1 cm, should be treated with adjuvant systemic therapy to include combination chemotherapy (and/or tamoxifen, 20mg/d) [IV]
• Appropriate use of any adjuvant systemic therapy in women with node (+) breast cancer[IV]
• Appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer[IV]
• Appropriate use of adjuvant systemic therapy after breast-conserving surgery[IV]
• Appropriate use of tamoxifen[IV]
• Appropriate use of tamoxifen in premenopausal women with node (-), intermediate risk, breast cancer[IV]
• Appropriate use of tamoxifen in postmenopausal women with node (-), intermediate risk, breast cancer[IV]
• Appropriate use of tamoxifen in postmenopausal women with node (-), high risk, estrogen receptor (+), breast cancer[IV]
• Appropriate use of tamoxifen in postmenopausal women with node (+)[IV]
• Appropriate use of chemotherapy and hormone therapy (tamoxifen) [IV]
• Appropriate use of chemotherapy and hormone therapy (tamoxifen) in premenopausal women, node (+), hormone receptor (+), breast cancer[IV]
• Appropriate use of chemotherapy[IV]
• Appropriate use of chemotherapy in women with node (-), high risk, estrogen receptor (-), breast cancer[IV]
• Appropriate use of chemotherapy in women with node (-), estrogen receptor (+), breast cancer[IV]
• Appropriate use of chemotherapy in premenopausal women with node (-), high risk, estrogen receptor (+), breast cancer[IV]

Appendix G. Listing of Quality Indicators

• Appropriate use of chemotherapy in premenopausal women with node (+), estrogen receptor (-), breast cancer[IV]
• Appropriate use of chemotherapy in postmenopausal women with node (+), estrogen receptor (-), breast cancer[IV]
• Appropriate use of chemotherapy in postmenopausal women with node (+), estrogen receptor (+), breast cancer[IV]
• Appropriate use of chemotherapy in women <50 years of age with node (+), breast cancer[IV]
• Appropriate use of chemotherapy &/or ovarian ablation in premenopausal women with node (+), estrogen receptor (+), breast cancer[IV]
• Appropriate decision not to provide adjuvant systemic therapy for women node (-), low risk, breast cancer[IV]
• Appropriate decision not to provide adjuvant systemic therapy for women > 65 years of age with high risk, estrogen receptor (-), breast cancer[IV]
• Quality of chemotherapy: proper doses administered (≥ 85% dose intensity [DI] & relative dose intensity [RDI]) of CMF[IV]
• Availability of office procedure manual used for chemotherapy administration[IV]
2.4 QOL and patient satisfaction relating to treatment
• Overall changes in QOL over time, before & after radiotherapy[Iac]
• Change in QOL in women with metastatic breast cancer[Iac]
• Women with a significant improvement in QOL in clinical phases of breast cancer[Iac]
• Change in QOL by time and treatment arm in postmenopausal, node (-) breast cancer women who underwent adjuvant therapy[Ia]
• Change in QOL over time[Iac]
• Satisfaction of women with breast cancer with the treatment choice[Iac]
• Participation of women with breast cancer in decision-making as much as they wanted[IV]
• Received enough information about surgery and radiotherapy[IV]
2.5 General category
• Board certified medical doctors in medical oncology[IV]
• Documentation of Continuing Medical Education credits for the 2 years preceding audit[IV]
• Referral to oncologist for treatment[IV]
• Women with breast cancer given the opportunity to see a breast cancer specialist nurse[IV]
• Evidence of discussion about surgical options[IV]
• ≥90% of women admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes[IV]
• Appropriate use of treatment sequences according to guidelines (including surgery; radiotherapy; chemotherapy; hormone therapy; initial examination; and followup)[IV]
• Appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy)[IV]
• Appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery + axillary lymph node dissection or adjuvant treatment)[IV]
• Cases not receiving recommended treatment (radiotherapy after breast-conserving surgery or systemic therapy) due to system failure[IV]
• Appropriate use: Women with metastatic breast cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent within 6 weeks of the identification of metastases[IV]
3. Followup
• Appropriate use: Women with a history of breast cancer should have a yearly mammography[IV]
• Appropriate use of guidelines for followup surveillance of breast cancer[IV]
• Women with breast cancer developing local recurrence within 5 years after breast-conserving surgery[IV]
• Women with breast cancer developing local recurrence within 5 years after mastectomy[IV]
• Appropriate use of prophylactic radiotherapy in women with high risk of flap recurrence[IV]

4. REPORTING/DOCUMENTATION
4.1 Pathology reporting/documentation
• Reporting gross observation of lesion[IV]
• Reporting verification tumor size (microscopic)[IV]
• Reporting number of positive lymph nodes (microscopic)[IV]
• Reporting nuclear grade (microscopic)[IV]
• Reporting mitotic rate (microscopic)[IV]
• Reporting extent of tubule formation (microscopic)[IV]
• Reporting laterality of surgical specimen (gross examination)[IV]
• Reporting identification of affected quadrant (gross examination)[IV]
• Reporting the orientation of the pathology specimen (gross examination)[IV]
• Reporting size of specimen (gross examination)[IV]
• Reporting tumor size (macroscopic)[IV]
• Reporting tumor size (microscopic)[IV]
• Reporting lymph node presence/absence (gross examination)[IV]
• Reporting number of lymph nodes present (gross examination)[IV]
• Reporting nature of specimen (gross examination)[IV]
• Reporting distance of tumor from nipple (gross examination)[IV]
• Reporting description of cut surface of the tumor (gross examination)[IV]
• Reporting description of skin (gross examination)[IV]
• Reporting size of overlying skin (gross examination)[IV]
• Reporting description of nipple (gross examination)[IV]
• Reporting presence or absence of fascia or skeletal muscle (gross examination) [IV]
• Reporting involvement of apical lymph nodes (microscopic)[IV]
• Reporting size of concurrent ductal carcinoma in situ (microscopic)[IV]
• Reporting description of background breast (microscopic)[IV]
• Reporting ductal carcinoma in situ (DCIS) present/absent (microscopic)[IV]
• Reporting measurement of macroscopic margins of carcinoma[IV]
• Reporting assessment of microscopic margins[IV]
• Reporting carcinoma confirmed microscopically[IV]
• Reporting histological type (microscopic)[IV]
• Reporting histological grade (microscopic)[IV]
• Reporting lymph-vascular invasion (microscopic)[IV]
• Reporting size of invasive carcinoma (microscopic)[IV]
• Reporting estrogen receptor status (microscopic)[IV]
• Reporting progesterone receptor status (microscopic)[IV]
• Reporting specimen inked (microscopic) [IV]
• Reporting Bloom Scarf Richardson scale (tumor grade) (microscopic)[IV]
• Reporting TNM staging (microscopic)[IV]
• Reporting distance to the closest margin (microscopic)[IV]
• Reporting pathological extent of primary tumor (microscopic)[IV]
• Reporting having performed flow cytometry (microscopic)[IV]
• Reporting cytometry ploidy (microscopic)[IV]
• Pathology reports on chart[IV]
4.2 Imaging reporting/documentation
• Size of mammographic abnormality[IV]
4.3 Chemotherapy reporting/documentation
• Presence of chemotherapy flow sheets in active treatment charts[IV]
• Presence of body surface area calculations on chemotherapy flow sheets[IV]
Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Listing of Reference Standards Used to Measure Quality of Breast Cancer Care in Included Studies

Author, Year	Reference standard(s)	Source(s)
Appleton, 1998[109]	• NHSBSP guidelines, 1991-1992	• Royal College of Pathologists Working Group. Pathology reporting in breast cancer screening. Sheffield: NHSBSP Publications, 1989
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James L. Connolly MD
Professor of Pathology
Harvard Medical School
Boston, MA

Mark N. Levine MD
Buffett Taylor Chair in Breast Cancer Research
McMaster University
Hamilton, ON

Elizabeth A. McGlynn PhD, MPP, BA
Director
Center for Research on Quality in Health Care
RAND
Santa Monica, CA

Dr. Maureen Trudeau
Head of Medical Oncology/Hematology
Toronto Sunnybrook Regional Cancer Centre
Toronto, ON

Timothy J. Whelan MD
Active Staff
CCO Hamilton Regional Cancer Centre
Hamilton, ON

Rodger J. Winn, MD
National Quality Forum
Houston, TX

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David Atkins, MD, MPH
Chief Medical Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
Rockville, MD

Thomas A. Buchholtz, MD
Associate Professor
M.D. Anderson Cancer Center
Department of Radiation Oncology
University of Texas
Houston, TX

Molla Sloane Donaldson, Dr.P.H., M.S.
Senior Scientist for Quality of Care
Research and Policy
Outcomes Research Branch,
National Cancer Institute
Rockville, MD

Suzanne W. Fletcher, MD, MSc
Professor of Ambulatory Care and
Prevention
Harvard Medical School
Chapel Hill, NC

Beth Kosiak, Ph.D.
AHRQ/CQuIPS
Rockville, MD

David I. Lewin, MPhil
Technical Publications Writer-Editor
Office of Communications and Knowledge
Transfer
Agency for Healthcare Research and Quality
Rockville, MD

Maurice McGregor, MD
Department of Medicine
Royal Victoria Hospital
Montreal, QC

Dr. Mark Richard Somerfield
American Society of Clinical Oncology
Alexandria, VA

Rodger J. Winn, MD
National Quality Forum
Houston, TX

Antonio C. Wolff, MD
Assistant Professor, Oncology Center
School of Medicine Dept. Oncology - Breast
Cancer
Johns Hopkins University
Baltimore, MD