

# RESEARCH ACTIVITIES

U.S. Department of Health and Human Services • No. 345, May 2009

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### Task Force recommends screening adolescents for clinical depression

he U.S. Preventive Services Task Force now recommends screening adolescents for clinical depression only when appropriate systems are in place to ensure accurate diagnosis, treatment, and followup care. This applies to all adolescents 12 to 18 years of age. In a separate recommendation, the Task Force found insufficient evidence to assess the balance of benefits and harms of screening children 7 to 11 years of age for clinical depression.

The Task Force reviewed new evidence on the benefits and harms of screening children and adolescents for clinical depression, the accuracy of screening tests administered in the primary care setting, and the benefits and risks of treating clinical depression using psychotherapy and/or medications in patients 7 to 18 years of age. Their conclusions are based on a report from a research team led by Selvi Williams, M.D., at the Kaiser Permanente Center for Health Research, which is part of AHRQ's Oregon Evidence-based Practice Center.

Clinical depression is an important cause of poor health and lower quality of life among children and adolescents. Depression can

cause difficulties in school and disruptions of family and social relationships as well as diminished quality of life. Children and adolescents with depression are at an increased risk of suicide, which is the third leading cause of death among people aged 15 to 24 and the sixth leading cause of death among those aged 5 to 14. Adolescents suffering from clinical depression are also more likely to suffer from depression in early adulthood.

There is adequate evidence that treating adolescents with selective serotonin reuptake inhibitors (SSRIs), psychotherapy, or combined therapy (SSRIs and psychotherapy) results in decreased clinical depression symptoms. Treating clinically depressed youths with SSRIs is associated with an increased risk of suicidality (suicidal thoughts, preparation, and attempts of suicide) and, therefore, should only be considered if careful clinical supervision is possible.

See "Screening and treatment for major depressive disorder in children and adolescents: US Preventive Services Task Force Recommendation Statement," by



#### **Depression**

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Ned Calonge, M.D., M.P.H., Diana B. Petitti, M.D., M.P.H., Thomas G. DeWitt, M.D., and others in the April 2009 *Pediatrics* 123(4), pp. 1223-1228.

**Editor's note:** The Task Force is the leading independent panel of experts in prevention and primary care. The Task Force, which is

supported by the Agency for Healthcare Research and Quality, conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications. Its recommendations are considered the gold standard for clinical preventive services. The

recommendations and materials for clinicians for these and previous Task Force recommendations are available on the AHRQ Web site at www.ahrq.gov/clinic/uspstf/ uspschdepr.htm. Clinical information is also available from AHRQ's National Guideline Clearinghouse at www.guideline.gov.

### Patient Safety and Quality

# AHRQ sponsors issue of *Health Services Research* that examines the implementation, assessment, and evaluation of patient safety initiatives

he Agency for Healthcare Research and Quality (AHRQ) sponsored a theme issue of the journal *Health Services Research*: April 2009 44 (2), Part II. Eight new studies in this issue, "Program Evaluation of the AHRQ Patient Safety Initiative," take an in-depth look at AHRQ's own patient safety initiative, including the findings from a 4-year RAND Corporation evaluation of more than 300 research projects and other activities.

In the first paper, RAND researcher Donna Farley, Ph.D., and AHRQ researcher James Battles, Ph.D., describe the purpose for this supplemental issue, as well as the framework and approach to evaluating these patient safety initiatives. Six process evaluation papers take a closer look at the assessment and experiences of AHRQ-funded patient safety projects, information technology initiatives, the AHRQ-sponsored Patient Safety Improvement Corps,

and the growth of patient safety partnerships across the United States. The final two papers explore the challenges inherent in measuring safety outcomes and present the overall findings from the 4-year evaluation. Brief summaries of the papers follow.

Farley, D. O., and Battles, J. B., "Evaluation of the AHRQ patient safety initiative: Framework and approach," pp. 628-645.

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### Patient safety initiatives

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Serving as the Patient Safety Evaluation Center, the RAND Corporation conducted a 4-year evaluation of AHRQ's initiative dealing with diverse patient safety issues and practices. This lead paper describes the Institute of Medicine's (IOM) mandate for this initiative and its evolution to date, as well as the program evaluation methods used to evaluate it. The authors explain the specific components of the Context-Input-Process-Product (CIPP) evaluation model selected by AHRQ, its application to the initiative, and the process of data collection and analysis. As the patient safety initiative has matured over the years, it has moved from basic knowledge development to testing actual practices deemed effective and informing end users about these outcomes.

Sorbero, M. E. S., Ricci, K. A., Lovejoy, S., and others, "Assessment of contributions to patient safety knowledge by the Agency for Healthcare Research and Quality-funded patient safety projects," pp. 646-664.

AHRQ's extensive portfolio of projects has addressed a wide range of patient safety issues, not only in hospitals, but also in other healthcare environments. Most of the projects focus on general patient safety and medication ordering or administration issues. Special populations, such as the elderly and minorities, are adequately included in the portfolio. Projects most often focus on such patient safety actions as the monitoring and reporting of adverse drug events, provider education and awareness, physical environment redesign, and technology innovation to reduce errors. Many of these

patient safety projects look at practices that still need more scientific evidence before their effectiveness can be completely determined. The RAND team recommends that AHRQ develop and implement a strategy to make sure project-generated knowledge and results reach front-line health care providers through organizational collaboration and the creation of new learning tools.

Taylor, S. L., Ridgely, M. S., Greenberg, M. D., and others, "Experiences of Agency for Healthcare Research and Quality-funded projects that implemented practices for safer patient care," pp. 665-683.

In this study, RAND researchers interviewed 60 groups who received 1 of 3 types of patient safety grants (original, challenge, and partnership) from AHRQ between 2003 and 2006. The selfreported data point to a number of similarities in shared experiences of the grantees, particularly when it comes to lessons learned. Key components of successful project implementation include existing partnering organizations, narrowing the project scope, the use of "champion" buy-in, and technical assistance availability. There were also several unexpected challenges, such as time delays, physician buyin, and the actual difficulty in changing staff practices. This study represents one of the first reported evaluations of patient safety implementation projects in the literature.

Damberg, C. L., Ridgely, M. S., Shaw, R., and others, "Adopting information technology to drive improvements in patient safety: Lessons from the Agency for Healthcare Research and Quality health information technology grantees," pp. 684-700.

Electronic health records (EHR), computerized physician order entry (CPOE), and data exchange networks are just some of the ways information technology (IT) is being used to improve patient safety in health care settings. AHRQ has promoted the innovative use of IT in this area by awarding grants totaling \$139 million to 104 health IT projects in 2004. This paper looks at the experiences of these projects and the lessons learned from their adoption, implementation, and long-term viability. Overall, the projects represented diverse facilities, geographic locations, and special populations served. The projects use IT to influence decision support and to implement EHR and CPOE. Important factors linked to the success of implementing patient safety IT projects were identified. These include end-user engagement, adequate pilot testing, effective communication, good leadership, and available training opportunities. The majority of grantees felt strongly that their gains in knowledge and implemented systems could be successfully replicated by other institutions.

Teleki, S. S., Damberg, C. L., Sorbero, M. E. S., and others, "Training a patient safety work force: The patient safety improvement corps," pp. 701-716.

As part of its patient safety initiative, AHRQ created the Patient Safety Improvement Corps (PSIC). This 1-year program trained patient safety teams in all 50 States and the District of Columbia for 3 years between 2003 and 2006. This study by the RAND team evaluated how yearly training assisted in creating a national infrastructure to support patient safety practices. After 1 year post-training, participants reported



### Patient safety initiatives

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coming away with valuable skills and the confidence to use them in their health care settings. They continued to use these effective patient safety interventions even after 2 years had passed since receiving the training. Its impact reached well beyond the immediate health care environment to affect patient safety actions made by state agencies in the form of legislation and oversight procedures. Following their training, participants became effective trainers of others at their institutions. Despite training approximately 250 individuals, the PSIC needs to strengthen and expand this network in order to create long-term improvements in patient safety practices and outcomes. Continued training of new participants as well as postgraduate modules for former trainees will help.

#### Mendel, P., Damberg C. L., Sorbero, M. E. S., and others, "The growth of partnerships to support patient safety practice adoption," pp. 717-738.

Part of RAND's evaluation of AHRO's patient safety initiative also included a critical look at the formation of organizational partnerships at the national level. In this study, researchers conducted two rounds of telephone interviews with 35 organizations in 2004 and 55 in 2006. These key organizations were found to be engaged in interorganizational partnerships of various sizes and reach. Over the time period, there was a considerable increase in notable activities, particularly the dissemination of patient safety information and the development of practical tools. Partnership network fragmentation decreased while

network centralization increased. The researchers found that AHRQ was centrally positioned within these partnerships to be a leader in these activities. As patient safety partnerships of all types continue to grow and expand, AHRQ's central role in these collaborations ensures the ongoing creation and dissemination of tools and practices.

# Greenberg, M. D., Haviland, A. M., Yu, H., and Farley, D. O., "Safety outcomes in the United States: Trends and challenges in measurement," pp. 739-755.

Patient safety is a complex issue that interrelates with a variety of health care settings, therapies, and patient risk levels. Such intricacies make tracking national trends difficult and challenging. Such is the conclusion of RAND researchers who analyzed data from a variety of medication error and other event-related databases. Each of these demonstrates the benefits and limitations of safety reporting systems. For example, the Joint **Commission Sentinel Events** database identifies the various factors causing serious health care incidents. However, incomplete reporting difficulties result in underestimates. This illustrates the limitations found in other external reporting systems, particularly those that are voluntary. These inherent limitations among databases negatively impact the ability to create an accurate, national picture of patient safety outcomes. Based on their analysis, the RAND team recommends that AHRQ track trends, not only in patient outcome measures, but also in the way evidence-based safe practices are implemented nationally. Other suggestions include gathering and analyzing data from nonhospital health care settings, using expert consensus methods, and paying

careful attention to consistent definitions and coding techniques.

# Farley, D. O., and Damberg, C. L., "Evaluation of the AHRQ patient safety initiative: Synthesis of findings," pp. 756-776.

In the concluding article, overall findings are summarized from the 4-year RAND evaluation. The researchers conducted interviews with AHRQ staff, its grantees, and other patient safety parties. They also reviewed materials published by AHRQ and various internal documents. During the period from 2001 through 2006, AHRQ made strong progress in developing new knowledge on patient safety epidemiology and practices. There was also a strengthening of infrastructure in order to support the adoption of safe practices among health care providers at the institutional level. Only limited progress was made in AHRQ's ability to create a monitoring and vigilance capability. Divergent views among stakeholders and lack of consensus have hampered the development of a national monitoring capability. According to those interviewed, the lack of engaged health care leadership and continued denial of safety issues within the health care community are just some of the reasons why progress remains frustratingly slow. Along with being grateful to AHRQ for its work to date on patient safety despite limited resources, stakeholders suggest that it work harder at getting evidence-based practices adopted by front-line providers. Partnering with other organizations may help with efficient and timely dissemination.

**Editor's note:** A limited number of copies of the *HSR* theme issue (AHRQ publication no. OM09-0059) are available from AHRQ.\*

# Hospital reports on patient safety incidents can be useful in identifying the contributing factors, but often need more detail

new study of the usefulness of hospital reports on patient safety incidents finds that most of the report narratives helped identify factors that contributed to the incident. However, each category of factors (patient, system, and provider factors) was identified in only a minority of the incident reports, and often little detail was provided about provider factors. The researchers conclude that strategies for obtaining narrative descriptions with more details are needed for incident reports to be truly useful in improving patient safety.

At least one contributing factor was identified in 80 percent of reports, with many reports identifying several contributing factors. Patient factors and system factors each showed up in 32 percent of the reports, while provider factors could be noted in 46 percent of the reports. Most of the patient factors were classifiable into subtypes, with the underlying illness being the most common (61 percent of the reports with patient factors). Personnel issues (primarily teamwork and availability of staff) and physical environment issues (unavailability or malfunction of a facility, device, or medicine) were the most common system factors

identified. Only slightly more than half of the provider factors could be subclassified; the most common provider factors were slips or lapses, both reflecting unconscious errors.

The researchers examined 2,228 incident reports collected in 2001 by voluntary, but not anonymous, reporting systems at a teaching hospital and an affiliated community hospital in a major metropolitan area. These reports were sampled so that the patients involved would be representative of the 2001 patient population at the two hospitals. Results were adjusted for the number of patients with more than one hospital admission during the calendar year. The study was supported, in part, by the Agency for Healthcare Research and Quality (HS11512).

More details are in "Contributing factors identified by hospital incident report narratives," by Teryl K. Nuckols, M.D., Douglas S. Bell, M.D., Ph.D., Susan M. Paddock, Ph.D., and Lee H. Hilborne, M.D. in the October 2008 issue of *Quality and Safety in Health Care* 17(5), pp. 368-371.

# Physicians correctly identify fewer than half of drug pairs with potentially dangerous interactions

n average of 2.3 medications are prescribed during each physician office visit. One risk associated with the use of multiple medications is the possibility of potentially dangerous drug-drug interactions (DDIs).

DDIs can lead to an emergency department visit, admission to the hospital, and sometimes death. Yet, 950 clinicians in a recent survey correctly identified only 43 percent of drug pairs with potential DDIs. This suggests that prescribers' knowledge of potentially clinically significant DDIs is generally poor,

conclude the researchers at the University of Arizona and the Arizona Center for Education and Research on Therapeutics (CERT).

They mailed a questionnaire to a national sample of 12,500 prescribers who were selected on the basis of a past history of prescribing drugs associated with known potential for DDI. Recipients were asked to classify 14 drug pairs as "contraindicated," "may be used together but with monitoring," or "no interaction." They could also state that they were "not sure."

The 950 responding prescribers classified 42.7 percent of all drug combinations correctly. Correct classification of specific drug pairs ranged from 18.2 percent for warfarin and cimetidine to 81.2 percent for acetaminophen with codeine and amoxicillin. The number of drug pairs correctly classified by individual prescribers ranged from 0 to 13. For half of the drug pairs, over one-third of the respondents answered that they were "not sure," and two of these drug pairs were contraindicated. One-

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**Note:** Only items marked with a single (\*) asterisk are available from the AHRQ Clearinghouse. Items with a double asterisk (\*\*) are available from the National Technical Information Service. See the back cover of *Research Activities* for ordering information. Consult a reference librarian for information on obtaining copies of articles not marked with an asterisk.



### **Drug-drug interactions**

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fourth of the prescribers used personal digital assistants (PDAs) to learn more about a potential DDI and a similar number used printed material. However, about two-thirds of prescribers reported their information on patients' potential exposure to DDIs usually came from pharmacists, underscoring the important role of pharmacists in reducing potential DDIs. The study was supported by the Agency for Healthcare Research and Quality (HS10385) to the Arizona University CERT. For more information on the CERTs program, please visit http://certs.hhs.gov/index.html.

More details are in "Prescribers' knowledge of and sources of information for potential drug-drug interactions," by Yu Ko, Ph.D., Daniel C. Malone Ph.D., R.Ph., Grant H. Skrepnek, Ph.D., R.Ph., and others, in *Drug Safety* 31(6), pp. 525-536, 2008. ■

# Kidney function is critical clue to reducing preventable medication problems

ccurate assessment of kidney (renal) function can help clinicians prescribe medication dosages that are less likely to cause adverse drug events (ADEs), according to a new study. Many medications are excreted via the kidney, so that impaired kidney function can lead to increased blood levels or prolonged retention of medications because of slowed removal from the body, with sometimes toxic results. To help avoid ADEs in patients with high or hidden risk of impaired kidney function, the researchers recommend that nurses routinely assess patient levels of creatinine in the blood and estimated rates of creatinine clearance, which are used together as measures of kidney function.

They collected information on 1,052 medication safety events (both actual and potential ADEs) including 318 medication errors reported on 17 clinical units at 2 urban, nonteaching community hospitals before the implementation of a commercial computerized physician order entry (CPOE) system. The researchers estimated creatinine clearance and used laboratory measurement of serum creatinine to classify each patient as being of high (144 patients), hidden (81 patients), or low (93 patients) risk of kidney-related medication events. High-risk patients had high levels of serum creatinine and low clearance rates, low-risk patients had low serum creatinine and high clearance rates, while hidden-risk patients had a combination of low serum creatinine and low clearance rates.

Age and sex were each significantly associated with renal risk groups: patients over 80 years old formed the largest group for hidden risk, while men were the largest group at high risk and more women than men had hidden risk. A third of the reported medication errors occurred in patients under 65 years old, a third in patients between ages 65 and 79 years, and a third among patients 80 years or older. Medication errors among patients with high or hidden risk of renal insufficiency primarily occurred during ordering or transcription of the order, and most often involved a wrong dose rather than wrong drug choice or frequency of administration. The researchers found that antibiotics accounted for a fourth and diabetes drugs accounted for a sixth of medication errors. Antibiotics accounted for more than a third of the errors in the high-risk group and less than a fifth of errors for the hidden-risk and normal-risk groups. The study, which is part of a larger study of the impact of CPOE systems on the outcome of ADEs, was funded in part by the Agency for Healthcare Research and Quality (HS13131).

More details are in "Reducing preventable medication safety events by recognizing renal risk," by Willa Fields, D.N.Sc., R.N., Christine Tedeschi, M.S., R.N., Justine Foltz, B.A., R.N., and others, in 2008 *Clinical Nurse Specialist* 22(2), pp. 73–78.

### Visit the AHRQ Patient Safety Network Web Site

AHRQ's national Web site—the AHRQ Patient Safety Network, or AHRQ PSNet—continues to be a valuable gateway to resources for improving patient safety and preventing medical errors and is the first comprehensive effort to help health care providers, administrators, and consumers learn about all aspects of patient safety. The Web site includes summaries of tools and findings related to patient safety research, information on upcoming meetings and conferences, and annotated links to articles, books, and reports. Readers can customize the site around their unique interests and needs through the Web site's unique "My PSNet" feature. To visit the AHRQ PSNet Web site, go to http://psnet.ahrq.gov/.



# Lack of resources and time, along with staff burnout, are barriers to sustaining quality improvement in community health centers

or a quality improvement (QI) intervention to be successful over the long term, dedicated staff time must be available for QI leadership, data entry, and management of a related patient registry, a new study reports. The study is based on surveys of community health center leaders and staff participating in the ongoing Health Disparities Collaboratives, a national effort to improve quality of care for chronic diseases.

Based on responses to a survey, the researchers found that team leaders spent nearly 11 hours per week (27 percent of work time) solely on activities tied to the collaboratives. Team members spent nearly 8 hours (19 percent of their time), chief executive officers spent nearly 3 hours (6 percent of their time), and physicians spent nearly 5 hours (10 percent of their time). Nearly all (91 percent) of the health centers designated personnel to spend at least some of their time on data entry for the collaboratives, 80 percent for using registry data to determine patient needs and 85 percent for leading QI interventions. In 20 percent of the centers, staff did these tasks on an unpaid basis, without having them part of their regular job descriptions. Only 24 percent indicated that there was sufficient funding and 31 percent that there were sufficient personnel resources to run the collaboratives.

The study was based on receipt of 1,006 surveys from 153

community health centers. Respondents included nurses (27 percent of surveys) and physicians (16 percent). Nurse practitioners and physician assistants provided 2.5 percent and 4.7 percent of the responses, respectively. The study was funded in part by the Agency for Healthcare Research and Quality (HS13635 and HS10479).

More details are in "Sustaining quality improvement in community health centers. Perceptions of leaders and staff," by Marshall H. Chin, M.D., M.P.H., Anne C. Kirchhoff, M.P.H., Amy E. Schlotthauer, M.P.H., and others, in the October-December 2008 *Journal of Ambulatory Care Management* 31(4), pp. 319–329.

# Physicians miss opportunities to give emotional support to cancer patients

Then a surgeon or oncologist talks with a newly diagnosed lung cancer patient, the physician often misses many chances to provide emotional support to the patient. Instead of noting and addressing the patient's worries and concerns, the physician often responds to patient concerns by talking about biomedical aspects of cancer diagnosis or treatment, a new study reports.

Based on the researchers' analysis of transcripts of 20 patient-doctor consultations concerning newly diagnosed lung cancer, researchers identified 384 empathic opportunities, but found that physicians provided empathic responses to only 39 (10 percent) of them. Half of the physicians' expressions of empathy occurred toward the end of the consultations with the patients, despite chances to provide such emotional support throughout the discussion. Physicians responded with empathy most often to opportunities involving health care system issues (23 percent) or statements about difficulty in making treatment decisions (21 percent). Less than 10 percent

of the empathic responses from physicians addressed patient concerns about symptoms and death related to the diagnosed cancer, although these were the concerns raised most frequently by patients.

The researchers suggest that their findings can be used to improve physicians' empathic responses, especially when communicating with patients who have a life-threatening illness. They suggest that physicians can offer empathy earlier and at intervals during their conversations with patients, and that such encounters could be brief while still helping to build rapport and trust. The study was supported in part by the Agency for Healthcare Research and Quality (HS10876).

Additional information can be found in "Missed opportunities for interval empathy in lung cancer communication," by Diane S. Morse, M.D., Elizabeth A. Edwardsen, M.D., and Howard S. Gordon, M.D., in the September 2008 *Archives of Internal Medicine* 168 (17), pp. 1853-1858.

# Tracking system ensures women with breast cancer see oncologists and receive additional treatment

fter surgery, women diagnosed with early stage breast cancer often benefit. from treatment with chemotherapy, radiation, or hormonal therapy. For this reason, surgeons typically refer these patients to oncologists. Unfortunately, some women, especially blacks and Hispanics, are not seen by the oncologist, though their surgeons assume they are. To keep these women from falling through the cracks, New York researchers developed a tracking system to find out if patients visited an oncologist and feed that information back to the surgeon so they could follow up with patients who did not connect with oncologists. Researchers compared the treatment of 639 women with early stage breast cancer who were seen at 6 New York City hospitals between January 1999 and December 2000 with 300 women who were seen between September 2004 and March 2006, the time period in which the tracking system was used.

Rates of oncology consultations, chemotherapy, and hormonal therapy were higher for all women after the tracking system was in place. The authors state that their tracking system eliminated the racial disparity that existed for black and Hispanic women regarding the underuse of radiation, chemotherapy, and hormonal therapy. For example, after the tracking system was implemented, underuse of radiotherapy declined from 23 to 10 percent, underuse of chemotherapy decreased from 26 to 6 percent, and underuse of hormonal therapy diminished from 27 to 11 percent for black and Hispanic women.

The authors suggest two ways to ensure patients receive proper care for early stage breast cancer. The first is by ensuring tumor registry personnel follow up with patients to determine if they visited oncologists. The second is having insurers require an oncology consultation for all patients diagnosed with invasive breast cancer to make sure these women receive appropriate treatment. This study was funded in part by the Agency for Healthcare Research and Quality (HS10859).

See "A tracking and feedback registry to reduce racial disparities in breast cancer care," by Nina A. Bickell, M.D., M.P.H., Kruti Shastri, M.P.H., Kezhen Fei, M.S., and others in the December 3, 2008 *Journal of the National Cancer Institute* 100(23), pp. 1717-1723.

# Women with a family history of colon cancer have good survival rates when diagnosed with that cancer

woman's likelihood of developing colorectal cancer also increases when her father, mother, or sibling develops that cancer. However, a new study finds that this increased risk for colorectal cancer does not negatively affect the woman's survival rate if she develops it.

Researchers tracked 1,391 women who were diagnosed with invasive colon cancer in Wisconsin. Of the 262 women with a family history of colon cancer, 44 died of the disease. In contrast, of the 1,129 women who had no family history of the disease, 224 died. Women who had two or more relatives with colorectal cancer appeared to have a lower risk of dying from the disease compared with women who had no family history of the cancer. Thus, inherited colorectal cancer may have better survival rates than sporadic cancers, the authors suggest.

Determining a family history of colorectal cancer is seen as a cost-effective way to identify an individual who may be at risk for developing it. These findings indicate that awareness of a family history of the disease may also serve as a clinical tool after diagnosis because of the variation in survival rates between those with and without a family history of colorectal cancer. This study was funded in part by the Agency for Healthcare Research and Quality (HS13853).

See "Family history and colorectal cancer survival in women," by Anne C. Kirchhoff, M.P.H., Polly A. Newcomb, Ph.D., M.P.H., Amy Trentham-Dietz, Ph.D., and others in the 2008 *Familial Cancer* 7(4), pp. 287-292.

# Clinical decision support systems are costly to develop and rely heavily on physician and pharmacist expertise

omputerized prescriber order entry (CPOE) systems allow clinicians to electronically enter medication orders. These systems can reduce medicationrelated errors because they eliminate the need to decipher handwriting, improve communication between providers, and standardize care. When a clinical decision support system (CDSS) is added to a CPOE, it provides the added value of integrating a medical knowledge base, patient data, and an inference engine to generate drug alerts on the case at hand.

To determine the cost of developing a CDSS, researchers studied a team that developed one at a long-term care facility in Canada. Patients in these facilities often have weakened kidney function and take multiple medications, which puts them at a high-risk of medication-caused health problems. The team created 94 alerts for recommended

maximum doses of 62 medications that could be prescribed to patients with weakened kidneys.

The cost of personnel to develop the CDSS was \$48,178 and 925 hours. Physicians logged the most hours (390) to prepare the detailed content, and pharmacists contributed 180 hours preparing content and testing the drug alerts. The costs were lowered since users were familiar with prescribing alerts, thus very little time was required to train and support users. The researchers estimated that if an off-the-shelf renal dosing CDSS were available, it could have reduced the total cost by \$24,483. However, the staff would still spend 241 hours evaluating the system and its alerts, because commercial companies tend to be conservative and include too many, rather than too few, alerts to avoid liability as well as to ensure that the alerts are consistent with local clinical practice. Hence, physicians and

pharmacists would likely need to spend time editing alerts and deactivating those that are considered extraneous. Researchers also estimated that if a database with dosing recommendations for patients with weakened kidneys were available and could be used with a CPOE, it could cut the cost by \$13,977. This study was funded in part by the Agency for Healthcare Research and Quality (HS10481 and HS15430).

See "Costs associated with developing and implementing a computerized clinical decision support system for medication dosing for patients with renal insufficiency in the long-term care setting," by Terry S. Field, D.Sc., Paula Rochon, M.D., M.P.H., Monica Lee, R.Ph., and others in the July/August 2008 Journal of the American Medical Informatics Association 15(4), pp. 466-472.

# Physicians who use electronic health records may be less likely to pay malpractice claims

assachusetts physicians in practices with electronic health records (EHRs) were significantly less likely to have a history of paid malpractice claims than physicians without access to EHR systems, according to a new study. However, after adjusting for factors such as sex, race, year of medical school graduation, and practice specialty, these findings were suggestive but not conclusive, the researchers said. Future studies should include information on when the physicians adopted an EHR, along with the date of any malpractice incident, the filing date of the lawsuit against them, and when it was settled. This would allow researchers to determine definitively whether or not an EHR was in use at the time of the incident.

The study, a survey of 1,345 randomly selected Massachusetts physicians, found that 6.1 percent of the physicians with EHRs had a history of paid malpractice claims versus 10.8 percent for those without EHRs. Overall, 33 percent of the responding physicians used EHRs in their practices. These physicians tended to be younger and less likely to be in solo practices than those not using EHRs. Physicians in solo practice were significantly more likely to have paid malpractice claims than physicians in practices with 10 or more physicians, even after adjusting for other factors.

Physicians who did not see outpatients or who did not have physician profiles on the Board of Registration in Medicine (BRM) Web site (which lists



### **Malpractice claims**

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malpractice claims paid within the last 10 years) were excluded, because data on whether participants had paid malpractice claims was collected from the BRM Web site. The study was funded in part by the Agency for Healthcare Research and Quality (HS15397).

More details are in "Electronic health records and malpractice claims in office practice," by Anunta Virapongse, M.D., M.P.H., David W. Bates, M.D., M.Sc., Ping Shi, M.A., and others, in the November 24, 2008 *Archives of Internal Medicine* 168(21), pp. 2362–2367. ■

### Outcomes/Effectiveness Research

# Patients with drug-coated stent implants have a lower risk of death and heart attack when compared with patients who receive bare metal stents

atients age 65 and older with heart disease who receive stents coated with medicine to prevent blockages are more likely to survive and less likely to suffer a heart attack than people fitted with stents not coated with medication, according to a new study supported by the Agency for Healthcare Research and Quality (AHRQ) and the American College of Cardiology's National Cardiovascular Data Registry.

The comparative effectiveness study of 262,700 Medicare patients who received stents—spring-like tubes to keep heart vessels open—is the largest ever to compare drug-coated stents with bare metal ones. Researchers from Duke University, AHRQ, and Kaiser Permanente found that, compared with patients who received bare metal stents, those fitted with stents coated with medication (called drug-eluting stents) had an 18 percent better survival rate over the 30-month study period and were 16 percent less likely to suffer a heart attack.

The researchers found that 16.5 percent of the patients implanted with bare metal stents died within 30 months of implantation, compared with 13.5 percent of those with drug-eluting stents, after adjusting for population differences. They also found that 8.9 percent of the patients with bare metal stents suffered heart attacks during the period, compared with 7.5 percent of those with drug-eluting stents—a 16 percent higher rate. The researchers further found that patients fitted with drug-eluting stents in 2005 and 2006 had a lower risk of death than those given the stents in 2004.

According to AHRQ's Art Sedrakyan, M.D., Ph.D., a coauthor of the study, better outcomes found for patients with drug-eluting stents may be partially explained because those patients are required to take blood-thinning drugs, such as clopidogrel, for a long time after their procedure. Patients who receive bare metal stents are usually prescribed blood-thinner

medications for a shorter period of time and may take them less often. In addition, patients with drug-eluting stents may visit their doctors more often after hospital discharge and may receive prescriptions for drugs and therapies to lower their cholesterol levels and manage other heart conditions more often than patients who received bare metal stents.

The researchers based their study on data from the American College of Cardiology's National Cardiovascular Data Registry on patients who underwent angioplasty with drug-eluting or bare metal stent implantation at 650 hospitals, together with Medicare national claims data to capture posthospital discharge information. The authors call for longer followup studies to further support the study's results and to confirm the possible effects of postimplantation treatment with blood-thinning drugs such as clopidogrel.

See "Clinical effectiveness of coronary stents in the elderly: Results from 262,700 Medicare patients in the American College of Cardiology-National Cardiovascular Data Registry," by Pamela S. Douglas, M.D., J. Matthew Brennan, M.D., Kevin J. Anstrom, Ph.D., and others in the 2009 *Journal of the American College of Cardiology* available online at http://content.onlinejacc.org/.

Editor's note: This study was funded through AHRQ's DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) research network, which is part of the Agency's Effective Health Care Program. The Effective Health Care Program sponsors the development of new scientific knowledge through studies on the outcomes of health care technologies and services. For more information about AHRQ's Effective Health Care Program and the DEcIDE Network, go to http://effectivehealthcare.ahrq.gov.

# Costs, morbidity, and mortality are high for patients with mechanical heart pumps

new study of outcomes for elderly patients with heart failure who received implanted mechanical heart pumps (ventricular assist devices, or VADs) to support their circulation finds that many patients still die during or shortly after surgery. Many of the survivors are readmitted to the hospital within 6 months, and treatment costs remain high. The researchers conclude that improving patient selection, to reduce deaths during and shortly after surgery, is important to improve overall outcomes.

Researchers examined claims from Medicare patients in fee-for-service plans over a 6-year period. Overall, 2,943 patients at 570 hospitals received VADs. Half of the patients had not had prior openheart surgery (the primary device group), while half had undergone open-heart surgery within 30 days before VAD implantation (the postcardiotomy group). Few of the hospitals performed more than 5 device implants annually (ranging

from 19 hospitals in the year 2000 to 28 in the year 2005).

For all years, 815 patients (55.2) percent) in the primary device group were discharged alive from the hospital with a VAD, while 140 (9.5 percent) received heart transplants and 455 (30.8 percent) died during their hospital stay. At 1 year after implantation of the VAD, 417 primary device patients (32.2) percent) were still alive with the device, 299 (20.7 percent) had received a heart transplant, and 617 (42.2 percent) had died. Among the patients with prior open-heart surgery, 493 patients (33.6 percent) were discharged live with a VAD, 21 (1.4 percent) underwent a heart transplant, and 824 patients (56.2 percent) died during their hospital stay. At 1 year of followup, 333 postcardiotomy patients (24.1 percent) were alive with a VAD implanted, 51 patients (3.5 percent) had received heart transplants, and 929 (63.4 percent) had died.

The researchers used retrospective data on all Medicare fee-for-service patients receiving

VADs, so the study provided a complete picture of the use of mechanical heart assist devices outside of clinical trials. They did not observe improved outcomes for prior cardiotomy patients from the beginning to the end of the study period, but saw a decline in 1-year survival from 41 percent in the year 2000 to 22 percent by 2006. The researchers suggest that this decline in survival may represent an increase over time in patients who would not have previously been considered for the procedure receiving VAD implants. The study was funded in part by the Agency for Healthcare Research and Quality (HS16964).

More details are in "Long-term outcomes and costs of ventricular assist devices among Medicare beneficiaries," by Adrian F. Hernandez, M.D., M.H.S., Alisa M. Shea, M.P.H., Carmelo A. Milano, M.D., and others, in the November 26, 2008, *Journal of the American Medical Association* 300(20), pp. 2398–2406.

# Use of a new heart failure therapy that resynchronizes contraction of ventricles varies

new study finds that use of cardiac resynchronization therapy (CRT), a treatment recommended for many patients hospitalized for congestive heart failure (CHF), varies. Patients with CHF commonly suffer from lack of coordinated contraction of their right and left ventricles. Such coordination is needed for proper movement of blood to the body, including the lungs. An implantable CRT device, much like a cardiac pacemaker, restores the coordination by stimulating both ventricles at the same time, as well as restoring the proper rhythm to the contraction of the right atrium and right ventricle. The study finds that the use of this treatment varies depending on the patients' race, what part of the country they live in, other health problems, and their age. Further studies and the use of quality-of-care initiatives

may help address these gaps in treatment, the researchers conclude.

The study analyzed data on 33,888 patients with CHF who were admitted over a 2-year period to 228 hospitals participating in an American Heart Association program to improve the treatment of this condition. The researchers found that 12 percent of these patients were discharged with CRT. The CRT patients were older than CHF patients not given CRT (70 percent of the CRT patients were Medicare beneficiaries), more likely to be white than black or of other races, had higher rates of kidney problems, and more than half had restricted blood flow to the heart muscle (ischemic cardiomyopathy).

### **Heart failure therapy**

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The likelihood of a patient receiving a new CRT implant was lower for patients living in the northeastern States, of black race, and older than 70 years. In contrast to studies of patients receiving

another kind of cardiovascular device (implantable cardioverter-defibrillators), black women and black men were equally likely to receive new CRT devices. The study was funded in part by the Agency for Healthcare Research and Quality (HS16964).

More details are in "Use of cardiac resynchronization therapy in patients hospitalized with heart failure," by Jonathan P. Piccini, M.D., Adrian F. Hernandez, M.D., M.H.S., David Dai, Ph.D., M.S., and others in the August 26, 2008, issue of *Circulation* 118, pp. 926–933.

### Clinical Decisionmaking

## Use of a clinical algorithm can reduce unnecessary antibiotic use for treatment of sore throat in adults

majority of adults with sore throat are prescribed antibiotics despite being infected with respiratory viruses which, unlike bacteria, do not respond to antibiotic treatment. Using a simple clinical scoring algorithm (the Centor Criteria), results in about 40 percent of adults getting a test for streptococcal bacteria and fewer than 20 percent getting antibiotics, finds a new study. The algorithm allows clinicians to sufficiently predict the presence or absence of group A b-hemolytic streptococci (GABHS) and avoid prescribing antibiotics to patients unlikely to have strep throat, explains Jeffrey A. Linder, M.D., M.P.H., of Brigham and Women's Hospital.

In evaluating patients with sore throat, the principal goal is identifying patients likely to have GABHS. Only 5 to 15 percent of adult patients seeking care for sore throat are likely to have GABHS. The clinical scoring algorithm known as the "Centor Criteria" consist of four findings that are each assigned one point: history of fever, absence of cough, tender or swollen lymph glands in the neck, and red and swollen tonsils. These criteria are easy to implement and accurately stratify adult patients with suspected GABHS. The recommended algorithm suggests that patients with 0 or 1 finding do not require testing or antibiotics. Patients with 2 or 3 findings should have a rapid strep test (rather than a

throat culture) performed, and the results should guide antibiotic treatment. Patients with four findings should receive antibiotics. Throat cultures are not recommended due to the time it takes to get the test results back from the laboratory. Patients with none of the criteria have a 3 percent chance of strep throat while those with all four have a 41 percent chance of the disease.

The author stresses that sore throats can be the result of other causes or infections that may or may not require antibiotics. For example, non-group A streptococci accounts for 5 to 26 percent of patients with sore throat. Other causes include Epstein-Barr virus, *Mycoplasma* and *Chlamydia* pneumonia, *Neisseria gonorrhea*, and *Hemophilus influenzae*. He also cautions that clinicians who treat patients who might be at risk for undiagnosed or untreated strep infection (such as those with a history of acute rheumatic fever or documented exposure) may want to use a lower threshold for diagnosing and treating GABHS.

The study was supported by the Agency for Healthcare Research and Quality (HS14563).

See "Evaluation and management of adult pharyngitis" by Dr. Linder in the Fall/Winter 2008 *Comprehensive Therapy* 34(3-4), pp. 196-203.

# Duration of illness strongly influences practitioners to prescribe antibiotics in treating acute respiratory tract infections

ntibiotics offer no help for acute respiratory tract infections (ARI) that are caused by viruses. Distinguishing which ARIs are caused by viruses and bacteria is primarily based on clinical examination, rather than a diagnostic test result. Practice guidelines have been developed by a variety of organizations to help clinicians distinguish viral vs. bacterial ARIs. According to a new study, the duration of illness appears to influence practitioners the most in deciding when to use antibiotics for ARI, particularly when the patient also has a fever or productive cough.

Researchers presented 101 primary care physicians, nurse practitioners, and physician assistants with a set of 20 patient vignettes describing patients with ARI symptoms. Practitioners indicated they would prescribe

antibiotics in 44.5 percent of the cases presented to them. On a scale from 0 to 100, their comfort level in making this decision was 78. When asked how strongly they would urge the patient to take antibiotics, their rating was 24. Among the variables in deciding when to use an antibiotic, duration of illness was deemed most important by 72 percent of the practitioners. This was the strongest decisionmaker for antibiotic use when it was accompanied by fever or productive cough.

The researchers also asked 8 internal medicine faculty to review published expert-panel guidelines from the CDC on managing ARI and then rate the same 20 cases. These clinicians prescribed antibiotics in only 20 percent of the cases, believing that 19.4 percent of them were bacterial in nature. The

researchers indicate that eliminating the effect of a productive cough in the first set of practitioners studied would bring their prescription rate close to that of the faculty members. Educational programs that target the use of antibiotics in relation to specific symptoms may help practitioners avoid overprescribing. The study was supported by the Agency for Healthcare Research and Quality (HS13001).

See "How do community practitioners decide whether to prescribe antibiotics for acute respiratory tract infections?" by Robert S. Wigton, M.D., M.S., Carol A. Darr, Ph.D., Kitty K. Corbett, Ph.D., M.P.H., and others, in the October 2008 *Journal of General Internal Medicine* 23(10), pp. 1615-1620.

### Chronic Disease

# Telephone nurse support can be cost-effective to help improve functioning and quality of life for patients with diabetes

Ithough diabetes-related damage to organs such as the kidneys and eyes is well recognized, diabetes also causes functional decline, depression, pain, and lost productivity. The good news is that telephone support from nurses on how to self-manage diabetes can improve patients' functioning and help them gain quality-adjusted life years (QALYs). A group of University of California, San Francisco researchers compared the cost effectiveness of automated telephone self-management (ATSM) plus nurse care management among 112 primary care patients with diabetes in 4 safety net clinics with usual care received by 114 similar patients.

ATSM used interactive phone technology to provide surveillance, patient education, and one-on-one counseling, and was implemented in languages for a 9-month period using a randomized control trial design. The per-patient cost to achieve a 10 percent increase in

the proportion of ATSM patients meeting American Diabetes Association exercise guidelines was estimated to be \$558 for all costs and \$277 for ongoing costs alone.

The annual cost of the ATSM intervention per QALY gained, relative to usual care, was \$65,167 for start-up and ongoing implementation costs combined, and \$32,333 for ongoing implementation costs alone. This is a cost-effectiveness similar to that of other accepted diabetes interventions related to medication intensification (for example, \$35,300 per QALY gained for intensive glucose control) and diabetes case management (\$44,941 per QALY gained). The study was supported in part by the Agency for Healthcare Research and Quality (HS14864 and HS17261).

#### **Diabetes**

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More details are in "Cost-effectiveness of automated telephone self-management support among patients

with diabetes," by Margaret A. Handley, Ph.D., M.P.H., Martha Shumway, Ph.D., and Dean Schillinger, M.D., in the November/December 2008 *Annals of Family Medicine* 6(6), pp. 512-518.

# Use of a chronic care model framework in primary care practices can influence patient health status

he chronic care model (CCM) is a comprehensive framework that can guide improvements in quality of health care. Most CCM research has centered on well-known illnesses, such as diabetes, hypertension, and asthma. A new research study, however, points to adapting the CCM as a counseling and prevention tool to improve patient health status in primary care practices.

The researchers examined data from 57 primary care practice-based research networks who implemented the CCM. The relationship between the CCM and three health measures—general health status, unhealthy days, and activity-limiting days—were examined.

General health status was found to vary significantly across CCM

elements such as organization of care, self-management support for behavior change, delivery system design, integration of decision support, use of clinical information systems, and community resources. Significant relationships were identified for almost all CCM components and both unhealthy and activity-limiting days. Patients who received care from practices that supported behavior change were nearly twice as likely to have better health status than patients in practices that were hospital/ university health system-owned, used group/individual planned visits for prevention, or PDAs for clinician-decision support. Practices that used patient registries, health promotion champions, and evidence-based guidelines for treating risk behaviors had patients

with fewer unhealthy or activitylimiting days compared with practices that used group/individual planned visits for prevention and patient reminder cards.

These findings reinforce the idea that organizational characteristics can influence patient health outcomes, according to the researchers. The study was supported in part by the Agency for Healthcare Research and Quality (HS17007).

See "The chronic care model and relationships to patient health status and health-related quality of life," by Dorothy Y. Hung, Ph.D., M.P.H., Russell E. Glasgow, Ph.D., L. Miriam Dickinson, Ph.D., and others, in the November 2008 *American Journal of Preventive Medicine* 35(5S), pp. S398-S406.

### Primary Care Research

# Simple, effective methods to promote increased physical activity introduced to older American Indians in a primary care setting yield positive results

tudies of geographically diverse American Indian tribes consistently show low levels of leisure-time physical activity, less frequent exercise, and a higher proportion being classified as sedentary. Researchers led by Craig N. Sawchuk, Ph.D., of the University of Washington found that physical activity among American Indian elders (aged 50-74) can be promoted in a brief, inexpensive manner in primary care. The study randomly divided 125 American Indians into 2 groups, with the first group receiving basic instruction in daily physical activity monitoring and the second group

receiving instruction in daily physical activity monitoring augmented with a pedometer to track and record their total daily step counts. At the end of the 6-week study, participant fitness was measured by performance in a 6-minute walk test. Both groups showed increases in walking frequency.

Contrary to the researchers' initial hypothesis, adding a pedometer to daily physical activity monitoring did not produce an increase in self-reported physical activity scores. The finding that a pedometer



#### **American Indians**

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did not confer an advantage over basic self-monitoring suggests that self-monitoring alone may be sufficient. This conclusion may be premature, however, given that participants using pedometers were not offered any instruction in daily step-count goal setting. The researchers further suggest that the act of self-monitoring can raise awareness of modifiable health habits, create an external environmental reminder to increase personal responsibility, improve self-efficacy, and provide ongoing feedback on progress.

The study included two face-to-face 60-90 minute clinic sessions with the research assistant at the

beginning and end of the study period. There were also two 10-minute phone calls during weeks two and four to reinforce participation in the study. During the initial session, the research assistant reviewed different types of physical activity and distributed an educational handout on the health benefits of increased physical activity. The study was supported by the Agency for Healthcare Quality and Research (HS10854).

See "A randomized trial to increase physical activity among native elders" by Dr. Sawchuk, Steve Charles, Yang Wen, M.S., and others in *Preventive Medicine* 47, pp. 89-94, 2008.

# Lack of self-efficacy keeps inner-city primary care providers from following national asthma management guidelines

Ithough asthma is a common disease, rates are particularly high among minorities who live in inner-city neighborhoods. For example, East Harlem in New York City has hospitalization and mortality rates that are several times the national average. Yet, several barriers prevent health care providers in these areas from adhering to national asthma guidelines.

Researchers surveyed 202 primary care providers working in East Harlem at 3 large general medicine clinics located in hospitals and 1 large community-based practice. Specific questions addressed the provider's adherence to 5 asthma management practices recommended in guidelines developed by the National Heart, Lung, and Blood Institute (NHLBI): use of inhaled corticosteroids, peak flow monitoring, asthma action plans,

allergy testing referrals, and influenza vaccination.

Among the providers surveyed, 70 percent were aware of the NHLBI guidelines. However, only 39 percent had actually read them, and 46 percent were using them to manage their asthma patients. Adherence to specific recommendations was highest for influenza vaccination (73 percent), the use of inhaled corticosteroids (62 percent), and peak flow monitoring (34 percent). There was little adherence among providers when it came to using asthma action plans (9 percent) and referring patients for allergy testing (10 percent).

The researchers also found several barriers that were significantly associated with poor adherence to the guidelines overall. One of the most important was the lack of self-efficacy among providers. Providers felt they did not have the ability or

confidence to execute specific guideline recommendations. Other barriers included not being fully familiar with the guidelines and the expectation that patients would not adhere to the various activities called for.

The researchers indicate that increased efforts are needed to bridge the gap between actual care and knowledge of the recommendations. The study was supported in part by the Agency for Healthcare Research and Quality (HS13312).

See "Barriers to adherence to asthma management guidelines among inner-city primary care providers," by Juan P. Wisnivesky, M.D., M.P.H., Jessica Lorenzo, M.P.H., Richard Lyn-Cook, M.D., M.P.H., and others, in the September 2008 *Annals of Allergy, Asthma & Immunology* 101, pp. 264-270.

# Giving patients drugs that interfere with fluoroquinolone antibiotic absorption may lead to resistant infections

evofloxacin and other fluoroquinolones are among the most frequently prescribed antibiotics for adults. A new study cautions against prescribing calcium and magnesium or other oral divalent or trivalent cation-containing compounds (DTCCs) with fluoroquinolones. This may be one way to decrease the number of fluoroquinolone-resistant microbial infections. DTCCs can interfere with gastrointestinal absorption of oral fluorquinolones by 25 to 75 percent, which reduces the effective dose of the drug.

Researchers at the Centers for Education and Research Therapeutics (CERT) at the University of Pennsylvania School of Medicine studied 3,134 patients who received a course of oral levofloxacin for 3 days or longer. For 895 patients, a DTCC was coadministered with 100 percent of levofloxacin doses. A levofloxacin-resistant isolate was identified in 198 patients (6.3 percent) after receiving a course of levofloxacin treatment. These organisms were of several types such as *Staphylococcus aureus* and *Klebsiella pneumoniae*. Coadministration of DTCCs was significantly associated with subsequent identification of a levofloxacin-resistant isolate.

It is recommended that DTCCs be given at least 3 hours before or after giving oral levofloxacin. Yet, at the study hospitals, if a patient was administered levofloxacin and a DTCC on the same day, the two medications were given within 2 hours of each other 77 percent of the time (also known as coadministration). Whether prescribers are unaware of the interactions between DTCC and fluoroquinolones or simply do not know the potential ramifications of coadministration is unknown. The study authors recommend that whenever possible, coadministration of DTCCs and fluoroquinolones should be avoided completely.

The study was supported in part by the Agency for Healthcare Research and Quality (HS10399). For more information on the CERTs program, please visit http://certs.hhs.gov/index.html.

See "Coadministration of oral levofloxacin with agents that impair absorption: Impact on antibiotic resistance," by Keira A. Cohen, B.S., Ebbing Lautenbach, M.D., M.P.D., M.S.C.E., Mark G. Weiner, M.D., and others, in the October 2008 *Infection Control and Hospital Epidemiology* 29(10), pp. 975-977.

### Patients who suffer heart failure do well if they take any betablocker rather than only those extensively tested for the condition

tudies have shown that patients who take certain beta-blockers for heart failure have improved survival rates. However, not all betablockers have been tested to treat heart failure. Three beta-blockers carvedilol (CoReg), metoprolol succinate (Toprol XL), and bisoprolol fumarate (Zebeta)—are referred to as evidence-based beta blockers (EBBBs) because they have been tested for patients with heart failure. However, a new study finds that elderly patients prescribed either EBBBs or non-EBBBs after hospitalizations for heart failure have similar survival rates.

Judith M. Kramer, M.D., M.S., of Duke University, and her

colleagues found that patients hospitalized with heart failure who took EBBBs had a 24-percent mortality rate 1 year after their hospitalizations. Those who took non-EBBBs had a 23-percent mortality rate. In contrast, patients who received no beta-blockers had a 28-percent mortality rate. Nearly 60 percent of patients received no beta blockers. The authors note that physicians who fail to prescribe beta blockers and patients who fail to take them may contribute to higher mortality rates from heart failure.

In the year following their hospitalizations for heart failure, patients who took EBBBs were rehospitalized more often than patients taking non-EBBBs or no beta blockers. These rehospitalizations may have occurred because the patients had other risks for rehospitalization or had physicians who provided better quality care and readmitted the patients to monitor them, the authors suggest.

Because patients were not randomly assigned to receive EBBBs or non-EBBBs, the authors caution that the findings need to be replicated. This study of 11,959 patients eligible for Medicare and Medicaid in North Carolina was funded in part by a grant from the



#### **Beta-blockers**

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Agency for Healthcare Research and Quality (HS10548) to the Duke Center for Education and Research on Therapeutics (CERT). For more information on the CERTs program, visit http://certs.hhs.gov/index.html.

See "Comparative effectiveness of β-blockers in elderly patients with heart failure," by Dr. Kramer, Lesley H. Curtis, Ph.D., Carla S. Dupree, M.D., Ph.D., and others in the December 8, 2008 *Archives of Internal Medicine* 168(22), pp. 2422-2428.

# Study explores the ethics of using cluster randomized trials to compare drug effectiveness

andomized controlled trials typically evaluate a drug's effectiveness compared to a placebo. Cluster randomized trials (CRTs), in which groups of patients are randomly assigned to different drugs, could provide a powerful way to compare different drugs to treat the same condition. However, CRTs have not been widely used, in large measure due to concerns about whether patients must give individual informed consent to participate in them. A new study concludes that CRTs of comparative drug effectiveness can ethically be conducted at health plans without requiring individual informed consent.

Researchers reached this conclusion after a review of the research ethics literature, consultation with a health plan ethics committee, interviews with patients, physicians, and health plan leaders, and their own ethical deliberations. They envision that physicians participating in the CRT would provide either drug A or drug B for a particular condition such as hypertension, which are both considered effective for that condition. Neither drug is considered "better" than the other (clinical equipoise).

Several health plans will participate with some favoring A and others favoring B. "Favor" means that

unless clinicians have specific reasons for choosing the nonpreferred agent, they will use the preferred one. Health plan databases will be used to follow patterns of side effects, medication changes, and clinical outcomes.

Since the choice of drug A or B mimics clinical practice pretty closely, and the drugs are both effective, there is no need to get patient's consent in any way that differs from ordinary practice, note the researchers. However, there is a need to show respect for patients by treating them as research partners and explaining the existence of the CRT and rationale for conducting it. The study was supported by the Agency for Healthcare Research and Quality (HS10391) to the HMO Research Network Center for Education and Research in Therapeutics (CERT). For more information on the CERTs program, please visit http://certs.hhs.gov/index.html.

More details are in "Comparing drug effectiveness at health plans: The ethics of cluster randomized trials," by James E. Sabin, M.D., Kathleen Mazor, Ed.D., Vanessa Meterko, and others, in the September-October 2008 *Hastings Center Report* 35 (5), pp. 39-48.

### Model prioritizes which drugs used off-label should be studied first

fter drugs go through rigorous clinical trials for determination of safety and efficacy, the U.S. Food and Drug Administration (FDA) approves the product and allows it to be labeled and marketed to treat specific conditions. Some clinicians, however, prescribe drugs to treat conditions for which they have not been approved. This practice, called "off-label" prescribing is allowed as part of the practice of medicine. However, in some cases there is little or no

evidence as to the effectiveness or safety of this off-label use.

Surrey M. Walton, Ph.D., and colleagues at the Chicago-Area Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Center, under an Agency for Healthcare Research and Quality contract (290-2005-0038), developed a model to prioritize research on drugs currently being used off-label. The model applies quantitative measures of the absolute number of off-label uses

for a drug, the scientific evidence for the drugs' off-label use, safety concerns, marketing activity, longevity, and drug cost.

The researchers identified 14 drugs, mainly antidepressants and antipsychotics, that were most worthy of further research, such as systematic comparisons of the available evidence. For instance, the atypical antipsychotics quetiapine, risperidone, and olanzapine are all approved to treat schizophrenia.

### Off-label prescribing

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However, they are also commonly prescribed off label to treat bipolar disorder and depression, even though the FDA has approved quetiapine and risperidone only for when a patient with bipolar disorder is experiencing a manic or depressive episode.

The authors recommend policymakers place a greater emphasis on comparative

effectiveness studies for these offlabel uses and require greater scrutiny of marketing efforts that encourage physicians to prescribe drugs off label. Finally, policymakers could call for diagnosis to become part of the prescription record to facilitate comparative effectiveness research of off-label uses. Electronic health records that capture documentation of a diagnosis for every prescribed drug could be useful tools in that endeavor. For more information about DEcIDE and the Effective Health Care program, please visit http://effectivehealthcare.ahrq.gov.

See "Prioritizing future research on off-label prescribing: Results of a quantitative evaluation," by Dr. Walton, Glen T. Schumock, Pharm.D., M.B.A., Ky-Van Lee, Ph.D., and others in the 2008 *Pharmacotherapy* 28(12), pp. 1443-1452.

### HIV/AIDS Research

# Treatment failure may take up to 90 days after patients stop taking their antiretroviral medication as directed

or treatment to succeed, patients with HIV infection must strictly adhere to their highly active antiretroviral therapy (HAART). If they do not, treatment failure (also called virological failure) occurs, which means that HIV increases in the blood to detectable levels and often it is a resistant strain that is harder to treat. A new study finds that the window between when patients stop adhering to an efavirenz-based HAART regimen and onset of virological failure can be as long as 90 days. This presents a window of opportunity for clinicians to take action as soon as nonadherence is detected, to prevent virological failure and maintain HIV suppression, suggest the study authors.

Investigators from the Center for Education and Research on Therapeutics (CERT) at the University of Pennsylvania School of Medicine and colleagues observed 116 adults with HIV infection with virological suppression (undetectable HIV RNA in the blood) on efavirenz-based HAART. Patients were seen each month and the study was stopped either at virological failure (more than 1,000 copies of HIV RNA/mL of blood) or 12 months, whichever came first. They used a monitoring system to measure the percentage of HAART doses taken during the study period. The results were summarized in four 90-day

adherence periods: immediately, 30 days, 60 days, or 90 days prior to virological failure.

HAART adherence was significantly lower for the seven patients with virological failure compared with the other 109 without virological failure. These differences were significant even up to 90 days prior to the virological failure date (57 percent adherence in the failure group vs. 95 percent in the nonfailure group). The study demonstrates the flaw in assuming that all HIV patients with undetectable viral loads are adherent and therefore should be encouraged to "keep doing what you're doing." It would be better for clinicians to either directly ask HIV patients with an undetectable viral load about their drug adherence or assess pharmacy refills or both with every clinic visit. The study was supported in part by the Agency for Healthcare Research and Quality (HS10399). For more information on the CERTs program, please visit http://certs.hhs.gov/index.html.

More details are in "How long is the window of opportunity between adherence failure and virologic failure on efavirenz-based HAART?" by Robert Gross, M.D., M.S.C.E., Warren B. Bilker, Ph.D., Hao Wang, Ph.D., and Jennifer Chapman, M.D., in the May-June 2008 *HIV Clinical Trials* 9(3), pp. 202-206.

### Sociodemographic factors influence early discontinuation of antiretroviral medication for HIV infection

reatment of HIV infection with antiretroviral therapy (ART) saves lives, but longterm adherence to ART is critical to its success in halting disease progression. Blacks and young people are more likely than others to stop taking their ART early, while women are more likely than men to stop taking some ART drugs than others, concludes a new study. The researchers looked at the influence of sociodemographic factors on early discontinuation of ART among 3,654 black and white adults enrolled in the Tennessee Medicaid (TennCare) program. These patients began taking either a non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor (PI) between 1996 and 2003.

PIs can cause nausea, vomiting, and diarrhea soon after treatment starts, and NNRTIs are linked to rashes and drug-induced hepatitis, which can also occur early in therapy. The NNRTI efavirenz can cause insomnia, dizziness, and intense dreams. In this study, about one-third of the group with HIV disease who began ART containing a PI or NNRTI discontinued therapy within 6 months of starting it. Blacks were more likely than whites to discontinue NNRTIs (37 vs. 28 percent) and PIs (36 vs. 25 percent).

Black race, female sex, and younger age were independent predictors of discontinuation among those starting PIs. Among persons starting NNRTIs, black race, younger age, and disability (based on TennCare enrollment category) predicted early drug discontinuation, but female sex did not. These use patterns may be due to greater and more severe side effects of ART related to genetic differences among blacks and/or

greater susceptibility to drug side effects among women than men, suggest the researchers. This study was funded in part by a grant from the Agency for Healthcare Research and Quality (HS10384) to Vanderbilt University Center for Education and Research on Therapeutics (CERT). For more information on the CERTs program, visit http://certs.hhs.gov/index.html.

See "Sociodemographic factors predict early discontinuation of HIV non-nucleoside reverse transcriptase inhibitors and protease inhibitors," by Shaheena Asad, M.B.B.S., M.S.P.H., Todd Hulgan, M.D., M.P.H., Stephen P. Raffanti, M.D., M.P.H., and others, in the December 2008 *Journal of the National Medical Association* 100(12), pp. 1417-1424.

### Health Care Costs and Financing

# State Medicaid programs vary in prior authorization policies for use of costly biologic antirheumatic drugs

atients suffering from rheumatoid arthritis (RA) and other rheumatologic diseases are often treated with disease-modifying antirheumatic drugs (DMARDs) to reduce their symptoms of fatigue, joint pain, and stiffness and to slow disease progression. However, State Medicaid programs are struggling to manage the costs of the newer biologic DMARDs, such as adalimumab and etanercept. A 1-month supply of these drugs may cost 100 times more than a year's supply of an older synthetic DMARD such as methotrexate or hydroxychloroquine. Many States have implemented prior authorization policies to limit use of biologic DMARDs. However, the policies vary, as do the clinical criteria patients must meet to be prescribed biologic DMARDs, according to a new study.

There are currently no clinical guidelines for when such medications should be started. In this study, 32 States required prior authorization for one or more biologic DMARDs. States varied in the specific medications covered and the criteria required for a drug to be authorized, note Michael A. Fischer, M.D., M.S., and Harvard Medical School colleagues. For example, some States required documentation that the patient had a prior inadequate response to one or more synthetic DMARDs, while others required the prescription be written by a rheumatologist (the toxicity of these drugs often requires complex monitoring).

The researchers obtained prior authorization policy information on biologic DMARDs from State Medicaid

### **Antirheumatic drugs**

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programs and calculated the proportion of DMARD prescriptions and spending attributed to two of the biologic DMARDs, adalimumab and etanercept, in 1999 and 2005. Initially, fewer patients in prior authorization States used biologic DMARDs, but use increased over time to a level similar to that in States that did not require prior authorization for these drugs. Thus, the prior authorization policies seemed to have

only a short-term effect on use of the targeted medications. The study was supported in part by the Agency for Healthcare Research and Quality (HS17151).

More details are in "Prior authorization for biologic disease-modifying antirheumatic drugs: A description of US Medicaid programs," by Dr. Fischer, Jennifer M. Polinski, M.P.H., M.S., Amber D. Servi, A.B., and others, in the November 15, 2008 *Arthritis & Rheumatism* 59(11), pp. 1611-1617.

# Low-risk patients under observation for chest pain often undergo costly interventions and care

hen patients go to the emergency department (ED) with chest pain, more than half will not have coronary artery disease (CAD). Some patients are admitted to observation units (OUs) where physicians can rule out any problems in low-risk patients. This type of chest-pain evaluation is cost-effective compared with standard hospital admission. However, when low-risk patients complete their OU evaluation with a positive or indeterminate stress test, they are admitted to the hospital and often undergo cardiac catheterization with negative results (i.e., less than 50 percent stenosis, absence of threevessel disease, and no percutaneous intervention completed) which, in turn, significantly increases costs.

The researchers retrospectively studied the charts of 1,194 patients

admitted to the OU over a period of 9 months. Chart reviews were conducted on all patients with positive and indeterminate stress tests and on a sample of patients with negative stress tests.

The majority of study patients (90.8 percent) had negative stress tests. Of the 59 patients who underwent cardiac catheterization, 41 were negative. The prevalence of positive or indeterminate stress tests with negative catheterization among all OU stress test patients was 3.4 percent. The prevalence of significant CAD at cardiac catheterization was 1.5 percent.

Costs increased across the board for patients with positive or indeterminate stress tests and subsequent negative catheterizations. When compared with costs for patients with negative stress tests, these patients had increases in ED (\$520 vs. \$467) and OU (\$440 vs. \$307) costs, total costs (\$7,298 vs. \$1,562), and total charges (\$23,499 vs. \$6,973). The researchers indicate that studies are needed to determine the effectiveness and cost/benefit of other methods to risk stratify patients with lost-risk chest pain. The study was supported in part by the Agency for Healthcare Research and Quality (HS00078).

See "Diagnostic uncertainty and costs associated with current emergency department evaluation of low risk chest pain," by Rahul K. Khare, M.D., F.A.C.E.P., Emilie S. Powell, M.D., M.B.A., Arjun K. Venkatesh, M.B.A., and D. Mark Courtney, M.D., F.A.C.E.P., in the September 2008 *Critical Pathways in Cardiology* 7, pp. 191-196.

### **Emergency Medicine**

# Vehicle accidents and patient mishandling are the most common reasons for legal claims against emergency medical services

s first responders, the emergency medical services (EMS) system delivers medical care in less than ideal settings outside of the hospital. Each year, 16 million patients are transported to emergency departments (EDs) in the United States. A variety of adverse events can occur, prompting legal action. A recent study found a low rate of medical carerelated claims against EMS providers; however, when

claims are filed, they are most often related to mishaps involving EMS vehicles and the handling of patients.

Researchers retrospectively analyzed 326 EMS liability insurance claims data provided by a major insurer of EMS systems. In each case, the adverse event was categorized. Characteristics on the emergency units, injured individuals, and associated



### **Emergency medical services**

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injuries were also identified. The analysis also included either an estimate of or the actual total incurred costs.

The most common adverse events identified were crashes of EMS vehicles and the mishandling of patients. Both of these categories accounted for more than 70 percent of the claims studied. In the crash-related claims, those most often injured were pedestrians, bicycle riders, and the occupants of other vehicles. Patient handling mishaps most often involved dropping the patient. This was the result of stretcher collapse, dropping the stretcher or wheelchair, or dropping the patient during transfer. Among the clinical management adverse events, errors in airway

management were the most common. Overall, a quarter of claimants either died or sustained a life-threatening or disabling injury.

The researchers point to the unique care elements associated with EMS. These include dispatch, response, patient extrication and movement, scene management, and transport. Efforts aimed at quality improvement in EMS must address these important and unique characteristics and not just the clinical aspects of care. The study was supported in part by the Agency for Healthcare Research and Quality (HS13628).

See "Tort claims and adverse events in emergency medical services," by Henry E. Wang, M.D., M.S., Rollin J. Fairbanks, M.D., M.S., Manish N. Shah, M.D., M.P.H., and others, in the September 2008 *Annals of Emergency Medicine* 52(3), pp. 256-262.

### Agency News and Notes

### Eating disorders are sending more Americans to the hospital

he number of men and women hospitalized due to eating disorders that caused anemia, kidney failure, erratic heart rhythms, or other problems rose 18 percent between 1999 and 2006, according to data from the Agency for Healthcare Research and Quality (AHRQ). AHRQ's analysis also found that between 1999 and 2006:

- Hospitalizations for eating disorders rose most sharply for children under 12 years of age—119 percent. The second steepest rise was for patients ages 45 to 64—48 percent.
- Hospitalizations for men also increased by 37 percent, but women continued to dominate hospitalizations for eating disorders (89 percent in 2006).

- Admissions for anorexia, the most common eating disorder, remained relatively stable.
   People with anorexia typically lose extreme amounts of weight by not eating enough food, overexercising, self-inducing vomiting, or using laxatives.
- In contrast, hospitalizations for bulimia declined 7 percent. Bulimia is binge eating followed by purging by vomiting or use of laxatives and can lead to severe dehydration or stomach and intestinal problems.
- Hospitalizations for less common eating disorders increased 38 percent. Those disorders include pica, an obsession with eating nonedible substances such as clay or

plaster, and psychogenic vomiting, which is vomiting caused by anxiety and stress.

For more information, see Hospitalizations for Eating Disorders from 1999 to 2006, HCUP Statistical Brief #70 (www.hcup-us.ahrq.gov/reports/ statbriefs/sb70.pdf). The report uses statistics from the 2006 Nationwide Inpatient Sample, a database of hospital inpatient stays that is nationally representative of inpatient stays in all short-term, non-federal hospitals. The data are drawn from hospitals that comprise 90 percent of all discharges in the United States and include all patients, regardless of insurance type, as well as the uninsured.

### Treating heart ailments costs \$78 billion

pening blocked arteries, trying to keep heart attack victims alive, fixing defective heart valves, and treating other heart ailments cost \$78 billion in 2006—roughly 8 percent of the more than \$1 trillion spent on all medical care for the community population, according to an analysis of data from the Agency for Healthcare Research and Quality (AHRQ). This figure reflects costs for hospital admissions, emergency department visits, visits to doctors' offices and hospital outpatient departments, home health care, and prescription drug spending. Of the \$78 billion spent for heart disease care in 2006, AHRQ found that:

- Hospital admissions absorbed \$43.9 billion, or 56 percent.
- Visits to doctors' offices and hospital outpatient departments accounted for \$15.3 billion, or 20 percent.

- Outpatient prescription drugs cost \$7.9 billion, nearly 10 percent.
- Home nursing and other home care services cost \$6.7 billion, or 9 percent.
- Emergency room care cost \$4.3 billion, or 6 percent.

This analysis was based on data from AHRQ's Medical Expenditure Panel Survey (MEPS). MEPS collects information each year from a nationally representative sample of the U.S. civilian noninstitutionalized population about their health care use, expenses, access to services, health status, and the quality of the health care they obtained. For more information, go to www.meps.ahrq.gov/mepsweb.

### Announcements

# AHRQ and the Ad Council encourage consumers to ask questions and get more involved in their health care

he Agency for Healthcare
Research and Quality
(AHRQ) has joined with The
Advertising Council and actress and
health advocate Fran Drescher to
launch a new series of national
public service advertisements
(PSAs) designed to encourage
consumers to get involved in their
health care by knowing and asking
appropriate questions when visiting
their doctors or other clinicians.

The new "Questions" PSAs, which were created pro bono by Grey New York, aim to encourage all patients to become more involved in their own health care by asking questions of their doctors or other clinicians. The ads feature people asking

questions in everyday situations, such as ordering food at a restaurant and buying a cell phone, but clamming up when their doctor asks if they have questions. The television, radio, print, outdoor, and Web ads direct audiences to visit a comprehensive Web site, www.ahrq.gov/questionsaretheanswer, to learn the 10 questions every patient should think about asking when visiting their doctor or other clinicians.

The new "Questions" PSAs are an extension of the Ad Council and AHRQ's patient involvement PSA campaign that launched in March 2007. The campaign is one of a series of campaigns that AHRQ and the Ad Council have

collaborated on to improve health care. Other campaigns encourage men to get appropriate preventive care screenings and encourage Hispanics to take care of themselves by visiting a doctor to get preventive tests. The Web site features tips for patients to become more involved in their health care, including a list of questions everyone should know when they visit their doctor or other clinician. The Web site also features a "Question Builder" tool that allows patients to develop a customized list of the questions they can take to their medical appointments.

# New plain language guides on the comparison of insulin treatments for Type 2 diabetes are available

he Agency for Healthcare Research and Quality (AHRQ) released a pair of plain-language guides for consumers and clinicians comparing the efficacy, effectiveness, and side effects of newer premixed insulin analogues with conventional insulin (human insulin) and other preparations used to control Type 2 diabetes.

The consumer guide—Premixed Insulin for Type 2 Diabetes: A Guide for Adults—is a primer on diabetes, diabetes testing, and treatments. The guide explains the differences among insulin analogues that last all day, insulin used at meal time, and the newer premixed insulin analogues that are both effective all day and after meals, a time when blood sugar levels can suddenly rise. Finally, the guide offers a cost comparison chart for different types of treatments under generic and brand names.

The clinician guide—Premixed Insulin Analogues: A Comparison with Other Treatments for Type 2 Diabetes—covers the same information as the consumer guide, but also includes a level of confidence scale for the information included in the guide, based on the systematic review of literature and assists clinicians in choosing the appropriate type of insulin based on patients' physiologic needs.

The new guides on treatments for type 2 diabetes show that:

- When newer premixed insulin analogues were compared with long-acting insulin analogues (insulin lasting all day), the premixed insulin analogues were better at lowering A1c levels and at lowering blood sugar after meals. The long-acting insulin analogues were found to be better at lowering fasting blood sugar levels, and showed fewer incidents of hypoglycemia and less weight gain.
- When conventional insulin (premixed human insulin)
  was compared with newer premixed insulin
  analogues, the latter was better at lowering blood
  sugar after meals, but both kinds of insulin were
  equally as effective at lowering A1c and lowering
  fasting blood sugar levels. They showed similar
  incidence of hypoglycemia and weight gain.

Premixed Insulin for Type 2 Diabetes: A Guide for Adults and Premixed Insulin Analogues: A Comparison with Other Treatments for Type 2 Diabetes are the newest in a series of comparative effectiveness guides from AHRQ's Effective Health Care program. Other AHRQ guides compare treatments for prostate cancer, osteoarthritis, pills for hypertension, pills for type 2 diabetes, depression, and other conditions. These guides and more information about the Effective Health Care program can be found at www.effectivehealthcare.ahrq.gov.

### Research Briefs

Bazzoli, G. J., Chen, H-F., Zhao, M., and Lindrooth, R. C. (2008, August). "Hospital financial condition and the quality of patient care." (AHRQ grant HS13094). *Health Economics* 17(8), pp. 977-995.

The mounting concerns about patient quality of care that were occurring during a period (1995-2000) of sustained hospital financial weakness raised the question of whether patients are harmed by declining hospital financial performance. The researchers examined the

relationship between hospital financial condition and patient care. Hospital financial performance was measured by two measures: operating margin and the ratio of cash flow to total revenues. Patient care was measured by patient safety and quality of care measures that were developed from the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Program State Inpatient Database. The study included more than 1,544 non-federal general acute care hospitals in 11 States.

The researchers found that operating margin did not have a significant effect on the incidence of adverse events in the following areas: surgical-related patient safety events, nursing-related patient safety events, and in-house mortality for diagnosis-related groups with typically low mortality rates. However, the poorest and second poorest performing groups (hospitals were divided into quartiles) in relation to cash flow to total revenues did have higher excess incidents in two of these areas.



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Berdahl, T. A. (2008, December). "Racial/ethnic and gender differences in individual workplace injury risk trajectories: 1988-1998." American Journal of Public Health 98(12), pp. 2258-2263. Reprints (AHRQ publication no. 09-R020) are available from AHRQ.\*

Very little is known about how individual workplace injury risk changes across occupations or how racial/ethnic and gender disparities in risk change over time. The researcher estimated individual workplace injury and illness risk over time ("trajectories") for a group of American workers who participated in the National Longitudinal Survey of Youth (1988-1998). The study found that white men had a high risk of injury relative to the other groups (white women, black men, black women, Latino men, Latino women) and experienced the greatest decline over time. Among women, black women had the greatest risk of injury. Workers who moved into jobs requiring more work hours had increased odds of injury. Working in higher-wage jobs did not protect against injury; moreover, unionized jobs and jobs with health insurance were associated with increased injury odds. Finally, environmental hazards were associated with elevated injury risk but the level of physical demand was not associated with a higher risk of physical injury.

Brady, J., Ho, K., and Clancy, C. M. (2008). "State snapshots—A picture of unacceptable variation: Are we destined to live with 'geography is destiny'?" (2008, November/December). American Journal of Medical Quality 23(6), pp. 492-495.

Variations in the quality of health care are based on region as well as on other factors. The Agency for Healthcare Research and Quality (AHRQ) annually produces a Web tool highlighting state-level data from its quality and disparities reports. The "State Snapshots" generated with this Web tool include information on performance strengths and weaknesses for each state. Analysis of these State-level data provide concrete, actionable information about where to focus quality improvement efforts, according to Carolyn M. Clancy, M.D., AHRO's director, and colleagues. For example, comparisons of two States (Maryland and Missouri) of similar populations show that Maryland performs weakly in preventive measures and in respiratory disease measures, while Missouri is below average in diabetes and heart disease measures. State-level data in their totality demonstrate two points: even States with comparatively strong overall health care quality have areas that need improvement and attention to variations in quality can help target resources for quality improvement efforts where they are needed most in each State. To see how a State fares against regional and national averages, visit AHRQ's State Snapshots Web page at statesnapshots.ahrq.gov.

Chernew, M., and Gibson, T. B. (2008, December). "Cost sharing and HEDIS performance." (AHRQ grant HS10771). Medical Care Research and Review 65(6), pp. 713-728.

Patient cost sharing is among the most commonly used levers to control health care costs. Therefore, efforts should be made to assess the extent to which cost sharing contributes to the failure of patients to receive high quality care. This

study is the first to investigate the impact of cost sharing on the most widely used measures of performance contained in the Health Plan Effectiveness Data and Information Set (HEDIS). Specifically, the researchers focus on all of the HEDIS measures related to prescription medications. Their analysis uses the 2000-2003 MarketScan Commercial Claims and Encounters database, which includes 6 million employees with employer-sponsored health insurance each year. Three types of patients were included: those with persistent asthma, those with a diagnosis of major depression, and those discharged from the hospital after a heart attack. Copayments for office visits or prescription drug payments had no appreciable effect on heart disease performance measures. By contrast, office visit copayments but not prescription drug copayments affected the asthma performance measure. The strongest copay effects were found for depression, where a \$10 increase in copayments yielded a reduction of 3.6 percent in the performance measure.

# Clancy, C. M. (2008, December). "Medicare policy marks new link between hospital payment, patient safety." *Journal of Patient Safety* 4(4), pp. 215-216.

Under a policy rule that took effect in October 2008, the Centers for Medicare & Medicaid Services will stop paying hospitals the extra costs they incur for eight hospital-acquired conditions whose serious consequences, experts believe, could be prevented. This rule is a much-anticipated change in the Federal government's response to patient safety events. Aligning hospital payments with improved patient safety has also gained steam among private health care



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purchasers, according to Carolyn M. Clancy, M.D., director of the Agency for Healthcare Research and Quality (AHRQ). A recent study by AHRQ researchers has estimated the costs to insurers of preventable patient safety events among surgical patients during and after a hospital stay. These potentially preventable medical errors could cost employers \$1.5 billion a year. Insurers paid an additional \$28,218 for surgical patients who experienced acute respiratory failure compared with patients who did not. Medicare's new payment policy demands that we focus our energies on conditions that evidence shows can be drastically reduced.

Conwell, L. J., and Boult, C. (2008). "The effects of complications and comorbidities on the quality of preventive diabetes care: A literature review." (AHRQ grant HS16219). Population Health Management 11(4), pp. 217-228, 2008.

The association between complications and comorbidities and the quality of preventive diabetes care is unclear but it may affect either the treatment of diabetes or other comorbid conditions. This literature review categorizes measures of complications and comorbidities in the studies of the quality of diabetes care, to document whether these studies adjusted for complications and comorbidities and to determine the extent to which these measures are valid for assessing the quality of care delivered to people with diabetes. The review identified and categorized 34 studies in which the quality of diabetes preventive care was assessed with process measures and complications or comorbidities were reported. Because of crossstudy variation among measures of complications and comorbidities and because very few studies address the independent effects of complications and comorbidities, the effects of complications and comorbidities on processes of care are unclear. The results of the review suggest that the effects of complications and comorbidities on the delivery of preventive services are complex, only partly understood, and not yet reliably quantified.

Gorelick, M., Scribano, P. V., Stevens, M. W., and others. (2008, November). "Predicting need for hospitalization in acute pediatric asthma." (AHRQ grant HS09825). *Pediatric Emergency Care* 24(11), pp. 735-744.

Traditionally, children treated for acute asthma on an emergency basis faced two possible dispositions: hospital admission or discharge to home in the care of a parent. Either of these dispositions could be in error, according to earlier studies. Recently, many emergency departments have incorporated short-stay units (SSUs) where patients may receive more intensive care for periods less than 24 hours. The researchers sought to develop a clinical prediction model, using explicit criteria for appropriateness, to assign an accurate disposition (discharge, SSU, or inpatient care) for children with acute asthma. Using only two variables—final clinical score at the time of disposition and number of albuterol treatments given in the emergency department (ED)—the researchers were able to develop a prediction score that predicted accurately those patients who could be discharged successfully to home from the ED without relapse versus

those requiring further care in the hospital. The prospective study was of children aged 2 years and older treated at two pediatric EDs for acute asthma.

Haggerty, C. L., Totten, P. A., Astete, S. G., and others. (2008, October). "Failure of cefoxitin and docycycline to eradicate endometrial *Mycoplasma genitalium* and the consequence for clinical cure of pelvic inflammatory disease." (AHRQ grant HS08358). *Sexually Transmitted Infections* 84(5), pp. 338-342.

Pelvic inflammatory disease (PID) is associated with the pathogen Mycoplasma genitalium; however, the efficacy of commonly used PID antimicrobials in treating M. genitalium upper genital tract infection is unknown. In the PID **Evaluation and Clinical Health** Study (PEACH), 682 women treated with cefotoxin and doxycycline for clinically suspected PID had stored cervical and endometrial specimens available for analysis. This study, a substudy of PEACH, is the first to investigate treatment failure among PID patients with M. genitalium identified in the endometrium. This pathogen persisted among 44 percent of women after 30 days despite a standard Centers for Disease Control and Preventionrecommended treatment of cefotoxin and doxycycline. The researchers conclude that M. genitalium is associated with endometritis and short-term PID treatment failure, as evidenced by persistent endometritis and continued pelvic pain.

Halm, E. A., Press, M. J., Tuhrim, S., and others. (2008, November/December). "Does managed care affect quality?



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Appropriateness, referral patterns, and outcomes of carotid endarterectomy." (AHRQ grant HS09754). American Journal of Medical Quality 23(6), pp. 448-456.

The New York Carotid Artery Surgery (NYCAS) study sought to determine whether Medicare patients enrolled in Medicare managed care plans (Medicare Choice MC plans) had lower rates of carotid endarterectomies (CEAs), operations more frequently performed in high-volume hospitals, or better perioperative outcomes compared with patients enrolled in fee-for-service (FFS) Medicare. The study group consisted of 8,691 Medicare beneficiaries with FFS coverage and 897 with MC coverage. The study found that there were no differences in rates of inappropriate surgery between FFS and MC cases (8.6 percent vs. 8.4 percent). FFS patients were more likely to be operated on in higher volume hospitals, mostly because fewer MC patients were operated on at the highest quintile facilities. Rates of death, nonfatal stroke, and myocardial infarction were similar for the two groups. The researchers concluded that MC plans did not have a positive impact on inappropriateness, referral to highvolume providers, or clinical outcomes.

Le Cook, B., McGuire, T. G., and Zuvekas, S. H. (2009, February). "Measuring trends in racial/ethnic health care disparities." *Medical Care Research and Review* 66(1), pp. 23-48. Reprints (AHRQ publication no. 09-R019) are available from AHRQ.\*

This study compares trends in disparities by three definitions of racial/ethnic disparities and assesses the influence of changes in socioeconomic status (SES) among racial/ethnic minorities on disparity trends. The researchers use data (1996-2005) from the Agency for Healthcare Research and Ouality's (AHRQ's) Medical Expenditure Panel Survey (MEPS). The three definitions used in the comparison are AHRO's definition, the Residual Direct Effect (RDE) definition, and the Institute of Medicine's (IOM) definition. The researchers found that black-white disparities in having an officebased or outpatient visit were roughly constant between 1997 and 2005 and Hispanic-white disparities increased for office-based or outpatient visits and for medical expenditure during this period. All three definitions tell basically the same story; however, for most analyses measuring disparities at a point in time, the AHRO unadjusted approach estimated the largest disparities and the RDE measured the smallest disparities. After discussing empirical differences among the definitions and the debate about the different definitions, the researchers state a preference for the IOM's definition (health care disparities are all differences not due to health status or need) because the definition captures what most researchers and policymakers are concerned about.

Liu, L., Ma, J. Z., and Johnson, B. A. (2008). "A multi-level two-part random effects model, with application to an alcoholdependence study." (AHRQ grant HS16543). Statistics in Medicine 27, pp. 3528-3539.

The researchers extend the twopart random effects model for clustered semi-continuous data to the multilevel setting. They apply a novel multilevel two-part model to the efficacy trial of topiramate for alcohol-dependent subjects. The estimation and inference are carried out through Gaussian quadrature technique, which is available in free software. The model takes into account the preponderance of zeros as well as the multilevel structure. The efficacy trial was conducted to compare the safety and efficacy of oral topiramate and placebo in a group of 150 alcohol-dependent subjects. When compared with the results of two simple models with respect to the positive number of drinks outcome, the novel model performed better in terms of Akaike information criteria. An important advantage of the new model is that it can be applied to other substance addiction studies because of its efficiency and simplicity.

Mutter, R. L., Wong, H. S., and Goldfarb, M. G. (2008, Fall). "The effects of hospital competition on inpatient quality of care." *Inquiry* 45, pp. 263-279. Reprints (AHRQ publication no. 09-R042) are available from AHRQ.\*

Studies thus far have had inconclusive findings about the effects of hospital competition on inpatient quality of care. Applying Quality Indicator software from the Agency for Healthcare Research and Quality to the 1997 Healthcare Cost and Utilization Project State Inpatient Databases, the researchers created 3 versions of 38 measures of inpatient quality. To assess competitiveness, they used 12 different hospital competition measures. The study used data for all patients in 22 States and up to 2,595 hospitals. The findings were not unidirectional. Hospital competition was associated with an



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improvement in inpatient quality for six Quality Indicators (QIs), including complications of anesthesia; however, it was also associated with a reduction in inpatient quality for six QIs, including decubitis ulcer. In general, the findings at the high and low end of HMO penetration were consistent with each other and with the findings at the mean level of HMO penetration. The exception was iatrogenic pneumothorax for which there were more incidences associated with high managed care penetration; yet, in markets with low managed care penetration, the opposite was true.

Novotny, N. L., and Anderson, M. A. (2008, November/
December). "Prediction of early readmission in medical inpatients using the probability of repeated admission instrument." (AHRQ grant HS15084). Nursing Research 57(6), pp. 406-415.

Up to 25 percent of hospitalized adults experience early readmission, and those within the first few months after discharge are more likely to have been avoidable than later readmissions. Welldeveloped and validated instruments to predict an individual's risk of readmission are rare. The probability of repeated admission (Pra) instrument incorporates select diagnostic, demographic, and self-rated psychosocial factors and has been shown to be a valid predictor for readmission within 4 years for outpatients older than 70 years. Since there is a need to predict this risk for patients of any age, this study assessed how well the Pra correctly identified and predicted adult medical patients' risk of early readmission. At a Pra score value of .47 or greater, the instrument

demonstrates good specificity. In this population, however, the Pra score value needs to be .38 or less to yield satisfactory sensitivity. At this time, the Pra is better than any other known instrument for the purpose of predicting early readmission but it is necessary to develop an instrument that will be more highly predictive of early readmission within a heterogeneous population.

Nyman, J. A., Barleen, N. A., and Kirdruang, P. (2008, November/December). "Quality-adjusted life years lost from nonfatal motor vehicle accident injuries." AHRQ grant HS14097). Medical Decision Making 28, pp. 819-828.

In describing the importance and severity of the health consequences of motor vehicle accident injuries, researchers are turning to qualityadjusted life years (QALYs) as the preferred measure because of their wide acceptance, standardized methodology, and rigorous theoretical origins. QALYs associated with nonfatal injuries are more problematic than those associated with fatalities because they require the researcher to determine the severity of the various injuries and then assign a quality-of-life decrement and a duration for each type of injury. The researchers used 1997-2004 data from the household component of the Medical Expenditures Panel Survey. They found that the QALY decrements associated with a motor vehicle accident injury are 0.0612 QALYs or 0.0360 QALYs, if discounted. The discounted OALY decrement is between 3 and 10 times smaller than the discounted estimates in the literature (0.127 and 0.356). This is probably because the baseline quality of life for calculating the decrement due to injury is not assumed to be 1.00 but rather the actual quality-of-life level before an injury (which averaged 0.865).

O'Malley, A. J., and Zaslavsky, A. M. (2008). "Domain-level covariance analysis for multilevel survey data with structured nonresponse." (AHRQ grant HS09205). Journal of the American Statistical Society 103(484), pp. 1405-1418.

Health care quality surveys such as the Consumer Assessments of Healthcare Providers and Systems (CAHPS®) are administered to individual respondents to evaluate the performance of hospitals and health plans. For a better understanding of dimensions of quality, the researchers analyze relationships among quality measures at the domain (i.e., hospital or health plan) level. They first fit generalized variancecovariance functions that take into account nonresponse patterns in the survey responses, then specify a likelihood function for the domain mean responses using these generalized variance-covariance functions. This allows them to model directly the relationships among domain means for different items. After calculating maximum likelihood estimates using the EM algorithm and sample under Bayesian models using Markov chain Monte Carlo, they perform factor analysis on the estimated or sampled between-domain covariance matrixes. Since this approach accommodates missing data at both the domain and individual levels, it is particularly useful when measures may have extensive data, very little data, or no data in various domains.

Paddock, S. M., and Ebener, P. (2008). "Subjective prior distributions for modeling



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longitudinal continuous outcomes with non-ignorable dropout." (AHRQ grant HS14805). *Statistics in Medicine* 28, pp. 659-678.

Substance abuse treatment research is complicated by the pervasive problem of important missing data related to unobserved outcomes. This occurs because some clients leave prior to completion of treatment. Missing data of this type are problematic when the goal is to measure the treatment process and its effects on post-treatment outcomes. To account for such factors, researchers have frequently used pattern-mixture models (PMMs) to jointly model the outcome and the missing data mechanism. Despite the widespread use of PMMs for longitudinal data analysis, no attention has yet been devoted to eliciting prior distributions from subject-matter experts about the identification of the rate of change (slope) parameter for persons who drop out of a study after completing just one assessment. Interviews with five substance abuse clinical experts revealed that their opinions differed dramatically from assumptions widely used to identify parameters in the PMM. The researchers concluded that those who plan to conduct sensitivity analyses using PMMs or selection models should make a serious effort to incorporate expert opinion into the model in order to address. concerns about nontestable assumptions.

Powers, B.J., Olsen, M.K., Oddone, E.Z., and others. (2008). "Literacy and blood pressure do healthcare systems influence this relationship? A crosssectional study," (AHRQ grant T32 HS00079). BioMed Central Health Services Research 8(219), pp. 1–9.

Limited literacy (reading below the 9th grade level) is associated with poorer health care outcomes. In this study, the researchers found evidence that differences in health care systems may influence the relationship between literacy and blood pressure in primary care patients with hypertension. They analyzed baseline data for 588 patients enrolled in a hypertension control trial within the Veterans Affairs health care system (VAHS) and 636 patients enrolled a hypertension control trial at the Duke University Health System (UHS). Overall, 38.4 percent of the VAHS patients and 27.5 percent of the UHS patients had limited literacy. There was a significant difference only in systolic blood pressure between the two health care settings. Systolic blood pressure for VAHS patients with limited literacy was 1.2 mm Hg lower than for patients with adequate literacy, but patients in UHS with limited literacy had systolic pressure 6.1 mm Hg higher than for patients with adequate literacy. This finding of sensitivity to the patient's health system was not true of diastolic blood pressure or blood pressure control.

Raab, S. S., Grzybicki, D. M., Condel, J. L., and others. (2008). "Effect of Lean method implementation in the histopathology section of an anatomical pathology laboratory." (AHRQ grant HS13321). Journal of Clinical Pathology 61, pp.1193-1199.

The lack of standardization in American anatomical pathology laboratories results in less than optimal quality, inefficiencies, and increased health care costs. The researchers sought to measure the effects of a Lean quality

improvement process on the efficiency and quality of a histopathology section of an anatomical pathology laboratory. They selected a Lean process known as Perfecting Patient Care (PPC). The setting for the study was a large urban hospital in Pittsburgh. One efficiency metric used was specimen turnaround time (TAT), defined as the time from when the gross examination was complete to the time when the slides from a case were verified and sent to a pathologist. The other efficiency metric was productivity, defined as the total number of work units (i.e., tissue blocks and slides) divided by the number of personnel full-time equivalents. The study found that the implementation of Lean processes decreased specimen TAT and increased productivity.

Schiff, G.D., and Galanter, W.L. (2009). "Promoting more conservative prescribing." (AHRQ grant HS16973). Journal of the American Medical Association 301(8), pp. 865–867.

In this commentary, the authors set out the reasons for and a set of principles to guide more conservative prescribing by clinicians. Such guiding principles, they say, can help reduce the prevalence of medication-related harm to patients and inappropriate prescribing. The commentary offers 25 principles to enlighten the thinking of clinicians-in-training about pharmacotherapy to emphasize care, caution, and reliance on evidence-based information. The authors organize their principles into six categories: (1) think beyond drugs; (2) practice more strategic prescribing; (3) heighten vigilance regarding adverse effects; (4) act with caution and skepticism regarding new drugs; (5) share your agenda with



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patients; and (6) weigh long-term, broader aspects of care. The authors then discuss barriers to conservative prescribing, such as time pressure, patient expectations, and the biases built into industry-funded research studies and educational programs.

Selim, A. J., Rogers, W., Fleishman, J. A., and others. (2008). "Updated U.S. population standard for the Veterans RAND 12-item Health Survey (VR-12)." Quality of Life Research 18, pp. 43-52. Reprints (AHRQ publication no. 09-R039) are available from AHRQ.\*

The Veterans RAND 12-item Health Survey (VR-12) is a Health-Related Quality of Life (HRQoL) survey instrument used in assessments of quality improvement activities and health care system accountability. The researchers' objective was to update the nonproprietary 1990 scoring algorithms for scoring the VR-12. To do this, they used data collected between 2000 and 2002 by the Agency for Healthcare Research and Quality's Medical Expenditure Panel Survey (MEPS). They found that changes in the U.S. population between 1990 and today make the old standards obsolete for the VR-12. The researchers present a robust method for deriving physical and mental summary scores for the VR-12 based upon an updated standard from the U.S. population. This standard has a contemporary mean of 50 in the general U.S. population, as represented in the MEPS 2000-2002. The updated standard made available here is widely available to serve as a contemporary standard for future applications for HRQoL assessments.

Short, V. L., Totten, P. A., Ness, R. B., and others. (2009, January 1). "Clinical presentation of *Mycoplasma genitalium* infection versus *Neisseria gonorrhoeae* infection among women with pelvic inflammatory disease." (AHRQ grant HS08358). *Clinical Infectious Diseases* 48(1), pp. 41-47.

The pathogens Neisseria gonorrhoeae and Chlamydia trachomatis cause 30 to 50 percent of cases of pelvic inflammatory disease (PID) in women. Mycoplasma genitalium may be at the root of PID cases that are neither gonococcal nor nonchlamydial. Left untreated, PID caused by M. genitalium can lead to infertility, ectopic pregnancies, and chronic pain. Researchers evaluated 722 women enrolled in a PID study to compare markers of PID caused by M. genitalium with those of N. gonorrhoeae. They found that the former's markers were closer to chlamydial infection, which tends to have no symptoms. In contrast, women whose PID was caused by N. gonorrhoeae had symptoms such as high pelvic pain scores and inflammation markers including elevated oral temperatures and elevated white blood counts.

Wang, H. E., Marroquin, O. C., and Smith, K. J. (2009, February). "Direct paramedic transport of acute myocardial infarction patients to percutaneous coronary intervention centers: A decision analysis." (AHRQ grant HS13628). Annals of Emergency Medicine 53(2), pp. 233-240.

For patients with acute STsegment elevation myocardial infarction (STEMI), consensus guidelines recommend rapid primary percutaneous coronary intervention. In following this guideline, emergency medical services (EMS) may bypass nearby community hospitals that offer fibrinolytic therapy in favor of transporting the patient to a more distant specialty center able to perform primary percutaneous coronary intervention. There are many factors to be considered, including travel time to the nearest percutaneous coronary intervention center, the expected survival benefit of each STEMI treatment option, the anticipated benefit decay with elapsed time, and the uncertainties in total treatment time. Using decision analysis based on parameter values from metaanalyses and North American clinical studies of STEMI and chest pain care published after 2001, the researchers found that 30-day survival rates were slightly higher for standard percutaneous coronary intervention when compared with standard community hospital fibrinolytic therapy. However, the survival rates were slightly lower when compared with best-case community hospital fibrinolytic therapy.

Wilt, T. J., Brawer, M. K., Barry, M. J., and others. (2009, January). "The prostate cancer intervention versus observation trial: VA/NCI/AHRQ cooperative studies program #407 (PIVOT): Design and baseline results of a randomized controlled trial comparing radical prostatectomy to watchful waiting for men with clinically localized prostate cancer." Contemporary Clinical Trials 30(1), pp. 81-87.

Undergoing surgery or radiation therapy to treat prostate cancer can leave men with bladder or erectile problems. As a result, some physicians and patients instead choose to monitor the cancer's progression, an option called watchful waiting. Researchers from

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the U.S. Department of Veterans Affairs, the National Cancer Institute, and the Agency for Healthcare Research and Quality are currently conducting a study comparing the options of watchful waiting and surgery to remove the prostate gland (radical prostatectomy). Called the Prostate Cancer Intervention Versus Observation Trial (PIVOT), the study enrolled 731 men from 1994 to 2002 whose prostate cancer was detected with the prostate specific antigen blood test. Almost a third of the men are black, which is significant because these men are at high risk of getting and dying from prostate cancer. Researchers hope to determine whether early surgical intervention improves the length and quality of life compared with watchful waiting combined with noncurative therapies. This article summarizes the study's rationale, design, recruitment, and enrollee characteristics. Study results are expected in mid 2010.

Wong, C., Mouanoutoua, V., and Chen, M.-J. (2008). "Engaging community in the quality of hypertension care project with Hmong Americans." (AHRQ grant HS110276). Journal of Cultural Diversity 15(1), pp. 30–36.

The culture of a minority community can pose tremendous challenges to researchers striving to improve the quality of health care in these communities. Because of its history of refugee status, low proportion of English speakers, and cultural beliefs, the Asian Hmong community in central California has been cautious about its involvement with health care institutions. In this study, the researchers used collaboration with leaders of the Hmong community to develop a community-sensitive survey on hypertension care. They developed questions in English and translated them into the two main Hmong dialects. After checking by independent back-translation into English, the survey questions were discussed with a group of Hmong community leaders. The survey was then presented to Hmong focus group participants to remove ambiguity or to point out areas of cultural sensitivity. For example, a question whether "your doctor [told] you about what side effects the blood pressure medicine might have?" was dropped because of the lack of a concept equivalent to side effects in Hmong. Based on input from these community members, the researchers were able to develop culturally and linguistically appropriate survey instruments while allowing the Hmong community to effectively voice its own health care needs.

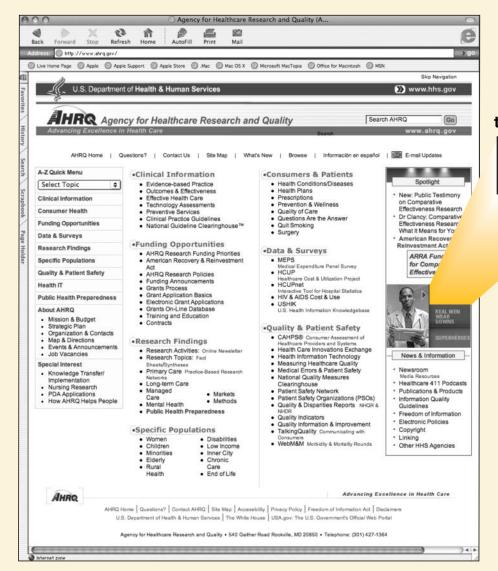
Unruh, L., Russo, L., Jiang, H. J., and Stocks, C. (2009, February). "Can state databases be used to develop a national, standardized

hospital nursing staffing database?" Western Journal of Nursing Research 31(1):66-88. Reprints (AHRQ publication no. 09-R040) are available from AHRQ.\*

Reliable data on hospital nurse staffing are difficult to find and researchers are asking for more valid and reliable national data. To respond to this need, the researchers conducted a State-by-State review of data reporting systems. They found that at least 25 States collect nurse staffing data; however, detailed information is not available from all of them. Only 12 States meet the availability, completeness, and usability criteria for a Level 1 database. Level 2 databases must meet further data quality and specificity criteria, which are to have separately delineated registered nurse (RN) and licensed practical nurse staffing categories measured in full-time employeecalculable numbers, with clearly delineated units of nursing work, levels of measurement, time frames, and nursing roles included in the RN measure. Only five States (Arizona, Pennsylvania, Tennessee, Virginia, and West Virginia) meet these more rigorous criteria. It is from these five States that a Level 1, State-by-State database could begin to be built.

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