



Research Activities



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Many chronically ill patients don't tell their doctors that they limit use of prescription drugs because of cost

Patients who are concerned about out-of-pocket medication costs often restrict their use of prescription drugs, according to a recent study. In addition, the study revealed that about two-thirds of chronically ill adults who cut back on their medications because of the cost don't tell their doctors in advance. The study was cofunded by the Agency for Healthcare Research and Quality (AHRQ grant HS10281) and the Department of Veterans Affairs.

John D. Piette, Ph.D., and his colleagues from the Center for Practice Management and Outcomes Research at the VA Ann Arbor Healthcare System surveyed a panel of 4,055 adults age 50 and older who reported taking prescription medication for diabetes, depression, heart problems, or high cholesterol. Of these, 660 patients reported forgoing some medication in the prior year due to cost pressures, and two-thirds of this group reported that they did not tell their clinicians in advance.

Approximately 35 percent of the 660 patients said that they had never discussed medication costs in the prior year with their clinicians.

The researchers found that most patients who failed to talk with their clinicians about medication costs said that none of their providers asked them about possible problems they might have in paying for their treatment. Patients also reported that they didn't think their clinicians would be able to help them with this problem, or that they were too embarrassed to discuss issues related to cost with their clinicians.

Most patients who did discuss the cost of prescription medication with their clinicians found their clinicians to be helpful and received various forms of assistance such as free samples or a change in their regimen to a less-expensive or generic alternative. However, less than one-third of the patients who spoke to their clinicians about the cost of prescription drugs reported that

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Chronically ill patients

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they had been given information about programs to assist patients

with medication costs or sources of lower cost refills.

More details are in “Cost-related medication underuse: Do patients with chronic illnesses tell their

doctors?” by Dr. Piette, Michele Heisler, M.D., M.P.A., and Todd H. Wagner, Ph.D., in the September 23, 2004, *Archives of Internal Medicine* 164, pp. 1749-1755. ■

Pharmaceutical Research

Study finds that some pregnant women are prescribed drugs that may be considered unsafe during pregnancy

Nearly half of pregnant women who receive medications other than vitamins may be taking drugs that the Food and Drug Administration classifies as having no human evidence of safety for use during pregnancy or that evidence has shown can harm a developing fetus. This findings is from a new study funded by the Agency for Healthcare Research and Quality (AHRQ grant HS10391) through the Centers for Education and Research on Therapeutics (CERTs) program.

The study, which is the largest to date to examine prescription drug use among women during pregnancy, was conducted by researchers at AHRQ's HMO Research Network CERT. The CERTs program is a national initiative to increase the awareness of the

benefits and risks of new, existing, or combined uses of therapeutics and devices.

Researchers reviewed data from eight health maintenance organizations in diverse geographic areas. They evaluated prescription drug use by 152,531 women who delivered an infant in a hospital from January 1, 1996, through December 31, 2000, based on the FDA's risk classification system of drugs used during pregnancy. The study did not include a review of the use of over-the-counter medications or drugs prescribed in hospitals.

Researchers found that 64 percent of women were dispensed a medication other than a vitamin or mineral supplement within the 270 days prior to delivery. Of those, nearly 40 percent of women were dispensed a drug for which human safety has not been established (Category C on the FDA's list). Nearly 5 percent were dispensed drugs from Category D, which the FDA classifies as having positive evidence of fetal risk, but the benefits of use may be acceptable despite the risk. An additional 5 percent of women were dispensed a drug from Category X, for which the evidence indicates definite fetal risks based on human or animal studies or based on human experience, and the risk of using the drugs clearly outweighs any possible benefit.

The other approximately 50 percent of prescriptions were classified as Category A (risk to the fetus is remote) and Category B (animal studies do not show fetal risk and there are no controlled studies in women; or animal studies show risk, but controlled studies in women fail to show risk).

The researchers conclude that routine medication audits and physician education as well as new technologies—such as computerized prescription systems with clinical supports—may have the potential to reduce inappropriate prescribing for pregnant women.

For more information, see “Prescription drug use in pregnancy,” by Susan A. Andrade, Sc.D., Jerry H. Gurwitz, M.D., Robert L. Davis, M.D., M.P.H., and others, in the August 2004 *American Journal of Obstetrics and Gynecology* 191, pp. 398-407. ■

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Oral erythromycin combined with a number of commonly used drugs may increase the risk of sudden cardiac death

Patients who took the antibiotic erythromycin with medications that inhibit CYP3A drug enzymes—such as certain calcium-channel blockers, certain anti-fungal drugs, and some anti-depressants—had a five times greater risk of sudden death from cardiac causes than patients who did not take the drugs at the same time, according to a new study that was cofunded by the Agency for Healthcare Research and Quality (AHRQ grant HS10384), the Food and Drug Administration, and the National Institutes of Health.

Erythromycin is a commonly used antibiotic because it is relatively inexpensive and considered to be very safe. In the study, Wayne A. Ray, Ph.D., and his colleagues at AHRQ's Center for Education and Research on Therapeutics (CERT) at Vanderbilt University, did not find the same increased risk for patients who took CYP3A inhibitors with other antibiotics, such as amoxicillin, or for those who had taken erythromycin in the past. The

CERTs program is a national initiative to increase the awareness of the benefits and risks of new, existing, or combined uses of therapeutics and devices.

Dr. Ray and his colleagues reviewed medical records for the Tennessee Medicaid program and identified patients who had experienced sudden death from cardiac causes during the period January 1, 1988, to December 31, 1993. They reviewed prescriptions for erythromycin, amoxicillin, and other medications from computerized Medicaid pharmacy files that included the drug, dose, and total medication dispensed. Behavioral risk factors, such as smoking and a lack of physical activity, were not studied. The researchers conclude that clinicians should avoid prescribing a combination of erythromycin and CYP3A inhibitors to patients at the same time because there are safer alternatives.

Details are in "Oral erythromycin and the risk of sudden death from cardiac causes,"

by Dr. Ray, Katherine t. Murray, M.D, Sarah Meredith, M.B., B.S., M.P.H., and others, in the September 9, 2004 *New England Journal of Medicine* 351(11), pp. 1089-1096. ■

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Clopidogrel is a cost-effective medication for patients with a recent stroke or peripheral arterial disease

Clopidogrel is more effective than aspirin in preventing recurrent strokes or heart attacks, but concerns about its high cost have limited use of this antiplatelet drug. According to a new study, clopidogrel is cost effective for patients with either peripheral arterial disease (PAD, slowed blood flow in the arteries, usually the legs, due to narrowing from fatty deposits) or a recent stroke, even at a daily cost that is almost twice the average

wholesale cost. However, clopidogrel is more expensive and less effective than aspirin for patients who have had a heart attack.

Mark D. Schleinitz, M.S., M.D., of Brown University, and his colleagues found that clopidogrel increased the life expectancy of PAD patients by almost 7 months (0.55 quality-adjusted life years, QALYs) compared with aspirin, at

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Clopidogrel

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an incremental cost-effectiveness ratio of \$25,100 per QALY. Clopidogrel increased life expectancy among stroke patients by just 2 months (0.17 QALYs) over aspirin, at a cost of \$31,200 per QALY. However for patients treated after a heart attack, life expectancy with clopidogrel was about 3 months (0.26 QALYs) shorter than with aspirin.

These findings are based on a model that based analyses on the lifetime treatment of a 63-year-old patient facing event probabilities (heart attack, stroke, amputation, vascular death, gastrointestinal bleeding, or intracranial hemorrhage) derived from the Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events (CAPRIE) trial. The model assessed the probability of events expected in a hypothetical group of 250,000 patients. Avoidance of hemorrhage

contributed to the cost-effectiveness of clopidogrel in all patient groups. The study was supported in part by the Agency for Healthcare Research and Quality (T32 HS00028).

See "Clopidogrel versus aspirin for secondary prophylaxis of vascular events: A cost-effectiveness analysis," by Dr. Schleinitz, J. Peter Weiss, M.S., M.D., and Douglas K. Owens, M.S., M.D., in the June 15, 2004 *American Journal of Medicine* 116, pp. 797-806. ■

Use of rofecoxib at 50 mg for more than 5 days for osteoarthritis should be discouraged due to dose-related problems

Rofecoxib (Vioxx[®]) is a nonsteroidal antiinflammatory drug (NSAID) licensed for chronic use for osteoarthritis at doses of 12.5 mg and 25 mg. A 50 mg dose is recommended for acute pain for a maximum of 5 days. Nevertheless, use of rofecoxib at 50 mg for more than 5 days is relatively common, according to a recent study by researchers at the Vanderbilt University Center for Education and Research on Therapeutics (CERT). The study was supported by the Agency for Healthcare Research and Quality through the CERTS program (HS10384).

Despite the relative gastrointestinal safety of rofecoxib, even at the 50 mg dose, drug-related hypertension and edema are relatively common. Since the 50 mg dose has not been shown to be more effective than lower doses, chronic use of high-dose rofecoxib should be discouraged, according to Marie R. Griffin, M.D., M.P.H., of the Vanderbilt CERTS.

Dr. Griffin and her colleagues analyzed the prevalence of chronic use of rofecoxib at 50 mg in

2001 among people aged 50 years and older who were enrolled in the Tennessee Medicaid program. On July 1, 2001, 14 percent of the group had a current prescription for an NSAID, with a supply of pills for more than 5 days. Of all NSAID prescriptions, 25 percent were for rofecoxib, and 17 percent of these prescriptions were for more than 25 mg daily.

Of those prescribed more than 25 mg daily, 71 percent filled prescriptions for at least 50 mg for 30 days. In this latter group, 60 percent filled another rofecoxib prescription within 1 week and 69 percent within 2 weeks at the end of their 30-day supply, suggesting that the 50 mg dose was indeed being used close to daily.

See "High frequency of use of rofecoxib at greater than recommended doses: Cause for concern," by Dr. Griffin, C. Michael Stein, M.D., David J. Graham, M.D., and others, in *Pharmacoepidemiology and Drug Safety* 13, p. 339-343, 2004. ■

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Although muscle relaxants are often prescribed for acute low back pain, they do not appear to speed recovery of function

Use of muscle relaxants is very common among patients suffering from acute low back pain. Yet they do not appear to speed recovery of function, according to the findings of a recent study that was supported by the Agency for Healthcare Research and Quality (HS06664). Seventy-eight percent of all 1,633 adults enrolled in the study used nonsteroidal antiinflammatory drugs (NSAIDs), and 49 percent used muscle relaxants at some point during the study.

Among patients seen initially by physicians (versus chiropractors), 64 percent used muscle relaxants. Patients who used muscle relaxants took 19 percent longer to reach functional recovery as those who

did not, after controlling for initial functional impairment, age, use of NSAIDs, and other factors.

Slower functional recovery among those taking muscle relaxants could be related directly to the medications. On the other hand, it could be due to factors indirectly related to muscle relaxant use that were not measured, such as greater time spent in bed after the injury or subtly worse prognosis in the group receiving muscle relaxants, according to Timothy S. Carey, M.D., M.P.H., of the Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill.

Dr. Carey and his colleagues, whose work was supported by the Agency for Healthcare Research

and Quality (HS06664), analyzed pain, functional status, medication use, health care use, and satisfaction with care for low back pain among the patients at baseline and at 2, 4, 8, 12, and 24 weeks. Of the 95 percent of patients who said they returned to their baseline functioning during the 6-month study period, the mean time to functional recovery was 16.2 days, with a median recovery time of 8 days from their initial visit.

See “The use of muscle relaxant medications in acute low back pain,” by Eric Bernstein, M.D., M.P.H., Dr. Carey, and Joanne Mills Garrett, Ph.D., in the June 2004 *Spine* 29(12), pp. 1346-1351. ■

Decision model can help doctors identify which patients will develop a cough from taking an ACE inhibitor

Angiotensin-converting enzyme (ACE) inhibitors improve the prognosis of patients with hypertension, heart attack, congestive heart failure, and renal diseases. The 5 to 25 percent of users of ACE inhibitors who develop a dry cough are often prescribed less effective and more costly angiotensin II receptor blockers (ARBs). However, switching from an ACE inhibitor to an ARB often entails additional clinic visits and medication costs. A new decision model can help doctors predict the likelihood that a given patient will develop a cough within 6 months from taking an ACE inhibitor.

In a study that was supported in part by the Agency for Healthcare Research and Quality (HS11169), researchers from Brigham and Women’s Hospital, Harvard University, and Japan’s Kyoto University developed the model by retrospectively collecting clinical data on 1,125 patients who were prescribed an ACE inhibitor for the first time and identifying correlates of ACE inhibitor-induced cough. They validated the resulting model with 567 patients. The 1,692 patients were followed for at least 180 days after an initial prescription for an ACE inhibitor to identify those who developed a cough within that period.

In the total group, 12 percent of patients developed ACE-inhibitor-induced cough. Independent predictors of cough were older age, female sex, non-black race (with East Asians having the highest risk), no history of previous ACE-inhibitor use, and a history of cough due to another ACE-inhibitor. These factors were used to develop a model stratifying patients into four risk groups: low-risk, average-risk, intermediate-risk, and high-risk. In the validation set, 4 percent, 14 percent, 20 percent, and 60 percent of patients in these four groups developed a cough, respectively.

The researchers conclude that use of this decision rule allows rapid estimation of risk of cough due to an ACE inhibitor within 6 months. This information may be valuable in clinical decisionmaking regarding starting ACE inhibitors and considering withdrawal of an ACE inhibitor or the need for a workup for cough.

See “Development and validation of a clinical prediction rule of angiotensin-converting enzyme inhibitor-induced cough,” by Takeshi Morimoto, M.D., M.P.H., Tejal K. Gandhi, M.D., M.P.H., Julie M. Fiskio, B.S., and others, in the June 2004 *Journal of General Internal Medicine* 19, pp. 684-691. ■

Many diabetes patients at high risk for kidney failure are not receiving medication to slow its development

Diabetes is the cause of 45 percent of end-stage renal disease (ESRD), that is, kidney failure, which leads to renal dialysis or kidney transplant. Diabetes patients with clinical risk factors—such as high blood pressure or albuminuria (high levels of the protein albumin in the urine, a sign of kidney disease)—and those who are black, Asian, or Latino are more likely to progress to kidney failure than other people with diabetes. However, a recent study shows that about half of patients in high-risk clinical groups are not receiving angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) to slow the progression of diabetes to kidney failure. The study was supported in part by the Agency for Healthcare Research and Quality (T32 HS00020).

Targeted efforts to increase use of ACE inhibitors and ARBs could

improve quality of care and reduce ESRD incidence both overall and in high-risk ethnic groups, suggests Allison B. Rosen, M.D., M.P.H., of the Harvard School of Public Health. Dr. Rosen and her colleagues examined data on pharmacy dispensing of ACE inhibitors or ARBs to 38,887 diabetes patients who were enrolled with pharmacy benefits in the 2000 Kaiser Permanente Northern California Diabetes Registry. Forty-one percent of the group had both hypertension and albuminuria, 30 percent had hypertension alone, and 12 percent had albuminuria alone. Also, 14 percent of the patients were black, 11 percent were Latino, 13 percent were Asian, and 63 percent were white.

The majority of eligible patients (61 percent) received indicated ACE inhibitor or ARB therapy in 2000. An ACE inhibitor or ARB was dispensed to 74 percent of patients

with both hypertension and albuminuria, but this treatment was dispensed to only 64 percent of those with hypertension alone and 54 percent of those with albuminuria alone. An ACE inhibitor or ARB was dispensed to 61 percent of whites, 63 percent of blacks, 59 percent of Latinos, and 60 percent of Asians. Among those with albuminuria alone, blacks were significantly less likely than whites to receive either medication (47 vs. 56 percent). No other ethnic disparities were found.

See “Use of angiotensin-converting enzyme inhibitors and angiotensin receptor blockers in high-risk clinical and ethnic groups with diabetes,” by Dr. Rosen, Andrew J. Karter, Ph.D., Jennifer Y. Liu, M.P.H., and others, in the *Journal of General Internal Medicine* 19, pp. 669-675, 2004. ■

Lack of insurance coverage is not the only barrier to medication access among older Americans with chronic conditions

Prescription drug benefits are not the only answer to improve drug access among sick and indigent elderly Medicare patients, concludes a study supported in part by the Agency for Healthcare Research and Quality (HS10318). One-fourth of elderly Medicare+Choice enrollees without a prescription drug benefit reported difficulty affording medications compared with the 17 percent who had medication coverage. However, lower income, fewer assets, and worse health also independently predicted

greater difficulty affording medications, irrespective of prescription drug coverage.

Barry Saver, M.D., M.P.H., of the University of Washington, and his colleagues analyzed survey and administrative data for 4,492 Medicare+Choice enrollees aged 67 and older with at least one chronic medical condition who were enrolled in a predominantly group-model health maintenance organization in 2000. They examined difficulty

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Note: Only items marked with a single (*) or double (**) asterisk are available from AHRQ. Items marked with a single asterisk (*) are available from AHRQ's clearinghouse. Items with a double asterisk (**) are also available through AHRQ InstantFAX. Three asterisks (***) indicate NTIS availability. 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.

Medication access

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affording medications and methods of coping with medication costs.

About one-fifth of respondents reported difficulty affording their medications some of the time to all of the time. Stretching medications to make them last longer was the most commonly reported coping mechanism, cited by 12 percent of those surveyed. Only 3 percent reported obtaining medications in another country. After adjustment for other factors, 24 percent of people with fair or poor health status reported difficulty affording their medications compared with 4 percent of those in excellent health.

Individuals with annual incomes below \$20,000 were much more likely to be unable to afford medications some of the time than those with incomes of \$50,000 or more. Similarly, those whose assets were estimated at less than \$10,000 were more than twice as likely to say they sometimes were unable to

afford medications as those with \$10,000 or more in assets. Higher out-of-pocket spending predicted greater difficulty affording medications but not stretching out medications.

Details are in "Seniors with chronic health conditions and prescription drugs: Benefits, wealth, and health," by Dr. Saver, Mark P. Doescher, M.D., M.S.P.H., J. Elizabeth Jackson, M.A., and Paul Fishman, Ph.D., in *Value in Health* 7(2), pp. 133-143, 2004.

Editor's note: Another study on a related topic showed substantial net health plan savings from reference drug pricing for angiotensin-converting enzyme inhibitors in elderly British Columbia residents. For more details, see Schneeweiss, S., Dormuth, C., Grootendorst, P., and others. (2004, July). "Net health plan savings from reference pricing for angiotensin-converting enzyme inhibitors in elderly British Columbia residents." (AHRQ grant HS10881). *Medical Care* 42, pp. 653-660. ■

Despite their high risk for cardiovascular disease, two-thirds of kidney dialysis patients are not treated for hyperlipidemia

The risk of atherosclerotic cardiovascular disease (ASCVD) in patients with end-stage renal disease (ESRD, kidney failure) on dialysis is 10 to 20 times higher than in the general population. Despite their high risk for cardiovascular disease, two-thirds of kidney dialysis patients are not treated for hyperlipidemia (high levels of cholesterol or triglycerides) as national guidelines suggest. Dialysis patients have a high risk of ASCVD, but dialysis patients with higher serum cholesterol have lower mortality rates. While this paradoxical effect is thought to be largely due to other coexisting medical problems and poor nutritional status of dialysis patients, it may discourage

clinicians from aggressively treating hyperlipidemia.

Clinicians might also be worried about drug safety issues in ESRD patients, explains Neil R. Powe, M.D., M.P.H., M.B.A., of Johns Hopkins University. In the study, which was supported in part by the Agency for Healthcare Research and Quality (HS08365), Dr. Powe and his colleagues assessed the prevalence, treatment, and control of hyperlipidemia in 812 hemodialysis (HD) and peritoneal dialysis (PD) patients at clinics in 19 States from 1995 to 1998.

Hyperlipidemia was present in 40 percent of HD and 62 percent of PD patients. Among those with hyperlipidemia, 67 percent of HD and 63 percent of PD patients were untreated, and only 22 percent of

HD and 14 percent of PD patients were both treated and controlled. Individuals who entered the study in 1997 and 1998, those with diabetes, males, and whites were more likely to be treated and controlled, while those on PD and those with ASCVD were less likely to be treated and controlled.

See "Undertreatment of hyperlipidemia in a cohort of United States kidney dialysis patients," by Caroline S. Fox, M.D., M.P.H., J. Craig Longenecker, M.D., Ph.D., Dr. Powe, and others, in the May 2004 *Clinical Nephrology* 61(5), pp. 299-307. ■

Interference of diabetes with social activities may be an early warning sign of subsequent disability

The degree to which one's diabetes interferes with participation in social activities—for example, going to church, the movies, or on day or overnight trips—may be an early indicator of subsequent disability in daily functioning and premature death. This is the conclusion of a recent study supported by the Agency for Healthcare Research and Quality (HS11618). By asking older diabetes patients about their social activities, clinicians can identify those who will benefit most from interventions to stem the future loss of independence, according to investigators at the University of Texas Medical Branch, Galveston.

The researchers used data from the Medicare Health Outcomes Surveys in 1998 (baseline) and 2000 (followup) on physical and mental health functioning, activities of daily living (ADLs, such as dressing or bathing oneself or walking without assistance), and medical conditions on 8,949 elderly community-dwelling diabetes patients enrolled in the Medicare Managed Care program. Study subjects had no ADL disability at baseline. The researchers derived

individual health-related social disengagement (degree to which physical health or emotional problems interfered with social activities) scores from the social functioning subscale of the Medical Outcomes Study Short Form-36 (SF-36).

For each 10-point increase in social functioning score at baseline, older diabetes patients experienced an 18 percent less chance of any ADL disability and a 12 percent less chance of death over a 2-year period, after adjusting for demographic factors, coexisting illnesses, depression, and general health. These findings suggest that even when no ADL disability is clinically evident, patients start, perhaps at an early presymptomatic stage of disability, to adjust their levels of social activities in response to their perceptions of physical and emotional disturbances.

Details are in "Health-related social disengagement in elderly diabetic patients," by Yong-Fang Kuo, Ph.D., Mukaila A. Raji, M.D., M. Kristen Peek, Ph.D., and James S. Goodwin, M.D., in the July 2004 *Diabetes Care* 27(7), pp. 1630-1637. ■

Certain biological factors that may represent insulin resistance are associated with a decline in physical functioning

Relatively healthy working age men and women with certain risk factors for development of coronary heart disease (CHD) are more likely to suffer from functional decline than others, according to a study supported in part by the Agency for Healthcare Research and Quality (HS06516). Those with a high waist-to-hip ratio and elevated levels of fasting insulin, triglycerides, and HDL cholesterol had twice the decline in physical functioning over a 3-year period as adults without these problems. This relationship was independent of exercise, smoking, and alcohol intake, which explained only 17 percent and 5.4 percent of the association in men and women, respectively.

These variables clustered with total cholesterol and may represent insulin resistance, note Michael Marmot, F.R.C.P., of University College London, and his colleagues. This suggests that insulin resistance may be an important determinant of subsequent physical functioning and a potential area of intervention to prevent functional decline. The size of the functional declines observed were small compared with observed disease-related declines, and their impact on daily life was unclear. However, they occurred in a relatively young and healthy working age group in a short followup period of 36 months. If continued at the same rate, this decline would lead to

marked disability, caution the researchers.

The researchers analyzed data from phase 3 (1991-1993) and phase 4 (1995) of the Whitehall II study of nearly 7,000 British civil servants. They correlated weight, height, fasting insulin, 2-hour post-load glucose, total and HDL cholesterol, fibrinogen, von Willebrand factor, blood pressure, and waist-to-hip ratio measured during phase 3 with functioning 3 years later.

See "Biological predictors of change in functioning in the Whitehall II study," by Meena Kumari, Ph.D., Teresa Seeman, Ph.D., and Dr. Marmot, in the April 2004 *Annals of Epidemiology* 14, pp. 250-257. ■

Osteoarthritis patients have less pain and better functioning after joint replacement surgery, but they need support at 1 month

Mean hospital stay has fallen to less than 5 days for hip or knee replacement surgery, and insurance pays for less postacute care than previously. As a result, many patients have to rely on a spouse or other household members for support during their recovery period. Help with basic physical functioning is particularly critical at 1 month after surgery, when joint replacement patients report a decline in physical functioning and are likely to be discharged from structured physical therapy, according to a recent study. The study was supported in part by the Agency for Healthcare Research and Quality (HS06573).

Physicians should identify patients who live alone and target postacute services for their increased need at that time, according to lead author John D. Fitzgerald, M.D., M.P.H., of the University of California, Los Angeles School of Medicine. Dr. Fitzgerald and his colleagues followed 222 osteoarthritis patients undergoing primary joint replacement surgery at a university hospital between 1990 and 1993. They assessed the patients' bodily pain and physical function

at 1, 6, and 12 months after surgery using the Medical Outcomes Study 36-item Short Form Health Survey (SF-36).

Bodily pain and physical function improved after both knee and hip replacement. However, at 1 month after surgery, despite reduced bodily pain, physical function deteriorated. Although patients reported significantly improved perceptions of bodily pain (55.6 vs. 36) at 1 month after surgery, they also reported significantly poorer physical function (24.1 vs. 35.9). At 12 months after surgery, bodily pain and physical function scores on the SF-36 were equal to or superior to age- and sex-adjusted mean scores for other patients in the United States. Patients who were married or living with someone reported greater improvements in bodily pain and physical function than those with less social support over the three followup periods.

See "Patient quality of life during the 12 months following joint replacement surgery," by Dr. Fitzgerald, E. John Orav, Ph.D., Thomas H. Lee, M.D., S.Sc., and others, in the February 15, 2004 *Arthritis & Rheumatism* 51(1), pp. 100-109. ■

Problems with mobility make it hard for people with Parkinson's disease to express their personality

Parkinson's disease is a neurodegenerative movement disorder that causes tremor (often made worse by stress or strong emotions), muscle rigidity, inability to initiate movement, expressionless face (facial masking), involuntary uncoordinated movements, poor balance, shuffling gait, and other symptoms. These symptoms often lead to misunderstandings and limit the ability of people who have the disease to express their personality, which is a source of great frustration for them. For example, due to facial masking, others may think the person with Parkinson's disease is angry when he or she is not feeling angry, or the other person may think the movement problems are due to intoxication.

For individuals in the early stages of Parkinson's disease, certain

expressive behaviors may provide cues to a person's personality, according to a study supported in part by the Agency for Healthcare Research and Quality (HS13292). Simple clues such as eyebrow furrowing and casual dress may help interpret a person's interest in and motivation for social interaction, explains Kathleen Doyle Lyons, Sc.D., O.T.R., of Dartmouth Medical School. Dr. Lyons and her colleagues obtained personality measurements (neuroticism, extroversion, openness to experience, agreeableness, and conscientiousness) prior to conducting and videotaping simulated health care interviews with 12 people with mild to moderate Parkinson's disease.

The researchers analyzed the videotapes to correlate expressive behaviors of the participants (for

example, eyebrow furrowing, slouching, formality of dress, voice inflection and loudness) with the personality measures. Participants who were neurotic (nervous or emotionally distressed) appeared more talkative, more formally dressed, and more inclined to move their bodies and furrow their brows during the interview. On the whole, participants' expressive behavior did not convey their levels of extroversion or significantly reflect agreeableness. Those more open to experience dressed less formally.

For more information, see "Behavioral cues of personality in Parkinson's disease," by Dr. Lyons, Linda Tickle-Degnen, Alexis Henry, and Ellen S. Cohn, in *Disability and Rehabilitation* 26(8), pp. 463-470, 2004. ■

Communication problems often contribute to untimely care of acute infections in nursing homes

Quick diagnosis and management of acute infections among nursing home residents require successful communication at multiple levels. However, communication breakdowns are common, and they create barriers to timely care of acute infections in nursing home residents, according to a study supported in part by the Agency for Healthcare Research and Quality (HS08551). Researchers from the University of Missouri-Columbia analyzed discussions of focus groups of nursing home physicians and nurses and interviews with nursing home residents, nurses, and physicians involved in acute illness care. Their goal was to identify factors that promoted or delayed timely identification and treatment of residents' acute infections.

The interviews revealed 22 factors that influenced timeliness of effective care, with communication problems commanding the central focus. Six communication barriers stood out: failure of the physician to receive a message; evening or weekend illness onset, problems in contacting the on-call physician; reliance on an intermediary (for example,

an office nurse) to convey orders from the physician; communication of inappropriate or inaccurate information; inadequate information transfer between nursing staff at shift changes; and a nurse's reluctance to talk with a physician perceived as difficult.

Focusing on these communication barriers may improve quality of care for acute infections in nursing home residents, suggest the researchers. More effective teamwork between physicians and nurses can improve care and avoid residents being unnecessarily transferred to the hospital for the treatment of acute illnesses. This approach could also save health care costs by intervening earlier in the causal chain that leads to hospitalization and poor outcomes in acute illness among nursing home residents.

See "Barriers to timely care of acute infections in nursing homes: A preliminary qualitative study," by Daniel R. Longo, Sc.D., Jake Young, M.A., David Mehr, M.D., M.S., and others, in the March 2004 *Journal of the American Medical Directors Association* 5, S5-S10. ■

Researchers compare treatment of U.S. and Dutch nursing home residents with dementia who develop lower respiratory infections

As people who have dementia develop advanced disease, neurological and functional deterioration predisposes them to lower respiratory tract infection (LRI), including pneumonia, which is often their immediate cause of death. Many question the appropriateness of aggressive care for these patients due to high mortality and the discomfort associated with aggressive care such as feeding tubes and intravenous fluids. Nevertheless, residents with dementia who develop LRI are treated much more aggressively in the United States than similar nursing home patients in the Netherlands. Dutch nursing homes focus on comfort care for

these patients, according to a recent study that was supported in part by the Agency for Healthcare Research and Quality (HS08551).

The study found that treatment of nursing home-acquired LRI in Missouri residents involved a larger number of antibiotics, more frequent hospitalization, and a greater use of intravenous antibiotics and rehydration therapy than in Dutch residents with equally severe dementia. Treatment of nursing home residents in Missouri was more aggressive particularly for residents with severe dementia, and intensive interventions were often provided irrespective of severe dementia. On the other hand, Dutch residents,

despite severe dehydration, did not receive invasive rehydration procedures. Feeding tubes and restraints, which we know are uncomfortable for cognitively competent individuals, were rare as well. By contrast, in both countries, treatments to relieve symptoms of LRI, such as oxygen, benzodiazepines, and bronchodilators, were provided for only a minority of residents. Dutch mortality rates were higher overall.

These findings are based on analysis of the results of two simultaneous studies of the health status and treatment of 701 nursing home residents from Missouri and

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LRI in nursing home residents

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551 residents in the Netherlands who were diagnosed with LRI and dementia.

See "Treatment of nursing home residents with dementia and lower respiratory tract infection in the United States and the Netherlands: An ocean apart," by Jenny T. van der Steen, Ph.D., Robin L. Kruse, Ph.D., M.S.P.H., Marcel E. Ooms,

M.D., Ph.D., and others, in the May 2004 *Journal of the American Geriatrics Society* 52, pp. 691-699. ■

Quality/Patient Safety

Despite overall national improvement in beta-blocker use after heart attack, the rate of improvement varies across hospitals

Use of beta-blockers following a heart attack (acute myocardial infarction, AMI) has been one area targeted to improve hospital quality of care since the mid-1990s. Rates of beta-blocker use after heart attack improved at some hospitals during the late 1990s but not at others, according to a study supported by the Agency for Healthcare Research and Quality (HS10407).

Researchers from Yale University School of Medicine, Yale-New Haven Hospital Center for Outcomes Research, and other institutions used data on 335,244 patients with AMI discharged from 682 hospitals from the National Registry of Myocardial Infarction and hospital characteristic data from the American Hospital Association Annual Survey of Hospitals. They examined associations between hospital characteristics and hospital-level rates of change in beta-blocker use during from 1996 to 1999.

The overall rate of beta-blocker use varied over time from about 46 percent of patients in April 1996 to more than 68 percent of patients in September 1999. On average, hospital rates of beta-blocker use for

patients with AMI increased 5.9 percentage points from the first half of the study (April 1996 to February 1998) to the second half of the study (March 1998 to September 1999). The range in hospital-level changes in beta-blocker rates was substantial, from a decline of 50 percentage points to an increase of 35.7 percentage points.

Several hospital characteristics were correlated with improved use of beta-blockers. For instance, larger AMI volume was associated with greater improvement rates, especially for hospitals without residency programs. Hospitals in the Northeast had the greatest rates of improvement over time. Despite their significance, the associations between these hospital characteristics and improved beta-blocker use were modest, and much of the variation in use of beta-blockers across hospitals remains unexplained.

Details are in "Hospital-level performance improvement: Beta-blocker use after acute myocardial infarction," by Elizabeth H. Bradley, Ph.D., Jeph Herrin, Ph.D., Jennifer A. Mattera, M.P.H., and others, in the June 2004 *Medical Care* 42(6), pp. 591-599. ■

In-hospital mortality is similar for cardiac surgery patients treated at either medium- or high-volume hospitals

Hospitals that perform a high volume of cardiac surgeries (400 or more cases per year) are considered to have better quality of care and patient outcomes than hospitals that perform fewer such surgeries. However, requiring a minimum hospital surgery volume may no

longer be an appropriate way to improve quality of cardiac care, according to a recent study. The researchers found no evidence of higher in-hospital deaths in patients undergoing coronary angioplasty at medium-volume hospitals (200 to 299 cases per year) compared with

patients treated at high-volume hospitals.

The 400 volume threshold was based on data in the late 1980s and early 1990s that identified increased mortality risk for patients treated at hospitals that performed

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In-hospital mortality

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fewer than 400 coronary angioplasties per year. In the past 5 to 10 years, however, there have been notable changes in angioplasty practice, including the adoption and widespread use of stents (scaffold-like mesh tubes that keep arteries propped open following angioplasty to allow free blood flow), new medications such as glycoprotein IIb/IIIa inhibitors, and an increase in the overall use of angioplasty, explains Andrew J. Epstein, M.P.P., of the Department of Health Care Systems, Wharton School of Business. His work was supported

in part by the Agency for Healthcare Research and Quality (National Research Service Award training grant T32 HS00009).

Dr. Epstein and his colleagues retrospectively analyzed AHRQ's Nationwide Inpatient Sample (NIS) hospital discharge database to evaluate in-hospital deaths among 362,748 patients who underwent coronary angioplasty between 1998 and 2000 at low- (5 to 199 cases per year), medium-, high-, and very high- (1,000 cases or more per year) volume hospitals. Crude in-hospital mortality rates were 2.56 percent in low-volume hospitals (21 percent higher than high-volume hospitals,

after adjustment for patient characteristics). Yet, mortality rates were similar among medium-volume (1.83 percent), high-volume (1.64 percent), and very high-volume hospitals (1.36 percent).

See "Hospital percutaneous coronary intervention volume and patient mortality, 1998 to 2000: Does the evidence support current procedure volume minimums?" by Dr. Epstein, Saif S. Rathore, M.P.H., Kevin G. Volp, M.D., Ph.D., and Harlan M. Krumholz, M.D., S.M., F.A.C.C., in the May 19, 2004 *Journal of the American College of Cardiology* 43(10), pp. 1755-1762. ■

Based on postoperative complication rates, teaching and nonteaching hospitals may provide similar quality of care

A study of hospital postoperative complications concludes that, at best, teaching hospitals deliver no better quality of care than nonteaching hospitals. Researchers at the Agency for Healthcare Research and Quality's Center for Primary Care, Prevention, and Clinical Partnerships retrospectively studied data on a sample of 3,818 acute care hospitals in the National Inpatient Sample (database of U.S. community hospital discharge claims) from 1990-1996. The quality indicators examined were postoperative problems that usually can be prevented with adequate and quality nurse and medical staffing. These included deep vein thrombosis/pulmonary embolism (DVT/PE), pulmonary compromise, pneumonia, and urinary tract infection (UTI).

Amar V. Duggirala, D.O., Frederick M. Chen, M.D., M.P.H., and Peter J. Gergen, M.D., M.P.H., classified hospitals as major teaching, other teaching, and nonteaching. Major and other teaching hospitals had higher rates of postoperative DVT/PE and pulmonary compromise than nonteaching hospitals (0.51 and 0.42 vs. 0.35 and 1.01 and 0.94 vs. 0.77 per 100 major operation discharges, respectively). Hospital characteristics such as hospital bed size, rural or urban

location, ownership, nurse staffing levels, percent of patients with Medicare or Medicaid, and geographic region were also considered. When these hospital characteristics were accounted for, only other teaching hospitals had higher rates of postoperative pulmonary compromise and UTI than nonteaching hospitals, and only major teaching hospitals had higher postoperative pneumonia rates than nonteaching hospitals.

These findings should not be seen as an indictment of teaching hospitals, caution the researchers. The findings do, however, raise concerns that medical students and residents may be learning the practice of medicine in settings that do not necessarily reflect the highest level of care. Teaching hospitals, especially major teaching hospitals, have a complex structure involving multiple levels of providers. The deleterious effects of multiple transfers of care to different providers in teaching hospitals may affect their rates of adverse events, conclude the researchers.

See "Postoperative adverse events in teaching and nonteaching hospitals," by Drs. Duggirala, Chen, and Gergen, in the July 2004 *Family Medicine* 36(7), pp. 508-513. Reprints (AHRQ Publication No. 04-R058) are available from AHRQ.* ■

Root cause analysis should be conducted after a wrong site surgery to reduce future errors

On average, five to eight cases of wrong site surgery (wrong side or site of the body, wrong procedure, or wrong-patient surgeries) are reported each month to the Joint Commission on Accreditation of Healthcare Organizations. A typical case of a man who had surgery on the wrong knee (left knee instead of right knee) is outlined in a recent article by Pascale Carayon, Ph.D., of the University of Wisconsin-Madison, and colleagues. Their work was supported by the Agency for Healthcare Research and Quality (HS11561).

A root cause analysis based on human factors engineering (HFE) analysis revealed several work system elements that contributed to the wrong site surgery. In this case, after the initial visit with the patient, the surgeon handed the patient's record to the nurse, asking her to schedule surgery for the right knee. The nurse, bogged down in a heavy workload that day, did

not find time to schedule the surgery until the end of the shift, when she had forgotten which knee was to have surgery. Consequently, she scheduled it for the left knee after seeing some notes about problems with that knee. On the day of the surgery, the nurse read the consent form to the hard-of-hearing patient in the noisy preop area, the patient assumed that the nurse said the surgery was to be on the right knee, and he signed the consent. The surgeon arrived, corrected the consent form to indicate the right knee but was called back to prior surgery before he could change the surgery schedule. At this point a resident surgeon was called in to begin the knee surgery and, when the original surgeon returned to the operating room, he discovered that surgery was underway on the wrong knee.

The nurse's high workload, the noisy preoperative environment, and unavailable technology for the surgeon to immediately record the

surgery procedure at the time of the decision and to change the surgery schedule at the same time he revised the consent form all contributed to the wrong site surgery. Correcting these problems may reduce future mistakes.

Details are in "Righting wrong site surgery," by Dr. Carayon, Kara Schultz, and Ann Schoofs Hundt, Ph.D., in the July 2004 *Joint Commission Journal on Quality and Safety* 30(7), pp. 405-410.

Editor's note: Another paper on a related topic provides a practical framework for improving patient safety in the complex environment of the intensive care unit. For more details, see Pronovost, P.J., Wu, A.W., and Sexton, J.B. (2004, June). "Acute decompensation after removing a central line: Practical approaches to increasing safety in the intensive care unit." (AHRQ grant HS11902). *Annals of Internal Medicine* 140, pp. 1025-1033. ■

Potentially preventable hospital readmissions may be determined by the severity and complexity of underlying chronic problems

Factors such as having a usual source of care, private insurance, and available primary care physicians tend to reduce the likelihood of preventable hospital admissions for conditions such as asthma and diabetes complications. However, preventable hospital readmissions may be more strongly determined by the severity and complexity of the patient's underlying chronic problems, according to a recent study. These readmissions may also indicate persistent problems in the hospital and in followup by families and physicians after discharge, explain Bernard Friedman, Ph.D., and Jayasree Basu, Ph.D., of the Agency for Healthcare Research and Quality.

To prevent these rehospitalizations, Drs. Friedman and Basu suggest identifying patients at risk for readmission before hospital discharge, followup strategies after discharge, and sufficient payment for

management of chronic diseases with office-based services and drugs. The researchers analyzed 1999 hospital discharge data for residents of New York, Pennsylvania, Tennessee, and Wisconsin from the Healthcare Cost and Utilization Project (HCUP). They estimated the rate and cost of preventable readmissions within 6 months after a first preventable admission by age group and by payer and race within each age group.

About 19 percent of individuals with an initial preventable admission had at least one preventable readmission within 6 months. Hospital costs for preventable readmissions during 6 months was about \$730 million (about \$7,400 per readmission). For children and nonelderly adults, the proportion with a

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Preventable hospital readmissions

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readmission was much lower for privately insured patients than for either Medicaid or self-pay patients. The likelihood of readmission was higher for blacks and Hispanics than for whites and members of other racial groups. Medicaid was not associated with a lower rate of readmission. Uninsured children had a higher rate of readmission but not uninsured adults.

See “The rate and cost of hospital readmissions for preventable conditions,” by Drs. Friedman and Basu, in the June 2004 *Medical Care Research and Review* 61(2), pp. 225-240. Reprints (AHRQ Publication No. 04-R056) are available from AHRQ.*

Editor’s note: Another study by these authors on a related topic found that in different States, private

health maintenance organization (HMO) enrollment was associated with fewer preventable hospital admissions than urgent admissions (insensitive to primary care) compared with private fee-for-service (FFS) plan enrollment. However, little difference was found between Medicaid HMO enrollees and Medicaid fee-for-service patients. The findings did not vary by the level of Medicaid managed care penetration in the study States. For more details, see Basu, J., Friedman, B., and Burstin, H. (2004, June). “Managed care and preventable hospitalization among Medicaid adults.” *Health Services Research* 39(3), pp. 489-509. Reprints (AHRQ Publication No. 04-R053) are available from AHRQ.* ■

Hospital providers’ understanding of patient safety is heavily influenced by their professional roles

A 3-year, multi-method research project funded by the Agency for Healthcare Research and Quality (HS11930) examined the organizational processes that influence the recognition of medical errors and assignment of responsibility for resolution of patient safety problems. The research was carried out in 29 small rural hospitals in nine Western States and involved seven substudies that used surveys, questionnaires, interviews, and case studies to gather data from nurses, physicians, administrators, pharmacists, and other health care workers.

The researchers found that when responding to case studies and surveys, participants agreed that medication-related errors were the most common kind of error. They also responded positively about their hospitals’ commitment to patient safety. Most believed that the hospital culture supported the idea that “anyone can make mistakes” (64 percent), and that the error reporting system was open to all employees (86 percent),

confidential (69 percent), and impartial (56 percent). On the other hand, providers’ understanding of patient safety was heavily conditioned by preconceived notions of what constitutes an error and professional roles, according to lead investigator Ann Freeman Cook, Ph.D., of the University of Montana in Missoula. As a result, the agreement as to errors related to diagnosis and treatment was less consistent.

For example, nurses noted that if their relationships with physicians were problematic or if they lacked the support of their hospital’s administration, they were hesitant to question clinical practices. Also, analyses of case studies showed that health care providers didn’t agree on what constitutes error or what kinds of events should be reported. In one substudy, a hospital-wide survey, even when there was overwhelming agreement (97 percent) that an error had occurred, only 64 percent of providers said they would disclose the error to the affected patient. Physicians, administrators, and

nurses tended to perceive patient safety as primarily a nursing responsibility. Only 22 percent of respondents to that survey said that physicians, nurses, pharmacists, and administrators should share responsibility equally for patient safety.

In an earlier study conducted by the investigators, only 8 percent of physicians identified nurses as members of the decisionmaking team. This could be a factor in nurses’ reluctance to question physicians’ clinical judgment or to take corrective action in response to error, according to Dr. Cook. Dr. Cook and her colleagues propose that a systems approach to patient safety be adopted, one in which responsibility for safety is shared by all members of the health care team.

Details are in “An error by any other name,” by Dr. Cook, Helena Hoas, Ph.D., Katarina Guttmannova, M.A., and Jane Clare Joyner, J.D., R.N., in the June 2004 *American Journal of Nursing* 104(6), pp. 32-43. ■

In certain situations, nurses should raise a “red flag” to protect patient safety

Three important steps can improve patient safety, suggests Ronda G. Hughes, Ph.D., M.H.S., R.N., senior health scientist administrator at the Agency for Healthcare Research and Quality. First, staff fatigue and stress must be minimized. A nurse should work no more than 12 hours per day for a maximum of 60 hours per week and should carry a small enough patient load to ensure each patient’s needs are met. Second, staff vigilance against potential threats to patient safety must be supported. For example, work schedules should be arranged so that no one works longer than the recommended daily and weekly hours. Third, what is known must be incorporated into practice now, which may require system redesign.

So what should a nurse do when she or he sees an error in the making? Dr. Hughes suggests some situations in which nurses should raise a “red flag.” These include when a nurse lacks the skills or training to perform a task; something doesn’t “seem right;” a nurse notices a deviation from standard procedure or a lack of consistency in how a procedure is performed; or a nurse believes that a complex procedure is being performed improperly.

To reduce these potential safety problems, nurses should gain more advanced skills and experience, learn to identify and act upon warning signs, follow procedures carefully, and determine whether and how a procedure can be simplified.

Other red flag situations include encountering unexpected findings (instruments can be incorrectly calibrated or the algorithm being used may be the wrong one); a procedure hasn’t been changed despite its association with previous errors or near misses; a necessary step or piece of information is missing or there has been miscommunication (in this case, stop the procedure or process and reevaluate); relying on memory when performing more than one task at a time or nearing the end of a shift when the information must be conveyed to the next shift (use automated or computerized technologies and write down any verbal communication).

See “First do no harm: Avoiding near misses,” by Dr. Hughes, in the May 2004 *American Journal of Nursing* 104(5), pp. 81-84. Reprints (AHRQ Publication No. 04-0052) are available from AHRQ.*

Editor’s note: A second article on a related topic describes the Port Huron Hospital’s “Nurse-On-Wheels” (NOW) program, which is designed to enable RNs to be relieved of some tasks unrelated to direct patient care, improve communication between shifts, and reduce the potential for medication errors. For more details, see Sokol, P.E. (2004, May). “Transforming the workplace environment: Port Huron Hospital’s transformation model.” (AHRQ grant HS12043). *Nursing Economics* 22(3), pp. 152-154. ■

Researchers examine the challenges of ensuring the safety of cardiovascular devices

More than 500,000 medical devices such as life-supporting implantable cardioverter defibrillators (ICDs) are marketed in the United States. The U.S. Food and Drug Administration (FDA) is responsible for market approval and post-approval surveillance (PAS) of medical devices. Two recent studies, which were supported by the Agency for Healthcare Research and Quality (HS10548) through the Centers for Education and Research on Therapeutics

(CERTs) program, examined issues involving the safety of cardiovascular medical devices. The studies, which were led by researchers at the Duke University CERT, are described here.

O’Shea, J.C., Kramer, J.M., Califf, R.M., and Peterson, E.D. (2004, June). “Sharing a commitment to improve cardiovascular devices. Part 1: Identifying holes in the safety net.” *American Heart Journal* 147(6), pp. 977-984.

According to the FDA’s Enforcement Report Index, since 1990 there have been more than 130 product recalls affecting more than 900,000 major cardiovascular devices and 16 safety alerts affecting almost 900,000 additional devices. Once a medical device is in the marketplace, its exposure to patients and real-world conditions can uncover new safety concerns that were not fully appreciated during the premarket phase. Premarketing approval is short, so

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Medical devices

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long-term problems with devices, for example, pacemaker batteries that fail without warning, do not surface until after the device is on the market.

Physicians also use devices for indications that were not part of the original approval, a practice known as off-label use, and such use may reveal additional unanticipated safety issues. Design problems, such as a heart valve strut failure, also can surface later, warranting an improved design. Sometimes problems develop in selected patient populations or due to operators who don't have enough training in use of the device.

Thus, post-approval oversight is needed to ensure the continued safety and effectiveness of marketed medical devices. The principal post-approval tools used by the FDA and the industry to achieve these goals are voluntary adverse event/product problem reporting and mandated post-approval studies by the manufacturer (usually targeted to a specific issue, such as long-term performance of a heart valve or pacemaker). However, this feedback loop is currently sporadic and inadequate. For example, despite

voluntary and mandatory reporting systems, less than 1 percent of all adverse events related to medical devices are reported to the FDA.

Peterson, E.D., Hirshfeld, J.W., Ferguson, T.B., and others. (2004, June). "Sharing a commitment to improve cardiovascular devices, Part II: Sealing holes in the safety net." *American Heart Journal* 147(6), pp. 985-990.

The authors of this article suggest how existing medical device evaluation and action mechanisms could be improved, based on ideas initially formulated at a 2001 conference, "Sharing a Commitment to Improve Cardiovascular Devices." The authors point out the unique interrelationship and dependency of clinicians, regulators, and industry in the process of ensuring proper use and safety of medical devices for optimal patient care. They call for collaboration and a culture of partnership among all players to promote early identification of device-related adverse events. The authors review four cardiovascular-device-specific areas as a means of identifying challenges to this new collaborative framework: left ventricular assist devices,

implantable cardioverter defibrillators, intracoronary brachytherapy, and vascular embolic protection devices.

The authors point out that although industry and regulatory monitoring systems exist, innovative PAS mechanisms may be needed to promote safety and design improvements for certain devices throughout the life cycle. Medical students should be taught early in medical school about these mechanisms and the method of reporting adverse events to the FDA. Once the FDA identifies a potential safety issue with a device, this information should be disseminated promptly and effectively to the clinical community.

The major cardiovascular professional societies should consider more active collaboration with the FDA to disseminate important device safety information. Industry can also improve its communication of device safety data via an e-mail notification system to clinicians. Finally, the authors emphasize the need for high-quality, multicenter device registries as an important strategy for ensuring adequate PAS. ■

Children's Health

Premature infants with bronchopulmonary dysplasia are rehospitalized at twice the rate of other premature infants

Premature infants less than 33 weeks gestational age (GA) with bronchopulmonary dysplasia (BPD) are rehospitalized at more than twice the rate of similarly premature infants without BPD, according to a study supported in part by the Agency for Healthcare Research and Quality (T32 HS00063). Bronchopulmonary dysplasia (BPD), which affects many low birthweight and premature babies, is marked by abnormal lung x-rays, respiratory compromise, and prolonged oxygen requirement. Because infants with BPD continue to have lung function abnormalities and

may have subclinical lung damage long past the neonatal period, they often are more susceptible to respiratory infections (for example, from respiratory syncytial virus, RSV) and bronchospastic conditions that can lead to hospitalization.

The goal of the study, which was conducted by Vincent C. Smith, M.D., M.P.H., of the Harvard School of Public Health, and his colleagues, was to describe rates and identify risk factors for

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Premature infants

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rehospitalization during the first year of life among infants with BPD. They retrospectively analyzed rates of BPD and rehospitalization for any reason before the first birthday among a group of infants born less than 33 weeks GA between 1995 and 1999. They defined BPD as needing supplemental oxygen and/or mechanical ventilation at 36 weeks corrected GA. About 15 percent of the infants studied had BPD. In the first year of life, 49 percent of infants with BPD (118 of 238) were rehospitalized, a rate more than twice that of non-BPD infants (23 percent, 309 of 1,359).

The researchers found no clinical or demographic factors that predicted rehospitalization of premature

infants with BPD. No measured demographic or physiologic factors discriminated between those infants with BPD who were and were not rehospitalized, even when only rehospitalizations for respiratory diagnoses were considered. Other factors that could be linked to rehospitalization of infants with BPD, such as air quality of the home environment, passive smoking exposure, RSV prophylaxis, breast feeding status, and/or parenting and primary care management styles, should be examined in future studies, conclude the researchers.

See "Rehospitalization in the first year of life among infants with bronchopulmonary dysplasia," by Dr. Smith, John A. Zupancic, M.D., Sc.D., Marie C. McCormick, M.D., Sc.D., and others, in the June 2004 *Journal of Pediatrics* 144, pp. 799-803. ■

Only 9 percent of children with out-of-hospital cardiopulmonary arrest survive, despite prolonged CPR and epinephrine

Only 9 percent of children who suffer an out-of-hospital cardiopulmonary arrest survive. Administration of more than three doses of epinephrine (adrenalin) or prolonged cardiopulmonary resuscitation (CPR) is futile, concludes the largest population-based study to date of cardiopulmonary arrest among pediatric patients.

Research to improve therapeutic measures and emergency medical services (EMS) protocols is needed. However, efforts to prevent conditions leading to out-of-hospital arrest (for example, sudden infant death syndrome [SIDS] burns, near-drowning, and poisoning) and community outreach to improve the rate of bystander CPR may have a greater impact on the survival of these children, suggests Marianne Gausche-Hill, M.D., of Harbor-University of California Los Angeles Medical Center.

In a study that was supported in part by the Agency for Healthcare Research and Quality (HS09065), the researchers conducted secondary analysis of data from an earlier trial (1994-1997) of out-of-hospital airway management of children 12 years of age or younger or weighing less than 40 kg. They studied 601 arrests in 599 children (54 percent were less than 1 year old, and 58 percent were male). Return of spontaneous circulation was achieved in 29 percent, 25 percent were admitted to the hospital, and 8.6 percent survived to hospital discharge. The most frequent causes of arrest were SIDS and trauma, followed by respiratory problems and near-drowning, which had relatively lower mortality.

One-third of the survivors (16 of 51) had good neurologic outcome. None of the survivors in this group received more than three doses of epinephrine or were resuscitated for longer than 31 minutes in the

emergency department. Survival was higher when fewer doses of epinephrine were needed, and in nearly half (49 percent) of the survival events, no epinephrine was required. Bystander CPR was not demonstrated to result in improved survival rates in this study, although the time between arrest and discovery by the bystander may have been too long for them to benefit. There was, however, a nonsignificant trend toward higher survival for patients with witnessed arrests who received bystander CPR.

See "A prospective, population-based study of the epidemiology and outcome of out-of-hospital pediatric cardiopulmonary arrest," by Kelly D. Young, M.D., M.S., Dr. Gausche-Hill, Christian D. McClung, M.D., M.Phil., and Roger J. Lewis, M.D., Ph.D., in the July 2004 *Pediatrics* 114(1), pp. 157-163. ■

Racial/ethnic composition of a county can affect residents' access to care

Most studies on racial/ethnic disparities in use of care in the United States have focused on individual characteristics. However, a recent study suggests that the racial/ethnic composition of the county in which one lives may also affect his or her access to care.

The study found that 4.3 percent of blacks experienced difficulty obtaining any type of health care when they lived in a county with a high prevalence of blacks (40 percent or more) compared with 18.8 percent of blacks who found it difficult to obtain health care in low-prevalence (less than 6 percent) counties. On the other hand, blacks in high-prevalence counties reported lower rates of financial barriers (did not receive a doctor's care or prescription medication because the family needed money to buy food, clothing, or pay for housing) than blacks living in low-prevalence counties (1.6 vs. 10.5 percent).

Latinos in a county with a high prevalence of Latinos also experienced less difficulty obtaining care than Latinos in low-prevalence counties (5 percent vs. 13.4 percent), but they did not experience fewer financial barriers to care (2.2 vs. 2.4 percent). Whites who lived in counties with a high prevalence of

Latinos were more likely to report difficulty obtaining care and financial barriers to care than whites living in counties with a low prevalence of Latinos (17.7 vs. 9.4 and 8.5 vs. 3.2 percent, respectively).

These differences remained after adjustment for a variety of both individual- and county-level characteristics. Thus, diminishing disparities in access to health care may require interventions that extend beyond the individual, concludes lead author, Jennifer S. Haas, M.D., M.S.P.H., of Harvard Medical School and the University of California, San Francisco. Dr. Haas and her colleagues analyzed data from the nationally representative 1996 Medical Expenditure Panel Survey of U.S. households. They correlated two measures of care access with county prevalence of blacks and Hispanics in 677 counties. This research was supported in part by the Agency for Healthcare Research and Quality (HS10771 and HS10856).

See "Variation in access to health care for different racial/ethnic groups by the racial/ethnic composition of an individual's county of residence," by Dr. Haas, Kathryn A. Phillips, Ph.D., Dean Sonneborn, M.A., and others, in the July 2004 *Medical Care* 42(7), pp. 707-714. ■

Half of doctors in State-sponsored financial support-for-service programs stay in underserved areas over 8 years, most working happily

Many States try to entice young generalist physicians into rural and medically underserved areas with financial support-for-service programs. These include scholarships, service-option loans, loan repayment, direct financial incentives, and resident support programs. It appears these programs are successful in meeting their overall goal, according to a recent study of all 69 State programs operating in 1996 that provided financial support to medical students, residents, and

practicing physicians in exchange for a period of service in underserved areas.

The programs as a whole placed physicians in small and needy rural towns and counties, where physicians estimated that nearly half of their patients were insured by State Medicaid programs for the poor or were without health insurance. Doctors who served in these State programs generally were more satisfied with their work and communities and remained in their service sites longer than nonobligated "mainstream"

generalists, according to the study which was supported by the Agency for Healthcare Research and Quality (HS09165).

In addition to studying the State programs, Donald E. Pathman, M.D., M.P.H., of the University of North Carolina at Chapel Hill, and his colleagues surveyed 434 generalist physicians who served in 29 of the State programs and a matched comparison group of 723 nonobligated young generalist physicians.

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Support-for-service programs

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Compared with young nonobligated generalist physicians, those serving obligations to State programs practiced in demonstrably needier areas and cared for more Medicaid and uninsured patients (48.5 vs. 28.5 percent). In addition,

State-obligated physicians were more satisfied than nonobligated physicians, and 9 out of 10 indicated that they would enroll in their programs again. Obligated physicians also remained longer in their practices than nonobligated physicians, with respective group retention rates of 71 percent versus 61 percent at 4 years and 55 versus 52 percent at 8 years. Retention

rates were highest for loan repayment, direct incentive, and service-option loan programs.

See "Outcomes of States' scholarship, loan repayment, and related programs for physicians," by Dr. Pathman, Thomas R. Konrad, Ph.D., Tonya S. King, Ph.D., and others, in the June 2004 *Medical Care* 42(6), pp. 560-568. ■

Collaborative care for acutely injured trauma survivors can reduce post-traumatic distress symptoms and alcohol abuse

Each year about 2.5 million Americans are so severely injured that they require hospitalization. Symptoms of posttraumatic stress disorder (PTSD) may develop in 10 to 40 percent of these acutely injured trauma survivors. Approximately 20 percent to 40 percent of injured patients admitted to trauma centers have current or lifetime alcohol abuse or dependence diagnoses.

Trauma centers can reduce PTSD symptoms and alcohol abuse/dependence among these patients by using a trauma support specialist to coordinate care in a collaborative care (CC) approach that includes case management, medication, and psychotherapy, according to a recent study. The study was supported in part by the Agency for Healthcare Research and Quality (HS11372) and led by Douglas Zatzick, M.D., of the University of Washington, Seattle.

The researchers recruited 120 male and female injured surgical patients 18 or older hospitalized at a level 1 trauma center in Washington State. They randomly assigned 59 patients to the CC group and 61 to the usual care (UC) group. The CC patients received stepped care that consisted of continuous post-injury case management tailored to the needs of the individual trauma survivor, motivational interviews targeting

alcohol abuse/dependence, and evidence-based medication and/or cognitive behavioral therapy for patients with persistent PTSD at 3 months after injury. The researchers examined PTSD symptoms using the PTSD checklist at baseline and 1, 3, 6, and 12 months after injury and alcohol abuse/dependence at baseline and 6 and 12 months after injury.

At the 3-month assessment, 24 percent of CC patients were diagnosed with PTSD and offered medication and psychotherapy. Over time, CC patients had significantly fewer symptoms than UC patients with regard to PTSD and alcohol abuse/dependence. Patients in the CC group demonstrated no changes in PTSD from baseline to 12 months, but patients in the UC group had a 6 percent increase in PTSD during the year. The CC group showed on average a 24 percent decrease in the rate of alcohol abuse/dependence, while the UC group had on average a 13 percent increase during the year.

See "A randomized effectiveness trial of stepped collaborative care for acutely injured trauma survivors," by Dr. Zatzick, Peter Roy-Byrne, M.D., Joan Russo, Ph.D., and others, in the May 2004 *Archives of General Psychiatry* 61, pp. 498-506. ■

Care is rarely coordinated for patients with mental disorders seeing both doctors and CAM providers

A new study found that about 20 percent of visits to complementary and alternative medicine (CAM) providers were for mental health problems. About one-third of these patients were receiving concurrent mental health care from a

conventional medical provider. Although the treating CAM provider was aware of concurrent medical treatment in 20 to 50 percent of visits, consultation or discussion with the treating conventional medical provider was reported in less than half of these

visits. Also, referral to a conventional medical provider following a CAM visit was rare, according to the study which was supported in part by the Agency for Healthcare Research and Quality (HS09565 and HS08194).

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Care for patients with mental disorders

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Conventional medical providers should ask patients with mental disorders about use of CAM treatment and, when appropriate, make efforts to coordinate care with the CAM provider, suggests Gregory E. Simon, M.D., M.P.H., of Group Health Cooperative in Seattle. Dr. Simon and his colleagues analyzed 8,933 visits to representative samples of acupuncturists, chiropractors, massage therapists, and naturopathic physicians in four States. They examined demographic characteristics,

presenting complaints, referral sources, treatments provided, disposition, and other sources of care for the presenting problem.

The proportion of visits for a mental health problem ranged from 7 to 11 percent for acupuncture, massage, and naturopathic physicians (similar to that in conventional primary care) to less than 1 percent for chiropractors. It could not be determined whether the low rate for chiropractic visits was due to a truly low rate of mental health problems or a lower rate of recording those problems by chiropractors. For acupuncturists, massage therapists, and naturopaths, 69 to 87 percent of

patients making mental health visits were self-referred. The CAM provider discussed care with a conventional medical provider in 6-20 percent of cases and was aware of concomitant conventional medical care in an additional 10-30 percent of cases. Only 1-5 percent of CAM patients were subsequently referred to conventional providers.

See "Mental health visits to complementary and alternative medicine providers," by Dr. Simon, Daniel C. Cherkin, Ph.D., Karen J. Sherman, Ph.D., and others, in *General Hospital Psychiatry* 26, pp. 171-177, 2004. ■

Primary Care Research

Diagnosis of pain by primary care doctors is influenced by pain severity, patient sex, and physician practice style

Appropriate pain control may speed patients' recovery and improve their quality of life and productivity. Yet, pain is frequently unrecognized and undertreated by physicians. The diagnosis of pain by primary care doctors is influenced by the severity of patient pain, the patient's sex, and the physician's practice style, according to a study supported by the Agency for Healthcare Research and Quality (HS06167).

Klea D. Bertakis, M.D., M.P.H., of the University of California, Davis, and her colleagues interviewed 509 patients who were randomized to care by one of 105 physicians. The researchers asked patients about their level of pain and then videotaped their initial physician visit to correlate patient and physician characteristics with pain diagnosis. Patients were interviewed a second time following the visit to assess their satisfaction with the visit.

The researchers used the Davis Observation Code to characterize physician practice style, and they reviewed each patient's medical record to assess physician recognition of patient pain. Overall, 18 percent of patients who reported zero to little pain had

their pain diagnosed compared with 47 percent of those reporting medium pain and 70 percent of those reporting severe pain. Female patients reported a greater amount of pain than male patients (46.4 vs. 32.3 on a global pain score scale ranging from 0 to 100). When patients were in severe pain, women were more likely than men to have their pain accurately recognized by their physician.

Surprisingly, the correct diagnosis of pain was not significantly related to patient satisfaction. Physician practice styles emphasizing technically oriented activities (for example, history taking, performing a physical exam or other procedures, and planning treatment) and health behavior discussions (for example, about compliance with medication or proper nutrition and exercise) were strongly predictive of the physician diagnosing patient pain.

For more information, see "Patient pain in primary care: Factors that influence physician diagnosis," by Dr. Bertakis, Rahman Azari, Ph.D., and Edward J. Callahan, Ph.D., in the May 2004 *Annals of Family Medicine* 2(3), pp. 224-230. ■

Even when primary care patients receive recommended treatment for their depression, nearly half remain depressed

Over half of depressed patients are treated in primary care. Yet, even when they receive recommended treatment for their depression, nearly half of them remain depressed, according to a study supported in part by the Agency for Healthcare Research and Quality (HS08349). Nonresponse to depression treatment was higher in patients not working at baseline (59 percent vs. 42 percent of workers), in those with suicidal ideation, that is, those who thought about death a lot or considered committing suicide (54 percent vs. 46 percent of those without such ideation), and in those who had stopped taking their psychotropic medication early (58 percent compared with 42 percent of those who did not stop early).

Nonresponders also received more counseling and combination

medications than responsive patients. This suggests that persistent depression may represent true treatment resistance and that doctors were searching for solutions, explains Cathy Sherbourne, Ph.D., of RAND. Dr. Sherbourne and her colleagues examined the sociodemographic and clinical characteristics of 542 depressed primary care patients who received treatment for depression that met at least minimal evidence-based standards. This included four or more specialty counseling visits over a 6-month period and/or use of antidepressant medication at or above the minimum dosage recommended by depression practice guidelines. The team compared treatment patterns and characteristics of those who remain depressed with those who recovered.

Of the 1,248 patients with followup data, 542 received at least minimally appropriate treatment. Of these, 442 received two courses of minimally appropriate treatment for two of three 6-month periods; 261 of these patients remained depressed, while 181 recovered. An additional 100 patients recovered and stayed recovered after receiving only one course of at least minimally appropriate treatment over the same interval.

See “Characteristics, treatment patterns, and outcomes of persistent depression despite treatment in primary care,” by Dr. Sherbourne, Michael Schoenbaum, Ph.D., Kenneth B. Wells, M.D., M.P.H., and Thomas W. Croghan, M.D., in *General Hospital Psychiatry* 26, pp. 106-114, 2004. ■

Health Care Costs and Financing

Researchers examine trends in spending on drugs for Medicare beneficiaries and insurance coverage for children

Findings from a new study by researchers at the Agency for Healthcare Research and Quality show that higher priced new drugs are playing a significant role in boosting expenditures by Medicare beneficiaries for prescription medicines. Two other studies by AHRQ researchers provide evidence on the progress of Federal efforts to provide low-income children with access to health care. All three studies, which appear in the September-October issue of *Health Affairs*, are described here. Reprints of these

staff-authored articles are available from AHRQ.* See the back cover of *Research Activities* for ordering information.

Moeller, J.F., Miller, G.E., and Banthin, J.S. (2004, September-October). “Looking inside the Nation’s medicine cabinet: Trends in outpatient drug spending by Medicare beneficiaries, 1997 and 2001.” *Health Affairs* 23(5), pp. 217-225.

John F. Moeller, Ph.D., formerly with AHRQ, and AHRQ researchers G. Edward Miller and

Jessica Banthin, Ph.D., found that Medicare drug spending increased by nearly 72 percent between 1997 and 2001 when adjusted for inflation. During that period Medicare drug spending rose from \$31.5 billion to \$54 billion per year. The surge was primarily driven by a 26 percent escalation in the average prescription price and a nearly 24 percent growth in the average number of medications used per beneficiary. The approximately 10 percent rise in the number of

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Health care expenditures

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seniors using prescription drugs played a smaller role.

Total spending increased the most for drugs to control cholesterol levels, diabetes medications, proton pump inhibitors, COX-2 inhibitors, antipsychotic medications, and antidepressants. Spending more than doubled for each of these classes of drugs between 1997 and 2001.

Moreover, by 2001, relatively new, high-priced drugs dominated the market, with no or declining competition from generic drugs. The highest price increases occurred in antipsychotic medications and diabetes drugs.

Contributing to the rapid growth in spending for several classes of drugs was a dramatic increase in the number of Medicare beneficiaries who used them, especially cholesterol-lowering drugs, proton pump inhibitors, and COX-2 inhibitors. For example, the number of Medicare beneficiaries who used a cholesterol-lowering drug more than doubled from 4.9 million in 1997 to 10.5 million in 2001. During the same period, the number of Medicare beneficiaries using proton pump inhibitors jumped from 2.1 to 5 million, while those using COX-2 inhibitors surged from none to 5.5 million.

Within the larger class of all cardiovascular drugs, findings show that by 2001, Medicare beneficiaries were more likely to be taking more than one type of medication than in 1997. The overall annual spending increase for all cardiovascular drugs during this period—from \$12.2 billion to \$18.9 billion—resulted primarily from a 21 percent increase in the number of Medicare beneficiaries using prescription medicines and a 15 percent increase in the number of prescriptions per user. In addition,

the average price per prescription for different types of cardiovascular drugs increased 11 percent over the same period.

The largest increases in the number of Medicare beneficiaries who used a cardiovascular drug of any type involved cholesterol-lowering drugs, beta-blockers, combinations of high blood pressure drugs, and ACE inhibitors. Reprints (AHRQ Publication No. 04-R064) are available from AHRQ.*

Selden, T.M., Hudson, J.L., and Banthin, J.S. (September-October 2004). "Tracking changes in eligibility and coverage among children, 1996-2002." *Health Affairs* 23(5), pp. 39-50.

AHRQ researchers led by Tom Selden, Ph.D., found that dramatic progress has been made in the provision of public health insurance for children. The study found that the percentage of children who were eligible for free or highly subsidized health insurance rose from 29 percent in 1996 to 47 percent in 2002, primarily due to the enactment of the State Children's Health Insurance Program (SCHIP).

Expanding children's eligibility for coverage has not always led to increasing enrollment, however. In 1996, children made eligible through Medicaid expansions had a take-up rate of only 61 percent. One result of low take-up (enrollment) rates was that 4.6 million uninsured children were eligible for public coverage in 1996 but had not enrolled. By 2002, the take-up rate among this same group of Medicaid eligible children had risen to 77 percent. Take-up rates also rose sharply with SCHIP, from 44 percent in 1998 to 60 percent in 2002.

According to the authors, improved enrollment in available programs likely reflects the major public and private efforts launched in the mid-1990s to reach out to

eligible but uninsured children. They say that while great progress has been made, outreach efforts must be sustained and enhanced if the problem of uninsurance among children is to be solved. During the first part of 2002, a total of 10 million children were uninsured in the United States and of this total, 6.2 million, or 62 percent, were eligible for public coverage but not enrolled. Somewhat more than half of these uninsured children were eligible for Medicaid but not enrolled (3.4 million), while the remaining 2.8 million uninsured children were eligible for SCHIP but not enrolled. Although increased outreach efforts yielded impressive enrollment gains over the period studied, as of 2002, the problem of uninsurance among children remained as much a problem of participation as of eligibility, say the authors. Reprints (AHRQ Publication No. 04-R067) are available from AHRQ.*

Cunningham, P., and Kirby, J. (2004, September-October). "Children's health coverage: A quarter-century of change." *Health Affairs* 23(5), pp. 27-38.

Peter Cunningham, Ph.D., of the Center for Studying Health System Change in Washington, DC, and AHRQ researcher James Kirby, Ph.D., tracked changes in the rates of uninsured children and those with private or public coverage between 1977 and 2001. They found that the percentage of children without health insurance of any type increased sharply between 1977 and 1987, but by 2001 it had dropped to nearly what the rate was in 1977. The researchers also found that the percentage of children with public coverage rose significantly during the period, while, conversely, the percentage of children with private health insurance declined. Reprints (AHRQ Publication No. 04-R065) are available from AHRQ.* ■

Children with special health care needs in Medicaid managed care plans receive more needed care than those in Medicaid FFS plans

Relatively few States have required that children with special health care needs (SHCN) enroll in capitated Medicaid managed care plans (providers are paid one fee per patient, regardless of type of care delivered). That's because the financial incentives inherent in such plans may lead to undertreatment, restrict access to specific services and providers, and have adverse effects on quality.

A recent study involved children with SHCN in Washington, DC, who qualified for Supplemental Security Income (SSI) and were enrolled in a partially capitated Medicaid managed care plan. The researchers examined the effects of enrollment in this plan on the children's access to care. The managed care plan was specifically designed for children who qualify for Medicaid because they receive Supplemental Security Income due to a disability (Health Services for Children with Special Needs or HSCSN). The researchers found that these dually enrolled children had fewer unmet health needs than those enrolled in Medicaid fee-for-service (FFS) plans.

The HSCSN's comprehensive care plan assessment, ongoing case management, primary care providers' gatekeeping role, and higher physician reimbursement may have reduced unmet need among children with SHCN, suggests principal investigator, Jean M. Mitchell, Ph.D., of Georgetown University. Dr. Mitchell and Darrell J. Gaskin, Ph.D., of Johns Hopkins University, conducted telephone interviews with a random sample of 1,088 caregivers of children with SHCN in Washington, DC, in 2002. Their work was supported in part by the Agency for Healthcare Research and Quality (HS10912). The researchers examined the children's usual source of care, unmet

need for certain health services during the 6-month period prior to the interview, and caregivers' ratings of dimensions of access to services.

The percentage of children who did not receive needed dental care, durable medical equipment/supplies, or prescription drugs was significantly higher among FFS enrollees than among children enrolled in the HSCSN. There were no significant differences by plan type in unmet need for physician/hospital care, mental health services, home health service, or therapy.

See "Do children receiving Supplemental Security Income who are enrolled in Medicaid fare better under a fee-for-service or comprehensive capitation model?" by Drs. Mitchell and Gaskin, in the July 2004 *Pediatrics* 114(1), pp. 196-204.

Editor's note: A second study on a related topic found that children dually enrolled in both Medicaid and Michigan's Children's Special Health Care Services for children with special needs who were under 1 year of age or had diagnoses of anemia, hemophilia, asthma, epilepsy, or juvenile diabetes had especially high rates of emergency department use. The study found significant geographic variation in ED use after controlling for diagnoses, race, and other factors. The researchers note the importance and difficulty of developing systems of care to manage complex chronic conditions in low-income populations. For more details, see Pollack, H.A., Dombkowski, K.J., Zimmerman, J.B., and others. (2004, June). "Emergency department use among Michigan children with special health care needs: An introductory study." (AHRQ grant HS10441). *Health Services Research* 39(3), pp. 665-692. ■

Expanded Medicaid eligibility reduced the risk of inadequate prenatal care in California during the 1990s

Beginning in 1990, California's Medicaid program, MediCal, expanded prenatal care coverage to more low-income women. The result was a substantial reduction in inadequate use of prenatal care in 1995 and 1998 and fewer women who were uninsured or self-paying compared with 1990, according to a study supported by the Agency

for Healthcare Research and Quality (HS10856). The proportion of live-born infants whose mothers had inadequate prenatal care (first physician visit after the fourth month of pregnancy) decreased from 20 percent in 1990 to 14 percent in 1995 and 12 percent in 1998. Also, the proportion of pregnant women who had no insurance or were self-paying fell

from 13.1 percent in 1990 to 4.2 percent in 1995 and 3.6 percent in 1998.

These improvements could be attributable to easier enrollment (due to a shortened application form) and expanded eligibility, which enabled more newly enrolled pregnant women to initiate prenatal care within the first trimester. In

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Expanded Medicaid eligibility

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contrast, improvements were smaller among women with private insurance, who were more likely to obtain insurance before pregnancy. The smaller improvements in the private insurance and other public groups suggest that other factors are important, including programs that promote awareness of the need for early prenatal care.

Although there have been improvements, easier access has

not resulted in full use of prenatal care. Expanded Medicaid eligibility eases financial barriers but does not directly address nonfinancial barriers involving awareness of the importance of early prenatal care, knowledge of Medicaid eligibility, availability of providers who accept Medicaid patients, and transportation to the sites where care is available. To further reduce ethnic disparities in use of prenatal services, the researchers call for the development of new policies to remove nonfinancial barriers to

early and continuous use of prenatal care. Their findings are based on analysis of California birth certificate data for 1990, 1995, and 1998, which included information on prenatal care insurance.

See “Reduced risk of inadequate prenatal care in the era after Medicaid expansions in California,” by Nancy A. Hessol, M.S.P.H., Eric Vittinghoff, Ph.D., and Elena Fuentes-Afflick, M.D., M.P.H., in the May 2004 *Medical Care* 42(5), pp. 416-422. ■

Researchers examine the effects of financial and nonfinancial incentives on health care use, costs, and quality

A supplement to the September 2004 issue of *Medical Care Research and Review* (volume 61, number 3) presents a series of commissioned papers and commentaries focusing on the analytic, conceptual, managerial, and policy challenges associated with the simultaneous and sometimes conflicting goals of delivering health care that is high in quality, safe, effective, and cost effective. The papers and commentaries were presented at an October 2002 conference, “Penetrating the Black Box: Mechanisms for Enhancing Healthcare Efficiency and Clinical Effectiveness,” which was held in Seattle, WA.

The conference was developed by Douglas A. Conrad, Ph.D., Professor, Department of Health Services and Director, Center for Health Management Research, University of Washington, and Jon B. Christianson, Ph.D., the James A. Hamilton Chair in Health Policy and Management, Carlson School of Management, University of Minnesota, and cosponsored by the Agency for Healthcare Research

and Quality (HS12076), the Robert Wood Johnson Foundation, and the California HealthCare Foundation.

The conference goal was to provide a venue for researchers, executives, and clinical leaders to examine not only the direct effects of financial incentives on quality but also the interactions between financial and nonfinancial incentives and the role of market and environmental conditions, organizational factors, and the characteristics of providers and consumers in shaping health care quality.

Some of the important conceptual, empirical, and policy questions considered by conference presenters and participants include:

- What is known regarding the effects of financial incentives on physician behavior?
- What are the resulting effects on quality? What are the effects on cost and resource use?
- What incentive arrangements are currently in place and emerging in the health care marketplace?

- In an era of complex health care organizations, what conceptual frameworks provide useful insights into the links between health care decisionmaking and its consequences for both efficiency and effectiveness?
- What are the major gaps in empirical evidence about the impact of physician incentives on quality and cost.

In addition to a foreword by Gloria Bazzoli and a preface by Drs. Conrad and Christianson, the supplement presents the following papers and commentaries.

Shortell, S.M. “Increasing value: A research agenda for addressing the managerial and organizational challenges facing health care delivery in the United States,” pp. 12S-30S.

This author proposes a framework for a set of management questions about financial incentives for quality. For example, what size of incentive is needed to influence physician organization behavior and, in turn, individual physician

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Financial and nonfinancial incentives

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behavior? Can “threshold effects” (a “tipping point”) be identified? How will incentive money earned by the physician organization be used to improve care for patients with chronic illness? How might financial incentives be structured to account for the differences between early and later adopters of innovations and of practices to improve quality, outcomes, and clinical efficiency?

Wilensky, G.R. “Framing the public policy questions: Financial incentives for efficiency and effectiveness,” pp. 31S-36S.

This author issues a set of challenges for public policy researchers. To hit the mark, research must consider both the intended and unintended consequences of particular policy interventions addressing efficiency, cost, effectiveness, access, and quality. Alternative means of achieving policy goals and the intended and unintended effects of these alternate means are important topics for research. To significantly inform the public policy process, research on incentives must address relevant policy levers, specifically structures and payment levels, but also the mechanisms for updating reimbursement, case mix classification, risk adjustment, private contracting rules, conditions of participation, and antitrust policies. Timely and actionable policy research on financial incentives by necessity will confront the tensions between restraining spending and maintaining access and between establishing the “right price” and rewarding quality. For policymakers, this often translates

into trying to approximate the competitive price.

Conrad, D.A. and Christianson, J.B. “Penetrating the ‘black box’: Financial incentives for enhancing the quality of physician services,” pp. 37S-68S.

A review of the available literature (through June 2004) by these authors found very few empirical studies of the direct effects of quality-based financial incentives on clinical quality. They did find some evidence that fee-for-service payment is related to increased patient compliance with physician recommendations concerning number of provider visits and to improved continuity of the patient-physician relationship compared with capitation or salary methods of physician payment. There was no evidence of a consistent, significant difference between the incentive effects of salary and capitation modes of payment. Very few empirical studies have examined the effects of direct quality incentives, such as physician compensation bonuses that are based on clinical performance or patient satisfaction. The few studies of direct quality incentives are cross-sectional, generally focus exclusively on preventive services, and do not allow policymakers to infer cause and effect. The authors also developed a formalized model of physician choice of quality and quantity and a more extended qualitative model of the determinants of quality.

Commentaries:

- Landon, B.E. “Commentary on penetrating the black box,” pp. 69S-75S.

- Gray, B.H. “Individual incentives to fix organizational problems,” pp. 76S-79S.

Town, R., Wholey, D.R., Kralewski, J., and Dowd, B. “Assessing the influence of incentives on physicians and medical groups,” pp. 80S-118S.

These authors discuss behavioral economics as an alternate framework for decisionmaking. This framework emphasizes two key dimensions: (1) the importance of how people subjectively perceive a given situation; and (2) the role of choice rules, heuristics, or “rules of thumb” (in contrast to optimizing behavior). The authors challenge the research community to investigate how these factors—including physician preferences, the organization of daily work, and rules and routines—influence clinical decisionmaking.

Commentary:

- Escarce, J.J. “Assessing the influence of incentives on physician and medical groups: A comment,” pp. 119S-123S.

Fishman, P.A., Hornbrook, M.C., Meenan, R.T., and Goodman, M.J. “Opportunities and challenges for measuring cost, quality, and clinical effectiveness in health care,” pp. 124S-143S.

These authors describe a new research paradigm for health services analyses of production and cost relationships in managed care. Most of the previous research on health care production in managed care settings has focused on single dimensions of output (e.g., visits, relative value units), probably for analytical convenience given the complex nature of health care consumption and production.

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However, numerous studies have established that output in a managed care setting is multidimensional. Thus, health outcomes and quality of life measures must be incorporated as measures of health system output. In addition, the authors discuss the opportunities and major implications of recent and likely future changes in the health care system, such as electronic medical

records and greater use of electronic data capture.

Commentaries:

- Luft, H.S. "Focusing on the dependent variable," pp. 144S-150S.
- Saver, B.G. "The fault lies not in our stars but in our system," pp. 151S-160S.

Editor's note: A public Web site has been established by the University of Washington to host the papers and commentaries from the conference, as well as a digest of the conference proceedings and

a list of conference participants and their affiliations. Go to <http://depts.washington.edu/hserv/articles/view.shtml?00016> to find these materials, as well as one paper and set of commentaries not described here and not included in the journal supplement. The paper by Robert Santos and Paula Diehr addresses the methodological challenges inherent in the research agenda proposed by conference presenters and participants and is accompanied by two commentaries, one by Danna Moore and Don Dillman and another by Doug Roblin. ■

Individuals are unlikely to recommend an insurance plan if they do not like the provider choices or preventive services covered

Health plan managers can look at enrollees' satisfaction with their choice of providers and preventive services coverage if they want to gauge enrollee satisfaction with the plan, according to a study supported in part by the Agency for Healthcare Research and Quality (HS10771 and HS10856). To explore the characteristics of individuals who are dissatisfied with their health plans, researchers at the University of California, San Francisco and Brigham and Women's Hospital analyzed data from the 1996 Medical Expenditure Panel Survey (MEPS) and the March 2003 MEPS dataset addressing plan satisfaction. This nationally representative survey includes data on health status, use and cost of medical care services, and health insurance among the U.S. noninstitutionalized population.

The researchers controlled for personal characteristics to determine the association between plan or provider attributes and unwillingness to recommend a plan (used as the measure of plan

dissatisfaction). The largest predictors of unwillingness to recommend a health plan to others were dissatisfaction with choice of providers and coverage for preventive services. The probability of being unwilling to recommend a health plan was 38 percent for individuals dissatisfied with the choice of providers and 34 percent for those dissatisfied with coverage for preventive services.

In contrast, provider and personal characteristics were not significant predictors of satisfaction. Although provider attributes did not predict plan dissatisfaction overall, these attributes did predict plan dissatisfaction for HMO and multiple plan members.

See "Willingness to recommend a health plan: Who is dissatisfied and what don't they like?" by Julie A. Sakowski, Ph.D., Kathryn A. Phillips, Ph.D., Su-Ying Liang, Ph.D., and Jennifer S. Haas, M.D., M.S.P.H., in the June 2004 *American Journal of Managed Care* 10(6), pp. 393-400. ■

AHRQ reports review quality of U.S. health care services and differences in use of these services for at-risk groups

In December 2004, the Agency for Healthcare Research and Quality released the first *National Healthcare Quality Report* (NHQR) and *National Healthcare Disparities Report* (NHDR) on behalf of the U.S. Department of Health and Human Services. A recent article by Ed Kelley, Ph.D., Director of the NHQR project, and his AHRQ colleagues summarizes the main findings of the reports on preventive care. The reports track more than 50 primary and secondary prevention quality-of-care measures in five clinical areas: cancer, diabetes, heart disease, maternal and child health, and respiratory disease.

The purpose of the NHQR and NHDR, according to the Congressional mandate that directed AHRQ to prepare them, is to document the state of health care quality for the Nation. In addition, Dr. Kelley notes, these reports contribute to the quality improvement cycle by providing national information on the state of health care quality, potential benchmarks, and changes that have occurred over time to support a broad community of concerned quality improvement professionals.

The reports basically reach three major conclusions: first, the promise of high quality health care is not a given, second, gaps in quality are particularly acute for

certain racial, ethnic, and socioeconomic groups, and third, improvement is possible.

For more details, see "Prevention health care quality in America: Findings from the first national healthcare quality and disparities reports," by Dr. Kelley, Ernie Moy, M.D., M.P.H., Beth Kosiak, Ph.D., Dan Stryer, M.D., and Carolyn Clancy, M.D., in the July 2004 *Preventing Chronic Disease* 1(3), pp. 1-5. Reprints of the article (AHRQ Publication No. 04-R057) are available from AHRQ.* The NHQR and NHDR can be accessed online at www.qualitytools.gov. ■

Announcements

New guide helps communities plan for vaccine and drug dispensing in response to bioterrorism or other public health emergencies

A new planning guide from the Agency for Healthcare Research and Quality is designed to help communities across the Nation make sure that appropriate drugs and vaccines are available to everyone who needs them in the event of a natural epidemic or bioterrorist attack. The guide was developed with AHRQ support (contract 290-02-0013) by a team of researchers in the Department of Public Health at Weill Medical College of Cornell University and New York-Presbyterian Hospital led by Nathaniel Hupert, M.D., M.P.H. This new guide complements the *Strategic National Stockpile Guidebook* prepared by the Centers for Disease Control and Prevention, which includes a chapter on dispensing medications and vaccines.

The new guide, *Community-Based Mass Prophylaxis: A Planning Guide for Public Health*

Preparedness, is designed to help State, county, and local officials comply with Federal requirements for public health emergency planning. The new guide:

- Provides a framework for understanding the components of epidemic outbreak response (surveillance, stockpiling, distribution, dispensing, and followup care) and the planning and implementation of dispensing operations using specially designated dispensing clinics.
- Applies these concepts to develop model pill-dispensing and vaccination clinics run on the Bioterrorism and Epidemic Outbreak Model (BERM), a computer staffing model (also developed by Dr. Hupert and his colleagues at Weill Medical College of Cornell University under

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Bioterrorism guide

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- contract to AHRQ) that can be customized to meet local community needs.
- Discusses implementation of a command and control framework for dispensing clinics based on the CDC's National Incident Management System.

Copies of *Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness*

(AHRQ Publication No. 04-0044) are available from AHRQ.* The guide is also available online at <http://www.ahrq.gov/research/cbmprophyl/cbmpro.htm>.

The guide is one of more than 50 studies, workshops, conferences, and other activities funded as part of AHRQ's bioterrorism research portfolio. Go to www.ahrq.gov/browse/bioterbr.htm to find out more about AHRQ's research and tools related to bioterrorism. ■

New tutorial for the National Guideline Clearinghouse™ now available from AHRQ

The Agency for Healthcare Research and Quality has released a new CD-ROM tutorial for the National Guideline Clearinghouse™ (NGC™). The NGC™ is a comprehensive, online resource of evidence-based clinical practice guidelines and related materials. The tutorial guides users through a series of informative demonstrations and scenarios and provides tips on how to use the enhanced NGC™ Web site, which includes over 1,300 evidence-based guidelines and other materials. The NGC™ is currently used by physicians, nurses, and other health care professionals to access objective, detailed information on clinical practice guidelines and to further the dissemination, implementation, and use of the guidelines. Go to www.guideline.gov to visit the NGC™ site. Copies of the tutorial (AHRQ Publication No. 04-M041-CD) are available from AHRQ. See the back cover of *Research Activities* for ordering information.* ■

Research Briefs

Andrews, J.E., Pearce, K.A., Sydney, C., and others. (2004). "Current state of information technology use in a U.S. primary care practice-based research network." (AHRQ grant HS13487). *Informatics in Primary Care* 12, pp. 11-18, 2004.

Greater attention should be given to enhancing information technology (IT) infrastructure in primary care, according to this study of Kentucky primary care practices. While interest in use of IT in primary care was high among the practices, IT adoption was variable, with use of several key technologies reported as low. All but one practice had Internet access; yet 34 percent had only dial

up service. Only 21 percent of practitioners used an electronic medical record (EMR), with cost being the barrier to use reported most frequently (58 percent). More than half of the office managers were "somewhat interested" (45 percent) or "very interested" (17 percent) in a low-cost standardized EMR. For practitioners, 71 percent were either somewhat or very interested in such as system.

Bakken, S., and Hripcsak, G. (2004, May). "An informatics infrastructure for patient safety and evidence-based practice in home healthcare." (AHRQ grant HS11806). *Journal for Healthcare Quality* 26(3), pp. 24-30.

Patient safety problems in home health care range from improper medication administration to injuries related to falls and wound infections. The authors of this paper outline the components of the informatics infrastructure of patient safety and evidence-based practice in home health care. Informatics infrastructure components include data acquisition methods; health care standards, including standardized terminologies, data repositories, and clinical event monitors; data-mining techniques; digital sources of evidence; and communication technologies. Applications that bring these components together to

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promote patient safety and enable evidence-based practice have demonstrated promising results in the acute care setting. However, the authors discuss a number of challenges that hinder their implementation in home health care.

Bent, S., Shojania, K.G., and Saint, S. (2004, June). “The use of systematic reviews and meta-analyses in infection control and hospital epidemiology.” (AHRQ grant HS11540). *American Journal of Infection Control* 32, pp. 246-254.

Traditional narrative review of infection control and other research studies allow authors to pick and choose the studies they discuss and the depth at which they discuss them, a process prone to bias. By adhering to a prospectively defined protocol that specifies how studies should be identified, evaluated, and statistically combined, systematic reviews can reduce the bias inherent in traditional narrative reviews. This article discusses the essential elements of a systematic review and provides a framework for evaluating the quality of articles that will help the infection control professional and hospital epidemiologist determine whether the results of such reviews should change clinical practice.

Bundy, D.G., and Feudtner, C. (2004, May). “Preparticipation physical evaluations for high school athletes: Time for a new game plan.” (AHRQ grant K08 HS00002). *Ambulatory Pediatrics* 4(3), pp. 260-263.

Sports-related injuries among high school athletes are common, ranging from 20 to 40 injuries per

100 athletes each year. For several decades, doctors have conducted preparticipation physical evaluations (PPEs) hoping to reduce the morbidity and mortality associated with high school sports. However, the authors of this commentary argue that the PPE as currently practiced is ineffective and illogical. Medical history and examination are inadequate to reliably detect and exclude rare life-threatening conditions. The evaluation is seldom connected with followup care to ensure that resulting recommendations are carried out. Finally, the PPE program is inconsistently and incompletely delivered. The authors propose a research agenda that would result in recommendations to more effectively promote the health of young athletes.

Dionne, C.E., and Chenard, M. (2004). “Back-related functional limitations among full-time homemakers: A comparison with women employed full-time outside the home.” (AHRQ grant HS06168). *Spine* 29, pp. 1375-1383.

This study found that the functional consequences of back pain had a similar nature and 2-year evolution among full-time homemakers and women employed full-time outside the home. The researchers compared these two groups of women, who were enrolled in a large health maintenance organization and had consulted a physician for nonspecific back pain. They conducted telephone interviews with the women 4 to 6 weeks after the consultation and 1 and 2 years later. Two-year back-related functional limitations were significantly associated with symptoms of depression, pain intensity, and the number of days

with back pain in the previous 6 months but not with employment status.

Fiscella, K., Franks, P., and Meldrum, S. (2004). “Estimating racial/ethnic disparity in mammography rates: It all depends on how you ask the question.” (AHRQ grant HS10295). *Preventive Medicine* 39, pp. 399-403.

This study examined the impact of different survey methods on estimates of racial disparity in mammography. The investigators compared responses from 3,090 women aged 40 and older to two different questions from the 1996 Medical Expenditure Panel Survey. They asked the women when they had last obtained a mammogram versus what medical services, including mammography, they received over a 4-month interval, aggregated across 1 year. There was no significant racial disparity in 1-year mammography prevalence based on the first question (3.3 percent difference between black and white women). In contrast, there was a 13.1 percent difference in 1-year mammography prevalence based on the medical services question. These results caution against exclusive reliance on annual self-reports for monitoring disparities in preventive care.

Guagliardo, M.F., Jablonski, K.A., Joseph, J.G., and Goodman, D.C. (2004). “Do pediatric hospitalizations have a unique geography?” (AHRQ grant HS11021). *BMC Health Services Research* 4(2), pp. 1-9.

U.S. small-area health services research studies are often based on hospital service areas (HSAs), which are determined by the geographic origins of Medicare

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Part A hospital patients, most of whom are seniors. However, Medicare-based HSAs may not be appropriate for all age groups and service types throughout the country, according to this study. The investigators conducted a cross-sectional analysis of California hospital discharges for two age groups, non-newborns 0 to 17 years of age and seniors, to identify the percentage of residents hospitalized in their home HSA (index of localization). The mean localization index for pediatric cases was 20 percentage points lower than it was for Medicare cases.

Halpern, J., Johnson, M.D., Miranda, J., and Wells, K.B. (2004, May). "The Partners in Care approach to ethics outcomes in quality improvement programs for depression." (AHRQ grant HS08349). *Psychiatric Services* 55(5), pp. 532-539.

These authors describe an approach to addressing patient centeredness and equity in a randomized trial of quality improvement (QI) for depressed primary care patients. For four ethics goals (autonomy, distributive justice, beneficence, and avoiding harm), the authors identify intervention features, study measures, and hypotheses implemented in Partners in Care, a trial of two QI interventions relative to usual care for depression. They conclude that it is feasible to address ethics outcomes in QI programs for depression, but substantial marginal resources may be required. Nevertheless, interventions so modified can increase a practice's ability to realize ethics goals.

Hogg, J.C., Chu, F., Utokaparch, S., and others. (2004, June). "The nature of small-airway obstruction in chronic obstructive pulmonary disease." (Cosponsored by AHRQ, NHLBI, and CMS). *New England Journal of Medicine* 350(26), pp. 2645-2653.

Chronic obstructive pulmonary disease (COPD) is a major public health problem associated with long-term exposure to toxic gases and particles. This study, a component of the National Emphysema Treatment Trial, examined the evolution of the pathological effects of airway obstruction in patients with COPD by surgically resecting lung tissue from 159 patients with stage 0 (at risk), 39 with stage 1, 22 with stage 2, 16 with stage 3, and 43 with stage 4 (very severe) COPD. The progression of COPD was associated with the accumulation of inflammatory mucous exudates in the lumen of the small airways and infiltration of the wall by innate and adaptive inflammatory immune cells that form lymphoid follicles. These changes were coupled to a repair or remodeling process that thickened the walls of these airways.

Hripcsak, G., Stetson, P.D., and Gordon, P.G. (2004, June). "Using the Federated Council for Internal Medicine curricular guide and administrative codes to assess IM residents' breadth of experience." (AHRQ grant HS11806). *Academic Medicine* 79(6), pp. 557-563.

These investigators estimated the breadth of experience of 41 internal medicine residents at one medical center over a 3-year period using a published curricular guide and an

electronic medical record (EMR). They mapped residents to the patients they cared for, the diagnoses those patients were assigned, and the Federated Council for Internal Medicine competencies covered. Residents covered 76 percent of priority 1 competencies (those learned through direct responsibility for patients) and 67 percent of all competencies. Thus, internal medicine residents had the potential to achieve most competencies via direct patient care, but no residents achieved full coverage. The EMR may provide a way to track residents and study training programs.

Kass-Bartelmes, B.L., and Hughes, R. (2004). "Advance care planning: Preferences for care at the end of life." *Journal of Pain & Palliative Care Pharmacotherapy* 18(1), pp. 87-109.

These authors discuss predictors of patient wishes for end-of-life care and the influence of family and clinicians, as well as research findings on patient decisions regarding preferences for end-of-life-care. They note that most patients have not participated in advance care planning. The authors document the need for more effective planning and describe appropriate times to discuss such planning. They describe patient responses to hypothetical scenarios of terminal cancer, chronic obstructive pulmonary disease, AIDS, stroke, and dementia. They also discuss the invasiveness of interventions, prognosis, and other factors that favor or discourage patient preferences for end-of-life care. Reprints (AHRQ Publication No. 04-R060) are available from AHRQ.*

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Keating, N.L., Landon, B.E., Ayanian, J.Z., and others. (2004, May). "Practice, clinical management, and financial arrangements of practicing generalists." (AHRQ grant HS09936). *Journal of General Internal Medicine* 19, pp. 410-418.

These researchers surveyed 619 generalist physicians caring for managed care patients in three Minnesota health plans during 1999. They collected information about physicians' personal characteristics, features of their practices, their compensation arrangements, and practice management strategies that are often used by health care organizations to influence care. They found that 26 percent of the physicians felt pressure to limit referrals, and 62 percent felt pressure to see more patients. One-fourth (24 percent) of the physicians surveyed said they were dissatisfied with their career in medicine. Physicians who reported pressure to limit referrals were 12 percent more likely to be dissatisfied than other physicians, and those who reported pressure to see more patients were 37 percent more likely to be dissatisfied. Pressure to see more patients was more frequent among physicians in practices owned by health systems, those using physician extenders (for example, certified nurse practitioners), and among physicians who were paid by salary with performance adjustment or received at least some income through capitation.

Kennedy, M.J., Abdel-Rahman, S.M., Kashuba, A.D., and Leeder, J.S. (2004). "Comparison of

various urine collection intervals for caffeine and dextromethorphan phenotyping in children." (AHRQ grant HS10397). *Journal of Clinical Pharmacology* 44, pp. 708-714.

Caffeine and dextromethorphan have been used successfully both alone and in combination to assess phenotype and enzyme activity in children of various ages. These researchers calculated the cumulative metabolite recoveries and molar ratios in urine collected from 24 children at 2, 4, 6, and 8 hours after caffeine (11.5 mg) and dextromethorphan (.5 mg/kg) administration to determine when respective urinary molar ratios stabilize and thus are likely to accurately reflect enzyme activity. The findings suggest that a 4-hour urine collection is adequate for the concurrent assessment of hepatic CYP1A2, NAT-2, XO, and CYP2D6 activity in children ages 3 to 8 years who are CYP2D6 extensive metabolizers using standard caffeine and dextromethorphan phenotyping methods. Longer collection periods may be required, however, in younger children and in those who are CYP2D6 poor metabolizers.

Morales, L.E., Elliott, M., Brown, J., and others. (2004). "The applicability of the Consumer Assessments of Health Plans survey (CAHPS®) to preferred provider organizations in the United States: A discussion of industry concerns." (AHRQ grant HS09204). *International Journal for Quality in Health Care* 16(3), pp. 219- 227.

These authors examined the applicability of a leading group of patient surveys, the Consumer Assessments of Health Plans Study (CAHPS®) surveys, to preferred

provider organizations (PPOs) in the United States. They conducted interviews with CAHPS users about experiences with and concerns about using the CAHPS surveys in PPO settings. Those interviewed included representatives of State and Federal government health care purchasers, commercial PPO plans, and survey vendors. Respondents raised concerns about the influence of out-of-network care on CAHPS reports and ratings of PPO health plans. Suggestions were made for adding PPO-relevant items to CAHPS, such as after-hours care, numbers and types of specialists in the PPO network, and disease management.

Ness, R.B., Brunham, R.C., Shen, C., and others. (2004, May). "Associations among human leukocyte antigen (HLA) class II DQ variants, bacterial sexually transmitted diseases, endometritis, and fertility among women with clinical pelvic inflammatory disease." (AHRQ grant HS08358). *Sexually Transmitted Diseases* 31(5), pp. 301-304.

These authors investigated associations between HLA class II DQ alleles, chlamydial and gonococcal cervicitis, endometritis, and infertility among 92 women with clinical signs and symptoms of mild-to-moderate pelvic inflammatory disease (PID). Among these women, carriage of the DQA *0301, DQA *0501, and DQB *0402 alleles altered the occurrence of lower genital tract infection, upper genital tract inflammation, and infertility. Chlamydial cervicitis, gonococcal cervicitis, endometritis, and infertility were all more common among women carrying the DQA *0301 allele after adjustment for

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race. Endometritis and infertility were somewhat less common (or pregnancy more common) among women carrying the DQA *0501 and DQB *0402 alleles.

Neumann, P.J. (2004, May). “Why don’t Americans use cost-effectiveness analysis?” (AHRQ grant HS10919). *American Journal of Managed Care* 10, pp. 308-312.

Cost-effectiveness analysis (CEA) offers decisionmakers a structured, rational approach with which to improve the return on resources expended. Yet, decades after its widespread promotion to the medical community, policymakers in the United States remain reluctant to use the approach formally. Indeed, the resistance to economic evidence in the United States in an era of evidence-based medicine is perhaps the most notable development of all, according to the author of this paper. He examines the resistance to CEA in the United States and explores ways to advance the field.

Reed, S.D., Lee, T.A., and McCrory, D.C. (2004). “The economic burden of allergic rhinitis.” (AHRQ contract 290-97-0014). *Pharmacoeconomics* 22(6), pp. 345-361.

These authors review the numerous economic analyses of allergic rhinitis that have been conducted, most of which have been burden-of-illness studies. Most estimates of the annual cost of allergic rhinitis range from \$2 billion to \$5 billion. The wide range of estimates can be attributed to differences in identifying patients with allergic rhinitis, differences in cost assignments, limitations of available data, and

difficulties in assigning indirect costs of allergic rhinitis. To date, the medical literature lacks a comprehensive economic evaluation of general treatment strategies of allergic rhinitis. The authors suggest development of a consensus on a summary measure of effectiveness that could be used in cost-effectiveness analyses of therapies for allergic rhinitis.

Saag, K.G., Olivieri, J.J., Patino, F., and others. (2004, June). “Measuring quality in arthritis care: The Arthritis Foundation’s quality indicator set for analgesics.” (AHRQ grant HS10389). *Arthritis & Rheumatism* 51(3), pp. 337-349.

To develop systematically validated quality indicators (QIs) addressing analgesic safety, these authors reviewed the literature on existing quality measures, clinical guidelines, and evidence supporting potential QIs concerning nonselective (traditional) nonsteroidal antiinflammatory drugs (NSAIDs) and newer cyclooxygenase 2-selective NSAIDs. An expert panel then validated or refuted potential indicators. A final 10 QIs for the safe use of NSAIDs focused on informing patients about risk, NSAID choice and gastrointestinal prophylaxis, and side-effect monitoring.

Unruh, M.L., Levey, A.S., D’Ambrosio, C., and others. (2004, May). “Restless legs symptoms among incident dialysis patients: Association with lower quality of life and shorter survival.” (AHRQ grant HS08365). *American Journal of Kidney Diseases* 43(5), pp. 900-909.

Symptoms of restless legs (overwhelming urge to move legs caused by uncomfortable or

unpleasant sensations in the legs, which often interferes with sleep) are common among patients with kidney failure who are treated with long-term hemodialysis. According to this study, symptoms of restless legs are severe in about 15 percent of dialysis patients. The researchers analyzed survey responses of 894 dialysis patients age 45 or older who participated in the CHOICE study from October 1995 to June 1998 and responded to questions about the severity of restless legs symptoms. The CHOICE study is a national prospective cohort study of patients undergoing hemodialysis or peritoneal dialysis in one of 80 clinics in Nashville, TN, and New Haven, CT. According to the study findings, restless legs is associated with lower quality of life and an increased risk of death. The prevalence of symptoms associated with restless legs were similar among patients regardless of dialysis mode and did not vary by race. Sleep quality was significantly improved among patients with severe restless legs who were prescribed opioids.

Uribe, J.I., Ralph, W.M., Glaser, A.Y., and Fried, M.P. (2004, March). “Learning curves, acquisition, and retention of skills trained with the endoscopic sinus surgery simulator.” (AHRQ grant HS11866). *American Journal of Rhinology* 18, pp. 87-92.

Intensive proctored training on the endoscopic sinus surgery simulator (ED3) can train inexperienced medical students to perform endoscopic sinus surgery (ESS) close to that of experienced sinus surgeons on the ED3, concludes this study. The investigators trained 26 medical students. In the novice mode (three-dimensional abstract images are used to teach the use of endoscopic surgical equipment) after 7 to 10

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trials, the students reached a plateau in their learning curves to within 90 percent of that of experienced sinus surgeons. In the intermediate mode (ESS is performed on a simulated patient with teaching aids), students were able to reach a plateau in their learning curves to within 80 percent of that of experienced surgeons. This performance was sustained in the advanced mode (simulate surgery without teaching aids).

Wang, P.S., Schneeweiss, S., Glynn, R.J., and others. (2004, April). "Use of case-crossover design to study prolonged drug exposures and insidious outcomes." (AHRQ grant HS10881). *Annals of Epidemiology* 14, pp. 296-303.

The case-crossover design was originally intended to study brief exposures with immediate and transient effects and acute outcomes with abrupt onsets. The study investigated whether case-crossover methods can be used to study prolonged exposures and insidious outcomes. It involved 8,220 elderly patients with central nervous system (CNS) adverse events such as delirium who were enrolled in several New Jersey health benefits programs between 1991 and 1995. The researchers assessed their exposures to active drugs with deleterious CNS effects and inactive regimens (multivitamins and statins) during case and control time periods lasting from 1 to 4 months. They observed significantly elevated risks for all three active drugs, regardless of which time window was used, which increased with longer time windows. No increased risks were observed for the two inactive regimens, regardless of window duration. These results

suggest that, with lengthened exposure assessment windows, case-crossover methods may be useful for studying exposures with prolonged effects and outcomes with insidious onsets.

Wolff, J.L., and Agree, E.M. (2004). "Depression among recipients of informal care: The effects of reciprocity, respect, and adequacy of support." (AHRQ grant T32 HS00029). *Journal of Gerontology* 59B(3), pp. S173-S180.

Perceived quality of the informal care arrangement has a bearing on the psychological health of care recipients, according to this study. The researchers found that individuals in more reciprocal relationships and in relationships where they felt respected and valued were less likely to be depressed than their counterparts. The researchers used generalized estimating equations to generate models of prevalent depression using a sample of 420 disabled elderly community-dwelling women receiving informal care. Findings confirmed a substantial prevalence of depression among older women with disabilities. Perceived reciprocity and respect afforded by one's primary caregiver as well as adequacy of instrumental support were associated with a lower likelihood of women being categorized as depressed, even after controlling for factors known to be related to depression.

Wolinsky, F.D., Metz, S.M., Tierney, W.M., and others. (2004). "Test-retest reliability of the Mirowsky-Ross 2x2 index of the sense of control." (AHRQ grant HS11635). *Psychological Reports* 94, pp. 725-732.

A sense of control measure, the 1991 Mirowsky-Ross 2x2 Index of the Sense of Control, has

acceptable test-retest reliability and is appropriate for use in longitudinal research, according to this study. The researchers randomly selected 304 individuals for test-retest interviews occurring 1 to 4 days after their regularly scheduled first followup interview. They assessed test-retest reliability at the item level using percent agreement and weighted kappa and found moderate to substantial item-level agreement. At the scale score level there was substantial agreement. Also, calculation of intraclass correlation coefficients (ICGs) within categories of demographic, socioeconomic, psychosocial, and functional status characteristics found no appreciable differences in ICG values.

Wutoh, R., Boren, S.A., and Balas, A. (2004). "eLearning: A review of Internet-based continuing medical education." (AHRQ grant HS10472). *Journal of Continuing Education in the Health Professions* 24, pp. 20-30.

Internet-based continuing medical education (CME) programs are just as effective in imparting knowledge as traditional formats of CME, concludes this study. However, we do not know whether these positive changes in knowledge are translated into changes in practice, caution the authors. They reviewed the literature on the effect of Internet-based CME interventions on physician performance and medical outcomes. Of the 16 eligible studies, six studies generated positive changes in participant knowledge over traditional formats; only three studies showed a positive change in practice. The remainder of the studies showed no difference in knowledge levels between Internet-based interventions and traditional CME formats.

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Wyrwich, K.W., Spertus, J.A., Kroenke, K., and others. (2004, April). "Clinically important differences in health status for patients with heart disease: An expert consensus panel report." (AHRQ grant HS10234 and HS11635). *American Heart Journal* 147, pp. 615-622.

The purpose of this study was to develop clinically important difference (CID) standards for patients with coronary artery disease and congestive heart failure that identify small, moderate, and large intraindividual changes over time in a modified version of the Chronic Heart Failure Questionnaire (CHQ) and the Medical Outcomes Study Short-Form 36-item Health Survey (SF-36). Based on experience using these measures and an extensive review of articles describing the development and use of these instruments, an expert panel agreed on small, medium, and large clinically relevant changes in scores for the CHQ and SF-36. They provide a useful tool for determining whether routine clinical health status assessments will benefit patients and enhance physicians' decisionmaking capacity in clinical settings.

Yealy, D.M., Auble, T.E., Stone, R.A., and others. (2004, June). "The emergency department community-acquired pneumonia trial: Methodology of a quality improvement intervention." (AHRQ grant HS10049). *Annals of Emergency Medicine* 43(6), pp. 770-782.

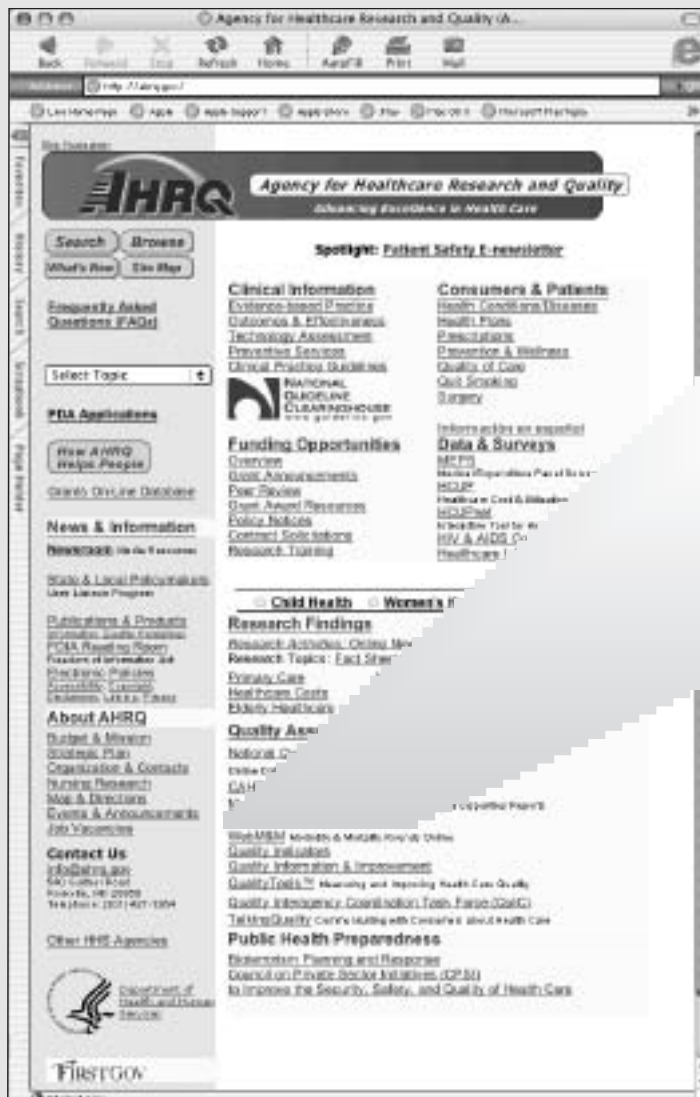
Nationwide, nearly 75 percent of community-acquired pneumonia (CAP) patients are initially evaluated and treated in hospital-based emergency departments (EDs). These investigators designed an ED-based quality improvement (QI) trial focused on the initial care of patients with CAP. The specific aims were to compare the effectiveness and safety of three guideline implementation interventions on site of treatment and process of care decisions by using established QI strategies at 32 sites in Pennsylvania and Connecticut. The QI interventions ranged in intensity from low to moderate to a multifaceted, high-intensity intervention.

Zou, K.H., Wells III, W.M., Kikinis, R., and Warfield, S.K. (2004). "Three validation metrics for automated probabilistic image segmentation of brain tumours." (AHRQ grant HS13234). *Statistics in Medicine* 23, pp. 1259-1282.

The validity of brain tumor segmentation is an important issue in image processing because it has a direct impact on surgical planning. The investigators examined segmentation accuracy based on three two-sample validation metrics against the estimated composite latent gold standard. The distribution functions of the tumor and control pixel data were parametrically assumed to be a mixture of two beta distributions with different shape parameters. The researchers estimated the corresponding receiver operating characteristic curve, Dice similarity coefficient, and mutual information over all possible decision thresholds. Based on each validation metric, they then computed an optimal threshold via maximization. They illustrated these methods on magnetic resonance imaging data from nine brain tumor cases of three different tumor types. The automated segmentation yielded satisfactory accuracy with varied optimal thresholds. ■

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