AHRQ

Research Activities

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Highlights

Departments

Regular Features

Two-thirds of elderly stroke survivors in nursing homes are not receiving medication to prevent further strokes

Stroke remains the third leading cause of death among Americans and the leading cause of nursing home placement. Unfortunately, two-thirds (67 percent) of stroke survivors in nursing homes do not receive anticoagulant or antiplatelet drug therapy to prevent further strokes, according to the findings of a recent study that was supported in part by the Agency for Healthcare Research and Quality (HS11256).

Those over 85 years of age were 14 percent less likely to be treated than those 65 to 74 years of age (odds ratio, OR 0.86). Black residents were 20 percent less likely to be treated than whites (OR 0.80), even though blacks have a greater risk of stroke. Residents with severe cognitive or physical impairment were about one-third less likely (OR 0.63 and 0.69, respectively) to receive treatment than those without impairments.

Patient contraindications to blood-thinning drugs, such as gastrointestinal bleeding and peptic ulcer disease, contributed to physicians' decisions not to treat them. However, they did not fully account for the large gap between recommended and observed levels of treatment, note Brown University researchers, Brian J. Quilliam, Ph.D., and Kate L. Lapane, Ph.D. Using the SAGE (Systematic Assessment of Geriatric drug use via Epidemiology) database, they obtained information on all residents diagnosed with stroke from 1992 to 1995 at Medicare/Medicaid-certified nursing homes in five States. They used logistic regression modeling to identify independent predictors of stroke prevention drug treatment, including aspirin, dipyridamole, ticlopidine, and warfarin alone or in combination with another drug.

Among those treated, most received aspirin alone (16 percent) or warfarin alone (10 percent). The prevalence of atrial fibrillation, which markedly elevates stroke risk, increased with age in these patients, but the use of warfarin decreased with advancing age. Perhaps doctors fear the increased risk of bleeding from warfarin among the elderly or feel they cannot adequately monitor high-

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Elderly stroke survivors

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risk patients, note the researchers. They suggest that pharmacist-run anticoagulant clinics might alleviate some of these concerns.

In conclusion, Drs. Quilliam and Lapane draw attention to their findings which indicate differential treatment along racial/ethnic lines. Because they did not have any information on educational level, income, or occupation, it was not possible for them to evaluate the effect of race/ethnicity within the context of socioeconomic position. They note that they are unaware of any physiological reasons justifying such differential treatment and voice concern about the underlying reasons for the disparities. The researchers call for further research to explore the effect of race/ethnicity within a social context on the decision to treat or not treat elderly stroke survivors.

See "Clinical correlates and drug treatment of residents with stroke in long-term care," by Drs. Quilliam and Lapane, in the June 2001 *Stroke* 32, pp. 1385-1393. ■

Pharmaceutical Research

ACE inhibitors, when included in an antihypertensive regimen, slow progression of nondiabetic renal disease

Chronic renal disease, often due to hypertension, is a major public health problem in the United States, with an estimated 357,000 people suffering from end-stage renal disease (ESRD) in 1999. The annual cost of treatment with dialysis and renal transplantation is nearly $16 billion. Patients undergoing dialysis have a reduced quality of life, a high rate of illness, and an annual mortality rate of 20 to 25 percent.

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AHRQ
Office of Health Care Information
2101 East Jefferson Street, Suite 501
Rockville, MD 20852
(301) 594-1364

Mary L. Grady, Managing Editor
Gail Makulowich, Contributing Editor
Joel Boches, Design and Production
Karen Migdail, Media Inquiries

Findings from a recent study indicate that angiotensin-converting enzyme (ACE) inhibitors should be the antihypertensive agents of first choice in slowing progression of nondiabetic renal disease, as they are in patients who have diabetes and renal disease. The study was led by Christopher H. Schmid, Ph.D., and Andrew S. Levey, M.D., of the New England Medical Center, and supported in part by the Agency for Healthcare Research and Quality (HS08532 and HS10064). The researchers did a meta-analysis of 11 randomized controlled studies on 1,860 patients with nondiabetic renal disease to compare the efficacy of antihypertensive regimens with and without ACE inhibitors.

After a mean of 2.2 years, patients in the ACE inhibitor group had a greater mean decrease in systolic and diastolic blood pressure (4.5 mm Hg and 2.3 mm Hg, respectively) and urinary protein excretion (0.46 g/d) than those in the non-ACE inhibitor group. Excessive urinary protein excretion (proteinuria) is an indicator of poor kidney functioning. After adjusting for patient differences and study characteristics, the ACE inhibitor group had nearly one-third less likelihood of developing ESRD or both doubling the baseline concentration of serum creatinine (which indicates progression of renal disease) or developing ESRD. This effect persisted even after adjusting for changes in blood pressure and urine protein during followup.

Significantly fewer patients in the ACE inhibitor group than in the control group developed ESRD

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Nondiabetic renal disease

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(7.4 vs. 11.6 percent), had either a doubling of baseline serum creatinine or ESRD (13.2 vs. 20.5 percent), or had a combined outcome of ESRD or death (9.6 vs. 12.8 percent). Patients with proteinuria at baseline (0.5 g/d or more; normal is less than 0.5 g/d) benefitted more from ACE inhibitor therapy than others. The researchers conclude that ACE inhibitors are indicated for treatment of nondiabetic patients with chronic renal disease and proteinuria and, possibly, those without proteinuria. The beneficial effect also appears to involve factors other than just the blood pressure and urine protein-lowering effects.

For more details, see "Angiotensin-converting enzyme inhibitors and progression of nondiabetic renal disease: A meta-analysis of patient-level data," by Tazeen H. Jafar, M.D., M.P.H., Dr. Schmid, Marcia Landa, M.A., and others, in the July 17, 2001 *Annals of Internal Medicine* 135(2), pp. 73-87. ■

Generalists tend to be more cautious than cardiologists in their use of drugs for heart attack patients

In recent years, numerous studies have compared the performance of generalist and specialist physicians in the management of common conditions such as acute myocardial infarction (AMI, heart attack). Typically, these studies have shown the underuse of proven effective therapies by generalists.

A recent study supported in part by the Agency for Healthcare Research and Quality (HS07357) found that generalist attending physicians are less likely than cardiologists to use effective, though risky, medications such as thrombolytics (blood thinners) for hospitalized patients suffering from AMI. On the other hand, generalists were as likely as cardiologists to discontinue the use of widely prescribed calcium channel blockers (CCBs) when these agents were linked to an increased risk of AMI.

The researchers measured use of CCBs during hospitalization for AMI before (1992-1993) and after the publication of a series of adverse reports regarding CCBs (1995-1996), in 5,347 AMI patients admitted to 37 community-based hospitals in Minnesota. They also examined use of effective medications (aspirin, beta blockers, thrombolytic therapy) and ineffective AMI treatments (lidocaine) among attending generalists, generalists with cardiologist consultation, and attending cardiologists.

Compared with cardiologists, generalists were less likely to use aspirin (37 percent vs. 68 percent), thrombolytics (29 vs. 64 percent), and beta blockers (20 percent vs. 46 percent), although much of the difference was explained by the fact that generalists' patients were older and had more severe comorbidity. For example, after multivariate adjustment, differences between generalists' and cardiologists' in the use of beta blockers were no longer significant. Patients cared for by generalist attendings in consultation with cardiologists tended to have intermediate use of effective therapies. From 1992-1993 to 1995-1996, the use of CCBs in patients with AMI decreased from 24 percent to 10 percent. The odds of not using CCBs after the adverse reports (adjusted OR 0.33) were independent of physician specialty.

For more information, see "Influence of physician specialty on adoption and relinquishment of calcium channel blockers and other treatments for myocardial infarction," by Sumit R. Majumdar, M.D., M.P.H., Thomas S. Inui, M.D., Sc.M., Jerry H. Gurwitz, M.D., and others, in the June 2001 *Journal of General Internal Medicine* 16, pp. 351-359. ■

Also in this issue:

One-third of elderly home health care patients are having problems with their medications

Inappropriate medication use among the elderly is particularly high. In fact, nearly one-third of elderly home health care patients surveyed in a recent study were taking a drug considered inappropriate for older people or had some other evidence of a potential medication problem. Elderly home health care patients are frequent medication users, and advanced age and frailty may increase their susceptibility to adverse medication effects. Indeed, the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) requires that home health care agencies record all medications their patients are taking and conduct a drug regimen review.

Results of a survey by researchers at the Center for Education and Research in Therapeutics (CERT) at Vanderbilt University indicate that more effective methods are needed to improve medication use in this vulnerable group. The study was supported in part by the Agency for Healthcare Research and Quality (HS10384) and the John A. Hartford Foundation.

The researchers surveyed elderly (age 65 or older) home health care patients cared for by two of the largest urban home health care agencies in the United States between 1996 and 1998. They used two sets of expert panel criteria to define possible medication errors. The Home Health Criteria identified symptoms that indicate a problem with medication, such as uncontrolled hypertension despite antihypertensive use or recent falls or confusion while on psychotropic medications. The Beers criteria identify patterns of medication use that have been shown to be risky in the elderly, such as use of muscle relaxants and short-acting benzodiazepines, which are used to treat anxiety and insomnia.

The 6,718 patients studied took a median of five drugs, with 19 percent of them taking nine or more medications. Based on Home Health Criteria, 19 percent of patients had possible medication errors; based on Beers criteria, 17 percent did; 30 percent had possible medication errors based on both Home Health and Beers criteria. Ten percent of those taking one to three medications had possible errors, compared with 32 percent of those taking nine or more drugs based on Home Health Criteria, 8 percent and 32 percent, respectively, based on Beers criteria, and 16 percent and 50 percent, respectively, based on both criteria.

See "Possible medication errors in home healthcare patients," by Sarah Meredith, M.B.B.S., M.Sc., Penny H. Feldman, Ph.D., Dennee Frey, Pharm.D., and others, in the June 2001 *Journal of the American Geriatrics Societ*y 49, pp. 719-724. ■

Clinical Decisionmaking

Men aged 50 to 75 should be advised about PSA testing so they can make an informed decision

Prostate-specific-antigen (PSA) screening for prostate cancer remains controversial because no randomized trials have shown that early detection and aggressive treatment of prostate cancer can reduce deaths from the disease. With the advent of PSA screening, the lifetime risk of a diagnosis of prostate cancer is now about 16 percent, whereas the lifetime risk of death from prostate cancer is about 3.4 percent. Obviously, most prostate cancers that are diagnosed in the United States are not destined to be fatal, notes Michael J. Barry, M.D., of Harvard Medical School, in a recent commentary.

Dr. Barry points out that PSA screening guidelines vary and that the optimal screening strategy remains unknown. On the basis of

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PSA testing

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available data, men who are 50 to 75 years of age (depending on risk factors and general health) should be made aware of the availability of the PSA test and its potential harms and benefits so that they can make an informed choice about screening, recommends Dr. Barry. His research was supported in part by the Agency for Healthcare Research and Quality (HS08397).

As Dr. Barry notes, the sensitivity and specificity of the PSA test and the threshold at which a result should prompt a biopsy are unclear. Men with suspicious findings on digital rectal exam and a PSA level of 4.0 ng per ml (upper limit of normal) or less have a probability of cancer of at least 10 percent, and a transrectal biopsy is usually recommended. The optimal number and pattern of biopsy specimens and number of times biopsies should be repeated are now hotly debated. Also, the specificity of the PSA test is suboptimal, and as a result, about 75 percent of men who undergo a prostate biopsy because they have PSA levels of 4-10 ng per ml do not have cancer. Finally, the optimal treatment of identified prostate cancers is controversial. Standard treatments, including radical prostatectomy, external-beam radiation therapy, and brachytherapy, are associated with serious side effects such as sexual dysfunction and incontinence.

More details are in "Prostate-specific-antigen testing for early diagnosis of prostate cancer," by Dr. Barry, in the May 3, 2001 *New England Journal of Medicine* 344(18), pp. 1373-1377. ■

New risk index can identify elderly people at increased risk for death within a year after hospital discharge

Many elderly people die within a year after they have been hospitalized for an acute medical illness. A newly developed risk index can be used at the bedside to help doctors assess the risk of hospitalized elderly patients dying within a year of discharge. This in turn can help guide their clinical strategy and counseling of patients and their families about needs for long-term care, home care, or other supportive services. The index was developed by researchers at the VA Medical Center and the University of California, San Francisco, Indiana University School of Medicine, the Cleveland Clinic, and the University of Connecticut. Their work was supported in part by the Agency for Healthcare Research and Quality (K02 HS00006).

The researchers initially developed the index by correlating medical factors with death 1 year after discharge in 1,495 elderly patients at one hospital and validated it in 1,427 elderly patients discharged from a different hospital. They identified six independent risk factors for postdischarge death, which they weighted according to level of risk: male sex (1 point); number of limitations in activities of daily living (ADLs), such as dressing or toileting oneself (one to four ADLs, 2 points; all five ADLs (5 points); congestive heart failure (2 points), cancer (solitary, 3 points; metastatic, 8 points); creatine level higher than 3.0 mg/dL (2 points), indicative of renal dysfunction; and low albumin level (3.0-3.4 g/dL, 1 point; less than 3.0 g/dL, 2 points), which is a marker of both malnutrition and general disease severity. The researchers added these risk scores for a total risk score.

In the group of patients from which they derived the score, 13 percent in the lowest risk group (0-1 point), 20 percent in the group with 2 or 3 points, 37 percent in the group with 4 to 6 points, and 68 percent in the highest risk group (more than 6 points) died within 1 year of hospital discharge. In the validation group, 1-year mortality was 4 percent in the lowest risk group, 19 percent in the group with 2 or 3 points, 34 percent in the group with 4 to 6 points, and 64 percent in the highest risk group. This index performed better in predicting 1-year mortality than other prognostic indexes that focus only on coexisting illnesses or physiologic measures, conclude the researchers.

More details are in "Development and validation of a prognostic index for 1-year mortality in older adults after hospitalization," by Louise C. Walter, M.D., Richard J. Brand, Ph.D., Steven R. Counsell, M.D., and others, in the June 20, 2001 *Journal of the American Medical Association* 285(23), pp. 2987- 2994. ■

Doctors should consider antibiotic treatment for women with tenderness suggesting pelvic inflammatory disease

Unfortunately, the clinical diagnosis of pelvic inflammatory disease (PID) is difficult and often inaccurate. PID is a sexually transmitted disease that can cause infertility, tubal pregnancies, and other problems. A new study finds that adnexal tenderness (tenderness of the ovaries and/or fallopian tubes) will identify over 95 percent of women with PID compared with 83 percent identified by the minimum criteria for diagnosing PID suggested by the Centers for Disease Control and Prevention (CDC)

The CDC criteria are: lower abdominal tenderness, adnexal tenderness, and cervical motion tenderness. The CDC recommends antibiotic treatment for sexually active young women if all criteria are present, unless another cause of the clinical signs can be identified. However, the new study concludes that doctors should consider antibiotic treatment for at-risk women with adnexal tenderness when there is no other obvious diagnosis to explain the patient's clinical signs and symptoms.

Also, a positive test for chlamydia or gonorrhea increased the odds of disease by a factor of 4.4. An elevated temperature and leukocyte count (above 10,000) were associated with a 6.7-fold increased risk of endometritis (inflammation of the endometrium or uterine lining). The probability of endometritis on the basis of clinical signs exceeded 65 percent only when there was an abnormal cervical-vaginal discharge and a positive test result for *N. gonorrhoeae* or *C. trachomatis.*

In the study supported by the Agency for Healthcare Research and Quality (HS08358), Roberta B. Ness, M.D., M.P.H., of the University of Pittsburgh, and her colleagues analyzed the baseline characteristics of 651 women enrolled in a multicenter randomized treatment trial for PID. They recorded clinical and laboratory findings for all patients and performed endometrial sampling. They calculated the sensitivity and specificity of clinical criteria based on results from the sampling.

Details are in "Clinical predictors of endometritis in women with symptoms and signs of pelvic inflammatory disease," by Jeffrey F. Peipert, M.D., M.P.H., Dr. Ness, Jeffrey Blume, Ph.D., and others, in the April 2001 *American Journal of Obstetrics and Gynecology* 184, pp. 856-864. ■

Nonprofit women's health centers better serve poor and vulnerable women than for-profit centers

As of 1994, an estimated 3,600 women's health centers were in operation in the United States. The majority of centers provide outpatient services only, and some offer a mix of outpatient and inpatient services, including primary care, reproductive health services, breast imaging/cancer services, maternity/birth services, and various other services. These centers serve about 14.5 million women, 7.8 million of whom use the centers as their usual source of care. According to a recent study comparing for-profit and nonprofit centers, nonprofit centers do a better job of serving the needs of disadvantaged women than for-profit centers. This research was supported by the Agency for Healthcare Research and Quality (HS09328).

Nonprofit centers serve larger proportions of uninsured women and rural women, and they offer reduced rates to more clients based on financial need. They also offer a broader range of primary care services, provide clinicians with more frequent training, and are more likely to involve consumers and women in center governance than for-profit centers.

Center ownership apparently does not affect services to women enrolled in Medicaid and minority women or provision of transportation or language translation services to clients, according to the researchers. They used data from the 1994 National Survey of Women's Health Centers on 108 for-profit centers and 296 nonprofit centers to examine the

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Women's health centers

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association between center ownership and community benefits.

Overall, the centers served substantial proportions of underserved women and provided a range of services. The average primary care/reproductive health center provided 23 out of the 37 primary care services examined. More than half of all centers offered translator services; provided training for physicians, nurses, or other clinicians; and had one or more consumers on their governing boards. Also, the average center provided five out of ten education/information services at no cost to clients. The threat to the survival of women's health centers from managed care may limit women's access to care, particularly women who use such centers as their usual source of care.

More details are in "Ownership type and community benefits of women's health centers," by Amal J. Khoury, Ph.D., M.P.H., Carol S. Weisman, and Chad M. Jarjoura, in the March 2001 *Medical Care Research and Review* 58(1), pp. 76-99. ■

Homeless women frequently have gynecological problems

The striking prevalence of gynecological problems among homeless women underscores the need for accessible gynecological services for these women, according to the authors of a recent study. The fact that one-fourth of the homeless women studied were either pregnant at the time of the study or had been pregnant during the preceding year suggests they need more accessible obstetrical and prenatal care as well, says Lillian Gelberg, M.D., M.S.P.H., of the University of California, Los Angeles, School of Medicine.

In a study supported by the Agency for Healthcare Research and Quality (HS08323), Dr. Gelberg and colleagues found that of nearly 1,000 Los Angeles County homeless women of reproductive age (15-44 years) they interviewed, two-thirds reported gynecological symptoms during the previous year. Their symptoms ranged from abnormal vaginal discharge, severe pelvic pain, and skipped periods (the most common symptom) to breast lumps and burning during urination. Four factors increased the likelihood that homeless women would have gynecological problems: a current pregnancy or a pregnancy completed during the past year; drug dependence; more episodes of homelessness, which probably make it difficult to maintain good hygiene and other preventive behaviors; and general physical health symptoms.

Of the women who experienced at least one symptom, 71 percent sought care for at least one of their problems. Homeless women with gynecological symptoms, younger age, better perceived health, and insurance coverage received more health care (more doctor visits) than other women, while women reporting recent drug use and rape received less care. Women who have been raped often have trauma-like responses during gynecological exams, which may explain their reluctance to seek gynecological care. These findings underscore the need for accessible health care and substance abuse treatment services for homeless women, conclude the authors.

For more details, see "Homeless women's gynecological symptoms and use of medical care," by Suzanne L. Wenzel, Ph.D., Ronald M. Andersen, Ph.D., Deidre S. Gifford, M.D., M.P.H., and Dr. Gelberg, in the *Journal of Health Care for the Poor and Underserved* 12(3), pp. 323-341, 2001. ■

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Few children with persistent asthma use controller medications that can reduce ER visits and hospitalizations

Uncontrolled asthma can lead to emergency room visits and hospitalizations. The increased use of antiinflammatory medications, especially inhaled corticosteroids (ICSs), has been linked to reduced asthma deaths and morbidity in many countries. Yet a decade after the release of U.S. guidelines recommending ICSs and other controllers (such as inhaled cromolyn sodium) for persistent asthma management, few children with persistent asthma symptoms (indicated by frequent use of beta agonists) use controllers regularly, according to a study of several managed care organizations (MCOs). This suggests that the group of young people with well-controlled persistent asthma is small, concludes Kevin B. Weiss, M.D., of Northwestern University Medical School. Dr. Weiss is principal investigator of the Pediatric Asthma Care Patient Outcomes Research Team (PAC-PORT), which is supported by the Agency for Healthcare Research and Quality (HS08368).

Controllers prevent or control lung inflammation that leads to asthma episodes. Beta agonists—adrenalin-like bronchodilators that quickly open up the airways—can help stop an asthma attack once begun, but they do not prevent an attack.

As part of the PAC-PORT, researchers conducted a 1-year study of 13,352 children with asthma who were cared for in three MCOs to identify age and other factors associated with controller medication use. Most children with frequent symptoms such as coughing or wheezing (judged by their frequent use of bronchodilators) received some medication to combat airway inflammation, but few were using sufficient controller medication to be considered "regular" users of preventive therapy, as recommended in national guidelines. Adolescents were most likely to have suboptimal asthma management.

Among children dispensed six or more beta agonist inhalers (indicating frequent breathing problems), only 39 percent also received five or more controller inhalers (indicating regular use) to prevent breathing problems. Adolescents were significantly less likely than younger children to receive five or more controllers (33 vs. 43 percent). Using 3- to 5-year-old children as the reference group, young people 12 to 15 years old were 40 percent less likely to receive five or more controller inhalers, and those 6 to 8 years old were 30 percent more likely to receive them. Fewer girls than boys received any controller therapy (37 vs. 41 percent).

More details are in "Use of inhaled anti-inflammatory medication in children with asthma in managed care settings," by Robert J. Adams, M.B.B.S., M.D., Anne Fuhlbrigge, M.D., M.S., Jonathan A. Finkelstein, M.D., M.P.H., and others, in the April 2001 *Archives of Pediatric and Adolescent Medicine* 155, pp. 501- 507. ■

Tube otorrhea is a common and often recurrent problem in children who have undergone tube placement for otitis media

Often when children experience middle ear infections followed by persistent middle-ear effusion (MEE) the doctor recommends myringotomy (creation of a hole in the eardrum) and tympanostomy-tube placement (TTP) to drain the liquid from the ear and to maintain middle-ear ventilation in order to prevent reinfection and hearing problems. In fact, TTP is the most commonly performed surgery among U.S. children beyond the newborn period. However, tube otorrhea (discharge of pus through the tube) is a common and often recurring complication in young children who have undergone tube placement for persistent MEE, concludes this study which was jointly funded by the Agency for Healthcare Research and Quality and the National Institute for Child Health and Human Development (HD26026).

The investigators, who were led by Jack L. Paradise, M.D., of the University of Pittsburgh School of Medicine and Children's Hospital of Pittsburgh, prospectively monitored the middle ear status of

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Tube otorrhea

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173 children who underwent bilateral TTP between 6 and 36 months of age. They treated episodes of tube otorrhea with oral antibiotics and, if persistent, with topical medication applied in the ear.

During the first 18 months after TTP, the proportion of children who developed one or more episodes of otorrhea increased progressively, reaching 75 percent after 12 months and 83 percent after 18 months. The mean number of episodes per child was 0.79 in the first 6 months, 1.50 in the first 12 months, 2.17 in the first 18 months, and 2.82 in the first 24 months. Overall, otorrhea occurred earlier and was most prevalent among urban children and occurred latest and was least prevalent among suburban children. The rate of otorrhea occurrence was found to be inversely related to maternal socioeconomic status, i.e., the extent of the problem was greatest in children whose SES was lowest and least in children whose SES was highest.

Episodes of tube otorrhea lasted a mean of 16 days, with 13 percent of episodes lasting more than a month. Also, 3.5 percent of children experienced one or more episodes that failed to improve satisfactorily with conventional outpatient management. Five of these children were hospitalized to receive parenteral antibiotic treatment, one child twice and one child three times, and one child also underwent tube removal. Doctors should inform parents of children who are being considered for TTP that, in addition to other potential complications and sequelae of the procedure—such as tympanic membrane perforation, atrophy, and tympanosclerosis—tube otorrhea is a frequent complication, caution the authors.

For details, see "Otorrhea in young children after tympanostomy-tube placement for persistent middle-ear effusion: Prevalence, incidence, and duration." by Collette Ah-Tye, M.D., Dr. Paradise, and D. Kathleen Colborn, B.S., in the June 2001 *Pediatrics* 107(6), pp. 1251-1258. ■

Researchers examine the available evidence on effective management of otitis media in children

Acute otitis media (AOM)—or inflammation of the middle ear—is common among children, with over 5 million episodes of AOM occurring in 1995 at a cost of nearly $3 billion. Unfortunately, AOM incidence is increasing, with doctors' visits for the problem doubling from 1975 to 1990. Antibiotics have been used routinely to treat uncomplicated AOM, but this approach is controversial, especially in children older than 6 months, due in part to concern about antibiotic resistance of bacteria associated with AOM.

Researchers at the Southern California Evidence-based Practice Center (EPC), which is supported by the Agency for Healthcare Research and Quality (contract 290-97-0001), reviewed the available scientific evidence on management of acute and persistent otitis media in children. Their findings are reported in the following two articles.

Takata, G.S., Chan, L.S., Shekelle, P., and others. (2001, August). "Evidence assessment of management of acute otitis media: I. The role of antibiotics in treatment of uncomplicated acute otitis media." *Pediatrics* 108(2), pp. 239-247.

Most children with uncomplicated AOM not initially treated with antibiotics (78 percent) no longer had pain or fever within 4 to 7 days and suffered no complications. Antibiotics offered them only a modest benefit, according to this review of the evidence. About 19 percent of children with AOM not treated with antibiotics experienced a 1- to 7-day clinical failure rate (pain, fever, or middle ear fluid) and few complications. When treated with amoxicillin, the clinical failure rate was reduced to 7 percent. In clinical terms, 8 children with AOM would have to be treated with ampicillin or amoxicillin to avoid one case of clinical failure during this time frame.

There was no evidence to support the superior efficacy of any particular antibiotic or dosing regimen. Adverse effects, primarily gastrointestinal, were more common among children on cefixime than among those on ampicillin or amoxicillin. They also were more common among children on amoxicillin-clavulanate than among those on azithromycin. However, the data were insufficient to draw conclusions about any particular age group, especially those younger than 2 years of age.

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Otitis media in children

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The EPC investigators synthesized the literature of seven electronic databases of articles published between 1966 and March 1999 on the natural history and antibiotic treatment of uncomplicated AOM. A panel of 11 multidisciplinary experts guided the systematic review of the literature. The authors were unable to generalize their results, since many studies failed to identify patient age and otitis-prone status.

Chan, L.S., Takata, G.S., Shekelle, P., and others. (2001, August). "Evidence assessment of management of acute otitis media: II. Research gaps and priorities for future research." ***Pediatrics*** **108(2), pp. 248-254.**

A panel of experts screened a total of 3,461 abstracts and titles of AOM studies from 1966 to March 1999, reviewed 760 full-length articles, and used a total of 80 studies in 85 articles. The panel concluded that although there is a large body of research literature on AOM, its quality is uneven and its findings are not generalizable. For example, although AOM is readily recognized as a clinical condition, clinicians and researchers do not agree on a standard definition of AOM, even among often-cited sources. Only half of the studies approximated the diagnostic criteria for middle ear effusion (MEE), almost none met the criteria for rapid onset, and only one-third met the criteria for signs and symptoms as defined by expert definition of AOM.

Also, disagreement exists about the relative importance of factors influencing the possible outcome of AOM treatment. In the description of the study population, only 36 percent of the 80 studies mentioned the two top ranking risk factors (age of child and otitis-prone status), 59 percent mentioned only age but not otitis-prone status, and 5 percent mentioned neither factor. In general, the type of outcome measure varied between studies, and the definitions of common outcomes, such as clinical failure, were not uniform. Only five studies reported the clinical failure rate between 1 and 7 days. Few studies reported on clinical failure, pain, fever, and MEE by age, and none reported these outcomes by otitis-prone status.

Explicitly defined AOM outcomes are needed to aid in comparing and synthesizing study results. Also, explicit descriptions of the populations studied, including age and whether or not the subjects are otitis-prone, are needed to assess the generalizability of study findings, according to the authors. Of the 74 randomized controlled trials studied, only 53 percent were of acceptable quality. Only 41 percent of these studies mentioned double-blinding, 70 percent described the characteristics of study dropouts, 38 percent used appropriate randomization methods, and 23 percent used appropriate blinding strategies.

Editor's note: Copies of the report from which these findings are drawn, *Management of Acute Otitis Media*, Evidence Report/ Technology Assessment No. 15 (AHRQ Publication No. 00-E010), as well as a 4-page summary of the report (AHRQ Publication No. 00-E008), are available from AHRQ. See the back cover of *Research Activities* for ordering information.* ■

Outcomes/Effectiveness Research

Researchers examine use of acupuncture, surgery, and imaging tests in treating back pain patients

Advanced diagnostic imaging, spinal surgery, and alternative therapies such as acupuncture, are widely used in the diagnosis and treatment of patients with low back pain. Three new studies, supported by the Agency for Healthcare Research and Quality, examine the use of acupuncture, surgery, and imaging tests for low back pain.

The first study shows that, like physicians, acupuncturists also vary in their treatment approach to low back pain. The second study finds that patients with moderate or severe sciatica due to a herniated disc who undergo surgery have better outcomes than those who don't after 5 years. A third study distinguishes certain magnetic resonance imaging (MRI) spinal changes that are common among people without back pain from those that more readily identify people who have experienced back pain.

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Treating back pain

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Kalauokalani, D., Sherman, K.J., and Cherkin, D.C. (2001, May). "Acupuncture for chronic low back pain: Diagnosis and treatment patterns among acupuncturists evaluating the same patient." (AHRQ grants HS09351, HS09989, and HS09565). *Southern Medical Journal* 94(5), pp. 486-491.

Acupuncturists practicing Traditional Chinese Medicine (TCM) varied substantially in their treatment recommendations for the same patient in this study, despite agreement on their diagnoses. The patient was an otherwise healthy 40-year-old woman whose low back pain developed after a head-on motor vehicle accident 20 years earlier. She had negative imaging results, found 6 months of chiropractic therapy to be of no benefit, and took 1,500 mg of acetaminophen each day for the discomfort. This same patient visited each of seven acupuncturists during a 2-week interval, but one failed to record treatment data. According to TCM, Qi stagnation (normal movement of energy or Qi is impaired in a particular organ, meridian, or other part of the body causing distension, soreness, or pain) and occasionally blood stagnation along the urinary bladder meridian are frequently the source of low back pain.

Not surprisingly, the most commonly assigned diagnoses were Qi stagnation (six acupuncturists), and blood stagnation (five). Despite general consensus on diagnosis, treatments differed substantially. Recommendations varied between use of 5 to 14 specific acupuncture points and from 7 to 26 needles. All but one acupuncturist chose points located throughout the back, and all but one chose points in the leg. However, of 28 acupuncture points selected, only 4 were used by two or more acupuncturists.

Four acupuncturists chose points on the urinary bladder meridian, and five combined points on this meridian with points from other meridians. The time that needles remained in place after insertion ranged from 15 to 30 minutes. All practitioners manipulated the needle to elicit *de qi*, the deep dull ache, numbness, or tingling associated with needle insertion, for at least some of their insertions. Most recommended various forms of adjuvant heat. The researchers point out that use of different acupoints along the same meridian may be considered a similar therapeutic option, diminishing some of the apparent variability in treatment.

Atlas, S.J., Keller, R.B., Chang, Y., and others. (2001). "Surgical and nonsurgical management of sciatica secondary to a lumbar disc herniation." (AHRQ grants HS06344, HS08194, and HS09804). *Spine* 26(10), pp. 1179-1187.

Patients with moderate or severe sciatica due to a herniated disc who undergo surgery improve more than those who don't after 5 years, according to this study. The researchers interviewed patients with moderate or severe sciatica from practices in Maine. They mailed the patients followup questionnaires at 3, 6, and 12 months and annually thereafter to 60 months. Patients were asked about symptoms of leg and back pain, functional status, satisfaction, and employment and compensation status.

Of the 507 patents initially enrolled, 5-year outcomes were available for 402: 220 had been treated surgically and 182 had been treated nonsurgically. Surgically treated patients had worse baseline symptoms and functional status than those initially treated nonsurgically. By 5 years, 19 percent of surgical patients had undergone at least one additional lumbar spine operation, and 16 percent of nonsurgical patients had opted for at least one lumbar spine operation. Overall, patients treated initially with surgery reported better outcomes. After 5 years, 70 percent of the surgical patients had improved back or leg pain versus 56 percent of those initially treated nonsurgically.

Similarly, a larger proportion of surgical patients reported satisfaction with their current status (63 vs. 46 percent). The relative advantage of surgery was greatest early in followup and narrowed over 5 years but still remained superior to nonsurgical treatment. There was no difference in the proportion of patients receiving disability compensation 5 years later. The least symptomatic patients at baseline did well regardless of initial treatment, although function improved more in the surgical group.

Jarvik, J.J., Hollingworth, W., Heagerty, P., and others. (2001). "The longitudinal assessment of imaging and disability of the back (LAIDBack) study." (AHRQ grants HS08194 and HS09499). *Spine* 26(10), pp. 1158-1166.

Many magnetic resonance imaging (MRI) findings are typical in patients without low back pain and therefore are of limited use in diagnosing patients with low back pain. On the other hand, less common MRI findings of moderate or severe central stenosis, root compression, and disc extrusions are likely to be diagnostically and clinically relevant, according to this study. The researchers randomly selected patients without low back

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pain in the past 4 months from clinics at a VA hospital to examine which findings were related to age or previous back symptoms.

The researchers found several MRI findings to be common among patients without low back pain. Of the 148 patients, 46 percent had never experienced low back pain. Yet about 83 percent of them had moderate to severe desiccation of one or more discs, 64 percent had one or more bulging discs, and 56 percent had loss of disc height. About 32 percent had at least one disc protrusion, and 6 percent had one or more disc extrusions. On the other hand, moderate or severe central stenosis, root compression, and disc extrusions were more likely to be diagnostically and clinically relevant.

For example, those who had experienced five or more episodes of previous low back pain were much more likely to have a disc extrusion than those who had never experienced low back pain. The prevalence of moderate or severe central stenosis or nerve root compromise was also higher in those with multiple previous episodes of low back pain. Unlike the other MRI findings, which were linked to aging, disc extrusions and nerve root compromise were not significantly associated with age but were associated with previous low back pain. ■

Health Care Costs and Financing

Researchers examine hospital costs for CABG surgery

The U.S. Medicare program spends about $4 billion each year on procedures related to coronary artery bypass graft (CABG) surgery. Under the prospective payment system (PPS), hospitals are paid per-case for bypass surgery based on the patient's diagnosis-related group (DRG), regardless of the intensity of care provided to each patient, except for extraordinary outlier costs. Physicians, however, are reimbursed per procedure based on the Medicare Physician Fee Schedule, in which they are paid for every additional service they provide, including daily hospital visits and consultations.

In May 1991, the Health Care Financing Administration chose four hospitals to participate in the Medicare Participating Heart Bypass Center Demonstration, in which Medicare paid a single global payment that covered both hospital and physician services provided to heart bypass patients. Three hospitals were included in the demonstration at a later date.

Two recent studies supported by the Agency for Healthcare Research and Quality (HS09559) examined hospital costs for CABG surgery. In the first study, researchers investigated the impact on costs of care for bypass patients of a single global payment to hospitals and physicians. In the second study, the researchers analyzed data collected to evaluate the Medicare heart bypass demonstration to examine the preoperative correlates of CABG hospital costs.

Liu, C-F., Subramanian, S., and Cromwell, J. (2001, Summer). "Impact of global bundled payments on hospital costs of coronary artery bypass grafting." ***Journal of Health Care Finance*** **27(4), pp. 39-54.**

Three hospitals had lower direct variable costs for CABG inpatient care when Medicare paid doctors and hospitals a single negotiated price for all inpatient care for heart bypass patients as part of the 1991 Medicare bypass demonstration project. These reduced costs held even after accounting for other factors affecting CABG costs, such as patient risk factors and postoperative complications. Direct variable costs included such costs as wages paid to nurses, costs of prescriptions, number of lab tests, length of intensive care unit stay, or routine nursing. By 1993, one hospital's total direct variable cost fell 27 percent (a reduction of $2,678 per patient), another fell 18 percent (reduction of 1,848 per patient), and a third fell 12 percent (a reduction of $1,124 per patient).

However, the patterns in cost reductions across major departments were different across hospitals. By 1993, costs for bypass patients with catheterization (diagnosis-related group or DRG 106) and without catheterization (DRG 107) were reduced at the first hospital by 55 and 56 percent, respectively, in routine nursing; 41 and 38 percent, respectively, in nursing intensive care unit (ICU); 33 and 32 percent, respectively, in operating room (OR) and recovery; 32 and 28 percent, respectively, in pharmacy; and 31 percent in catheter lab for DRG 106 patients.

The cost reductions by 1993 at the second hospital came from

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Hospital costs for CABG surgery

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pharmacy (38 and 35 percent, respectively), nursing ICU (26 and 38 percent, respectively), and routine nursing (21 percent for DRG 106 patients). A third hospital experienced a significant 6 percent cost increase in OR and recovery for both DRGs 106 and 107 patients by 1993.

Hospital cost reductions may have reflected changes in patient care management. For example, all three hospitals introduced a new 24-hour protocol for postsurgical ICU stays and began using shorter acting anesthetic agents to promote early extubation in the ICU. As a result, all three hospitals showed a reduction in their ICU per-patient costs ranging from 31 to 41 percent for DRG 106 patients and from 29 to 38 percent for DRG 107 patients. These reduced costs apparently did not diminish CABG quality of care based on in-hospital and 1-year mortality rates. These findings were based on analysis of micro-cost and clinical data on every Medicare patient undergoing CABG at each hospital from 1991 through 1993.

Subramanian, S., Liu, C-F., Cromwell, J., and Thestrup-Nielsen, S. (2001, June). "Preoperative correlates of the cost of coronary artery bypass graft surgery: Comparison of results from three hospitals." ***American Journal of Medical Quality*** **16(3), pp. 87-91.**

Preoperative factors that influence the cost of CABG surgery can be quite different among hospitals. Therefore, results from one hospital cannot be broadly generalized to others, concludes this study. Of three hospitals studied, patient age, urgent/emergent surgical priority, previous CABG, and chronic obstructive pulmonary disease (COPD) significantly contributed to CABG hospital costs. However, the cost impact of these factors varied among the three hospitals.

For teaching hospital A, the major factors influencing CABG costs were minority race (31 percent), COPD (26 percent), and preoperative insertion of an intra-aortic balloon pump or IABP (25 percent). For teaching hospital B, previous CABG (31 percent) had the most significant cost impact by far. For the nonteaching hospital, preoperative insertion of the IABP (36 percent) and previous CABG (21 percent) were the main correlates of cost.

The cost impact of patient risk factors also differed among hospitals. Recent heart attack, stroke, hypertension, and low ejection fraction (indication of ventricular dysfunction) significantly increased costs only for the nonteaching hospital. Previous coronary angioplasty increased marginal cost in teaching hospital B but not in the others. At teaching hospital A, minority race was a significant cost driver but not at the other two hospitals.

The mean direct variable costs for CABG surgery were $10,285 at teaching hospital A, $9,880 at teaching hospital B, and $10,363 at the nonteaching hospital. The average length of stay for the CABG procedure was 12.3, 11.6, and 10.3 days for teaching hospital A, teaching hospital B, and the nonteaching hospital, respectively. Given the differences in patient risk factors and their link to hospital CABG costs among the hospitals studied, the researchers question whether optimum reimbursement for CABG procedures can be set using risk-based contracts. ■

Reducing Medicaid benefits or restricting eligibility would disproportionately affect nursing home stays of elderly blacks

Few elderly people covered by Medicaid have short-term recovery stays at nursing homes, which typically involve high-cost medical procedures that often are not reimbursed proportionally to nursing homes. Among elderly people, blacks are significantly less likely than whites to have recovery stays; Latinos are as likely as whites to have recovery stays. Both blacks and Latinos are as likely as whites to have terminal stays at nursing homes.

Medicaid coverage explains this difference because when it is taken into account, there is no significant difference in recovery stays between blacks and whites and still not much difference between Latinos and whites. Neither family income nor social support explained the observed racial differences in type of stay, according to a study supported jointly by the Agency for Healthcare Research and Quality and the National Institute on Aging (HS08034).

Since Medicaid coverage equalized recovery nursing home stays for blacks compared with whites, reductions in Medicaid benefits or restrictions in eligibility would negatively and disproportionately affect the nursing home stays of elderly blacks, conclude the researchers. They used data from the

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1987 Institutional Population Component of the National Medical Expenditure Survey to identify factors that influenced the type of stay by various racial/ethnic groups. Recovery patients in general were less often poor and reliant on Medicaid and more often had private insurance in addition to Medicare.

All other factors being equal—such as health status and insurance—elderly blacks and Latinos were as likely as elderly whites to have recovery and terminal stays. Older individuals and females were more likely to have long stays, perhaps reflecting the frailty of the oldest of the old and the longer life expectancy of women. Those living in the West were the most likely to have recovery stays. Being poor did not affect type of stay in the presence of Medicaid coverage, while the existence of social support, such as children, reduced the likelihood of long-term stays. Of all the elderly, those covered by Medicaid prior to admission were 53 percent less likely to have recovery stays and 43 percent less likely to have terminal stays.

For details, see "Postadmission disparities in nursing home stays of whites and minority elderly," by Nadereh Pourat, Ph.D., Ronald Andersen, Ph.D., and Steven Wallace, Ph.D., in the *Journal of Health Care for the Poor and Underserved* 12(3), pp. 352-366. ■

Costs for end-of-life care are only slightly higher for those who die than for survivors with similar characteristics

About one-fourth (27 percent) of Medicare costs are for the last year of life, unchanged from 20 years ago. These high costs reflect care for multiple severe illnesses typically present near death. In fact, much of what has been labeled the "high cost of dying" is just the cost of caring for severe illness and functional impairment, according to the authors of a recent study that was supported by the Agency for Healthcare Research and Quality (HS10561).

Decedents' costs are, roughly speaking, not much different from those of survivors with similarly complex medical needs, note the researchers. They found that 38 percent of Medicare patients have some nursing home use in the year of their death, and hospice care is now used by half of dying Medicare cancer patients and 19 percent of dying Medicare patients overall.

Since most of us will suffer a substantial illness burden and functional or cognitive impairment prior to death, we should judge a proposed future Medicare system, at least in part, on the likelihood that it will provide good care to people at the end of life, concludes Joanne Lynn, M.D., of RAND's Center to Improve Care of the Dying. Dr. Lynn and her colleagues analyzed Medicare claims data for 1993 through 1998, Medicare Current Beneficiary Survey Cost and Use files for 1991 through 1996, and the 1993 National Mortality Followback Survey on death certificates to characterize Medicare decedents and health care costs during the last year of life.

For the mid-1990s, decedents' per capita Medicare program outlays were about six times higher than outlays for survivors. A typical decedent suffered from nearly four serious diseases in the last year of life, while survivors averaged slightly more than one in a typical calendar year. About three-fourths of decedents had some mention of heart disease in the claims data; roughly one-third had cancer, stroke, chronic obstructive pulmonary disease, or pneumonia/influenza; and more than one-fourth had some form of dementia. Yet, when compared with similarly old and sick survivors, decedents had less than 30 percent higher medical costs during the last year of life, perhaps attributable in part to a more likely episode of nursing home care during the year.

See "Medicare beneficiaries' costs of care in the last year of life," by Christopher Hogan, June Lunney, Jon Gabel, and Dr. Lynn, in the July 2001 *Health Affairs* 20(4), pp. 188-195. ■

No-fault approaches to medical injury may improve care quality over the current malpractice litigation environment

Leading proposals to improve patient safety focus on systems approaches to reducing errors and improved tracking of incidents, which evidence suggests usually involves more than one person's oversight or mistake. However, these approaches call for candor among health care practitioners about the causes and consequences of medical injury. This is difficult for clinicians to do in the present medical malpractice environment, where admitting personal blame makes them vulnerable to lawsuits.

Harvard School of Public Health researchers, David M. Studdert, L.L.B., Sc.D., M.P.H., and Troyen A. Brennan, M.D., J.D., M.P.H., describe an alternative to litigation that does not predicate patient compensation on proof of practitioner fault. This would make it easier for health care providers to identify and correct medical errors. The researchers propose a no-fault system of compensation based on enterprise liability, which is similar to workers' compensation schemes in most States, and it is used in health care systems in countries such as Sweden.

Enterprise liability means that individuals (such as physicians) do not directly bear the costs associated with an injury. Instead, the enterprise—whether it be a large group practice, hospital, or health plan—would be "strictly liable" by meeting the costs of liability premiums for all affiliated staff. Premium levels could then be experience-rated. For instance, a hospital would pay more in a given year if there was a rash of avoidable injuries and less if quality improvement initiatives curtailed the incidence of such events. Enterprise liability can effectively target financial incentives at institutions, even specific processes within institutions, according to the researchers.

Drs. Studdert and Brennan point out that most hospitals and doctors are not prepared for a rapid shift to a no-fault model, much less enterprise liability. Rather than wholesale replacement of the tort system with a no-fault system, they advocate enabling legislation at the State level that would allow selected organizations to experiment with no-fault/enterprise liability models. They note that such laws would probably survive the sort of legal challenges that originally confronted workers' compensation schemes and no-fault auto insurance. Dr. Studdert's work was supported by the Agency for Healthcare Research and Quality (KO2 HS11285).

More details are in "No-fault compensation for medical injuries: The prospect for error prevention," by Drs. Studdert and Brennan, in the July 11, 2001 *Journal of the American Medical Association* 286(2), pp. 217-223. ■

Highly active antiretroviral therapy has extended AIDS-free survival time for some patients

Since its widespread clinical use in 1996, highly active antiretroviral therapy (HAART) has become the standard of care for patients with advanced HIV infection. HAART has extended AIDS-free survival time. The gains in survival are not as great among women or intravenous drug users (IDUs), but they do not differ by race, according to a study supported in part by the Agency for Healthcare Research and Quality (HS07809).

Researchers from the Johns Hopkins University School of Hygiene and Public Health compared time to AIDS development and time to death among HIV-infected patients in an urban HIV clinical practice during the era of monotherapy and combination therapy (era 1, 1990-1995) versus the HAART era (era 2, 1996-1999). In era 2, women who were less ill (CD4 cell counts greater than 200 at baseline) increased their median disease-free survival time by 14 percent and women who were sicker (CD4 cell counts of 200 or less) by 34 percent compared with era 1.

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Antiretroviral therapy

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For men, survival increased much more, by 43 and 100 percent, respectively. In fact, women were 34 percent more likely to progress to AIDS than men in era 2 (relative hazard or RH 1.34; 1 is equal hazard) compared with era 1.

Disease-free survival time increased by 16 percent for less ill IDUs and 34 percent for more ill IDUs in era 2 compared with era 1, whereas for non-IDUs disease-free survival time increased by 65 and 135 percent, respectively. IDUs were 39 percent more likely than non-IDUs (RH 1.39) to progress to AIDS in era 2 compared with era 1. There were no significant differences between the two eras by race or other HIV transmission risk group.

Women and IDUs were less likely to be on any form of antiretroviral therapy than men and non-IDUs. In fact, after adjustment for receipt of HAART and for achieving an undetectable HIV-1-RNA level, there were no significant differences between men and women or between IDUs and non-IDUs. IDUs have been shown to not use HIV therapy in previous studies, and doctors may not prescribe it for them because of their unstable living conditions and their greater tendency to miss appointments than non-IDUs. Optimal results of HAART require adherence to complex dosing regimens that may overwhelm many patients, especially those using intravenous drugs and women who lack social support.

See "Differences in HIV disease progression by injection drug use and by sex in the era of highly active antiretroviral therapy," by Katharine E. Poundstone, Richard R. Chaisson, M.D., and Richard D. Moore, M.D., in the June 2001 issue of *AIDS* 15(9), pp. 1115-1123. ■

Announcements

AHRQ publishes evidence report summaries on breast disease and three other topics

The Agency for Healthcare Research and Quality recently released four new evidence report summaries: management of specific breast abnormalities, Ayurvedic interventions for diabetes, surgical treatment of coexisting cataract and glaucoma, and treatment of pulmonary disease following cervical spinal cord injury. These evidence report summaries are now available from AHRQ, both online at www.ahrq.gov and in print from the AHRQ Clearinghouse. Copies of the full evidence reports will be available in the near future.

AHRQ's evidence reports and summaries provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. There are 12 AHRQ-supported EPCs; they systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments. The goal is to inform health plans, providers, purchasers, and the health care system as a whole by providing essential information to improve health care quality.

Management of Specific Breast Abnormalities. **Evidence Report/Technology Assessment No. 33.**

EPC researchers at MetaWorks, Inc., of Medford, MA, (contract 290-97-0016) found strong evidence for performing an excisional biopsy following a stereotactic core needle biopsy for diagnosis of atypical ductal hyperplasia (ADH), as the excisional biopsy results often lead to a change in diagnosis. ADH, a condition where the cells lining the milk ducts of the breast grow abnormally, can only be diagnosed by examining a sample of breast tissue under a microscope. Although ADH is a noncancerous condition, cancer tissue also can be found with ADH. Stereotactic core needle biopsy removes only small fragments of breast tissue through a hollow needle and may fail to capture cancerous tissue in its sampling. An excisional biopsy removes breast tissue through a surgical procedure and allows for a larger volume of tissue to be tested.

Both ADH and lobular carcinoma in situ (LCIS), a noncancerous abnormality of the cells contained in the milk-producing lobules of the breast, place women at greater risk for developing breast cancer in the future. Although data are limited, the evidence suggests that tamoxifen therapy markedly decreases the incidence of breast

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cancer following a diagnosis of ADH or LCIS, but it is associated with an increased risk of endometrial cancer, thromboembolic disease, and other complications.

According to the results of this extensive review of the literature, studies to date suggest sentinel lymph node biopsy is successful in determining whether breast cancer has spread throughout the regional lymph nodes in most patients. However, the MetaWorks researchers caution that long-term cancer outcomes and survival data are required before sentinel lymph node biopsy can be considered a standard of care. They also suggest that future research should examine breast disease risk factors and breast symptoms and how these relate to cancer diagnoses. Further research also is needed to identify new and additional risk factors.

This topic was nominated for review by Kaiser Permanente of Northern California. Copies of the summary (AHRQ Publication No. 01-E045) are available from AHRQ.** Copies of the full report (AHRQ Publication No. 01-E046) will be available in late fall 2001.*

Ayurvedic Interventions for Diabetes Mellitus: A Systematic Review. **Evidence Report/ Technology Assessment No. 41.**

Ayurveda is the traditional Hindu system of medicine, based largely on homeopathy and naturopathy. The Southern California/RAND EPC (contract 290-97-0001) conducted a broad search of the published literature and found sufficient research to support a systematic review of the use of Ayurvedic therapies for the treatment of diabetes. They identified 54 articles presenting the results of 62 studies; because of the heterogeneity of the studies, a meta-analysis was not possible.

More than 45 single herbs or combination herbal therapies were tested. The most common single herbs studied were *Gymnema sylvestre, Coccinia indica,* fenugreek (*Trigonella foenum-graecum*), and *Eugenia jambolana*. They concluded that there is evidence to suggest that the single herbs *Coccinia indica,* holy basil, fenugreek, and *Gymnema sylvestre* and the herbal formulas Ayush-82 and D-400 have a glucose-lowering effect and deserve further, more rigorous study.

A summary of the report (AHRQ Publication No. 01-E039) is now available from AHRQ.** The full report (AHRQ Publication No. 01-E040) is expected to be available in late fall 2001.*

Surgical Treatment of Coexisting Cataract and Glaucoma. **Evidence Report/Technology Assessment No. 38.**

Performing surgery for coexisting glaucoma and cataract at the same time results in lower intraocular pressure (IOP) than cataract surgery alone, according to this evidence report. Increased IOP is a hallmark feature of glaucoma and results from fluid buildup in the eye. Unless the pressure is controlled, the optic nerve may be damaged, resulting in vision loss.

The research was undertaken by the Johns Hopkins EPC (contract 290-97-0006) to identify the most important questions regarding surgical treatment of the coexisting conditions, review the quality and content of existing evidence on surgical treatment, and identify future areas of promising research. The EPC concluded that because the progression of glaucoma is slow, long-term studies (5 years or longer) are needed to assess the effects of surgery on quality of life. Also, few of the studies included significant numbers of blacks, a population that has a high prevalence of glaucoma. Blacks may respond differently to glaucoma surgery and should be included in larger numbers in future studies.

The report identifies four topics for future research: development of cataract after a patient undergoes glaucoma surgery; control of IOP after cataract surgery in glaucoma patients; long-term control of IOP after cataract surgery in glaucoma patients; and determination of the optimal surgical technique, including a comparison of the benefits of staged vs. combined procedures.

A summary of the report (AHRQ Publication No. 01-E049) is now available from AHRQ.** The full report (AHRQ Publication No. 01-E050) is expected to be available in late fall 2001.*

Treatment of Pulmonary Disease Following Cervical Spinal Cord Injury. **Evidence Report/ Technology Assessment No. 27.**

The incidence of spinal cord injury (SCI) in the United States is approximately 10,000 new cases each year or 32 to 35 people per million population. Because people with SCI are surviving longer, the prevalence has been increasing and there are now more than 200,000 people with SCI in the United States. Injuries at the cervical level of the spinal cord, depending on the completeness of the lesion, can lead to quadriplegia, loss of sensory function, and paralysis of the respiratory muscles. Respiratory failure is the most common cause of death for patients with cervical injuries during the acute phase of hospitalization.

Researchers at the Duke EPC (contract 290-97-0014) assessed the evidence currently available on

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the prevention and treatment of pulmonary disease following traumatic cervical SCI. They found that patients with cervical SCI are at significant risk for ventilatory failure, and this risk differs by the level and completeness of injury. Ventilatory support is needed for a majority of patients with C5 and higher injuries and virtually all patients with C3 and higher injuries in the acute phase. In the report, the EPC researchers assess the available evidence on a variety of therapeutic and clinical assessment strategies, including active respiratory muscle exercise, deflating cuffed tracheostomies, electrophrenic respiration, manual assisted cough, rotating beds, and many other approaches.

A summary of the report (AHRQ Publication No. 01-E013) is available now from AHRQ.** Copies of the full report (AHRQ Publication No. 01-E014) are expected to be available in late fall 2001.* ■

New MEPS reports are now available from AHRQ

Several new reports are now available from the Medical Expenditure Panel Survey (MEPS). MEPS is the third in a series of nationally representative surveys of medical care use and expenditures sponsored by the Agency for Healthcare Research and Quality. MEPS is cosponsored by the National Center for Health Statistics (NCHS). The first survey, the National Medical Care Expenditure Survey (NMCES), was conducted in 1977; and the second survey, the National Medical Expenditure Survey (NMES) was carried out in 1987.

MEPS collects detailed information on health care use and expenses, sources of payment, and insurance coverage of individuals and families in the United States. MEPS comprises four component surveys: The Household Component, the Medical Provider Component, the Insurance Component, and the Nursing Home Component.

The following two chartbooks, methodology report, and reprint of statistical tables are newly released from the MEPS program. Copies are available from AHRQ.* See the back cover of *Research Activities* for ordering information.

***Health Care Expenses in the Community Population, 1996. MEPS Chartbook No. 5* (AHRQ Publication No. 01-0027). Machlin, S.R., Cohen J.W., Zuvekas, S.H., and others.**

This report presents estimates from the MEPS of spending for medical services and supplies in 1996. This kind of detailed information has not been available since data for 1987 were released a decade ago. Charts show overall expenses, per capita expenses, expenses by type of service, and out-of-pocket expenses. In 1996, the average expense per person in the U.S. civilian noninstitutionalized population (including people with no expenses) was $2,038. The average for people with an expense (about 85 percent of the population) was $2,389. However, median expenses were much lower than average expenses because a small percentage of people incurred a disproportionately large share of medical expenses. Median expenses averaged $395 overall and $566 for people with expenses. Hospital inpatient stays made up the largest share of national health care expenses, followed by ambulatory services from both physician and nonphysician providers. Over 80 percent of medical expenses were paid for by third-party payers, with the remainder being out-of-pocket payments by individuals and their families.*

***Nursing Home Expenses, 1987 and 1996. MEPS Chartbook No. 6* (AHRQ Publication No. 01-0029. Rhoades, J.A., and Sommers, J.P.**

This report presents estimates from MEPS on changes in nursing home expenses and sources of payment from 1987 to 1996. In that time period, total annual expenses increased from $28 billion to $70 billion, and annual expenses per resident day increased from $56 to $118. Medicare paid a greater portion of the nursing home bill in 1996 than in 1987, and this held for residents in all age and income categories. The share paid by Medicaid decreased for all racial/ethnic groups, particularly for minorities. Residents who were not married, did not own a home, or were covered by Medicaid tended to have higher annual expenses per resident but lower annual expenses per day. In 1996, the lowest annual expenses per resident, but the highest annual expenses per day, were for people

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New MEPS reports

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residing in the nursing home for the shortest time period (both admitted and discharged during the year or both admitted and dying during the year). Medicare paid the largest proportion of the total nursing home bill for these residents.*

***Outpatient Prescription Drugs: Data Collection and Editing in the 1996 Medical Expenditure Panel Survey. MEPS Methodology Report No. 12* (AHRQ Publication No. 01-0002). Moeller, J.F., Stagnitti, M.N., Horan E., and others.**

For the first time in a national expenditure survey, the 1996 MEPS included a detailed collection of information on prescription medicines obtained from pharmacy providers frequented by household-sampled individuals. The information was collected by means of a linked survey of pharmacy providers. This report describes the procedures adopted to collect and edit these prescription drug data for public release. It includes efforts made to retrieve complete and/or partial missing pharmacy data, the editing techniques used to fill in remaining missing data in the pharmacy database, and the matching/imputation procedure that linked every prescription drug mentioned by the respondent in the MEPS Household Component to a specific prescription drug from the Pharmacy Component (part of the Medical Provider Component).*

***Health Care Expenses in the U.S. Civilian Noninstitutionalized Population, 1997* (AHRQ Publication No. 01-R089). July 2001.**

These statistical tables present descriptive data from the MEPS on spending in 1997 for hospital, office-based, home health, and other types of care by source of payment and characteristics of users. Data for all types of health care combined and for each type of service are presented, as follows: events, charges, and expenses for health care services and supplies by event type; total health services; hospital inpatient services; ambulatory services; prescription medications; dental services; home health services; and other medical equipment and services.* ■

AHRQ funds new projects

The Agency for Healthcare Research and Quality recently funded the following research projects, small project grants, training grants, and conference grants. Readers are reminded that findings usually are not available until a project has ended or is nearing completion.

Research Projects

Multicenter trial of academic hospitalists

Project director:	David Meltzer, M.D., Ph.D.
Organization:	University of Chicago Chicago, IL
Project number:	AHRQ grant HS10597
Project period:	7/25/2001 to 6/30/2004
First year funding:	$1,273,578

Program of collaborative care for Alzheimer disease

Project director:	Christopher Callahan, M.D.
Organization:	Indiana University Indianapolis, IN
Project number:	AHRQ grant HS10884
Project period:	8/1/2001 to 7/31/2005
First year funding:	$552,095

Safety and financial ramifications of emergency department copayments

Project director:	John Hsu, M.B.A., M.D.
Organization:	Kaiser Permanente Oakland, CA
Project number:	AHRQ grant HS11434
Project period:	7/15/2001 to 6/30/2003
First year funding:	$331,946

Small Research Grants

Assessing regression to the mean and intervention effect

Project director:	Hung-Mo Lin, Sc.D.
Organization:	Pennsylvania State University Hershey, PA
Project number:	AHRQ grant HS11452
Project period:	8/1/2001 to 6/30/2003
First year funding:	$48,308

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Effects of drug advertising on prescription choice
Project director: Marta Wosinska, B.A.
Organization: University of California
Berkeley, CA
Project number: AHRQ grant HS11600
Project period: 9/15/2001 to 9/14/2002
Funding: $32,154

Quality-adjusted cost functions for HMOs
Project director: Todd Caldis, B.A., J.D.
Organization: University of Minnesota
Minneapolis, MN
Project number: AHRQ grant HS11515
Project period: 9/1/2001 to 8/31/2002
Funding: $32,400

Race, psychosocial factors, and regular mammography use
Project director: Lisa Calvocoressi, M.S.W.
Organization: Yale University
New Haven, CT
Project number: AHRQ grant HS11603
Project period: 9/1/2001 to 8/31/2002
Funding: $31,403

Training Grants

Health plan choice: Implications for consumers and purchasers
Project director: M. Kate Bundorf, M.P.H., Ph.D.
Organization: Stanford University
Stanford, CA
Project number: AHRQ grant K02 HS11668
Project period: 9/1/2001 to 8/31/2006
First year funding: $72,364

Testing the quality health outcomes model in cancer care
Project director: Laurel Radwin, Ph.D.
Organization: University of Massachusetts
Boston, MA
Project number: AHRQ grant K08 HS11625
Project period: 9/1/2001 to 8/31/2006
First year funding: $118,600

Health and economic outcomes of pulmonary hypertension
Fellow: Shirin Shafazand, M.D.
Organization: Stanford University
Stanford, CA
Project number: NRSA F32 HS11767
Project period: 9/1/2001 to 8/31/2002
Funding: $60,714

Conference Grants

Conference on behavioral health workforce education
Project director: Michael Hoge, Ph.D.
Organization: American College of Mental Health Administrators
Project number: AHRQ grant HS10965
Project period: 9/1/2001 to 8/31/2002
Funding: $25,000

National Quality Forum: Annual meeting
Project director: Kenneth Kizer, M.D., M.P.H.
Organization: National Forum for Healthcare Quality Measurement and Reporting
Washington, DC
Project number: AHRQ grant HS10966
Project period: 9/1/2001 to 8/31/2002
Funding: $25,000 ■

Glauber, J.H. (2001, June). "Does the HEDIS asthma measure go far enough?" (AHRQ National Research Service Award training grant T32 HS00063). ***American Journal of Managed Care*** **7(6), pp. 575-579.**

The asthma measure of the Health Plan Employer Data and Information Set (HEDIS) 2000 may lead to overlooking important dimensions of quality, risking unintended negative consequences on the overall quality of asthma care, according to this author. HEDIS 2000 measures the percentage of individuals who meet a claims-based definition of persistent asthma and receive at least one controller medication (for example, inhaled corticosteroids or cromolyn sodium) in the measurement year. It also identifies those with persistent asthma by such measures as at least one emergency department visit or hospitalization for asthma during the prior year, dispensing of asthma medication on at least four occasions, or at least four outpatient asthma visits and at least two asthma medication dispensing events. This new HEDIS asthma measure may be setting the bar too low and encouraging more casual prescribing of controller medications, rather than encouraging the more painstaking disease severity assessment that would define the need for, and level of, controller use, concludes the author.

Jarvik, J.G. (2001, April). "Fundamentals of clinical research for radiologists." (AHRQ grant HS09499). ***American Journal of Radiology*** **176, pp. 873-878.**

This author asserts that randomized trials focusing on patient outcomes are the only way to investigate the efficacy of diagnostic technologies such as x-rays with absolute assurance that bias is being avoided. Such trials should be conducted when the stakes are high enough. However, three other types of studies can be quite powerful in their own right and, because they are simpler and less expensive, they should be used in certain situations, depending on their relative advantages and disadvantages. Case-control studies are particularly useful for examining rare outcomes because subjects are selected on the basis of having the outcome of interest. Conversely, cohort studies are useful for rare risk factors because subjects are chosen on the basis of having a particular exposure. Measuring all variables at a single time is the distinguishing characteristic of cross-sectional studies, for example, magnetic resonance imaging studies in patients with low back pain. Although cross-sectional studies are relatively easy to perform, it is often impossible to determine if the exposure preceded the disease or vice-versa.

Localio, A.R., Berlin, J.A., Ten Have, T.R., and Kimmel, S.E. (2001, July). "Adjustments for center in multicenter studies: An overview." (AHRQ grant HS10399). ***Annals of Internal Medicine*** **135(2), pp. 112-123.**

These researchers suggest adjustments for centers in multicenter studies to account for the possible confounding effects of the centers themselves when treatments are administered across several centers. They point out that although convenient and expedient, the simple pooling of data in multicenter studies as if they arose from a single population can produce incorrect results. The researchers suggest, for example, that the correlation or clustering resulting from the similarity of outcomes among patients within a center requires an adjustment to confidence intervals and P values, especially in observational studies and in randomized multicenter studies in which treatment is allocated by center rather than by individual patient. Multicenter designs also warrant testing and adjustment for the potential bias of confounding by center and for the presence of effect modification or interaction by center. Patient populations at different centers might not react the same way, perhaps because of unmeasured population or environmental factors or variation in adherence to protocols. This possibility increases in observational studies and meta-analyses, in which exposures or protocols are likely to vary across centers.

Zhou, X-H., Li, C., Gao, S., and Tierney, W.M. (2001). "Methods for testing equality of means of health care costs in a paired design study." (AHRQ grants HS90217 and HS09083). ***Statistics in Medicine*** **20, pp. 1703-1720.**

The authors of this paper propose five new tests for the equality of paired means of health

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Research briefs

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care costs. The first two tests are the parametric tests—a Z-score test and likelihood ratio test—both derived under the bivariate normality assumption for the log-transformed costs. The third test (Z-score with jackknife) is a semi-parametric Z-score method, which only requires marginal log-normal assumptions. The fourth and fifth tests are the nonparametric bootstrap tests, one based on a t-test statistic and the other based on Johnson's modified t-test statistic. The authors describe the results of a simulation study they conducted to compare the performance of these tests, along with some commonly used tests when the sample size is small to moderate. ■

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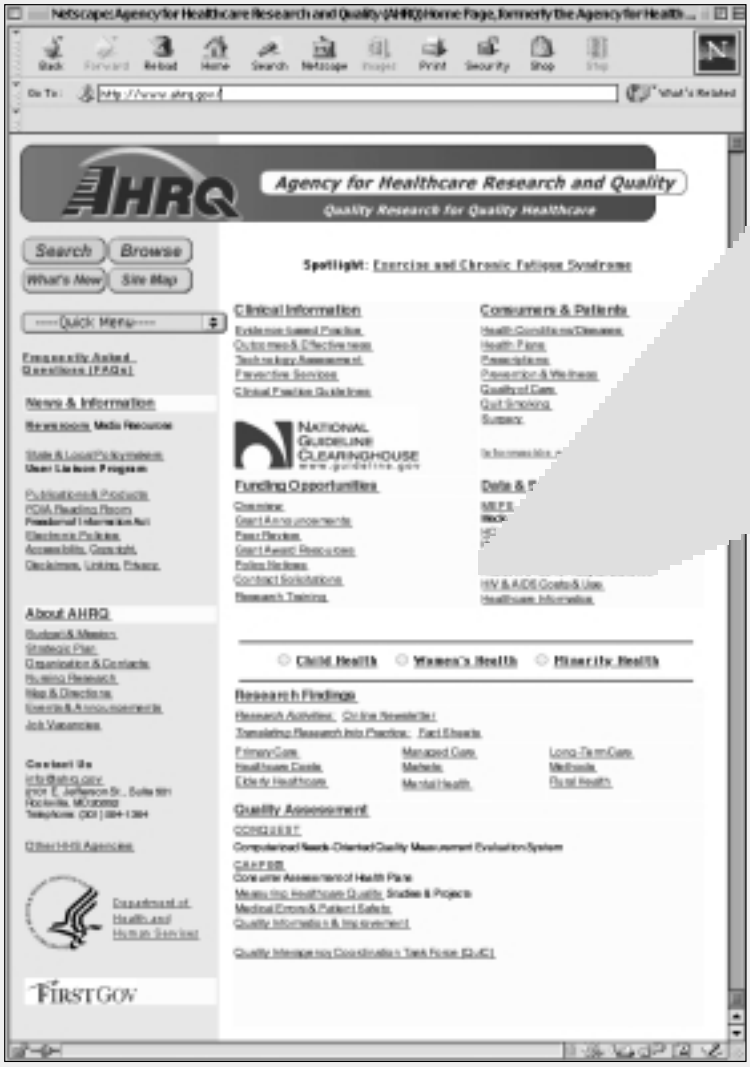

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