AHRQ

Research Activities

No. 245, January 2001

Highlights

Departments

Regular Features

Researchers underreport drug safety problems

Researchers conducting randomized controlled trials (RCTs)—the gold standard for evaluating medications—appear to largely underreport or even neglect to report problems involving drug safety, according to a recent study supported by the Agency for Healthcare Research and Quality (HS10345). They found that, on average, medical journal articles about drug trials devote only about one-third of a page to safety information—such as side effects of medications and the frequency and reasons for patient withdrawals from drug studies—roughly the same space they devote to naming the contributors and their affiliations.

According to the study's authors, John P.A. Ioannidis, M.D., of Tufts University School of Medicine and Greece's University of Ioannina School of Medicine, and Joseph Lau, M.D., of the New England Medical Center, the quality of safety reporting also appears to be inadequate. The researchers examined safety reporting in 192 randomized drugs trials, each involving a minimum of 100 patients and at least 50 patients in each study arm. More than 130,000 trial subjects were involved overall. The trials involved testing of medications for seven treatment areas: HIV therapy; antibiotic therapy for acute sinusitis; thrombolysis (clot dissolving drugs) for heart attack patients; nonsteroidal antiinflammatory drugs for rheumatoid arthritis; high blood pressure treatment in the elderly; antibiotic treatment of Helicobacter pylori, a major cause of stomach ulcers; and selective decontamination of the gastrointestinal tract.

The severity of medication side effects and drug toxicity revealed by abnormal laboratory test results was adequately explained in only 39 percent and 29 percent, respectively, of drug trial reports, and a further 11 percent and 8 percent of trials had partial reporting of side effects and drug toxicity. Also, while the numbers of patients in each trial study arm who had to be withdrawn because of drug toxicity were cited in 75 percent of trial reports, the

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Attention researchers:
See page 15 for information on AHRQ's FY 2001 budget for research.

Drug safety problems

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specific reasons for these discontinuations were given only 46 percent of the time.

According to the authors, major strides have been made in standardizing the collection, analysis, and reporting of efficacy data in clinical trials, but efforts to evaluate and improve the quality of analysis and reporting of safety data lag behind.

For more information, see "Completeness of safety reporting in randomized trials: An evaluation of 7 medical areas," by Drs. Ioannidis and Lau, in the January 24/31, 2001 *Journal of the American Medical Association* 285(4), pp. 437-443. ■

Outcomes/Effectiveness Research

Two-thirds of adults report improved functioning and quality of life following surgery for low back pain

A new community-based study led by surgeons in private practice in Washington State shows that two-thirds of patients with degenerative changes, herniated disc, instability, or spinal stenosis were satisfied with their improved functioning and quality of life following surgery for low back pain. The Back Pain Outcomes Assessment Team, supported by the Agency for Healthcare Research and Quality (HS06344 and HS08194), surveyed 281 adults before back surgery and again 1 year later. Patients were asked preoperatively about their symptoms, sociodemographic factors, and preoperative clinical signs and postsurgically about their functioning and treatment satisfaction. The study was led by principal investigator Richard A. Deyo, M.D., M.P.H., of the University of Washington.

Sixty-five percent of back surgery patients reported much better functioning, 64 percent reported a great improvement in quality of life, and 68 percent had a very positive opinion about their treatment outcome. The following factors were associated with worse patient outcomes: older age, previous low back surgery, workers' compensation coverage, and consultation with an attorney before surgery. The negative influence of financial compensation and litigation on recovery has been shown in previous studies and is a controversial issue in the treatment of low back problems. The design of the current study could not determine whether compensation or litigation caused outcomes to be worse or whether patients with worse conditions were more likely to seek compensation and litigation.

Orthopedists and neurosurgeons performed the back surgeries, which ranged from laminectomy and discectomy to fusion. Patients undergoing a fusion procedure were more likely to report good outcomes. But because of the small number of patients, varied diagnoses, and possible selection bias, these fusion-related findings should be interpreted cautiously, according to Dr. Deyo.

See "Patient-oriented outcomes from low back surgery: A community-based study," by Victoria M. Taylor, M.D., M.P.H., Dr. Deyo, Marcia Ciol, Ph.D., and others, in the October 2000 *Spine* 25(19), pp. 2445-2452. ■

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Breast cancer treatment in older women often depends on the woman's age and treatment preferences

Nearly half of new breast cancer cases and nearly two-thirds of deaths from this disease occur among women 65 years of age or older. Breast conservation surgery and radiation therapy are often recommended for treating localized breast cancer, but a woman's age and her treatment preferences strongly influence the type of treatment an older woman will receive for this type of cancer.

A recent study supported by the Agency for Healthcare Research and Quality (HS08395) found that women who were concerned about body image were nearly twice as likely to receive breast conservation surgery and radiotherapy as women without this concern. In contrast, women who preferred to have no therapy beyond surgery were nearly four times as likely to undergo mastectomy as other women.

Compared with women 67 to 79 years of age, women 80 years and older were 3.4 times as likely to have radiotherapy omitted after breast conservation surgery (increasing their risk of local recurrence) and 70 percent less likely to receive chemotherapy. The older women also were less likely to have been referred to a radiation oncologist (28 percent) than the younger women (44 percent). Women with estrogen receptor positive tumors were 4.3 times more likely to receive tamoxifen (an anti-estrogen) than women with estrogen receptor negative tumors. However, women aged 80 and older received tamoxifen almost twice as often as women 67-79 years of age, after accounting for health, clinical, and other factors.

These findings show that many of the women 80 years of age and older were undertreated by current standards and lend support to potential age biases in breast cancer treatment, concludes Jeanne Mandelblatt, M.D., M.A., of Georgetown University School of Medicine. Dr. Mandelblatt and her colleagues analyzed data that tracked treatment of women 67 years of age or older with primary early-stage invasive breast cancer for which breast conservation and mastectomy were considered "equivalent choices." The subjects were drawn from a sample of 29 hospitals in five regions.

See "Patterns of breast carcinoma treatment in older women: Patient preference and clinical and physician influences," by Dr. Mandelblatt, Jack Hadley, Ph.D. Jon F. Kerner, Ph.D., and others, in the August 1, 2000 *Cancer* 89(3), pp. 561-573. ■

Researchers explore the effectiveness and cost-effectiveness of cervical cancer screening

Pap smears, which detect preinvasive and early invasive cervical cancer, reduced the incidence of this cancer in the United States by 43 percent and reduced deaths from the disease by 46 percent over the last two decades. The U.S. Food and Drug Administration recently approved several new screening technologies intended to reduce false-negative results of conventional Pap smears (smears that indicate no cancer in women who have cervical cancer). Three new studies, supported by the Agency for Healthcare Research and Quality, examine the effectiveness and cost-

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effectiveness of these screening tests.

The first study (AHRQ contract 290-97-0014) shows that new screening technologies with increased sensitivity are more costly than conventional Pap smears. The second study (AHRQ grant HS07373) concludes that a 3-year screening interval could be as effective as yearly screening in women who have a previous normal Pap smear. The third study (AHRQ grant HS08395) finds that cognitive strategies are the best way to improve women's compliance with followup of abnormal Pap smear screening tests. The three studies are summarized here.

Myers, E.R., McCrory, D.C., Subramanian, S., and others. (2000, November). "Setting the target for a better cervical screening test: Characteristics of a cost-effective test for cervical neoplasia screening," *Obstetrics & Gynecology* 96(5), pp. 645-652.

According to this study by the AHRQ-supported Evidence-based Practice Center at Duke University, technologies that increase sensitivity of cervical cytologic screening also increase overall costs. This is true even if the cost of the technology is identical to that of conventional Pap smears. Apparently, the more sensitive tests uncover a high prevalence of low-grade lesions, which rarely lead to cancer but do prompt further costly testing.

In this study, the researchers used a model that included various costs and screening intervals. For example, if a new technology had no extra cost per slide compared with conventional Pap tests, increasing sensitivity was cost-saving with 3-year screening intervals if the cost of evaluating and treating low-grade squamous intraepithelial lesions (SILs) was $550. That was the only variable and only screening frequency that resulted in a cost savings. At any marginal per slide cost above $3, increasing sensitivity was not cost saving even if the cost of treating low-grade SILs was $0.

Efficient cervical cancer screening requires methods with greater specificity for detecting lesions that are most likely to become cancerous (that is, high-grade lesions). In fact, new, more sensitive technologies are likely to be cost effective compared with Pap smears only if they are associated with improved specificity, permit decreased screening frequency, or are used in conjunction with less expensive treatments of low-grade lesions. New tests based on specific types of human papillomavirus (HPV), which is associated with development of cervical cancer, or that use biomarkers might meet all three requirements, according to the researchers.

They used a model of the natural history of cervical cancer to estimate the effects of sensitivity, specificity, and screening frequency on cost-effectiveness of screening for cervical cancer. The model was based on the assumption that all cervical cancer arises from infection with HPV, which progresses sequentially from low-grade through high-grade SILs to invasive cervical cancer.

Sawaya, G.F., Kerlikowski, K., and Lee, N.C. (2000, August). "Frequency of cervical smear abnormalities within 3 years of normal cytology." *Obstetrics & Gynecology* 96(2), pp. 219-223.

Annual cervical cancer screening has been standard practice for many years, and doctors are reluctant to change a screening system that has been highly effective in controlling cervical cancer. However, this study suggests that screening every 3 years might be sufficient. These researchers found that within 3 years after normal Pap smear results, cervical smears interpreted as high-grade squamous intraepithelial lesions (SILs) or worse were uncommon. Also, women screened 1, 2, and 3 years after normal Pap smears had the same risk of developing high-grade SILs or worse.

The researchers studied a group of 128,805 women at community-based clinics throughout the United States who were screened for cervical cancer within 3 years of normal smears. They determined the incidence of cytologic abnormalities defined as atypical squamous cells of undetermined significance (ASCUS), low-grade

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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.

Cervical cancer screening

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SILs (unlikely to develop into cancer), and high-grade SILs or suggestive of squamous cell cancer. Age-adjusted incidence rates of high-grade SILs or worse were similar for women screened at 9 to 12 months (25 of 10,000), 13 to 24 months (29 of 10,000), and 25 to 36 months (33 of 10,000) after normal Pap smears. Age-adjusted incidence rates of ASCUS, the most common cytologic abnormality, did not change.

Incidence of smears interpreted as low-grade SILs increased as time from the normal smear increased. Low-grade SILs are usually of no clinical importance, but they do prompt further costly tests and procedures that cause unfounded patient anxiety. The risks of overscreening should be balanced against its benefits to develop optimal screening strategies for women with recent normal Pap smears, conclude the authors.

Yabroff, K.R., Kerner, J.F., and Mandelblatt, J.S. (2000). "Effectiveness of interventions to improve follow-up after abnormal cervical cancer screening." ***Preventive Medicine*** **31, pp. 429-439.**

For cervical cancer screening to be effective, women who have an abnormal Pap smear must return to receive followup, timely diagnosis, complete cancer staging, and appropriate treatment. Unfortunately, many women fail to receive timely, or for that matter any, resolution of an abnormal screen. In fact, between 7 and 49 percent of women with abnormal Pap smear tests do not receive appropriate followup. Either they face financial barriers, fear diagnostic procedures or diagnosis, or misinterpret or receive inadequate communication from doctors about test results and conclude the results are normal.

The authors performed a meta-analysis of studies of cognitive, behavioral, or sociologic interventions intended to improve followup after an abnormal cervical cancer screening test. Cognitive strategies such as telephone counseling or pamphlets provided new information and education, increased existing knowledge, and clarified misperceptions. Behavioral interventions, such as mailed and telephone reminders, altered cues or stimuli associated with followup behavior. Finally, sociologic interventions used social norms or peers to increase compliance.

According to this study, cognitive interventions using interactive telephone counseling were the most effective, improving compliance by 24 to 31 percent. Behavioral interventions, such as patient reminders, were also effective, increasing followup to 18 percent. The single sociologic intervention used videotaped peer discussions to provide a message about abnormal Pap smears and appropriate followup, but it was not associated with increased followup after an abnormal test. ■

Increasing postpartum hospital stays may reduce readmission of newborns twice as much as previously thought

Concerns about the health of newborns discharged too early from the hospital have led the Federal Government and most State legislatures to pass laws mandating minimum 48-hour hospital stays following vaginal deliveries and 96 hours following cesarean sections. A 12-hour increase in length of hospital stay could reduce the newborn readmission rate by 0.6 percentage point or twice as much as estimates obtained using conventional statistical methods, concludes a study supported by the Agency for Healthcare Research and Quality (HS09342). Since there are about 3.9 million births each year in the United States, a 0.6 percentage point reduction in the readmission rate implies 23,400 fewer newborn readmissions.

These readmissions are costly, may reduce mother-infant bonding, and may increase parents' anxiety, notes Jesse D. Malkin, Ph.D., of Covance Health Economics and Outcomes Services, Inc. In a large retrospective study of postpartum length of stay, Dr. Malkin and his colleagues analyzed data on more than two-thirds of the births in Washington State in 1989 and 1990 to determine the effect of postpartum length of stay on newborn readmission. The data used in this study were collected by the AHRQ-supported Patient Outcomes Research Team on Management and Outcomes of Childbirth (PORT Contract 290-90-0039). The researchers compared the predicted probability of readmission for newborns with 39-hour stays (the mean among vaginally delivered newborns in the sample) with the predicted probability of readmission for newborns with 51-hour stays, that is, a 12-hour increase.

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Postpartum hospital stays

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Dr. Malkin and his colleagues used hour of birth and method of delivery as instrumental variables influencing length of stay. Hour of birth influences length of stay because it affects whether a newborn will spend an extra night in the hospital. Method of delivery influences length of stay because mothers need more time to recuperate after a cesarean section than a vaginal delivery, and newborns are rarely discharged before their mothers.

See "Do longer postpartum stays reduce newborn readmissions? Analysis using instrumental variables," by Dr. Malkin, Michael S. Broder, M.D., M.S.H.S., and Emmett Keeler, Ph.D., in the December 2000 *Health Services Research* 35, pp. 1071-1091. ■

Most women would rather risk a procedure-related miscarriage than have a baby with Down syndrome

Prenatal testing for Down syndrome is currently recommended for women 35 years of age and older (or women whose blood or ultrasound tests suggest their risk of having such a baby are greater than that of an unscreened 35-year-old). This threshold was chosen because 35 is the age at which the risk of miscarriage due to these diagnostic procedures (about 0.5 percent) is equal to that of having a baby affected by Down syndrome.

This recommendation presumes that women regard these outcomes equally. But this is not the case, according to a recent study by researchers at the University of California, San Francisco Medical Effectiveness Research Center for Diverse Populations. The center is led by A. Eugene Washington, M.D., M.Sc., and supported in part by the Agency for Healthcare Research and Quality (HS07373).

The researchers found that on average, regardless of racial, ethnic, or educational background, women felt that having a child with Down syndrome would be worse than having a miscarriage due to amniocentesis or other prenatal diagnostic procedure. Only the subgroup of women who were eligible for but chose to forego prenatal diagnosis viewed both prospects as equally burdensome.

This variation in individual preferences calls into question the basis for prenatal testing guidelines. Current guidelines do not consider individual preferences in lower risk women, but they should, concludes the study's first author Miriam Kuppermann, Ph.D., M.P.H. Dr. Kuppermann and her colleagues assessed responses to interviews and survey questions for 539 sociodemographically diverse pregnant women who sought obstetric care at various practices in the San Francisco Bay area. The women were asked about the prospects of procedure-related miscarriage versus a Down syndrome-affected birth.

The researchers used time trade-off and standard gamble techniques for quantifying preferences for health outcomes and calculated the difference in preference scores for the two outcomes. On average, procedure-related miscarriage was preferable to Down-syndrome, as indicated by positive differences in preference scores that were significantly greater than zero: a mean 0.09 time trade-off difference and a mean 0.11 standard gamble difference. However, individual preferences for these outcomes varied profoundly and correlated strongly with attitudes about miscarriage, Down syndrome, and diagnostic testing.

More details are in "Procedure-related miscarriages and Down-syndrome-affected births: Implications for prenatal testing based on women's preferences," by Dr. Kuppermann, Robert F. Nease, Jr., Ph.D., Lee A. Learman, M.D., Ph.D., and others, in the October 2000 *Obstetrics & Gynecology* 96(4), pp. 511-516. ■

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No one clinical factor can identify which cystic fibrosis patients more urgently need lung transplants

Patients who are listed for lung transplants face a long wait, with the 1996 median waiting time to transplantation of 567 days. Donor lungs are distributed to patients (who match blood type and body size) solely according to who has been waiting longest on the United Network for Organ Sharing national waiting list. Recently, the Department of Health and Human Services advocated a revision of the organ allocation system that would also consider medical urgency. But for patients with cystic fibrosis, a common indication for lung transplantation, no single clinical factor reliably determines which patient among many is in most urgent need of a donor lung, according to a study supported in part by the Agency for Healthcare Research and Quality (National Research Service Award fellowship F32 HS00124).

Roger D. Yusen, M.D., of Washington University School of Medicine in St. Louis, MO, and his colleagues reviewed the records of 146 cystic fibrosis patients at one medical center who were listed for lung transplantation. They compared the characteristics of patients who died awaiting transplantation with those of patients who survived until transplantation or the end of the study.

Patients who either walked a shorter distance in 6 minutes, had higher systolic pulmonary artery pressure, or suffered from diabetes mellitus were significantly more likely to die while waiting for a lung transplant. For each 50 meter increase in the 6-minute walk distance, the risk of death decreased by 31 percent, and for each 5 mm Hg increase in the systolic pulmonary artery pressure, the chance of death increased by 41 percent. Finally, the presence of diabetes mellitus increased the risk of death before transplantation by 57 percent. However, these factors and other features overlapped considerably between the group of patients who died waiting and the group who lived until transplantation or the end of the study. These findings underscore the difficulties of trying to devise legitimate medical urgency criteria for allocating donor lungs.

See "Outcome of patients with cystic fibrosis awaiting lung transplantation," by Carmine Dario Vizza, Dr. Yusen, John P. Lynch, and others, in the September 2000 *American Journal of Respiratory and Critical Care Medicine* 162, pp. 819-824. ■

Injectable and IV heparin have similar overall care costs and effectiveness for treating deep vein thrombosis

About 170,000 patients are hospitalized each year for deep vein thrombosis (blood clot in the vein), and an additional 90,000 patients are hospitalized for recurrent thrombosis. Intravenous heparin, an anticoagulant, has been the standard treatment for this condition for over 30 years. However, enoxaparin, a low-molecular-weight heparin that can be injected under the skin once or twice daily, is similarly effective and safe.

Even though enoxaparin is a more costly medication ($476 for once-daily and $645 for twice-daily injections versus $28 for a full course of IV heparin), the overall cost of care for patients with venous thrombosis is similar for all three treatment regimens. The higher cost of enoxaparin, which can be administered on an outpatient basis, was offset by savings associated with fewer hospital readmissions, according to a study supported by the Agency for Healthcare Research and Quality (NRSA fellowship F32 HS00124).

Roger D. Yusen, M.D., of the Washington University School of Medicine, and his colleagues did a cost minimization analysis of a 3-month trial. They randomized 339 hospitalized patients with symptomatic lower extremity deep vein thrombosis to one of the three therapies, followed by long-term oral anticoagulant therapy. Based on the cost of medical resources used by each patient, the average total cost for the 3-month episode of care was similar for all treatments: $12,166 for a once-daily dose of enoxaparin, $10,744-$12,915 for twice-daily enoxaparin, and $12,146 for IV unfractionated heparin.

However, the IV heparin group had higher readmission rates than the once- and twice-a-day

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Treating deep vein thrombosis

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enoxaparin groups (26 percent vs. 21 and 17 percent, respectively). Besides reducing readmissions, injectable heparin has the economic advantage of not needing anticoagulant monitoring (its blood thinning effects are more predictable), facilitating outpatient therapy.

More details are in "Costs for inpatient care for venous thrombosis: A trial of enoxaparin vs. standard heparin," by Gregory de Lissovoy, Ph.D., Dr. Yusen, Theodore E. Spiro, M.D., and others, in the November 13, 2000 *Archives of Internal Medicine* 160, pp. 3160-3165. ■

Patient self-assessments of health provide information not captured by clinical assessments or medical histories

How men and women assess their own health provides unique information not captured by standard clinical assessments or medical histories. This applies even more to men than to women, according to a study supported in part by the Agency for Healthcare Research and Quality (HS07002). The researchers found that how individuals assessed their own health predicted survival for men and, to some extent, predicted functional limitations for both men and women. This information was not rendered superfluous by the inclusion of data from a standardized physical exam and a set of laboratory tests, according to Ellen L. Idler, Ph.D., of Rutgers University.

Dr. Idler and her colleagues examined relative hazards for death and functional limitations according to self-ratings of health using prospective data from the NHANES I Epidemiologic Follow-up Study, a representative sample of U.S. adults aged 25-74 years. Individuals in the study sample have been followed since the First National Health and Nutrition Examination Survey (NHANES I) was conducted in 1971-1975.

There was an indirect relationship between men's self-rated health and their risk of death. Men who reported excellent health had a 48 percent lower risk of death than men who reported poor health, men who reported very good health had a 44 percent lower risk of death, and those who reported good health had a 32 percent lower risk of death. Self-reports of excellent, very good, and good health did not significantly reduce the risks of death compared with self-reports of poor health among women.

In 1992, men's excellent self-rated health subtracted 9.5 points from functional limitation scores, and self-ratings of fair health reduced scores by 7.3 points, with scores for very good and good health falling in between in dose-related fashion. There was no significant relationship for women's self-rated health and functional limitation scores in 1992, after adjusting for prior limitations.

More details are in "Survival, functional limitations, and self-rated health in the NHANES I Epidemiologic Follow-up Study, 1992," by Dr. Idler, Louise B. Russell, Ph.D., and Diane Davis, B.A., in the *American Journal of Epidemiology* 152(9), pp. 874-883, 2000. ■

HIV/AIDS Research

Women are less likely than men to receive antiretroviral drug therapies for HIV/AIDS

Treatment of AIDS has become both more effective and more costly with recent development of antiretroviral drug therapies such as protease inhibitors and nonnucleoside analog reverse transcriptase inhibitors. These drugs have been found to suppress replication of the human immunodeficiency virus (HIV) that causes AIDS, increase production of CD4 cells that bolster the immune system, reduce morbidity, and prolong survival among HIV-infected people.

Unfortunately, women are less likely than men to receive these life-prolonging therapies, according to a study of Florida Medicaid data. States need to investigate this disparity in use of antiretroviral drug therapies and develop policies

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to foster better access of women to these treatments, conclude Kathryn H. Anderson, Ph.D., of Vanderbilt University, and Jean M. Mitchell, Ph.D., of Georgetown University.

In a study supported by the Agency for Healthcare Research and Quality (HS09560), they analyzed Florida Medicaid eligibility, enrollment, and claims data for people living with HIV or AIDS (PLWHAs) from 1993 through 1997. They used the claims data to identify patients who received two nucleoside analogs (TWONUKES) or one protease inhibitor and a nucleoside combination (PI+NUKES) and constructed the probability of dying from eligibility and enrollment data. The probabilities of receiving TWONUKES and PI+NUKES were 0.16 and 0.09, respectively, lower for women relative to men. Blacks were more likely to receive TWONUKES than whites, but the reverse was true for Hispanics (0.04 higher probability for blacks and 0.03 lower probability for Hispanics compared with whites). In contrast, blacks were significantly less likely to receive PI+NUKES.

Both drugs had significant negative effects on the probability of death. PLWHAs who received PI+NUKES were 60 percent as likely to die each month as those who did not receive this combination therapy. The receipt of TWONUKES lowered patients' relative hazard of death by close to 66 percent each month compared with patients who did not receive the drugs. Despite lower use of antiretroviral therapies, women were only 56 percent as likely to die as men. The survival of women with AIDS could be improved even more if their access to antiretroviral therapy was equal to that of men.

More details are in "Differential access in the receipt of antiretroviral drugs for the treatment of AIDS and its implications for survival," by Drs. Anderson and Mitchell, in the November 13, 2000 *Archives of Internal Medicine* 160, pp. 3114-3120. ■

Vitamin A deficiency may contribute to the development of cervical cancer lesions in HIV-infected women

Women infected with the human immunodeficiency virus (HIV) that causes AIDS have a higher prevalence of vitamin A (retinol) deficiency than the general population. Furthermore, this deficiency is significantly associated with cervical cancerous lesions, squamous intraepithelial lesions (SILs). This association remains intact independent of markers of HIV disease stage, status of human papilloma virus (HPV, implicated as causing cervical cancer) infection, and overall nutritional state, according to new findings from the Women's Interagency HIV Study (WIHS). This multicenter longitudinal study of HIV-infected and at-risk women was cosponsored by the Agency for Healthcare Research and Quality, the National Institutes of Health, and the Centers for Disease Control and Prevention.

Lead author, Audrey L. French, M.D., of Cook County Hospital and Rush Medical College, and her colleagues measured serum retinol concentrations in 1,314 women enrolled in the WIHS and correlated the results with concurrent cervical cytology. At the initial visit, 15.5 percent of the women had retinol concentrations consistent with deficiency (less than 1.05 μmol/L). Cervical SILs were nearly twice as likely to be found in women with retinol concentrations less than 1.05 μmol/L in the group overall (odds ratio, OR 1.63) and in a subset of women with genital herpes virus (OR 1.75).

These findings suggest that retinol deficiency may contribute to the development of cervical SILs in HIV-infected women. Also, vitamin A deficiency among the women studied was due to socioeconomic and behavioral factors rather than advanced HIV disease. This was indicated by the lack of association of CD4 cell count (indicator of immune status) and HIV type 1 RNA with retinol concentrations, as well as by the relative health of the HIV-infected women. A nutritional adjunct to therapy for cervical dysplasia would probably have widespread appeal, but the potential benefit would have to outweigh the risk (high doses of vitamin A are toxic and tumor-forming).

See "Association of vitamin A deficiency with cervical squamous intraepithelial lesions in human immunodeficiency virus-infected women," by Dr. French, Lynn M. Kirstein, L. Stewart Massad, and others, in the October 2000 *Journal of Infectious Diseases* 182, pp. 1084-1089. ■

People with Medicaid coverage and a usual source of care are less likely than others to delay care after HIV diagnosis

Delayed medical care after an initial diagnosis of HIV infection prevents patients from receiving medical therapies that may preserve their immune system and reduce the risk of serious disease-related complications. Unfortunately, delays of several months or longer between HIV diagnosis and first medical care are not uncommon, concludes a study supported by the Agency for Healthcare Research and Quality (HS08578).

In a study led by Barbara J. Turner, M.D., of the University of Pennsylvania, researchers examined responses from interviews of a nationally representative sample of people with HIV infection receiving care in the United States (the HIV Cost and Services Utilization Study–HCSUS) to determine time from diagnosis to first care. They found that 1,540 patients in group A, diagnosed by February 1993, were in care within 3 years; the 1,960 patients in group B, diagnosed by February 1995, were in care within 1 year of diagnosis. A delay of more than 3 months occurred for 29 percent of group A and 17 percent of group B. Having a usual source of care at diagnosis reduced delay in group A by 40 percent (adjusted odds ratio, OR 0.61) and by 30 percent in group B (OR 0.70). Patients covered by Medicaid at diagnosis were half as likely to delay treatment as privately insured patients (group A, OR 0.52 and group B, OR 0.48). People who were not sick and those who tested positive for HIV in 1991 or earlier were more likely to have delayed care. Also, people 25 years of age or younger, Hispanics and blacks, and those with HIV exposure from intravenous drug use, were more likely to report more than 3 months' delay in receiving care. Delay was also more likely for people who were tested in an anonymous testing center or a non-health care setting such as a prison or blood donation center.

More details are in "Delayed medical care after diagnosis in a U.S. national probability sample of persons infected with human immunodeficiency virus," by Dr. Turner, William E. Cunningham, M.D., M.P.H., Naihua Duan, Ph.D., and others, in the September 25, 2000 Archives of *Internal Medicine* 160, pp. 2614-2622. ■

Rural Health

Rural hospitals that treat few heart attack patients may rely on protocols to guide use of aspirin and clot-busting drugs

Many studies have shown that "practice makes perfect" when it comes to medical procedures—that is, hospitals or physicians who perform a higher volume of a given procedure usually have better outcomes than those who perform few such procedures. In this study, the researchers examined the association between hospital and physician volume and the use of aspirin and reperfusion therapy in eligible patients in the first 24 hours after acute myocardial infarction (AMI, heart attack).

They reviewed charts of 2,215 patients treated at 35 Minnesota hospitals for AMI between October 1992 and July 1993. They found that the lowest volume hospitals (treating less than 30 AMI patients over 10 months) had a 50 percent reduction in the odds of using aspirin compared with the highest volume hospitals (treating more than 200 patients). Unexpectedly, the study also found that the low-volume hospitals—many of which were in rural areas—were about 20 percent more likely to use thrombolytics for AMI patients.

The researchers attribute this to the clinicians' lack of access to alternatives, such as cardiac catheterization labs and cardiologists. They simply had no alternative, and the use of thrombolytics may have been a "desperation reaction," suggests Donald Willison, Sc.D., lead author of the study at Harvard Medical School. This research was supported in part by the Agency for Healthcare Research and Quality (HS07357).

Dr. Stephen Soumerai, principal investigator of the AHRQ study, and his colleagues reviewed the medical

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Aspirin and clot-busting drugs

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charts of 2,215 patients treated at 35 Minnesota hospitals for AMI in 1992 and 1993. They compared the use of aspirin and thrombolytic therapy in eligible patients across different physician and hospital volume categories. They found that hospital volume and physician volume of patients treated were only weakly associated with use of aspirin and reperfusion therapy. Differences appeared chiefly in the lowest volume hospitals.

Because heart attack is an emergency condition, timing is very important for saving lives, and selective referral of patients to higher volume hospitals or physicians generally is not an option. Almost half of the hospitals participating in this study were in rural locations and treated less than three AMI patients per month. Also, 35 percent of the physicians who were identified as primary prescribers treated five patients or less in the entire 10-month study period. At such low volume, it is difficult to maintain expertise. The widespread use of protocols and rural outreach projects conducted by urban cardiologists at the time may well have compensated for the lack of individual physician or hospital experience in treating AMI patients, concludes Dr. Willison.

For more details, see "Association of physician and hospital volume with use of aspirin and reperfusion therapy in acute myocardial infarction," by Drs. Willison and Soumerai and R. Heather Palmer, M.B., B.Ch., S.M., in the November 2000 *Medical Care* 38(11), pp. 1092-1102. ■

Minority Health

Health plans need culturally and linguistically appropriate materials for non-English-speaking patients

Residents of the United States speak at least 329 languages. In some U.S. cities, less than 60 percent of the population speaks English. Also, the Census Bureau estimates that by 2030, the Hispanic population will increase by 113 percent, and the number of Asian Americans will grow 132 percent. Health plans need to develop culturally and linguistically appropriate materials (CLAMs) to help diverse populations overcome language barriers to effective treatment.

CLAMs help health plan managers and providers inform and educate members and patients and, at the same time, comply with accreditation standards, explain Sandra Smith, M.P.H., C.H.E.S., and Virginia Gonzales, Ed.D., M.S.W., M.P.H., of the University of Washington Center for Health Education and Research. They point out in a recent commentary that Federal and State civil rights laws and Medicaid regulations require that patients have access to medical information in their own languages. These laws form the basis for accreditation standards that require plans and providers to position themselves for a multicultural future. For example, the Joint Commission on Accreditation of Healthcare Organizations requires hospitals to document that patients and families received and demonstrated understanding of linguistically appropriate explanations and instructions.

One cost-effective way to develop CLAMs is to translate printed materials already in use by plans to convey information to English speakers, explain the researchers. They describe a process they developed for producing foreign language CLAMs on prenatal health information from materials written in English. With support from the Agency for Healthcare Research and Quality (HS09836), the researchers used the written pamphlet, "Beginnings: A Practical Guide Through Your Pregnancy," to develop a guide suitable for both college-educated women and those with less than a 9th-grade education. By forming a partnership with a team of perinatal outreach workers from five Spanish-speaking cultures, they produced translated materials acceptable and persuasive to Spanish speakers from various Hispanic cultures in the United States.

For details, see "All health plans need CLAMs," by Ms. Smith and Dr. Gonzales, in the September 2000 *Healthplan* 41(5), pp. 45-48. ■

Screening for colorectal cancer every 5 years reduces mortality at costs similar to other cancer screening procedures

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States. A recent expert panel recommended that people at average risk of CRC undergo screening for CRC beginning at age 50 using one of several strategies. Screening for CRC as recommended by the panel is as cost effective as other forms of cancer screening, concludes a study supported in part by the Agency for Healthcare Research and Quality (HS07038).

Graham A. Colditz, M.D., Dr.P.H., of Harvard Medical School, and his colleagues performed a cost-effectiveness analysis of 22 CRC screening strategies used in simulated clinical practices in a hypothetical group representative of the 50-year-old U.S. population at average risk for CRC. Compliance was assumed to be 60 percent with the initial screen and 80 percent with followup or surveillance colonoscopy.

The most effective strategy for white men was annual rehydrated fecal occult blood testing (RFOBT) plus sigmoidoscopy (SIG)—followed by colonoscopy if either a low- or high-risk polyp was found—every 5 years from age 50 to 85 years. This strategy resulted in a 60 percent reduction in cancer incidence and an 80 percent reduction in CRC mortality compared with no screening. It also resulted in a cost-effectiveness ratio of $92,900 per year of life gained compared with annual unrehydrated FOBT (UFOBT) plus SIG every 5 years.

The researchers found similar health and economic benefits of CRC screening for white women and black men and women. Because of increased life expectancy (white women) or increased cancer mortality (blacks), CRC screening was even more cost effective among these groups.

All other strategies recommended by the expert panel (annual FOBT, SIG every 5 years, double-contrast barium enema [DCBE] every 5 to 10 years, or colonoscopy every 10 years) were either less effective or cost more per year of life gained than the alternatives. However, the choice of screening strategy in clinical practice should be determined not by cost-effectiveness but by provider competence and patient preferences, suggest the researchers. For example, a one-time screen at 55 years of age with colonoscopy can reduce CRC mortality 30 to 50 percent, depending on the level of compliance.

For more details, see "Cost-effectiveness of screening for colorectal cancer in the general population," by A. Lindsay Frazier, M.D., M.Sc., Dr. Colditz, Charles S. Fuchs, M.D., M.P.H., and Karen M. Kuntz, Sc.D., in the October 18, 2000 *Journal of the American Medical Association* 284(15), pp. 1954-1961. ■

Not all types of HMOs benefit financially from so-called "selection bias"

Previous studies have shown that health maintenance organizations (HMOs) tend to attract healthier beneficiaries, who tend to use fewer health services. Clearly, HMOs can benefit financially from this so-called "selection bias." However, a review of studies published after 1993 on selection bias in HMOs concludes that not all Medicare HMOs, Medicaid HMOs, and employer-based HMOs necessarily profit from selection bias.

In their review, Agency for Healthcare Research and Quality investigators Fred J. Hellinger, Ph.D., and Herbert S. Wong, Ph.D., found that healthier individuals are still more likely to join HMOs in the Medicare and Medicaid programs but not in the workplace. Because no selection bias was found in the market for employer-based insurance, selection bias does not result in HMOs being overpaid in the private sector. Even in Medicaid, because most States are moving toward mandatory Medicaid HMO programs, concern about the impact of selection bias on the appropriateness of HMO payments is diminishing. On the other hand, there is still concern about the impact of selection bias on the appropriateness of Medicare HMO payments. Also, there is conflicting evidence about whether Medicare HMOs are overpaid.

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HMO's and "selection bias"

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Medicare HMOs still attract healthier beneficiaries. Medicare rates were transformed in the past year to include a health-based measure that is calculated using inpatient data. However, there are seemingly contradictory findings that are difficult to reconcile. Medicare payments to HMOs were between 6 and 7 percent too high before implementation of the current diagnosis-based risk adjustment system that reduced payments by 7 percent. Yet, health status, as measured by functional status and self-reported general health status between HMO and fee-for-service enrollees remains quite different, even after implementation of a diagnosis-based risk adjustment system.

For more information, see "Selection bias in HMOs: A review of the evidence," by Drs. Hellinger and Wong, in the December 2000 *Medical Care Research and Review* 57(4), pp. 405-439. Reprints (AHRQ Publication No. 01-R026) are available from AHRQ.* ■

Acquisition of local nonprofit hospitals by regional hospital systems may weaken community control of local hospital pricing

The period 1994 to 1997 was a record time for hospital mergers and acquisitions, reportedly reaching levels of more than 600 per year. The pace of this merger activity has reignited a long-standing debate over how government antitrust enforcement agencies should approach mergers involving nonprofit hospitals.

Some contend that traditional antitrust policy, driven by the principle that competition promotes consumer welfare, should not apply to mergers involving nonprofit hospitals because these hospitals typically yield to community pressures not to raise prices. Others argue that the acquisition of local hospitals by regional hospital systems could replace local governance arrangements with centralized control, which would weaken the control typically exercised by local communities over a nonprofit hospital's use of market power or pricing.

In a recent study, researchers examined three types of nonprofit hospitals. They found that members of non-local systems priced their inpatient services more aggressively in the presence of market power than did either hospitals operating independently or hospitals operating as members of local systems. The study also found a marked tendency among all nonprofit hospitals studied to exercise market power in the form of higher prices, doing so at a faster clip in more concentrated markets.

These results point to the need for some degree of antitrust oversight for mergers and acquisitions involving nonprofit hospitals, especially where there will be relatively weak community control over the hospital in question. Antitrust risks may be particularly great when a merger that will have a substantial impact on competition involves a non-local system, notes Fred Hellinger, Ph.D., of the Agency for Healthcare Research and Quality. Dr. Hellinger and his colleagues at Boston University used a panel data set to examine the relationship between market concentration and price growth for three types of nonprofit hospitals in California: independent facility, member of a local hospital system, and member of a non-local hospital system.

For more details, see "Community control and pricing patterns of nonprofit hospitals: An antitrust analysis," by Gary J. Young, J.D., Ph.D., Kamal R. Desai, Ph.D., and Dr. Hellinger, in the December 2000 *Journal of Health Politics, Policy & Law 25,* pp. 1051-1081. Reprints (AHRQ Publication No. 01-R019) are available from AHRQ.* ■

Primary care physicians can successfully use tympanometry to diagnose children's middle ear infections

Tympanometry is recommended when the diagnosis of acute otitis media (middle ear infection with effusion) is uncertain. A tympanometer measures the mobility and impedance of the tympanic membrane and ossicles of the middle ear and provides an objective assessment of middle ear status. For some children, it correlates with hearing loss.

Primary care physicians (PCPs), who have been trained in using hand-held tympanometers and interpreting tympanograms (graphic representations of middle ear activity), interpret tympanograms as accurately as experts, according to a study supported by the Agency for Healthcare Research and Quality (HS07035). Thus, PCPs can accurately interpret tympanograms to diagnose children's middle ear infections during daily practice, concludes principal investigator Jack Froom, M.D., of the State University of New York—Stony Brook.

The researchers determined the level of agreement between experts and PCPs in practice-based research networks in The Netherlands, United Kingdom, United States, and Canada, for interpretation of tympanograms of children aged 6 to 180 months. One comparison used 6,358 individual ear tracings, and a second used 3,179 office visits by children as the unit of analysis.

Results showed that the distribution of expert interpretation of all tympanograms was 51.3 percent normal, 42 percent abnormal, and 6.8 percent uninterpretable; for visits, 37.8 percent were normal, 55.6 percent abnormal, and 6.6 percent could not be classified. There was a high degree of agreement in the interpretation of tympanograms between experts and PCPs across networks, age groups of children, and types of visits. The authors conclude that interpretations of tympanograms by PCPs can be used with confidence, and that primary care physicians can provide high quality data for research purposes.

For details, see "Tympanometry interpretation by primary care physicians," by Larry A. Green, M.D., Larry Culpepper, M.D., M.P.H., Ruut A. De Melker, M.D., and others, in the October 2000 *Journal of Family Practice* 49(10), pp. 932-936. ■

Primary care physicians generally have a positive view of hospitalists when their use is not mandatory

Most European nations long ago delegated inpatient care to hospital-based physicians, so-called hospitalists, with primary care physicians (PCPs) providing only outpatient care. The United States, where patients have always counted on having their own PCPs at their hospital bedside, is following suit. PCPs are being pushed out of U.S. hospitals by hospitalists, physicians employed by managed care organizations and hospitals to care for hospitalized patients in a more efficient way. Despite initial concerns about problems with continuity of care and doctor-patient communication, most California PCPs felt that hospitalists had a positive effect on patients and on their own practice satisfaction in 1998.

This was true especially in voluntary hospitalist systems that decreased the workload of PCPs and did not threaten their income. However, California PCPs, particularly internists, were less accepting of mandatory hospitalist systems, according to a study supported by the Agency for Healthcare Research and Quality (HS09557). Doctors don't like to be forced to hand over their patients at the hospital door, explains principal investigator Andrew B. Bindman, M.D., of the University of California, San Francisco.

The researchers mailed a survey to randomly selected general internists, general pediatricians, and family practitioners in California who had experience with hospitalists to ask the physicians about their views of hospitalists. Of the 524 responding physicians, 64 percent had hospitalists available to them, and 23 percent were required to use hospitalists for all admissions.

Physicians perceived hospitalists as increasing (41 percent) or not changing (44 percent) the overall quality of care. Sixty-nine percent reported that hospitalists did not affect their income, and about half said that hospitalists increased their practice

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PCPs' view of hospitalists

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satisfaction (50 percent) and decreased their workload (53 percent). On the other hand, 28 percent of PCPs believed that hospitalists decreased the quality of the doctor-patient relationship. Internists, physicians who attributed loss of income to hospitalists, and those in mandatory hospitalist systems viewed hospitalists least favorably.

For more details, see "Friend or foe? How primary care physicians perceive hospitalists," by Alicia Fernandez, M.D., Kevin Grumbach, M.D., Lara Goitein, M.D., and others, in the October 23, 2000 *Archives of Internal Medicine* 160, pp. 2902-2908. ■

Computers in Medicine

Intranets can help clinicians share patient information

CareWeb is an intranet that enables doctors to share emergency medical information between several Boston area hospitals and satellite outpatient clinics. Even though each site has different clinical computing systems, distinct institutional vocabularies, and varying completeness of information, CareWeb is able to consolidate medical records virtually. As a result, an emergency care provider, using a standard Web browser, can create a query about an emergency patient and obtain the needed information, according to John D. Halamka, M.D., M.S., of Harvard Medical School and Beth Israel Deaconess Medical Center. Dr. Halamka's work was supported jointly by the Agency for Healthcare Research and Quality and the National Library of Medicine through a cooperative agreement (HS08749).

With this system, the emergency room doctor submits the query to CareWeb, which, in turn, generates a request for information to both the Beth Israel and Deaconess hospital systems. At each site, a site-specific CareWeb program has knowledge of that site's computer systems. It translates hospital-specific information into standard vocabularies and standard diagnostic coding, as well as standard drug and laboratory codes to convey information about the patient's demographics, medical problems, medications, records of allergies, notes, and visits. CareWeb interprets the incoming messages and creates a single, unified presentation that it returns to the emergency provider as a series of Web pages. Tool bars enable full navigational control, allowing the medical record to be scanned using a tab folder-like paradigm.

Security and confidentiality concerns pose a major barrier to sharing patient information in this way. To this end, CareWeb authenticates each CareWeb user and conducts audit trails at each site. Each hospital site server captures patient identification information; the requester; the requester's location, date, and time; and information requested. Security is maintained by a complex series of hardware controls that limit connectivity from outside the institution. Using these "firewalls," network administrators limit system access to users physically located within the campus.

More details are in "Intranets can help clinicians share patient information," by Dr. Halamka, in the November 1, 2000 *Ophthalmology Times*, pp. 8-13. ■

Agency News and Notes

AHRQ budget rises $70 million in FY 2001

On December 15, 2000, the U.S. Congress passed the fiscal year 2001 appropriations bill for the Departments of Labor, Health and Human Services, Education, and related agencies. The bill, which was signed into law by President Clinton on December 22, 2000, gives AHRQ $269,943,000 in FY 2001. This amount is approximately $70 million above the FY 2000 level and represents a 35 percent increase. It is the highest percentage increase among the Public Health Service agencies.

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AHRQ FY 2001 budget

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The Congress directed AHRQ to spend $50 million to conduct and support research to enhance patient safety. The increase includes $10 million to support research in worker health, especially to examine the relationship between the health care workplace and its impact on medical errors and the quality of care provided to patients. AHRQ also will make approximately $15 million available for investigator-initiated grants, continue activities in support of the National Quality Report, as well as research on disparities, training and early career development, and other extramural research initiatives.

AHRQ releases new evidence report on use of milk thistle to treat liver disease

The Agency for Healthcare Research and Quality recently released the summary of an evidence report on *Silybum marianum*, also called milk thistle, an herbal remedy often used to treat liver conditions. Milk thistle is a member of the aster or daisy family and was used by ancient physicians and herbalists to treat a range of liver and gallbladder diseases and to insulate the liver from a variety of poisons.

Ten key research questions guided development of the evidence report. The questions focus on whether milk thistle supplements, compared with other therapies, alter the physiologic markers of liver function, reduce illness or mortality, or improve the quality of life of adults with alcohol-related, toxin-induced, or drug-induced liver disease.

The EPC researchers were unable to clearly establish the clinical efficacy of milk thistle due to insufficient evidence. They reviewed 11 electronic databases searching for evidence about milk thistle and ultimately narrowed the field to 16 placebo-controlled studies. However, research methods varied widely among the studies, and the researchers found it difficult to assess the evidence because of incomplete information. Overall, their analysis did suggest that there may be positive effects associated with milk thistle, but poor study methods and poor reporting of research findings hampered their ability to draw definitive conclusions from the evidence. The review did show that taking milk thistle at typical doses is unlikely to cause harm.

The evidence report was prepared for AHRQ by the San Antonio Evidence-based Practice Center (EPC) at the University of Texas Health Science Center and the Veterans Evidence-based Research, Dissemination, and Implementation Center (contract 290-97-0012). AHRQ sponsored development of the report at the request of the National Center for Complementary and Alternative Medicine, a component of the National Institutes of Health. AHRQ-supported evidence reports provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies.

For more information, see *Milk Thistle: Effects on Liver Disease and Cirrhosis and Clinical Adverse Effects.* Copies of the summary (AHRQ Publication No. 01-E0240) are available now from AHRQ.** Copies of the full report (AHRQ Publication No. 01-E025) will be available in spring 2001.* ■

Announcements

AHRQ funds new projects

The following research projects and conference grants were funded recently by the Agency for Healthcare Research and Quality. Each listing includes the project title, principal investigator, performing organization, project number and dates, and funding. Readers are reminded that findings usually are not available until a project has ended or is nearing completion.

Research Projects

Brief risky high-benefit procedures

Project director:	Colin F. Mackenzie, M.D.
Organization:	University of Maryland Baltimore, MD
Project number:	AHRQ grant HS11279
Project period:	9/30/00 to 8/31/03
First year funding:	$173,195

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New research projects

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Developing best practices for patient safety
Project director: Mark B. McClellan, M.D., Ph.D.
Organization: Stanford University
Stanford, CA
Project number: AHRQ grant HS11114
Project period: 9/30/00 to 8/31/03
First year funding: $421,804

Enhancing the capacities of a national pediatric practice-based research network
Project director: Richard Wasserman, M.D.
Organization: American Academy of Pediatrics
Elk Grove Village, IL
Project number: AHRQ grant HS11192
Project period: 9/30/00 to 9/29/01
Funding: $92,974

Evaluation of coronary heart disease in men and women prior to first AMI
Project director: Barbara P. Yawn, M.D.
Organization: Olmsted Medical Center
Rochester, MN
Project number: AHRQ grant HS10239
Project period: 9/29/00 to 8/31/03
First year funding: $253,537

Physician intervention to improve diabetes care
Project director: Patrick O'Connor, M.P.H.
Organization: Healthpartners Research Foundation
Minneapolis, MN
Project number: AHRQ grant HS10639
Project period: 9/30/00 to 8/31/03
First year funding: $375,888

Primary and secondary prevention of coronary heart disease and stroke
Project director: Steven Ornstein, M.D.
Organization: Medical University of South Carolina
Charleston, SC
Project number: AHRQ grant HS11132
Project period: 9/30/00 to 8/31/03
First year funding: $351,231

Promoting effective communication and decisionmaking
Project director: A. Eugene Washington, M.D.
Organization: University of California
San Francisco, CA
Project number: AHRQ grant HS10856
Project period: 9/27/00 to 8/31/05
First year funding: $1,391,147

Quality factors in nursing home choice
Project director: Joann G. Congdon, Ph.D.
Organization: University of Colorado
Denver, CO
Project number: AHRQ grant HS10926
Project period: 9/30/00 to 8/31/03
First year funding: $247,391

Translating chlamydia screening guidelines into practice
Project director: Robert S. Thompson, M.D.
Organization: Group Health Cooperative of Puget Sound
Seattle, WA
Project number: AHRQ grant HS10514
Project period: 9/30/00 to 6/30/03
First year funding: $457,274

Conference Grants

Association of Health Care Journalists Conference
Project director: Melinda S. Voss, M.P.H.
Organization: Association of Health Care Journalists
Minneapolis, MN
Project number: AHRQ grant HS10927
Project period: 1/15/01 to 1/14/02
Funding: $30,000

Asthma education in the emergency department
Project director: Robert J. Camargo, Dr.P.H.
Organization: Massachusetts General Hospital
Boston, MA
Project number: AHRQ grant HS10940
Project period: 12/15/00 to 12/14/01
Funding: $30,000

Conference on economics of antimicrobial resistance
Project director: Ramanan Laxminarayan, Ph.D.
Organization: Resources for the Future
Washington, DC
Project number: AHRQ grant HS10943
Project period: 1/15/01 to 1/14/02
Funding: $28,000

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New research projects

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Improving emergency medical services for children through outcomes research

Project director: Ellen F. Crain, M.D., Ph.D.
Organization: Ambulatory Pediatric Association
McLean, VA
Project number: AHRQ grant HS10942
Project period: 1/1/01 to 12/31/01
Funding: $35,000

Improving implementation of screening and examinations for juvenile diabetes

Project director: Robert Goldstein, M.D., Ph.D.
Organization: Juvenile Diabetes Foundation International
New York City, NY
Project number: AHRQ grant HS10929
Project period: 12/15/00 to 12/14/01
Funding: $25,000

International conference on objective measurement

Project director: Kendon J. Conrad, Ph.D.
Organization: University of Illinois
Chicago, IL
Project number: AHRQ grant HS10941
Project period: 1/15/01 to 1/14/02
Funding: $20,000

Improvements and innovations in end of life care: National congress

Project director: Joanne Lynn, M.D.
Organization: RAND
Santa Monica, CA
Project number: AHRQ grant HS10945
Project period: 1/1/01 to 12/31/01
Funding: $32,000

Small grant program for conference support

Project director: Jordan H. Richland, M.P.H.
Organization: American College of Preventive Medicine
Washington, DC
Project number: AHRQ grant HS10938
Project period: 1/1/01 to 12/31/01
Funding: $37,547

State of the art telehealth/telemedicine

Project director: Rashid Bashshur, Ph.D.
Organization: University of Michigan
Ann Arbor, MI
Project number: AHRQ grant HS10936
Project period: 1/1/01 to 12/31/01
Funding: $25,000 ■

Grant final reports now available from NTIS

The following grant final reports are now available for purchase from the National Technical Information Service (NTIS). Each listing identifies the project's principal investigator (PI), his or her affiliation, grant number, and project period and provides a brief description of the project. See the back cover of *Research Activities* for ordering information.

Analysis of X-inefficiency in U.S. hospitals. **Michael D. Rosko, Ph.D., Widener University, Chester, PA. AHRQ grant HS09845, project period 4/1/99-3/31/00.**

These researchers examined the correlates of X-inefficiency in 1,966 U.S. urban hospitals in 1997. Stochastic frontier analysis was used to estimate inefficiency scores for each hospital in the study. The estimated level of X-inefficiency ranged from 3 percent to 84.2 percent, with a mean of 12.6 percent. Preliminary results confirm many of the hypotheses developed from X-inefficiency theory. The results suggest that X-inefficiency is inversely associated with financial pressure (i.e., HMO penetration, dependence on Medicare and Medicaid, and uncompensated care), and competition. Further, not-for-profit hospitals were more X-inefficient than their for-profit counterparts. The estimated inefficiency scores were found to be robust over a variety of model specifications and had the anticipated correlations with a number of variables expected to be associated with inefficiency, including teaching status, size, cost per adjusted admission, for-profit status, full-time staff per patient day, and profitability. (Abstract, executive summary, and final report, NTIS accession no. PB2001-100369; 42 pp, $25.50 paper, $12.00 microfiche)***

Compensation and the Quality of Hospital Care. **June F. O'Leary, M.S., University of California, Los Angeles. AHRQ grant HS09681, project period 9/30/97-9/29/00.**

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Grant final reports

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The goal of this study was to examine the effects of market competition and managed care penetration on hospital quality by focusing on one condition (acute myocardial infarction or AMI), in one State (California) during the period 1992 though 1995 (n = 306 hospitals x 4 years = 1,224). Competition was measured using a Hirschman-Herfindahl Index (HHI) with managed care represented by county HMO (health maintenance organization) penetration. Quality was measured using the hospital risk-adjusted 30-day AMI mortality rate developed under the California Hospital Outcomes Project. Using process of care data from the Cooperative Cardiovascular Project, the researchers were able to validate this measure as an indicator of quality. When comparing the hospitals with the lowest mortality to those with the highest mortality, differences in the rates of aspirin use during hospitalization, ACE (angiotensin converting enzyme) inhibitors at discharge, aspirin at discharge, and volume were all found to be statistically significant. The researchers conclude that in this study increased competition was associated with greater mortality. (Abstract and executive summary of dissertation, NTIS accession no. PB2001-101441; 20 pp, $23.00 paper, $12.00 microfiche)***

Dissemination of Guidelines for Pneumonia Length of Stay. **Michael J. Fine, M.D., M.Sc., University of Pittsburgh, Pittsburgh, PA. AHRQ grant HS08282, project period 9/30/96-3/31/00.**

This randomized trial was designed to assess the effect of implementing a project-designed medical practice guideline intervention for reducing the duration of intravenous (IV) antibiotic therapy and length of stay (LOS) for patients hospitalized with community-acquired pneumonia (CAP). Physician groups in seven Western Pennsylvania hospitals were randomized to either the multifaceted guideline dissemination intervention or the control (no intervention). A total of 608 study patients were enrolled: 283 in the intervention arm and 325 in the control arm, with no significant differences in baseline patient characteristics between the two arms. The estimated hazard of stopping IV therapy was 1.19, and the estimated hazard of hospital discharge was 1.14 for LOS, adjusted for pneumonia risk class and site. Hazard ratios for LOS varied from 0.71 to 2.28 by site. There were no differences in mortality, morbid complications, rehospitalization, symptoms, functional status, return to usual activities, or satisfaction with care between intervention and control patients. There were no significant differences overall in medical costs between study arms, most likely due to large variability among patients. Guideline dissemination effectively reduced duration of IV antibiotic therapy and LOS without adversely affecting patient outcomes. (Abstract, executive summary, and final report, NTIS accession no. PB2001-100508; 142 pp, $36.00 paper, $17.00 microfiche)***

Factors Influencing Hospital Contracting with Managed Care. **Jack Zwanziger, Ph.D., University of Rochester, Rochester, NY. AHRQ grant HS09529, project period 6/1/97-5/30/00.**

The objective was to study the factors that influenced the contracting decision between managed care plans and general acute hospitals during 1994-1998 and any changes that occurred between 1993 and 1996-1997. The researchers identified managed care organizations that contracted in 46 metropolitan statistical areas for inclusion in the study. A response rate greater than 80 percent resulted in 400 plans participating in the study. Each plan provided a list of hospitals included in their network. Multivariate analyses were used to determine which plan and hospital characteristics significantly influenced the contracting patterns of managed care organizations. Between 1993 and 1996-1997, the size of the hospital networks tended to increase over time, but the contracting patterns did not change significantly. That is, those hospitals considered to be desirable in 1993 were still desirable in 1996. (Abstract, executive summary, and final report, NTIS accession no. PB2001-100462; 38 pp, $25.50 paper, $12.00 microfiche)***

Immunization Barriers: A Study of Generalist Physicians. **Richard K. Zimmerman, M.D., M.P.H., University of Pittsburgh, Pittsburgh, PA. AHRQ grant HS08068, project period 7/1/94-6/30/99.**

The researchers used computer-assisted telephone interviews in 1995 to survey 1,236 primary care physicians across the country about childhood immunizations. Half (47 percent) of the respondents said they were less likely to vaccinate children seen during acute-care visits compared with those seen during well-child visits, while 52 percent treated the situations the same. Some physicians were overly cautious when interpreting contraindications. More than half (58 percent) reported that they would be likely to refer an uninsured child to a public health

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Grant final reports

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vaccine clinic but were unlikely to refer an insured child. Almost all (90 percent) of the physicians who did not receive free vaccine supplies were likely to refer an uninsured poor child, compared with 44 percent of physicians who received free vaccine. The researchers compared provider responses with immunization data from children they vaccinated and found that a greater percentage of children were vaccinated on time when providers received free vaccine (77 percent vs. 48 percent for MMR and 82 percent vs. 66 percent for DTP#4). (Abstract, executive summary, and final report, NTIS accession no. PB2001-100177; 86 pp, $29.50 paper, $12.00 microfiche)***

Improving Health Outcomes in Diverse Populations. **Barbara Tilley, Ph.D., Case Western Reserve University, Detroit, MI. AHRQ grant HS09824, project period 9/1/98-2/28/99.**

AHRQ funded 11 Medical Treatment Effectiveness Program (MEDTEP) Research Centers on Minority Populations in 1991. These MEDTEP centers carried out many research projects across multiple disease areas, with a special emphasis on understanding racial/ethnic differences in health status and barriers to care in vulnerable populations. This 1-day conference gave the centers a forum in which to discuss their research findings and progress, specifically the "lessons learned" from this activity. The conference also included a discussion of future research priorities involving minority health issues. In addition, the researchers discussed their experiences in developing minority investigators and methodological developments, including advancements in measuring health status and outcomes. (Abstract and executive summary of conference proceedings, NTIS accession no. PB2001-101442; 16 pp, $23.00 paper, $12.00 microfiche)***

Incentives in a Specialty Care Carve-Out. **Moira Inkelas, Ph.D., Santa Monica, CA. AHRQ grant HS10008, project period 9/30/98-4/30/00.**

This study focused on the impact of a managed care carve-out policy on expenditures and "case-finding" for children with chronic disabling conditions in California. The study population included about 200,000 children with Title V-eligible medical diagnoses. Monthly Medicaid claims covering pre- and post-carve-out periods (1994-1997) were analyzed as a panel with control group comparisons. Control groups included children in mandatory managed care, voluntary or excluded managed care, and fee-for service. There was a significant increase in Title V program participation and substantial provider response to the carve-out policy's financial incentives. Carving-out medical care services from a Medicaid managed care expansion can affect provider behavior, program costs, and case-finding of children with special health needs. (Abstract, executive summary, and dissertation, NTIS accession no. PB2001-100337; 396 pp, $65.00 paper, $25.50 microfiche)***

Measurement of Homeless Patients' Satisfaction with Care. **Carol L. Macnee, Ph.D., East Tennessee State University, Johnson City, TN. AHRQ grant HS09834, project period 9/30/98-12/31/99.**

The goal was to develop and validate a reliable measure of satisfaction with care among homeless clients. The study was conducted in two phases: face-to-face interviews with 17 homeless individuals to explore their experiences of satisfaction with health care and the evaluation of several tools used to measure satisfaction with care. Five themes that represent satisfaction with health care were defined and were the basis for development of the 30-item Homeless Satisfaction with Care Scale (HSCS). A descriptive cross-sectional comparison was used to evaluate the HSCS and two established satisfaction measures in a sample of 168 homeless clients using a rural nurse-managed clinic or an urban Health Department clinic. The HSCS had good internal consistency, reliability, and correlated significantly with scores on the other two measures. Black homeless clients had significantly lower satisfaction scores than white homeless clients, suggesting the need to evaluate the relevance of items on satisfaction scales for black clients, as well as the appropriateness of primary care services for homeless clients who are black. (Abstract, executive summary, and final report, NTIS accession no. PB2000-108079; 32 pp, $25.50 paper, $12.00 microfiche)***

Mental Health Delivery in Primary and Specialty Care Settings. **Annie G. Steinberg, M.D., Children's Seashore House, Philadelphia, PA. AHRQ grant HS09813, project period 4/1/98-6/30/99.**

Over the last 10 years, children's mental health benefits have deceased significantly, primary care visits have become shorter, and interventions for children and adolescents have focused more on psychopharmacologic options. The evidence base for pediatric psychopharmacologic interventions is limited, with a widening gap

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between research in outcomes assessment and clinical practice. This, along with diminished access to services and rapid changes in the roles of the primary care provider and specialist, have dramatically altering "the playing field" of children's mental health. In response to these changes, the Children's Mental Health Alliance Project (CMHAP) was developed. CMHAP was a 1-year project that produced recommendations about the integration of evidence-based practice into primary and speciality care, made policy recommendations that optimize mental health services for children and adolescents, and provided direction for future research in the field. (Abstract, executive summary, and final conference report, NTIS accession no. PB2001-101443; 20 pp, $23.00 paper, $12.00 microfiche)***

Nursing Home Consumer Information System. **Charlene A. Harrington, Ph.D., University of California, San Francisco. AHRQ grant HS07574, project period 4/1/95-3/31/99.**

The goal of this study was to develop a nursing home consumer information system using data from the On-Line Survey Certification and Reporting (OSCAR) system data. The researchers created a uniform data base for calendar years 1991 through 1998 and prepared annual reports for each State for the Health Care Financing Administration's (HCFA) Web site. Using information from a survey of stakeholder opinions, an expert panel, and a factor analysis of Federal deficiencies, eight major quality factors were identified: quality of care; environment; treatment of residents; diet and nutrition; resident rights and assessment; drugs; and administration. A model consumer information system was developed and tested for usefulness with consumers. The final information system presented data on facility characteristics, resident characteristics, staffing, and deficiencies. The researchers worked with HCFA to implement the consumer information system on HCFA's Web site for all 16,500 nursing facilities in the United States. This was developed into the Medicare Nursing Home Compare Web site located at www.hcfa.gov in the fall of 1999. (Abstract, executive summary, and final report, NTIS accession no. PB2001-100360; 16 pp, $23.00 paper, $12.00 microfiche)***

Pilot Feasibility Study for Heart Failure Surveillance. **Robert J. Goldberg, Ph.D., University of Massachusetts Medical School, Worcester, MA. AHRQ grant HS09830, project period 9/30/98-3/31/00.**

The researchers investigated the feasibility of population-based surveillance for heart failure (HF) by reviewing the hospital and outpatient medical records of metropolitan Worcester, MA residents with possible HF. The medical records of patients hospitalized in 1997 for possible HF and related diagnostic categories in three Worcester hospitals were reviewed. The outpatient records of greater Worcester residents with possible HF seen in 1999 at the Fallon HMO, the largest managed care plan in Central Massachusetts, were also reviewed to determine the usefulness of outpatient records for identifying cases of confirmed HF. Separate standardized data abstraction forms were developed for the review of hospital and outpatient medical records. A computerized database was developed and is being used for the entry of all study data. After reviewing eight possible ICD-9 discharge diagnosis codes for possible HF, the diagnostic category of 428 (HF) yielded a high proportion of cases of confirmed HF. Data analyses are presently ongoing to explore in greater depth the utility of using hospital and outpatient medical records to establish population-based surveillance for HF. (Abstract and executive summary, NTIS accession no. PB2000-108078; 18 pp, $23.00 paper, $12.00 microfiche)***

Practice Variations in Pain Control at the End of Life. **Charles S. Cleeland, Ph.D., The University of Texas, Houston. AHRQ grant HS09820, project period 8/1/98-7/31/00.**

Very little is known about pain among noninstitutionalized elderly people in the United States. Using data from the Asset and Health Dynamics Among the Oldest Old (AHEAD), these researchers examined the prevalence and impact of pain on perceived health status among the general population aged 70 or older. AHEAD is a longitudinal population-based survey begun in 1993 that examines the dynamic interactions between health, family, and economic variables in the postretirement period. In this study, the researchers used 1993 public release data on 8,215 respondents to examine predictors of perceived health status. They found that elderly people who often have pain are more than twice likely to characterize their health status as "poor." Other factors include functional impairment, chronic disease, minority race, lower level of education, physician visits, illness severity, and depression. This study provides empirical

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evidence on the widespread prevalence of pain and its significant impact on perceived health status in a previously understudied population. (Abstract, executive summary, and final report, NTIS accession no. PB2001-101139; 26 pp, $23.00 paper, $12.00 microfiche)***

***Pressure Ulcer Rates in Describing Nursing Home Quality*. Dan R. Berlowitz, M.D., M.P.H., Boston Medical Center, Boston, MA. AHRQ grant HS09768, project period 4/1/98-3/31/00.**

Assessing and improving the quality of nursing home care remains a priority. Central to this task is the development of risk-adjusted outcome measures for use in profiling care. Pressure ulcer development is a particularly important measure of nursing home quality in that pressure ulcers are a common condition, associated with significant morbidity, that usually can be prevented by following best practices. The researchers used the Minimum Data Set (MDS), a national, comprehensive, resident assessment instrument to derive and validate a risk-adjustment model for development of pressure ulcers in nursing homes. They compared the model with other risk-adjustment models and demonstrated how Bayesian hierarchical modeling can be used to improve reports of nursing home performance. They found that the risk-adjusted rates of pressure ulcer development declined by more than 25 percent between 1991 and 1995 in a sample of over 100 nursing homes. (Abstract, executive summary, final report, and appendix, NTIS accession no. PB2001-100181; 66 pp, $27.00 paper, $12.00 microfiche)***

***Prohibition on Health Insurance Underwriting: A Means of Making Health Insurance Available or a Cause of Market Failure?* Mark J. Browne, Ph.D., University of Wisconsin, Madison. AHRQ grant HS08941, project period 6/1/98-5/31/00.**

Underwriting restrictions are passed to discourage insurers from discriminating contrary to social policy. In addition to prohibiting socially unacceptable discrimination, underwriting restrictions also have the effect of changing the consumption of insurance. Health insurance underwriting restrictions that prohibit insurers from using disability status, sex, and age to classify risks will in theory result in greater insurance consumption by certain groups, including disabled individuals, women, and the elderly. Conversely, the prohibitions are expected to result in less health insurance consumption by others, including able-bodied individuals, males, and younger adults. The researchers analyzed data from the Current Population Survey to test their hypotheses in both the small group and individual markets for health insurance and found evidence consistent with the theory. (Abstract, executive summary, and final report, NTIS accession no. PB2001-100461; 20 pp, $23.00 paper, $12.00 microfiche)***

***Quality Improvement Organizations and Business Coalitions: A Guidebook to Collaborating for Quality Improvement.* Virginia M. Paganelli, M.Ed., M.S.N., Center for Clinical Quality, Washington, DC. AHRQ grant HS10076, 8/1/99-7/31/00.**

In 1999, several private-sector organizations convened a followup invitational workshop on community-based quality improvement in health care. The initial workshop, held in January 1997, included representatives from selected quality improvement organizations (QIOs), peer review organizations (PROs), and business coalitions from nine States who discussed opportunities for collaboration on quality improvement efforts. They reported on their collaborative activities at the followup meeting in 1999. They provided profiles and examples that can serve as a guide to promote collaboration between QIOs and business coalitions on community-based health care quality improvement projects. The conference report includes these profiles and examples, makes the "business case" for collaboration, and provides constructive guidance on the major steps involved in getting started. It also includes contact information for experts in community-based quality improvement. (Abstract, executive summary, and final report of a conference, NTIS accession no. PB2001-100179; 12 pp, $23.00 paper, $12.00 microfiche)***

***Quality of Home Health Care: A Rural-Urban Comparison.* Peter W. Shaughnessy, Ph.D., University of Colorado, Denver. AHRQ grant HS08031, project period 9/30/93-9/29/99.**

The researchers measured quality by using patient outcomes–primarily discharge status and end-result outcomes (for example, improvement in ambulation between admission and discharge). They used primary and secondary national data from 1995-1996 on more than 7,200 rural and urban elderly men and women. The data covered home health care from admission to discharge or 120 days. The findings suggest less favorable outcomes for rural patients.

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Although end-result outcomes were similar for rural and urban nonhospitalized patients, rural patients had lower rates of discharge with goals met and higher rates of hospitalization. Also, total visits and resource use were lower for rural patients. (Abstract, executive summary, and final report, NTIS accession no. PB2001-101765; 168 pp, $41.00 paper, $17.00 microfiche)***

Specialty Societies and Health Care Purchasers Discuss a New Approach to Quality Improvement. **Mark W. Legnini, Dr.P.H., M.P.H., Economic and Social Research Institute, Washington, DC. AHRQ grant HS10090, project period 1/18/00-7/18/00.**

There is a huge gap between the quality of average medical care in this country and the quality of the best care that we know is possible and indeed available from certain providers. These researchers describe an approach that directly affects quality through the creation of externally accountable quality improvement programs involving collaboration between purchasers and providers. The ultimate objective of such programs would be on-going assessment by physicians of the relationship between process and outcomes in an environment that encourages changes in practice to improve outcomes. (Abstract, executive summary, and final report of a conference, NTIS accession no. PB2001-100178; 22 pp, $23.00 paper, $12.00 microfiche)***

Statistical Method for Monitoring Nonacceptable Diagnosis Related Groups (DRGs). **Marjorie Rosenberg, Ph.D., University of Wisconsin, Madison. AHRQ grant HS09826, project period 9/30/98-9/29/00.**

The Medicare program, private insurers, and managed care organizations reimburse hospitals for inpatient admissions using the Diagnosis Related Group (DRG). The DRG is determined from a complicated algorithm based on patient medical records. Previous studies have generated concerns about "DRG upcoding," whereby incorrect DRG codes may be selected to obtain a higher reimbursement. Insurers rely on expensive manual audits of claims to verify the appropriateness of the underlying DRG coding. As part of a larger statistical system, these researchers developed a hierarchical Bayesian logistic regression for detecting claims with incorrect DRG coding using insurer claims data together with results from a manual audit. Estimates were developed from an insurer's 1993-1995 audited claims data and applied to 5,278 additional audited claims from the same timeframe (1,671 claims were coded incorrectly). For these 5,278 claims, the proposed system achieved 98 percent of the recovery of a complete audit at 88 percent of the cost of investigating the claim. (Abstract, executive summary, and final report, NTIS accession no. PB2001-101420; 18 pp, $23.00 paper, $12.00 microfiche)*** ■

Research Briefs

Barr, D. and Vergun, P. (2000, December). "Using a new method of gathering patient satisfaction data to assess the effects of organizational factors on primary care quality." (AHRQ grant HS09350). ***Joint Commission Journal on Quality Improvement*** **26, pp. 713-723.**

A common measure of quality of care is patient satisfaction with the care process. These researchers evaluated a quality assessment tool they developed that measures both patient satisfaction with care and how organizational factors within practice organizations affect satisfaction. They evaluated the tool in a random sample of patients visiting a large, multispecialty group practice in California. The patients arrived for an office visit accompanied by a survey worker who recorded objective characteristics of the visit (for example, waiting time), surveyed patients about their impressions of certain aspects of the visit related to satisfaction, and administered a standardized visit satisfaction survey. Control patients who visited the same doctor on the same day were contacted by phone and given the satisfaction survey, a traditional survey method. The new concurrent method provided significant information about organizational factors that influenced patient satisfaction.

Barry, M.J., Williford, W.O., Fowler, Jr., F.J., and others. (2000, November). "Filling and voiding symptoms in the American Urological Association symptom index: The value of their distinction in a Veterans Affairs

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randomized trial of medical therapy in men with a clinical diagnosis of benign prostatic hyperplasia." (AHRQ grant HS08397). ***Journal of Urology*** **164, pp. 1559-1564.**

Lower urinary tract symptoms in older men that may be associated with benign prostatic hyperplasia (BPH) traditionally have been separated into obstructive and irritative categories. It has been proposed that these symptom categories should be calculated as separate filling and voiding subscores on the American Urological Association symptom index to reflect more accurately the association of each symptom with a different phase of the process of storing urine and emptying the bladder. While these subscores are psychometrically valid, they are not clinically useful, conclude these authors. They used data from a large Veterans Affairs trial of medical therapy for men with BPH to evaluate calculating these separate filling and voiding subscores. The subscores did not result in differential correlations with measures of disease interference or severity, nor did they enable the researchers to predict a better symptomatic or uroflowmetry response to medical therapy.

Cagney, K.A., Wu, A.W., Fink, N.E., and others. (2000). "Formal literature review of quality-of-life instruments used in end-stage renal disease." (AHRQ grant HS08365). ***American Journal of Kidney Diseases*** **36(2), pp. 327-336.**

These authors conducted a formal literature review to determine how quality of life has been conceptualized, measured, and evaluated for patients with end-stage renal disease (ESRD). Of 78 articles they reviewed, only 32 percent defined quality of life. Few articles defined quality-of-life domains or adequately described instrument development and testing. The most frequently assessed quality-of-life domains were depression (41 percent), social functioning (32 percent), positive affect (30 percent), and role functioning (27 percent). Quality-of-life testing was completed for test-retest reliability in 20 percent of studies; interrater reliability, 13 percent; internal consistency, 22 percent; content validity, 24 percent; construct validity, 41 percent; criterion validity, 55 percent; and responsiveness, 59 percent.

Chapman, R.H., Stone, P.W., Sandberg, E.A., and others. (2000). "A comprehensive league table of cost-utility ratios and a sub-table of `panel-worthy' studies." (National Research Service Award training grant T32 HS00020). ***Medical Decision Making*** **20, pp. 451-467.**

Ranked listings of the cost-effectiveness ratios of various health and medical interventions, often called "league tables," have been used to facilitate comparisons across cost-effectiveness analyses. These comparisons of ratios are needed because it is not possible to determine whether a program is a good value until it is compared with the benefits derived from resources expended in other programs. One criticism is that many utility analyses vary widely in the methods used for estimating and reporting costs, effectiveness, and preference weights. These authors compiled a comprehensive league table of cost/quality-adjusted-life-year (QALY) ratios (available on the Web) and a standardized table of analyses satisfying selected reference case criteria from the U.S. Public Health Service Panel on Cost-Effectiveness in Health and Medicine. They identified 228 cost-utility analyses through literature searches and abstracted data on methods and cost-utility ratios.

Downs, S.M., and Wallace, M.Y. (2000). "Mining association rules from a pediatric primary care decision support system." (AHRQ grant HS09507). ***Journal of the American Medical Informatics Association,*** **Symposium Supplement, pp. 200-204, 2000.**

One goal of clinical computing is to capture clinical data that can provide decision support at the point of care. The process of identifying novel and potentially useful patterns in data, "data mining" or "knowledge discovery," facilitates the conversion of clinical data into evidence for future decision support. The purpose of this study was to apply an unsupervised data mining algorithm to a database containing data collected at the point of care for clinical decision support. The authors applied a pattern discovery algorithm to data from the Child Health Improvement Program, a preventive service tracking and reminder system in use at the University of North Carolina. The program has data on over 30,000 visits. The algorithm discovered 16 2nd-order associations and 103 3rd-order associations, revealing that both tobacco smoke exposure and chronic cardiopulmonary disease were associated with failure on developmental screens. [Editor's note: See "Travers and Downs," below, for more information on this project.]

Ioannidis, J.P., Schmid, C.H., and Lau, J. (2000). "Meta-analysis in hematology and oncology." (AHRQ grant HS10064).

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***Hematology/Oncology Clinics of North America* 14(4), p. 973-989.**

Between 5 and 10 percent of clinical trials published each year deal with cancer or cancer-related conditions, easily taxing the ability of any clinician to keep current. Indeed, a recent survey found that about 70 percent of clinicians rely on review articles written by experts to guide their clinical decisionmaking. These authors point out the many deficiencies of what they describe as mostly unsystematic, narrative reviews, ranging from lack of critical appraisal of study methods to lack of a formal, quantitative synthesis of the reported treatment benefits. They provide guidelines for conducting a meta-analysis of cancer studies that may vary in the patient populations studied and stage or severity of disease studied. The authors contend that proper meta-analysis of cancer studies can point out deficiencies in the study design of past and current studies, suggest the need for new studies, and inform researchers about the size and design of these studies.

Lobach, D.F., and Kerner, N. (2000). "A systematic process for converting text-based guidelines into a linear algorithm for electronic implementation." (AHRQ grant HS09436). *Journal of the American Medical Informatics Association,* Symposium Supplement, pp. 507-511.

Clinical practice guidelines (CPGs) have gained importance as a tool to standardize practice patterns and improve the quality and efficiency of health care delivery. Unfortunately, most of the available CPGs exist only in a text-based format, which is difficult to integrate into the patient care process. This paper describes a systematic process to convert text-based CPGs into a linear algorithm with structured content as an intermediate step to electronic implementation. The process has been used successfully to prepare more than two dozen guidelines for computerization. It has been tested by several physicians and informatics experts and shown to be transferable to various user groups.

Malone, R.E. (2000, September). "Dimensions of vulnerability in emergency nurses' narratives." (AHRQ grant HS08412). *Advances in Nursing Science* 23(1), pp. 1-11.

The saving of strangers is the essence of emergency nursing, and nurses are constantly confronted with the existential, physical, emotional, economic, and social vulnerability of their patients. In turn, emergency department (ED) nurses are vulnerable. In this commentary, the author uses data from an ethnographic study conducted in two hospital EDs to illustrate tensions between two types of vulnerability as they are reflected in emergency nurses' narratives. One type of vulnerability is equated with susceptibility to particular harmful agents, conditions, or events at particular times and is considered something to be avoided or resisted. Another type of vulnerability is the ever-present, common condition of all sentient beings and a condition of nurses' access to understanding patients' experiences.

Rodenberg, C., and Zhou, X-H. (2000, December). "ROC curves estimation when covariates affect the verification process." (AHRQ grant HS08559). *Biometrics* 56, pp. 1256-1262.

An ROC curve is commonly used to measure the accuracy of a medical test. It is a plot of the true positive fraction (sensitivity) against the false positive fraction (1-specificity) for increasingly stringent positivity criteria. Bias can occur when estimating an ROC curve if, for example, only some of the tested patients are selected for disease verification and if analysis is restricted only to the verified cases. This is known as verification bias. The authors address the problem of correction for verification bias in estimation of an ROC curve when the verification process and efficacy of the diagnostic test depend on covariates. The authors also address the issues associated with selecting and checking the research model.

Sanders, G.D., Nease, Jr., R.F., and Owens, D.K. (2000). "Publishing Web-based guidelines using interactive decision models." (AHRQ grant HS08362). *Medical Decision Making* 20(2), pp. 145-159.

These authors developed a Web-based system, ALCHEMIST, which takes previously developed decision models and automatically creates evidence-based global guidelines that can be disseminated over the Web. To demonstrate the ability of a user to tailor and update global guidelines using the ALCHEMIST system, they chose three clinical problems: chlamydia screening for adolescent women, antiarrhythmic therapy for the prevention of sudden cardiac death, and genetic testing of women for the BRCA breast cancer mutation. For example, they show how a clinician could use ALCHEMIST to incorporate a woman's preferences for relevant health states and thereby develop patient-specific recommendations for BRCA testing. In this case, the patient-specific recommendation improved

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quality-adjusted life expectancy by 37 days.

Sim, I. Owens, D.K., Lavoir, P.W., and Rennels, G.D. (2000). "Electronic trial banks: A complementary method for reporting randomized trials." (AHRQ grant HS08362). *Medical Decision Making 20*, pp. 440-450.

Decision-support systems that access shared, up-to-date trial banks could help clinicians manage, synthesize, and apply evidence from randomized clinical trials (RCTs) more effectively, assert these authors. They propose that RCTs be reported into electronic knowledge bases—trial banks—in addition to being reported in the literature. Using the competency decomposition method, they specified the ideal trial-bank contents as the information necessary and sufficient for completing the task of systematic reviewing. They decomposed the systematic reviewing tasks into 4 top-level tasks and 62 subtasks; 162 types of trial information (related to the trial's design, execution, administration, and results) were necessary and sufficient for completing these subtasks. They found that trial-bank publishing of these 162 items would capture into computer-understandable form all the information needed for critically appraising and synthesizing trial results.

Travers, D.A., and Downs, S.M. (2000). "Comparing user acceptance of a computer system in two pediatric offices: A qualitative study." (AHRQ grant HS09507). *Journal of the American Medical Informatics Association*, Symposium Supplement, pp. 853-857.

This paper presents a qualitative study of user acceptance of a computer system, the Child Health Improvement Program, which was implemented in two pediatric offices in the Southeast. The researchers gathered data through staff interviews, observations in the clinical area, and a review of system implementation records. One practice was still using the program 5 months later, but the other practice had discontinued its use. Differences in user acceptance at the two practices were related to benefits versus costs, organizational cultures, relationship of the information system with the clinical staff in the practices, experiences in the two practices after implementation, and difficulty with transfer of technology from the academic center to private practice. These findings indicate a need to develop and validate tools to measure health care organizational climate and readiness for change. [Editor's note: See "Downs and Wallace," above, for more information on this study.] ■

Research Activities - 2000 Author Index

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AHRQ Pub. No. 01-0015
January 2001