POLICY & PRACTICE

U.S. System Gets Failing Grade

The U.S. health care system ranked 15th out of 19 countries in number of preventable deaths, according to a comparison of 37 indicators of health outcomes, quality, access, equity, and efficiency. Compared with other nations, the United States scored particularly low on efficiency, getting an average score of 51 out of 100. The report blames this partly on the lack of electronic medical records—used by only 17% of American physicians, compared with the benchmark, which was 80% in the top-performing three nations in 2000-2001. Scores for quality and equity of access were highest, at 71. "Our purpose in issuing this scorecard is to bring attention to opportunities to improve, with benchmarks to motivate change," said Dr. James Mongan, chairman of the 18-member commission that conducted the study and CEO of Partners HealthCare in Boston. "We applaud the commission for providing us with a comprehensive, comparative set of measures to use as a basis for improving the performance of our nation's health care system," the American Board of Internal Medicine said in a statement. The full report is available at www.cmwf.org.

Target Opens In-House Clinics

Target, the Minneapolis-based retail powerhouse, is opening in-house clinics at 8 of its 1,443 stores. The company is rolling out the concept in its corporate hometown and soon will add at least four more in that region. According to Target, the clinics will feature a private waiting area and exam rooms and will offer services such as flu shots and treatments for strep throat, bronchitis, and skin conditions. Prices for services—most under $50—will be clearly listed. The clinics are staffed by licensed nurse-practitioners and physician assistants. Medcor will provide clinic management, and physicians from Fairview Health Services will provide oversight and consultation. The company said in a statement that it will "meet or exceed the American Medical Association and the American Academy of Family Physicians guidelines for retail healthcare."

Low Physician E-Mail Use

Physicians are rarely using e-mail to communicate with patients, according to one study, yet patients overwhelmingly report that they would like to use e-mail to set appointments, talk with the doctor, and receive test results, according to a separate poll. The Center for Studying Health System Change found that only 24% of physicians said they used e-mail to discuss a clinical issue with a patient in 2004-2005, a 4% increase from the previous study period of 2000-2001. Almost half of physicians in academic settings and staff or group HMO practices use e-mail for clinical discussions, compared with about 20% in practices of 10 or fewer physicians. Physicians in nonmetropolitan areas or who have large numbers of Medicaid and/or Medicare patients say they are less likely to use e-mail, because of patients' lack of access to the technology. Some reasons for not using e-mail are lack of reimbursement for consultations, cost of implementing a secure system, and fears that e-mail will add to workloads. A recent Wall Street Journal–Harris Interactive poll of 2,624 adults found that 74% want to communicate directly with doctors by e-mail, 67% want to receive test results, and 75% want to schedule appointments via the Internet.

Insurance Premiums Continue Rise

Employer-sponsored health insurance premiums rose 7.7% in 2006, outpacing wages and inflation, according to a report from the Kaiser Family Foundation and the Health Research and Educational Trust. The annual survey of employer health benefits found that family health coverage costs an average of $11,480 annually, with workers contributing an average of $2,973 toward their premiums. "We are still losing the race between premiums and workers' earnings, and if that trend persists, employer-based coverage will continue to decline as fewer employers and workers can afford the cost of coverage," Jon Gabel, coauthor of the study and vice president of the Center for Studying Health System Change, said in a statement. Most individuals opted for coverage through preferred provider organizations (60%), with others choosing HMOs (20%), point-of-service plans (13%), and conventional indemnity plans (3%). About 4% of individuals enrolled in high-deductible plans with a savings option. This year, about 7% of employers—mostly those with 1,000 workers or more—offered some form of high-deductible plan in 2006. The information is from a telephone poll of 3,159 randomly selected public and private employers. To obtain more information, visit www.kff.org/insurance/7527.

Reporting on Quality

More than 3,300 hospitals around the country have reported data on quality measures to Medicare and consumers, according to the Centers for Medicare and Medicaid Services. Of the 3,490 acute care hospitals eligible to participate in the federal program that links hospital payments to reporting of quality measures, 99% opted to report data. Under the program, hospitals that submit quality information to CMS are eligible to receive the full 2% payment update for inpatient services in 2007 under Medicare, while those who do not report will see a 2% payment reduction. "This is more evidence that paying for reporting and improving quality can help patients get better care," Dr. Mark McClellan, outgoing CMS administrator, said in a statement. "Consumers can use this information to evaluate care, and doctors and hospitals can use it to help improve their performance.

—From staff reports

Report Faults FDA for Lack Of Postmarketing Focus

BY ALICIA AULT
Associate Editor, Practice Trends

The Food and Drug Administration should shift its emphasis from the preapproval period to postmarketing, when new drugs pose the greatest risk of safety problems, a sweeping report from the Institute of Medicine recommends.

Many safety-related issues in recent years—including the widely publicized recall of Vioxx (rofecoxib), and struggles over labeling changes for antidepressants—have led to a lack of confidence in drug development and regulation, according to the 15 experts impaneled by the IOM.

"The credibility of FDA, the industry, the academic research enterprise, and health care providers has become seriously diminished in recent years," the committee said in its report.

The FDA, in particular, has floundered, hampered by a lack of funding and mismanagement that has led to internecine strife and miscues that may have resulted in delays in addressing safety issues, said the panel, which was made up of academicians, ethicists, and the head of the U.K. Medicines and Healthcare Products Regulatory Agency.

"FDA's reputation has been hurt by a perceived lack of transparency and accountability to the public, a legacy of organizational changes that have not been completed or sustained, and an apparent slowness in addressing lack of sponsor compliance," according to the report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public."

The committee recommended that FDA consider requiring new molecular entities to carry a special caution that the products' true risks and benefits are unknown. FDA also should consider restricting or banning direct-to-consumer advertising of those products during that early marketing period, the committee said.

After 5 years, the FDA should formally review all available data on those products and publicize the findings, the panel said.

Also, results of phase II-IV clinical trials submitted to the FDA should be published on the Web site www.clinicaltrials.gov.

Most label changes are voluntary and many companies have not conducted requested postmarketing studies, so the FDA needs more power to enforce regulations, including the ability to more quickly and directly levy fines or secure injunctions against companies that do not comply, the committee said. But the FDA should not be given unilateral authority, the panel said.

"We understand that offering discretion does not mean offering dictatorial power," said R. Alta Charo, a bioethicist at the University of Wisconsin Law School.

Among the IOM panel's other recommendations:

- FDA funding and staff should be vastly increased.
- FDA commissioners should be appointed to a 6-year term in order to bring stability to the agency's leadership.
- Staff from the FDA's Office of Surveillance and Epidemiology should join the teams that review new drugs, to increase the safety focus from the start.
- At least 60% of the membership of each FDA advisory committee should have no significant financial involvement with the sponsors of the products being reviewed.

Some of these changes—such as a shift in resources from the preapproval to the postapproval side—could be done administratively. Others, however, such as giving the agency new enforcement authority, would require an act of Congress.

In a press briefing after the report was released, FDA officials acknowledged that there have been some difficulties, but they largely deflected the criticism by instead discussing initiatives the agency has undertaken in the last 2 years to shore up postmarketing safety efforts.

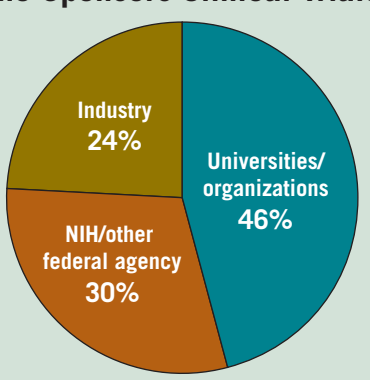
"The FDA has led an aggressive effort, which includes developing new tools for communicating information to patients and new resources for drug safety, to improve the management of the process for how we uncover and communicate important drug safety issues," acting FDA Commissioner Andrew von Eschenbach said at the briefing.

Dr. Janet Woodcock, deputy commissioner for operations, said that the Center for Drug Evaluation and Research "has recognized a number of these issues for quite some time and has been systematically addressing them," by doing things like establishing a drug safety board. "We are committed to continuing to address the issues that have been raised after we've fully absorbed this report," she added.

The Pharmaceutical Research and Manufacturers of America also defended FDA's recent strides and the industry's safety record. ■

DATA WATCH

Who Sponsors Clinical Trials?



Note: Based on nearly 14,000 international clinical trials currently recruiting as of Dec. 1, 2005.
Source: Clinicaltrials.gov, National Institutes of Health

Elsevier Global Medical News