

Panel Seeks Citizen Input on Health Care Reform

Comments on the current state of health care will be gathered via community meetings and the Internet.

BY NELLIE BRISTOL
Contributing Writer

WASHINGTON — American health care could be in for the world's largest customer satisfaction survey as the U.S. Citizens' Health Care Working Group seeks comments nationwide on how to reform the system.

"In order to make health care work for all Americans, we need to hear from all Americans," said working group member Rosario Perez, a registered nurse and vice president of Mission Integration and Outreach Services for CHRISTUS Santa Rosa Health Care in San Antonio. "We want to hear from individuals across the country. That means your parents, your relatives, your coworkers, and people in your community." Perez spoke at a briefing sponsored by the Citizens' Health Care Working Group.

Established by the 2003 Medicare Modernization Act, the 14-member panel will collect as many comments and suggestions as possible before April 15. Submissions will serve as the basis for panel recommendations for Congress and President Bush to consider next spring. The recommendations will address costs, care affordability, and quality improvement.

"Despite increases in medical care spending that are greater than the rate of inflation, population growth, and Gross Domestic Product growth, there has not been a commensurate improvement in our health status as a nation," according to the law that established the working group.

Among areas of interest highlighted by the working group are consumer concerns about health care delivery, benefits that should be provided, how health care should be paid for, and acceptable tradeoffs to ensure broad access to services.

Comments will be collected via the group's Web site (www.citizenshealthcare.gov) and through "town hall"-style community meetings planned for every state. The effort is the bipartisan brainchild of Sen. Orrin Hatch (R-Utah) and Sen. Ron Wyden (D-Ore.).

The press briefing was held in the same Senate room as the 1912 hearings on the sinking of the Titanic, and Sen. Wyden said the U.S. health care system could suffer a similar dire fate "if something dramatic isn't done to save it."

Sen. Wyden suggested citizen input may engender systemic change that has stymied Congress for the last 6 decades. A "citizens' road map" for change could help "overcome the feeding frenzy by special interests," he argued.

The panel is made up of health care professionals, economists, benefits experts, and advocates from across the country, and includes Health and Human Services Secretary Michael Leavitt. The group is chaired by Randall L. Johnson, head of corporate benefits for Motorola Inc.; vice chair is

Catherine McLaughlin, Ph.D., a health economist at the University of Michigan.

To jump start the discussion, the group developed a 30-page "Health Report to the American People," which summarizes the current state of U.S. health care.

"Having this information prepares us as a country to ask some tough questions about whether we are getting the services we need and want, [and] whether we are getting our money's worth and choices we need and are willing to make to have health [access] for all Americans," said Dr. McLaughlin.

She said that the working group aims to develop recommendations that would address health care as a whole. "Our health care system is a lot like our natural environment, an ecosystem in which any significant change in one area has ripple effects throughout the others," she said. "We need to address the entire health care system, not just specific problems like cost, quality, or access—no matter how urgent they may seem from our different perspectives." ■

Electronic Health Record Interfaces May Cause Errors

BY PATRICE WENDLING
Chicago Bureau

LOS ANGELES — Electronic health records have been proposed as one way to reduce medical errors, but their design can contribute to errors as well, Melonie Nance, M.D., said at the annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Foundation.

"The way doctors work, and the way we think about patient problems and diseases is often completely mismatched with the way things are presented in electronic records," Dr. Nance, said in an interview.

Dr. Nance and her colleagues at the University of Pittsburgh analyzed two cases of preventable medical errors that occurred in part because of computer interface design. In neither case did the error lead to patient injury, thus both were "near misses."

In the first case, a resident reviewed the pathology report of an operative biopsy prior to a composite resection and noted that the diagnosis was squamous cell carcinoma, but failed to recognize that the date of the biopsy was from the previous year.

In the electronic record used, multiple pathology reports were displayed on the same screen. Further, pathology and operative reports were stored in separate categories and were not linked, even though both reports resulted from the same procedure. The problem consisted of both time-line and data-fragmentation errors.

Rather than presenting critical data in a way that links related information, the electronic record in this case had re-created a problem seen with traditional paper files where information is stored by data type, Dr. Nance said.

Standardized time lines, unambiguous links between related information, and

data organized by problem are all potential solutions to this problem, Dr. Nance said. For example, pathology reports of a head and neck cancer should be displayed with other information about the specific cancer, whereas reports of a liver biopsy should be linked to other information about the patient's liver disease.

In the second case, a patient was discharged in acute renal failure 30 minutes after the renal failure had been noted and documented by the critical care fellow. The fellow had entered the diagnosis into the electronic record at the end of a lengthy note but had not communicated the information to the otolaryngology resident who discharged the patient. The error was discovered quickly and the patient was readmitted 2 hours later.

The primary problem in this case was that data entry was mistaken for thorough communication. Critical patient information was hidden from the discharging physician and the record contained excessive information.

Dr. Nance and her colleagues suggested that a severity scale could be used to bring attention to important information such as abnormal lab data. Copied-and-pasted notes, a strategy often used to generate complete documentation, could be marked with color coding, time stamps, or a notation similar to the "track changes" function on word processors.

The authors further suggest that communication failures such as this case illustrates could be reduced with an automated warning system triggered by attempts to discharge patients with worsening conditions. Electronic medical records also could be equipped with a message system similar to e-mail that notifies parties when a message has been retrieved. ■

Ethical Conflicts Surface Around FDA's Black Box Label Warnings for SSRIs

BY JOYCE FRIEDEN
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MONTREAL — When members of the Food and Drug Administration's advisory panels make recommendations about placing "black box" labels on selective serotonin reuptake inhibitors, many factors influence their decision-making processes, Philip J. Candilis, M.D., said at the annual meeting of the American Academy of Psychiatry and the Law.

First is the obvious issue of direct pharmaceutical industry influence on the panels, as seen in the cases of Bextra, Vioxx, and Celebrex, Dr. Candilis said. "Early on in the debate on anti-inflammatories, the panels had endorsed their continued use," he said. "But look at the experts who declared ties to the pharmaceutical industry." Of the 32 experts on the panel, 10 had declared some ties to the pharmaceutical industry. Each panelist had to vote "yes" or "no" to recommending each of the three medications.

"Those [10] who had consulted to the pharmaceutical industry voted 28 of their total of 30 votes in favor of these medications. Those without such conflicts cast 37 of their 66 votes in favor," he said. "So there was a substantial and statistically significant difference in how people were supported and how they voted."

But broader influences are at play as well. For instance, the FDA regulates one-quarter of the gross national product, which comes to "hundreds of billions of dollars," said Dr. Candilis, of the law and psychiatry program at the University of Massachusetts, Worcester. And to do part of that job, the agency receives millions in fees from the pharmaceutical industry—\$825 million from 1993 to 2001, he said.

"So there's already a dependence there: 40%-50% of the [FDA's] budget comes from fees that industry pays in order for the FDA to govern the medications that they submit."

The agency also exerts pressure on its own employees, he continued. He noted that one physician testified before Congress that he'd been asked by FDA officials to alter his affidavit concerning the increased risk of suicide in children and youth taking antidepressants.

"There was an e-mail from FDA general counsel that read as follows: 'General Counsel did not think it necessary to indicate that this document represents a version of the earlier one by noting that things had been omitted. That simply invites the committee to ask further questions about what was omitted from the affidavit,'" Dr. Candilis said. "And when Congress got ahold of this e-mail and others that suggested to FDA staff that they not speak with congressional staff, they were very, very angry."

Slowly, people are becoming more aware of these conflicts and taking action to mitigate them, Dr. Candilis said. For example, Congress is now insisting that pharmaceutical companies register the results of all clinical trials, including negative results. And some professional organizations are precluding experts from peer review entirely if they have conflicts of interest.

The take-home message is this: "If we don't regulate it, Congress will, others will, people with an agenda will," Dr. Candilis said. "We have to start doing full public disclosure of [conflicts of] interest, a transparency model, more explicit policies, less management and more refusal. We must step away from just saying, 'I'm going to tell you what I own.'" ■