



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS

Plan Ahead to Smooth the Path Toward ICD-10

BY JOYCE FRIEDEN
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WASHINGTON — Transitioning as smoothly as possible to ICD-10 will require a little advanced planning.

At a meeting sponsored by the American Health Information Management Association, Dr. Lee Hilborne said that the medical community “has been very resistant and was fighting approval [of ICD-10], but at this point they need to [set about] finding a solution” to anticipated problems.

Physicians have challenged ICD-10 adoption because of concerns about:

- ▶ Having to hire more certified coders, or recertify current coders.
- ▶ Needing new computer technology and new billing and collection systems.
- ▶ Having limited resources for staff training.
- ▶ Expecting lower reimbursement at first because coding accuracy and productivity will drop in the short term.
- ▶ Needing better medical record documentation to support the more detailed codes.

Some physicians subscribe to the theory that the new codes are simply “an-

other strategy to pay physicians less,” said Dr. Hilborne, medical director of care coordination at the University of California, Los Angeles.

While “organized medicine does not oppose the transition,” they have expressed concern “about the cost and the impact on physician practice,” said Dr. Hilborne.



ICD-10 proponents need to work with physicians to develop crosswalks between ICD-9 and ICD-10, he said. “We should begin discussing this now to ease anxiety, but train later,” because the deadline for implementing the new code isn’t until 2013.

The American Medical Association must be a key player in the transition because of its prominent role in the coding process, Dr. Hilborne continued.

Those affected by ICD-10 need to start asking themselves what its impact will be on every decision they make, advised Harry Reynolds Jr., vice president and in-

formation compliance officer for Blue Cross and Blue Shield of North Carolina. For example, consider the 5010 form, the electronic form used to submit Medicare and other insurance claims. “You don’t want to have to change some-

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DR. HILBORNE

thing [now] on the 5010 because the ICD-10 affects it” and it will have to be changed again in a few years, he said. “The 5010 is not separate; it’s the runway to get you to ICD-10.”

The ICD-10 also will affect the way electronic medical records are kept, Mr. Reynolds noted. From an insurance standpoint, ICD-10 is challenging because “there are a whole lot more codes in ICD-10 than in ICD-9,” he said.

The North Carolina Blues plan has decided to ease the transition by putting in the same prices for the equivalent ICD-10 family of codes that were there for a specific ICD-9 code. Those prices will be revisited 6 months later to see how providers are using them, according to

Mr. Reynolds. “If I go from 1 code to 50 codes and every provider picks the highest [reimbursement] code, that’s not a good thing,” he said. “But if everyone’s coding properly ... that will allow us to transition in a way that’s honorable and done for strategic reasons.”

Holt Anderson, executive director of the North Carolina Healthcare Information and Communications Alliance, said that his organization was collaborating with the Workgroup for Electronic Data Interchange (WEDI) and other groups to develop a timeline for changing the 5010 form to accommodate ICD-10.

“The impacts on payers and providers are significant,” he said. Any organization can go to www.wedi.org and download the estimated timeline. “Put your own activities in and see how your vendors are doing, because if they’re slipping, your timeline will slip,” he suggested.

One of the biggest problems faced by health care organizations is fear of change, Dr. Hilborne said.

“People fear what they don’t know. We need to convince people that it’s going to be a lot of work, but it’s not that bad,” he concluded. ■

Expert Panel Narrowly Endorses Atrial Fib Device

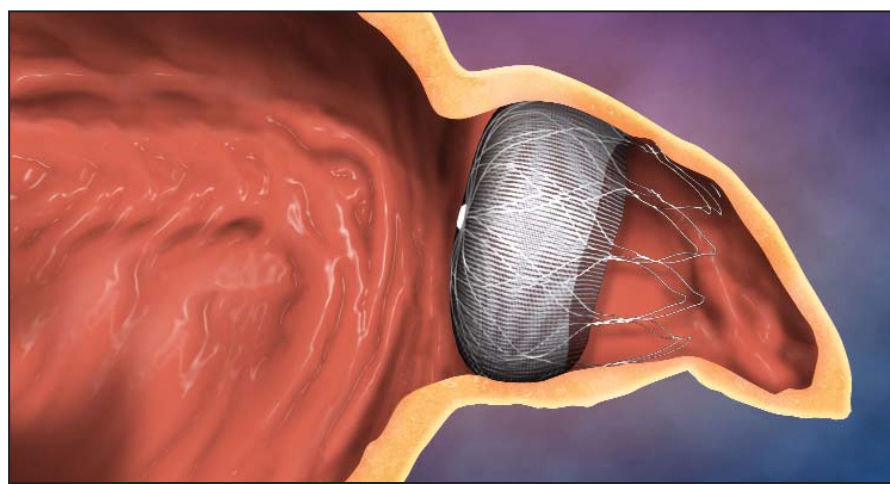
BY ELIZABETH MEHCATIE
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GAITHERSBURG, MD. — More than half of a federal advisory panel voted in favor of approving a device designed to reduce the risk of stroke in people with nonvalvular atrial fibrillation, with conditions.

The Food and Drug Administration’s Circulatory System Devices Panel voted 7-5 that the Watchman device was “approvable” as a “noninferior” treatment to long-term warfarin therapy in warfarin-eligible patients with nonvalvular AF, for reducing the risk of stroke, cardiovascular death, or systemic embolism.

The panel agreed that based on the results of the PROTECT AF trial, the device had been shown to be generally effective and safe in the population studied.

The conditions for approval included requiring postmarketing studies that would follow patients enrolled in the trial for 5 years, and a registry study monitoring acute procedural complications and long-term outcomes in about 2,000 patients for 2 years. Other conditions were that the device be implanted only in facilities with access to urgent cardiac surgery at the time of implantation, and that rig-



The Watchman device, made of nitinol, is placed via catheter in the left atrial appendage to prevent thrombus formation.

orous physician certification be put in place. There was unanimous or near-unanimous support for all the conditions.

The Watchman implant is made of nitinol, with an atrial surface covered with a thin permeable, polyester material. It is percutaneously placed, delivered via a catheter, in the left atrial appendage (LAA), and is available in different sizes. In PROTECT AF, the proportion of patients with no stroke, cardiovascular

death, or systemic embolism—the primary effectiveness end point—was lower in those with the device (3.4 events per 100 patient-years) compared with those on warfarin (5 per 100 patient-years), a relative risk reduction of 32%. The death rate and hemorrhagic stroke rates were 0.6% and 0.2% in the implant group, respectively, compared with 2% and 2.5% in the control group. Most of the patients had a CHADS₂ score of 1 or 2, and 32%

had a score of 1. Patients with NYHA class IV, LVEF below 30%, a recent MI or stroke, or carotid disease were excluded from the study. The results of PROTECT AF were presented in March at the American College of Cardiology annual meeting.

The manufacturer, Atritech Inc., has proposed that the device be used to prevent embolization of thrombi that “may form in the left atrial appendage (LAA),” thereby preventing the occurrence of ischemic stroke and systemic thromboembolism. Although Atritech representatives said that the LAA has been identified as the source of thrombi in most of this patient population, Dr. Julie Swain, the cardiovascular surgeon consultant to the FDA who presented an FDA analysis of the data, said that there was no “level 1 scientific evidence” supporting this premise.

Voting against approval, Dr. Thomas Vassiliades of the division of cardiothoracic surgery, Emory University, Atlanta, was concerned about the device’s use in the general population, because most of the patients in the study had a low CHADS₂ score and because 2-3 year data “were so minuscule,” he said. ■

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Hospital Errors Drop With Use of Root Cause Analysis

BY PATRICE WENDLING
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CHICAGO — As a tool for quality improvement, root cause analysis has left its mark on American business, most notably the auto and nuclear industries, but has made little headway into health care.

Root cause analysis (RCA) has been implemented at less than one-third of American hospitals, despite medical errors in hospitals claiming as many as 98,000 lives each year.

At Chicago's Northwestern Memorial Hospital, which arguably has one of the most mature RCA programs in the country, the analyses are part of a quality-improvement program that employs lean thinking and the DMAIC (define, measure, analyze, improve, and control) methodology.

RCA is a retrospective and multidisciplinary process for identifying the cause or causes of a serious adverse event, sentinel event, or "near miss." The goal is to determine what happened, why it happened, and what can be done to prevent it from happening again, Dr. Charles Watts said at the annual meeting of the Society of Hospital Medicine.

Since launching its quality-improvement program in late 2002, Northwestern has completed roughly 162 DMAIC projects, trained more than 400 staff members (including 98% of its management team) in a 1-day DMAIC course, and trained 53 staff members as improvement leaders through an advanced

6-month course, said Dr. Watts, chief medical officer and senior vice president of medical affairs at Northwestern Memorial.

The resulting improvement has influenced more than 400,000 patient encounters, yielding an average annualized financial benefit of \$7 million after program costs are subtracted.

By taking a similar approach to other problems, the hospital has achieved a 47% decrease in preventable codes outside the ICU since January 2006 and a 78% reduction in severe adverse events since 2004. Based on these figures, the hospital estimates it saved \$8 million in malpractice insurance, Dr. Watts said.

The most impressive effect of Northwestern's initiatives may be found in its delivery room. As in other delivery rooms across the country, the unit had wrestled with a predictable approach to shoulder dystocia, an unpredictable and potentially life-threatening complication during delivery. As one of the top three reasons for lawsuits in obstetrics nationally, shoulder dystocia associated with nerve injury historically translated into an automatic \$2 million settlement in Chicago's litigious Cook County, where Northwestern is located.

After analyzing the problem, the hos-

pital designed an evidence-based protocol, including documentation, and formed a shoulder dystocia rapid response team. The hospital also conducted 57 training sessions, each lasting 1 hour, to introduce all ob.gyn. providers and labor and delivery nurses to the new

At Northwestern Memorial Hospital, RCA has achieved a 78% reduction in severe adverse events since 2004.

DR. WATTS

protocol using birthing simulators and a series of drills that enabled them to practice maneuvers as a team. Part of the new protocol included communicating with the patient and family.

Since implementation of the protocol, the incidence of brachial plexus injury associated with shoulder dystocia dropped during a 1-year period from 12% to 4% (a benchmark level), and has stayed at 4%, Dr. Watts said.

Although Northwestern has reaped benefits from its use of RCA, the effectiveness of the approach in medicine is debated. A recent study suggests there are few data showing that RCAs actually improve quality of care (JAMA 2008;299:685-7). Dr. Watts said he believes the article illustrates the fundamental need to link RCA to a quality-improvement process that has the resources and buy-in from management to make the necessary changes identified in an analysis and if necessary fundamentally change the process of care.

The first step of any RCA is to construct the chronology of an event through chart reviews and interviews. This is necessary to overcome hindsight bias, or the tendency for people to assume they know the cause of an adverse outcome. Interviews are typically done by risk management personnel and completed within 48 hours of an event at Northwestern.

"It's better to do it fast because then people don't have time to get their stories straight, and you actually find out what happened," he said. "If you don't get this right, then you can't go on to the next step."

The next step is a mandatory meeting of key participants, content experts, quality-improvement experts, and hospital leadership. The focus is primarily on systems or processes, rather than individual performance. An atmosphere of confidentiality and civility must be maintained, Dr. Watts said. At Northwestern, if someone personalizes the error or criticizes another person, they will get a warning and be asked to leave the room.

The meeting should yield an understanding of the root cause(s) of the problem and approaches to quality improvement. Solutions should be easy to use, designed and tested by caregivers on the front line, and allow for feedback and modifications. Performance metrics should be defined and monitored, with follow-up available on outcomes. Finally, improvements in patient safety should be celebrated, Dr. Watts said. ■

FDA Announces Transparency Task Force

BY JOYCE FRIEDEN
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In one of her first public acts at the Food and Drug Administration, new commissioner Dr. Margaret Hamburg announced that the agency aims to be more transparent about its daily work and decision-making process.

"The agency has been referred to as a 'black box' that makes important decisions without disclosing them. The agency can and should communicate in a way that provides more transparency, not less," Dr. Hamburg said in announcing the launch of a transparency task force.

"This will be an agency-wide effort charged with figuring out how to make the FDA and its processes more transparent to the public," declared Dr. Hamburg, who took over at FDA in May.

The transparency task force will include the directors of all FDA centers as well as the agency's associate commissioner for regulatory affairs, its chief counsel, and its chief scientist. The task force met in June and plans to meet again in the fall. All meetings will be open to the public.

The task force "expects to submit a written report to the commissioner about 6 months from now," according to FDA principal deputy commissioner and task force chair Dr. Joshua Sharfstein.

Being clearer about why the agency decides things a certain way is one area of interest for Dr. Sharfstein. "People don't understand why the FDA may have done something or not done something. In many cases, the agency has an explanation, but you don't necessarily hear that explanation very clearly."

Dr. Hamburg said she expects a wide

range of recommendations to emerge. Some recommendations "will be in areas that we can implement swiftly, but there may be other types of information that will take more time, and there may be some area where we have limitations within the current law and need to examine whether appropriate changes can and should be made," she said.

Both Dr. Hamburg and Dr. Sharfstein emphasized, however, that a balance will need to be struck between providing more information and the appropriate use of confidentiality.

Another balancing act will come in terms of clinical trials, Dr. Sharfstein continued. "What is the argument for different amounts of data [being disclosed] at different points in the drug development process, and on the other side, what are the confidentiality concerns and the reasons for them?"

The call for transparency comes at a time when FDA already has a backlog of requests under the Freedom of Information Act. Asked how she planned to handle personnel needs at a time when the agency is behind in its work, Dr. Hamburg said, "When the recommendations come in, I will work with the task force and others on implementation. Some activity may result in more work, and some may result in decreased work. If we make more information available, there may be fewer Freedom of Information Act requests and citizen petitions." ■

More information about the formation of the task force is available online at www.federalregister.gov/OFRUpload/OFRData/2009-12902_PI.pdf. Comments on the task force's mission are being accepted through Aug. 7.