Guidance aims for safer use of lab data in EHRs

Kevin B. O'Reilly

March 2014—A wide-ranging set of recommended health information technology safety practices recently issued by the Department of Health and Human Services is likely to accentuate the essential role that pathologists and laboratory leaders play in minimizing the adverse consequences of health IT.

Pathologists and lab experts involved with developing the guidance say it could serve as a North Star for how health care organizations can improve IT safety, especially with regard to better test tracking and results display. But some of the functionalities the recommendations call for are not yet widely available, and the recommended practices could represent a big implementation challenge for laboratories.

The recommendations, dubbed Safety Assurance Factors for Electronic Health Record Resilience, were released as nine separate self-assessment guides encompassing 158 best practices that are designed for health care organizations to complete in consultation with their IT vendors. These so-called SAFER guides were released in January by the HHS Office of the National Coordinator for Health Information Technology, or ONC.

Teresa Darcy, MD, served as a pre-release reviewer for the SAFER guide that focuses on test results reporting and followup. She is medical director for clinical laboratories at the University of Wisconsin Hospital and Clinics.

"The labs should look at this as a good roadmap, a kind of checklist to insist that patients are safer," she says.

The guidance comes in response to rising concern over how the move from paper to electronic systems is leading to instances of IT-related patient harm. A November 2011 Institute of Medicine report, "Health IT and Patient Safety: Building Safer Systems for Better Care," called on the federal government to develop a system to monitor these IT hazards and work to prevent them. The SAFER guides represent one part of the ONC's broader response, detailed in its July 2013 "Health IT Patient Safety Action and Surveillance Plan." The guides are available as downloadable, interactive PDFs at www.healthit.gov/saferguide. They were beta-tested with a handful of inpatient and outpatient sites in Texas and California.

The SAFER guides are designed to inspire productive, multidisciplinary, interdepartmental collaborations on how to reduce IT-related hazards, says Hardeep Singh, MD, MPH, one of three experts who developed the checklists under contract from the ONC. He is associate professor of medicine at Baylor College of Medicine and chief of the Health Policy, Quality and Informatics Program at Michael E. DeBakey Veterans Affairs Medical Center.
"It's not an us versus them situation," he says. "It's about people coming together, talking about EHR safety, and bringing whatever it takes to improve patient safety and make patient safety the priority. That means having meaningful conversations with my vendor, with my lab person, maybe with my quality officer, maybe my office manager and CEO to make sure that what we do is right. Now that we have this technology in medicine, we have to figure out how to make it work. We can't go back to paper."

The guides cover a sweeping set of areas relevant to a health care organization's approach to IT safety issues, dealing with topics such as organizational responsibilities, contingency planning, system interfaces, system configuration, clinician communication, patient identification, and computerized physician order entry with clinical decision support. Each of these checklists includes guidance that touches upon the laboratory world.

For example, the patient identification guide recommends that the correct ID be verified at key points in the care process, including test order entry. The CPOE guide, meanwhile, calls for the EHR to allow cancellation and acknowledgment of receipt of laboratory tests and other orders. The CPOE checklist also says the IT systems should automatically suggest and group together corollary or followup tests so that changes are reflected when the original order is rescheduled, renewed, or discontinued. To help address alert fatigue, the CPOE guide also says pop-ups should be limited to laboratory and other orders related to high-risk, high-priority conditions.

The SAFER guide on test results reporting and followup includes 23 recommended practices that target how tests are ordered, stored, structured, reported, acknowledged, amended, flagged, tracked, and followed up on within the EHR. Among other things, the guide recommends that:

- Test names, values, and interpretations for laboratory results are stored in the EHR as structured data using standardized nomenclature.
- Predominantly text-based reports (e.g. radiology or pathology reports) have a coded (e.g. abnormal/normal, at a minimum) interpretation associated with them.
- Display of results (e.g. numeric, text, graphical, or image) should be easily accessible, clearly visible (and not easily overlooked), and understandable. For other recommendations, see the Box.

The need for this kind of organizational self-assessment of the test results reporting and followup process seems clear, as studies have found that health IT is not eliminating paper-related mixups and sometimes creates new problems. A study led by Dr. Singh found that office-based physicians using the EHR at a VA facility failed to acknowledge alerts about clinically meaningful abnormal imaging results 18 percent of the time.

Advice on handling test results in EHRs

Of the 23 items in a recently released checklist for improving test results reporting and followup in EHRs, these are especially notable, experts say. The complete list is available at http://tinyurl.com/safertest.

- The EHR is able to track the status of all orders and related procedures (e.g. specimen received and collected or test completed, reported, and acknowledged).
- The ordering clinician is identifiable on all ordered tests and test reports and, if another clinician is responsible for followup, that clinician is also identified in the EHR.
- Send-out tests are electronically tracked, and their results are incorporated into the EHR with a coded test name, result value, and interpretation. n Written policies specify unambiguous responsibility for test result followup with a shared understanding of that responsibility among all involved in providing followup care.
- There is an EHR-based process for clinicians to either assign surrogates for reviewing notifications or enable surrogates to look at the principal clinicians' inboxes.
- There are mechanisms to forward results and results notifications from one clinician to another.
- Summarization tools to trend and graph laboratory data are available in the EHR.

- As part of quality assurance activities, organizations monitor practices such as clinician followup on abnormal test results and address test results sent to the wrong clinician or never transmitted to any clinician (e.g. due to an interface problem or patient/provider misidentification).

Nearly eight percent of the time, the ordering doctors failed to take action on the results within a month. More than a quarter of the tests that initially were overlooked resulted in the diagnosis of a new disease, with 42 percent of those being cancer diagnoses (*Arch Intern Med.* 2009; 169(17): 1578–1586).

Many of the SAFER guide recommendations are aimed at using computing power to help prevent ordering physicians from overlooking results, Dr. Singh says.

“We want to separate the signal from the noise,” he says. “We need to figure out how to code that signal so the computer knows what’s the signal versus what’s noise.”

Sawchuk

Then there are the cases where seemingly simple formatting issues lead to big problems, says Megan E. Sawchuk, MT(ASCP), a health scientist in the Centers for Disease Control and Prevention’s Division of Laboratory Program, Standards, and Services. Sawchuk and her colleagues on the LabHIT Team reviewed the SAFER guides before they were released for use. Through their work, Sawchuk is familiar with a case in which the EHR truncated the text in a report. Instead of saying “No cancerous cells seen,” as was intended, the “no” was truncated so that the text read, “Cancerous cells seen.”

At one major academic medical center, the IT vendor used an exclamation point as a flag for critical values. This was placed in front of a glucose result that was abnormally low. But that exclamation point was mistakenly read as a 1 preceding the abnormally low number, making the result appear to be above normal. The patient received insulin and had an adverse outcome, Sawchuk says.

“That’s a great example of a very small formatting issue that probably made a lot of sense to the people who programmed the system, but when it was implemented it was not really usable in the clinical setting,” Sawchuk says.

“The majority of the recommended practices in the SAFER guides are elements that laboratory professionals would already expect to see on their test reports,” she adds. “The laboratory has gone to great effort and pain over numerous decades to format lab reports in ways that are highly readable and interpretable by the clinician. But now we’re converting to an almost 100 percent electronic environment and the lab is no longer really in charge of the format that’s getting transmitted downstream. The SAFER guides empower the laboratory professionals to step out of the lab and see how things are actually being implemented, and also to be able to identify the issues and communicate them to their internal leadership, their CIO, and EHR vendor.”

Dr. Darcy, from the University of Wisconsin labs, also notes the difficulty with properly transmitting results from the laboratory information system to the EHR.

“Laboratorians have to be in the electronic record looking at lots and lots of results when building it into the test environment, and after production,” she says. “So when we get a call from the clinician that they didn’t get a

result, we have to see what they saw. Something that works well in the lab system doesn't necessarily translate well into the electronic record."

In a recent medical journal article she co-wrote, Dr. Darcy noted several other examples of problems with displaying lab results. For example, many EHRs do not allow commas and don't justify columns of data at the decimal point. This makes it hard to interpret numeric data. "A tumor marker of a result of 2220 may be misinterpreted as 22220 and vice versa," the authors write (Walz SE, et al. *Clin Lab Med.* 2013; 33(1):183–194).

Dr. Hoffman

Noah Hoffman, MD, PhD, says many of the ONC recommendations will pose a challenge to labs because they are items that are outside their direct control and sometimes not yet technically possible. Dr. Hoffman is assistant professor in the Department of Laboratory Medicine at the University of Washington Medical Center and associate director of its informatics division.

"Many of these imperatives really force coordination between the lab, and providers, and other users of the EHR system, which is probably the intent," he says. "Assessing the feasibility of these things will depend on who your partner is and whether you're working toward the same ends."

Addressing the problem of too many test result alerts is one example where collaboration will be essential, Dr. Hoffman says.

"The directive to reduce alert fatigue is important, but it's not a trivial undertaking to work with the providers who will be receiving the results to arrive at mutually agreeable criteria for sending notifications," he says.

"Many labs have the concern that providers do err on the side of only looking at results that are flagged as positive or abnormal," Dr. Hoffman adds. "That's a very crude measure of whether something is worth looking at. I think our lab has the concern that important negative results might not be reviewed."

Another significant challenge is the recommendation to use coded names for all send-out tests, which are often now categorized as miscellaneous reference tests. "To have a coded test name—that implies you've created a battery with the coded test names and corresponding entries. Creating a defined test is a process. The overhead of doing that for one-off tests is pretty high," he adds. "Right now, it's just too tall an order."

Dr. Hoffman notes that the separate recommendation to send more than 40 percent of results as structured data is already a core requirement for stage one of meaningful use under the Centers for Medicare and Medicaid Services' EHR incentive program. Despite the requirement, a February ONC data brief found that one-third of about 5,000 randomly sampled labs surveyed in May 2013 lacked the capability to electronically send results in structured format to an EHR.

In extensive comments, the Electronic Health Records Association—which represents EHR vendors—expressed concern that some recommendations were not technically feasible. For example, the ONC says that all critical result details should be displayed on one screen without scrolling to allow for easier interpretation. But, the EHRA notes, "This is device dependent and not all form factors will support a full display."

Sarah Corley, MD, chairs the association's patient safety workgroup and is chief medical officer at IT vendor NextGen Healthcare. She says the SAFER guides should evolve in consultation with EHR vendors and as technology changes.

“We think this is a great idea,” she says of the ONC guidance. “But some of the recommendations include functionality that isn’t widely available right now. For the most part, the recommendations are what vendors have been recommending for our clients. We applaud having a neutral party recommend these items to have safe, effective implementation of IT use.”

In response, Dr. Singh says he is aware that some of the recommendations may depend on IT functionalities that are not yet available.

“That’s the point. The systems have to get better and we have to have innovations,” he says.

Better IT systems should dovetail with laboratory professionals’ efforts to improve quality assurance, says Kim Futrell, MT(ASCP), products marketing manager at LIS vendor Orchard Software.

“The lab down in the basement is doing QA on everything they can think of, but it rarely reaches beyond the lab. Having QA processes in place can only make EHR usage better and increase patient safety,” she says. “For example, followup on items such as clinician use of results in the EHR, and results sent to the wrong clinician, absolutely needs to be reviewed and acted upon. How can you fix these errors and processes if you aren’t tracking them?”

Dr. Henricks

Laboratory leaders have an imperative to take a greater, hands-on role in how the EHR is chosen, implemented, and monitored for its impact on lab quality, safety, test utilization, and more, says Walter H. Henricks, MD. He is medical director of the Cleveland Clinic’s Center for Pathology Informatics and vice chair of the CAP’s Diagnostic Intelligence and Health Information Technology Committee.

“We have to accept that EHR issues as they relate to laboratory data are part of running the lab,” he says. “Laboratories need to allocate resources to this activity. Someone has to pay attention to the orders coming in and how the results are displayed. That’s the bread-and-butter stuff.

“This should be part of lab management, like a quality management plan, or an accreditation plan, is,” Dr. Henricks adds. “It’s an important role in patient care, just as validating a new assay or validating a new instrument is.”
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