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INSIDE

EPs welcome new focus on reducing diagnostic errors

Lengthy report calls for large, systemic changes, including liability reforms, new mechanisms to facilitate provider feedback

Sixteen years after its heralded "To Err Is Human: Building a Safer Health System"[1] report, which precipitated a continuing push for improvements in safety and quality, the Institute of Medicine (IOM) is now taking direct aim at diagnostic errors. In a new 369-page report, "Improving Diagnosis in Health Care," the authors conclude that while most people will likely experience a significant diagnostic error in their lifetime, the importance of this problem is under-appreciated.

Specifically, the report suggests that according to conservative estimates, 5% of adults who seek outpatient care each year experience a diagnostic error, and that research over many decades shows that diagnostic errors contribute to roughly 10% of all deaths. The authors also note that medical record reviews indicate that diagnostic errors cause 6% to 17% of hospital adverse events. They further point out that diagnostic errors are a key driver of medical malpractice claims. In short, the IOM report states that diagnostic errors continue to occur in all types of care settings, and that they cause harm to an unacceptably high number of patients.[2]

> WHILE ARRIVING AT A CORRECT DIAGNOSIS CAN OFTEN BE CHALLENGING, LEADERS SEEM READY TO EMBRACE SWEEPING CHANGES.

It's an issue that is of particular concern to emergency physicians (EPs), many of whom make scores of diagnoses every week, often under pressure and extremely stressful circumstances. While arriving at a correct diagnosis in the emergency setting can often be challenging, emergency medicine lead-

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ers seem ready to embrace a number of the sweeping recommendations for improvement made in the IOM report.

Tort reform is key

Michael Gerardi, MD, FAAP, FACEP, president of the American College of Emergency Physicians, praises the investigators involved in the IOM report, and suggests EPs are likely to support the findings.

"This is not the real, definitive plan, but [the report] does a good job of highlighting what the problem areas are to try to get to the bottom of this and come to some solutions," he explains. "We should think about this a lot ... one of our biggest risks as EPs is diagnostic error."

> THE REPORT CALLS FOR MORE INTER-PROFESSIONAL AND INTRA-PROFESSIONAL TEAMWORK THROUGHOUT THE DIAGNOSTIC PROCESS.

Of particular interest to Gerardi is the report's call for changes to the reporting environment and medical liability system so that healthcare professionals are encouraged to identify and report diagnostic errors and near misses. This is closely related to another recommendation in the report that calls on healthcare organizations to establish a culture that supports improvements in the diagnostic process, including policies and practices that encourage a non-punitive environment for reporting errors.

"I am all for transparency and exposing the problems in making an accurate diagnosis if there is protection for highlighting and researching this area," Gerardi says. "Right now, if you admit to making a mistake regarding safety or quality, and if it is not in a tightly controlled hospital peer-review, it is discoverable. People keep things very contained and are hesitant to share."

Gerardi notes that litigation is a constant threat, even when EPs closely adhere to the recommendations of national guidelines.

"There are always doubters who say [the guidelines] are not 100% reliable and that you should use your own clinical judgement," he says. "There are all these countervailing forces. [People] want us to decrease testing and follow guidelines and pathways, and yet there are no protections if we do."

Improve HIT, teamwork

Another recommendation suggests ensuring that health information technology (HIT) supports both patients and providers in the diagnostic process. On this point, Gerardi is particularly keen on interoperability and the importance of being able to access patient medical records.

"When you have a good central repository for records, and/or physicians who know the patient, it makes it so much safer to have follow-up so that [these physicians] can continue the workup, and not

try to come up with the diagnosis in the ED all the time," Gerardi explains. "Health information exchanges [HIE] are going to help improve that. In some environments where I have worked, I was able to bring up every CT a patient had within 50 square miles."

However, when such records are not readily available, and a primary care physician (PCP) is not accessible, the EP is sometimes unfairly blamed for initiating an expensive workup, Gerardi notes.

This point also relates to teamwork, the focus of another recommendation from the IOM report. The authors state that more steps should be taken to facilitate inter-professional and intra-professional teamwork throughout the diagnostic process. The recommendation refers to collaboration among pathologists, radiologists, and other healthcare professionals. It also stresses that patients and families should be included in the diagnostic process.

"I find it very hard to get someone's PCP to call me during the time when people tend to present [to the ED], which is after [normal business office] hours," notes Gerardi, adding that he hears similar complaints from the accountable care organization (ACO) that operates in his region. "The ACO laments about the fact that they don't get notified when their patient was [in the ED]."

Part of the problem is that some electronic medical record (EMR) systems are not robust enough to communicate with other systems, but that isn't the only issue.

"A lot of physicians are hesitant to get on their computers and log into a hospital portal for labs and [other information] on patients who have been there," Gerardi notes. "There is a lag in the culture."

EXECUTIVE SUMMARY

Emergency medicine leaders welcome a major new report from the Institute of Medicine (IOM) calling on providers, policy makers, and government agencies to institute changes to reduce the incidence of diagnostic errors. The 369-page report, "Improving Diagnosis in Health Care," states that the rate of diagnostic errors in this country is unacceptably high and offers a long list of recommendations aimed at addressing the problem. These include large, systemic changes that involve improvements in multiple areas, including health information technology (HIT), professional education, teamwork, and payment reform. Further, of particular interest to emergency physicians are recommended changes to the liability system.

- The authors of the IOM report state that while most people will likely experience a significant diagnostic error in their lifetime, the importance of this problem is under-appreciated.
- According to conservative estimates, the report says 5% of adults who seek outpatient care each year experience a diagnostic error. The report also notes that research over many decades shows diagnostic errors contribute to roughly 10% of all deaths.
- The report says more steps need to be taken to facilitate inter-professional and intra-professional teamwork throughout the diagnostic process.
- Experts concur with the report's finding that mechanisms need to be developed so that providers receive ongoing feedback on their diagnostic performance.

Institute feedback mechanisms

The IOM report calls for improvements in professional education in the diagnostic process, noting that training should be based on evidence and cover such topics as the appropriate use of testing and HIT, teamwork, communications, and clinical reasoning. The report also calls on professional organizations to ensure clinicians maintain competency in these areas.

Gerardi agrees that these elements should be a focal point for future improvements, but he also points to the ACEP's expert panel on Ebola as one way the emergency profession is stepping up efforts to ensure that frontline clinicians quickly receive the information and education they need to make accurate diagnoses.

"The panel can stand up within hours and start preparing [information] for physicians," he explains.

It's an example of the type of professional collaboration that will help to prevent missteps like those that occurred last year when a patient with Ebola was misdiagnosed on his first trip to a Dallas ED, touching off a nationwide crisis, Gerardi explains. He adds that the ACEP and the CDC have collaborated in similar fashion to address measles outbreaks and other infectious threats.

In another recommendation, the IOM report calls for developing approaches to identify and learn from diagnostic errors. The authors say this requires action on several fronts, from accreditation organizations to government agencies and providers themselves. Such efforts should include methods for monitoring the diagnostic process and mechanisms for providing feedback on diagnostic

CONSIDER ENVIRONMENT, CONTEXT WHEN REDUCING DIAGNOSTIC ERRORS

In developing ways to reduce diagnostic errors, it is important for emergency physicians to consider not just their thought process or skill level, but also the impact of contextual factors, observes **Robert Trowbridge**, MD, FACP.

"Recently, we've come to recognize the importance of context on diagnostic reasoning, not just the content of a particular encounter, but also factors specific to the patient and the environment," he explains.

For example, whether the ED is busy or quiet, crowded or empty, or whether it is day or night are all factors that can impact diagnostic reasoning, notes Trowbridge, who has performed extensive research on the factors that contribute to diagnostic errors.[1,2]

"What we may do with a specific patient may vary greatly depending on the environment we're in, even if the patient presentation is absolutely identical," he says. "We need to be cognizant of these contextual factors when we're looking at the decisions we make and the outcomes we have."

Trowbridge notes that the way a patient makes a clinician feel can impact the diagnosis process.

"We like some patients and don't like other patients, and this affects our thinking," he says. "We may have a difficult time admitting or acknowledging this, but it really can have a significant effect. In addition, clinician fatigue, burn-out, emotional state, and a whole host of other physician-based factors can have an impact on our thinking in an individual situation."

What can healthcare leaders and administrators do to ensure that such factors do not negatively impact diagnostic accuracy? Trowbridge states that they need to support clinicians.

"Ensure they have adequate time, space, and support to do the work they need to do," he says. "Ensure there is adequate back-up when times are busy [and] build a culture that not only condones, but promotes asking for help." ■

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performance to individual providers, as well as care teams and clinical leaders.

Robert Trowbridge, MD, FACP, the division director of General Internal Medicine at Maine Medical Center in Portland, ME, is pleased to see this recommendation, as he provided input to the investigators preparing the IOM report.

"As it stands right now, we tend not to use identified errors as a means of personal and institutional improvement, and that needs to change," he says. "We need to have systemic and rigorous means of identifying errors on multiple levels and, just as importantly, have a means of responding to those errors." (*See above "Consider environment, context when seeking to reduce diagnostic errors."*)

Trowbridge adds that clinicians often do not hear about when they made a decision that resulted in a bad outcome, much less when they made a decision that resulted in a good outcome. This is certainly the case for EPs, as they do not often see or hear from their patients after they have been discharged from the ED.

"We need to have all sorts of feedback on our diagnostic performance, good and bad, if we're going to improve as individual clinicians," he explains. "We need to have learning clinicians within learning institutions within a learning healthcare system. Feedback on performance is key to achieving this."

Take action to improve

Other recommendations in the IOM report call for changes to the payment and care delivery environment so that needed tests and evaluations are fully covered. Additionally, the report also calls for more dedicated funding specifically for research pertaining to diagnostic errors.

Gerardi acknowledges that all the recommendations outlined in the IOM report involve big, systemic changes that will be difficult to implement, but he reiterates that they represent steps that EPs can get behind.

"The [ACEP] supports this because we can have an open discussion now about what is a good way to approach diagnosis, and what is an acceptable error rate and what is not," he explains. "I would like to see an open debate."

Trowbridge suggests that the IOM did a good job of tackling a very difficult issue, and he is hopeful that providers, policy-makers, and other stakeholders will move without delay to implement many of the report's recommendations.

"There really is no excuse for an

institution not to immediately examine what it has been doing in terms of diagnostic error and what it needs to do now," he says. "As the IOM points out, nearly every American at some point in his or her life will be subject to a diagnostic error. You can't say that about many other patient safety issues." ■

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Adequate number of clinicians on usability tests lacking, says study

Experts say more clinicians need to be willing to participate in EMR usability tests, document and report challenges to vendors

Electronic medical records (EMR) were always supposed to make things better for emergency clinicians, but they have turned into a major source of aggravation. Critics say they operate too slowly, interfere with the natural workflow of a busy ED, and forces clinicians to work harder to find information. New information suggests why, at least in part, this may be the case.

An analysis of the usability tests performed by 41 of some of the largest EMR vendors shows that 34% of vendors did not meet certification standards established by the Office of the National Coordinator for Health Information Technology (ONC), specifying that they state their user-centered design process. Further, 63% of the vendors failed to include at least 15 representative end-user participants. In fact, only 15% of the vendors used at least 15 participants who had clinical backgrounds. The authors, led by **Raj Ratwani**, PhD, scientific director of the National Center for Human Factors in Healthcare at the MedStar Institute for Innovation in Washington, DC, note that one vendor didn't use any clinicians in its usability testing, 17% of the vendors didn't have any physician participants, and 5% used their own employees to conduct the usability tests.[1]

"Certainly our results don't speak to all vendors, but the results do show that there seems to be tremendous variability in the vendors' user-centered design processes, and their employment of different usability processes overall," Ratwani observes. "Unfortunately, we are seeing some vendors that are running [usability tests with] only a handful of participants, and they are not stating their user-centered design process."

Ratwani stresses that some vendors do an exceptional job with their usability tests, going above and beyond the certification requirements. When following such practices, Ratwani notes that it is clear from the literature that 95% of any usability challenges that a user might face are captured. However, he notes that the high variability in the user-centered design processes used by vendors is a problem.

"If all vendors were adhering to the certification requirements, we really should not be seeing so much variability," he says.

What is not clear from the study is why EMR products that have not met the standards for usability testing have been certified.

"It could be that the authorized certification bodies that are tasked with reviewing the actual reports from the vendors may not have clear guidance as to what the requirements actually are," Ratwani suggests. "The requirements may be a little bit unclear and there could be some confusion on what vendors are actually supposed to do, but that is an open question as to why there are vendors who appear to not be meeting the requirements who are being certified."

Despite the troubling findings, there are things that emergency

providers can do to ensure that their own organizations select products that meet certification standards, and that these products are optimized to meet their needs. Further, it is important to understand that while individual clinicians may prefer one EMR product over another, whether or not a product meets usability standards is another matter entirely.

Consider components of usability

Usability is not in the eye of the beholder, Ratwani stresses.

"It is a subcomponent of human factors, which is a science, and there are quantitative measures of usability," he explains, noting that the measures generally fall under three categories:

- effectiveness, which captures what kinds of errors participants make;
- efficiency, which is how long it takes for people to complete tasks;
- satisfaction.

Ratwani notes that the certification requirements reflect guidelines that have been established by the National Institute of Standards and Technology (NIST), which recognizes the three components of usability.

While there are well-developed measures around each of these three different components, there will be variability in the participants and the speed with which they perform tasks, Ratwani says.

"Include enough participants to ensure that you are capturing the majority of what people would do when they are working with these tasks," he explains. "When the tests are performed properly, you generally end up with a usable and safe product."

Usability testing is certainly not unique to healthcare, Ratwani notes.

"If you looked at any other industry, whether it be defense, aviation, or nuclear regulation … each of those different domains takes usability very seriously and measures it in a quantitative way to ensure that a product is usable and safe," he says.

Ratwani acknowledges that sometimes there are tradeoffs between safety and efficiency, and that those decisions should be made by the developers and the designers of the software that goes into EMR systems.

"That is not a new problem. We have seen that in several industries," he says. "But all those components are measured."

Participate in usability testing

While some of the chief critics of EMR products are the physicians and nurses who use them, EMR vendors say it is difficult to get these end-users to actually participate in usability testing. Ratwani has visited a number of EMR vendors to observe their user-centered design practices and hear about their challenges. He acknowledges that a number of these companies struggle to assemble representative groups of users to test out their products.

"The ability to get physicians and nurses to engage in the user-centered design processes and be participants in these studies … is difficult and expensive," he says.

However, Ratwani emphasizes that usability tests are a core component of the process.

"If we suggest and even require vendors to engage in these usability processes, which is the right path, that means that end-users need to be willing to participate in these studies," he says. "We can't blame only vendors for the challenges we are seeing in [EMR] usability. This is not a vendor-centric problem. There are several different things we need to change in order to improve these products and one of those is getting end-users to participate in these

EXECUTIVE SUMMARY

A new study reveals that some of the largest EMR vendors failed to meet certification standards, specifying that they state their user-centered design processes, and that they include at least 15 representative end-user participants in their usability tests. It is not clear why these vendors were certified despite not meeting the standards established by Office of the National Coordinator for Health Information Technology (ONC), but investigators suggest that emergency clinicians and administrators should engage with vendors early on, querying them about their user-centered processes.

- An analysis of the usability tests performed by 41 of some the largest EMR vendors found that 34% of them did not meet certification standards, specifying that they state their user-centered design process. Also, 63% of the vendors failed to include at least 15 representative end-users in their usability tests.
- Only 15% of the vendors used at least 15 participants who had clinical backgrounds in their usability tests.
- Experts urge clinicians to engage with EMR user groups to share best practices for optimizing specific EMR products.

studies."

What else can frontline emergency clinicians and ED administrators do to improve the usability of their EMR systems? Ratwani says that it is critically important to document the challenges with the system and to convey these challenges to the vendor.

Busy clinicians develop workarounds, becoming accustomed to various capabilities and functionalities within the EMR that are not working properly, Ratwani notes.

"However, without reporting those issues, documenting them, and sharing them with the [EMR] vendor, it is very difficult for the vendor to make improvements," he says.

It will take extra time, and clinicians may not receive immediate feedback from such reports, but without capturing and reporting problems, the vendors will not be aware of them, Ratwani adds.

Ask about user-centered processes

For hospital administrators or ED professionals who are in the market for a new EMR, be sure to investigate the usability processes that each vendor has employed in developing their product, Ratwani advises.

"There is currently no *Consumer Reports* for [EMR] vendor products, but that shouldn't stop clinicians from querying vendors about the user-centered processes that were employed," he notes.

For instance, Ratwani suggests providers ask questions such as:

- How do you build a usable product?
- How many participants tested your product?
- What were the backgrounds of the testing participants?

LOOK OUT FOR RAPID TASK-SWITCHING, POTENTIAL ERRORS

A new study raises concern about the potential for safety lapses that can occur when an ED transitions from a home-grown EMR to a commercial product. Observing 14 EPs over a four-month period during which their ED transitioned to a new commercial EMR product, investigators from the National Center for Human Factors in Healthcare (NCHFH) at the MedStar Institute for Innovation observed that the physicians performed more tasks per minute following the transition to the new EMR than they did on the older system.[1]

Specifically, the investigators found that the number of tasks physicians engaged in per minute increased from 1.7 prior to implementation of the commercial EMR to 1.9 following implementation, and the higher rate was sustained even three months after the transition to the new EMR system.

Raj Ratwani, PhD, a co-author of the study, notes that while investigators did not measure errors, they know from the large body of human factors and cognitive science literature that this sort of very rapid task switching and increased task load has a measurable impact on individual stress levels. "We also know that this rapid task switching increases the likelihood of error," he explains.

It's a problem that both providers and administrators need to be aware of given the high number of such EMR-transitions that are taking place. "Home-grown systems tend to be very customized to the work processes of that particular institution, and sometimes they are a really good fit because they've specifically been developed to meet their needs," Ratwani says. "In transition, it is important to see where the breakdowns may occur as people move to a more commercially available product that doesn't have all of that customization."

The study results resonate with **Christopher Corbit**, MD, FACEP. "When we were going from a home-grown system to an enterprise HIS [health information system], the amount of clicks I had to perform went up 10-fold just to do discharge instructions," he recalls.

HIS systems focus on the entire hospital, making them not as focused as ED information systems, Corbit observes. "There is just not that optimization," he offers. However, Corbit acknowledges that more healthcare organizations are moving away from software products that cater to niche departments, such as the ED, in favor of enterprise systems.

Before making such a transition, Ratwani advises clinicians to carefully consider their entire workflow process, from the moment they begin to see a patient through the process of ordering medicines and viewing lab results. It is a matter of thinking about how things happen in a particular ED to ensure clinicians don't see either increased task switching or segmented workflows that can be very frustrating, Ratwani observes.

Such attention on the front end of the implementation of a new EMR product requires an investment of time, expertise, money, and other resources, Ratwani adds. But he emphasizes that these investments are worthwhile. ■

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• Was the EMR tested with EPs and emergency nurses?

• Under what conditions was the EMR tested?

• Was the EMR product tested with appropriate use cases that represent the way EPs and nurses perform their work?

Such questions reveal the usability and safety of a product, and provide clinicians a better understanding of what processes vendors are using, Ratwani observes.

"That can shape your decision-making in selecting a product," he says. (*See also: "Look out for rapid task-switching, potential for errors," p. 139*)

While some vendors give clinicians an opportunity to use their EMR products before a purchase decision, the value of such an experience is limited because the EMR on display does not actually represent what the clinicians will use once the customization process has occurred, Ratwani explains.

"What you are using early on during the decision-making process doesn't always match what you get when you actually purchase and use the product," he says. "That discrepancy can be a real challenge … and points to one area where we need to focus when we start talking about how we might change or modify certification requirements to really make … usability more optimal."

Engage with EMR vendors

Christopher Corbit, MD, FACEP, the chief medical informatics officer for Emergency Medicine Physicians, suggests the alignment of financial incentives affects the usability of EMRs.

"The [EMR] vendors don't sell to end-users. Typically, they sell to hospital boards and CEOs, and a lot of the decisions come from the CFO on which products to go with," he explains. "I have been through many vendor selection committees, and there is always talk about how the end-users would feel. [The committees] bring the vendor in and perform a demo. The doctors will take a quick peek, but they never engage in a real, in-depth, hands-on, full analysis of exactly how [the EMR product] is going to affect workflows."

Therefore, EMR development is not geared toward clinicians, but rather what makes the system work best for administrators and hospital executives, Corbit notes.

> EMR DEVELOPMENT IS NOT GEARED TOWARD CLINICIANS, BUT RATHER WHAT MAKES THE SYSTEM WORK BEST FOR ADMINISTRATORS AND HOSPITAL EXECUTIVES.

"That is the environment that makes it difficult for physicians to use [EMR systems] because they don't put the majority of the work into fine-tuning the workflows and the user interfaces for clinicians to use the system," he says.

However, Corbit explains there are some steps that could mitigate this problem.

"The issue lies both with administrators and the physicians. A lot of physicians don't put the time in that they need to evaluate the systems because they are very busy, and [usually] this is uncompensated time," he explains. "Hospitals don't budget for physicians to take a significant amount of time to look at the workflows."

Corbit also emphasizes that EPs need to be part of the vendor selection process, and not just because they would pick a better system for their own workflow purposes.

"If they are engaged from the beginning, even if they still end up with the same EMR system … the amount of effort that they will put into it will be higher because they have been part of the process."

Further, once an EMR vendor is selected, clinicians should be brought into the process right away to discuss building the system.

"Some systems are more built out than others, but each one still requires work. Getting clinicians [involved] at the very beginning and mapping out workflows is not done as well as it could," Corbit says. "Many physicians don't want to do this without some sort of compensation, and, often, hospitals don't offer that, or don't budget it into their planning, so they don't have it."

However, Corbit observes that if clinicians are not engaged in this build-out process, there is often dissatisfaction with the system.

Assemble in-house expertise

Corbit agrees with the notion that there is not enough communication between end-users and EMR vendors.

"Typically, end-users don't talk to vendors, so there needs to be some work on [the part of] hospitals to create a committee that looks at these issues, has a direct line to the vendor, and to work directly with the vendor," Corbit suggests.

However, Corbit adds that what many physicians don't understand is that a lot of the improvements that clinicians would like to see are actually passed on to a hospital's IT staff to carry out.

"Each hospital can make tweaks in the system to make it better," Corbit notes, but adds that hospitals often don't have the staff or in-house expertise to make the needed improvements. "A systems analyst may not have the training or knowledge to really perform some of the more advanced work in the EMR. I have seen some hospitals that do have [this expertise], and the clinicians are much happier."

Consequently, Corbit would like to see hospitals take steps to ensure they have the appropriate expertise to be responsive to requested tweaks to their EMR systems, and to develop processes for handling such requests. But he reiterates that physicians need to be more engaged.

"Employ someone who has an interest in [health IT], wants to take up the cause, and wants work on this," he advises. "They need to develop the networking and the relationships to get their voices heard in the hospital, and to get connected with the vendor."

Corbit explains that this physician representative needs to work with the hospital's IT staff, get to know both the hospital's CIO and CEO, and to push to get on committees that talk about information technology and EMRs. Further, the physician representative needs to be on the team at the hospital that talks directly with the vendors, Corbit observes.

"Be there at the table because the vendors need to hear from the hospital," he says.

There is no question that clinicians tend to get frustrated with the process, but there are times when vendors do listen, Corbit observes.

"Vendors aren't evil empires," he notes. "The problem is the financial incentives and who the vendors are trying to please, and unfortunately, right now [a lot of them] are not focused on the users."

HOSPITALS SHOULD TAKE STEPS TO ENSURE THEY HAVE THE APPROPRIATE EXPERTISE TO BE RESPONSIVE TO REQUESTED TWEAKS TO THEIR EMR SYSTEMS AND DEVELOP PROCESSES FOR HANDLING SUCH REQUESTS.

Participate in user groups

One tactic that can be very helpful in guiding improvements to EMR systems is for clinicians to engage in EMR user groups. Various EMR vendors offer some of these, but practice groups can also develop their own user groups. For instance, Corbit notes that EMP has developed a user group around each EMR used so that clinicians from different hospitals can come together and share ideas they have employed to improve the system.

"There is a lot of variability with the same EMR between different institutions," Corbit notes. "I have seen how each hospital handles their build and what they have done with their build. Some have done amazing things with the tracker board, and some have done amazing things with CPOE [Computerized Physician Order Entry]."

In fact, this sharing of ideas within the user groups gives Corbit hope that EMRs will eventually fulfill their promise.

"I have seen a lot of good things," he says. "The vendors take pride in their systems and they want them to be the best, so over time [they] will chip away. [The improvement] is just slower than what people were hoping for." ■

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DOJ turns up heat on individuals for illegal coding/billing practices

This quarterly column is written by Caral Edelberg, CPC, CPMA, CAC, CCS-P, CHC, President of Edelberg Compliance Associates, Baton Rouge, LA.

The Department of Justice (DOJ) Office of the Deputy Attorney General released a memorandum on September 9 that outlines the tough stance DOJ plans to take on individuals involved in corporate fraud. The "Individual Accountability for Corporate Wrongdoing" memorandum initiates a move toward holding individuals as well as corporations accountable for corporate misconduct and indicates that the government will take a much stronger approach to finding and punishing the individuals involved in corporate misconduct.

What does this mean for coding and billing vendors, as well as emergency medicine practices? Individuals involved in illegal billing practices may be held accountable, along with the corporations that employ them if they participated in illegal coding and/or billing practices or knew about the commission of the illegal activities. By extending accountability to individuals who knowingly participated in corporate misconduct, the DOJ hopes to increase the amount of employee participation in corporate investigations.

Investigations will require that corporations accused of misconduct identify all individuals who may have known of or participated in corporate wrongdoing. The DOJ plans to fully leverage its resources to identify culpable individuals at all levels in corporate cases. Coming from a workgroup of senior attorneys with significant experience in corporate wrongdoing, the DOJ has identified what they believe to be the most effective methods to pursue individuals, not just corporations, for corporate wrongdoing.

The DOJ will focus on six key steps to strengthen the pursuit of individual corporate wrongdoing. Some of the goals of the DOJ reflect policy shifts in order to strengthen enforcement and recoupment actions.

BY EXTENDING ACCOUNTABILITY TO INDIVIDUALS WHO KNOWINGLY PARTICIPATED IN CORPORATE MISCONDUCT, THE DOJ HOPES TO INCREASE THE AMOUNT OF EMPLOYEE PARTICIPATION IN CORPORATE INVESTIGATIONS.

1. In order to qualify for any cooperation credit, corporations must provide to the DOJ all relevant facts relating to the individuals responsible for the misconduct.

2. Criminal and civil corporate investigations should focus on individuals from the inception of the investigation.

3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.

4. Absent extraordinary circumstances or approved departmental policy, the DOJ will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation.

5. Department attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases.

6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.

DOJ attorneys are encouraged to be proactive in investigating individuals at every step of the process, which takes place before, during, and after any corporate cooperation. Department attorneys are expected to vigorously review any information provided by companies and compare it to the results of their own investigation, in order to ensure that the information provided is complete and does not seek to minimize the behavior or role of any individual or group of individuals.

According to the memorandum, the DOJ will first maximize its ability to "ferret out the full extent of corpo-

rate misconduct." Because a corporation only acts through individuals, according to the DOJ, investigating the conduct of individuals is the most efficient and effective way to determine the facts and extent of any corporate misconduct.

Second, by focusing their investigation on individuals, the DOJ expects to increase the likelihood that individuals with knowledge of the corporate misconduct will cooperate with the investigation and provide information against higher-ranking corporate officers.

Third, by focusing on individuals from the very beginning of an investigation, the DOJ expects to maximize the chances that the final resolution of an investigation uncovering the misconduct will include civil or criminal charges against culpable individuals as well as the corporation.

Both criminal and civil liability will survive any corporate resolution made between the DOJ and a corporation, as DOJ attorneys are expected to preserve the ability to pursue individuals. Again, the DOJ is focusing on all individuals with knowledge of or participation in corporate misconduct, in addition to the corporate entity.

Now is an opportune time to revisit internal compliance plans and activities, develop processes that encourage reporting, and address and immediately remedy potential corporate misconduct within your organization. The DOJ will take a hard stance on any policy that includes an agreement to dismiss charges against or provide immunity for individual officers or employees involved in corporate misconduct. ■

CME/CNE OBJECTIVES

After completing this activity, participants will be able to:

1. Apply new information about various approaches to ED management;
2. Discuss how developments in the regulatory arena apply to the ED setting; and
3. Implement managerial procedures suggested by your peers in the publication.

COMING IN FUTURE MONTHS

- Leveraging mobile stroke units
- Using data to reduce wait times
- Improving sepsis care, outcomes
- How to get a handle on super-users

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CME/CNE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

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CME/CNE QUESTIONS

1. **A new report from the Institute of Medicine states that according to research over many decades, diagnostic errors contribute to roughly what percentage of all deaths?**

   A. 2%
   B. 5%
   C. 10%
   D. 15%

2. **In developing ways to reduce diagnostic errors, it is important for emergency physicians to consider not their thought process or skill level, but also the impact of:**

   A. time.
   B. contextual factors.
   C. peer review.
   D. fatigue.

3. **The quantitative measures of usability generally fall under three categories, including effectiveness, efficiency, and:**

   A. complexity.
   B. familiarity.
   C. logistics.
   D. satisfaction.

4. **To guide useful improvements in electronic medical record (EMR) systems, clinicians should engage in:**

   A. EMR user groups.
   B. vendor-sponsored forums.
   C. hospital IT committee meetings.
   D. private study of software platforms.

ED ACCREDITATION UPDATE
COVERING COMPLIANCE WITH JOINT COMMISSION STANDARDS

TJC: Time to curb patient falls in healthcare settings

While falls in the ED are not uncommon, experts note that the environment presents some unique challenges

With troubling data in hand about patient injuries and deaths, The Joint Commission (TJC) has issued a Sentinel Event Alert, notifying healthcare organizations that they need to up their game when it comes to preventing patient falls. Since 2009, the accrediting agency says it has received 465 reports of patient falls with injuries, with 63% of these falls resulting in death. Further, the agency reports that patient falls with serious injury are among the top 10 sentinel events that are reported to the agency. While some of these falls occur in non-hospital organizations, TJC says the majority occur in hospital settings.

Why are patients falling in healthcare settings? In reviewing five years of data collected on patient falls with injury, TJC reviewers note that the most common contributing factors are inadequate fall assessments, communication failures, and a lack of adherence to protocols and safety practices. TJC also cites deficiencies in staff orientation about patient falls, supervision, and problems with staffing levels or the skill mix. Other key contributing factors include deficiencies in the physical environment and a lack of leadership around this issue.

TJC makes clear that this is not just a matter of patient safety, although that is of prime importance. Falls also hit hospitals hard in the pocketbook. Studies suggest that patient falls with injury can add a number of days to a patient's hospital stay. In fact, TJC reports that the average cost associated with a fall with injury is about $14,000. When you consider that hundreds of thousands of patients fall in hospitals every year, with 30% to 50% of these falls resulting in injury, it is easy to see how such costs can pile up.

TJC NOTES THAT THE MOST COMMON CONTRIBUTING FACTORS ARE INADEQUATE FALL ASSESSMENTS, COMMUNICATION FAILURES, AND A LACK OF ADHERENCE TO PROTOCOLS.

Identify risk at triage

To prevent falls, TJC recommends that hospitals initiate several steps, starting with a high-profile effort to raise awareness of the need to address the issue. The agency also calls on healthcare organizations to establish an interdisciplinary falls injury prevention team, use a standardized, validated tool to identify fall risk factors, develop individualized care plans for identified fall and injury risks, standardize and apply best practices, including a standardized handoff communication process and one-to-one patient education, and conduct a series of post-fall management practices such as post-fall huddles and a system of reporting and analyzing falls. (*See TJC's recommendations and supporting information at www.jointcommission.org/sea_issue_55/.*)

However, the fast-paced environment of a busy ED presents some unique challenges. For example, most of the existing fall risk assessments are really geared more to

Financial Disclosure: Associate Managing Editor **Jonathan Springston**, Author **Dorothy Brooks**, and Nurse Planner **Diana S. Contino** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Executive Editor **James J. Augustine** discloses that he is a stockholder of EMP Holdings. Executive Editor **Shelly Morrow Mark** reports her husband works for a company that creates advertising for Uroplasty.

the inpatient setting, says **Danette Alexander**, the nurse director of the ED at Hartford Hospital, a level I trauma center in Hartford, CT, that sees more than 96,000 patients a year.

"It is not necessarily that they won't work well, but you need to identify [patients at risk for a fall] quickly at triage, and the inpatient tools typically are done every four to six hours," she explains.

Observing that triage nurses don't have the time to go through all the elements on a standard fall risk assessment, Alexander teamed up with colleagues to develop a streamlined fall risk assessment tool that could be integrated easily into the triage process without slowing the workflow.

"I came from the inpatient side. I had never been in the ED. I sort of brought that inpatient mentality with me," Alexander adds.

Terry Kinsley, RN, MSN, CEN, who is now director of the nursing learning lab and simulation at the University of St. Joseph in West Hartford, CT, worked with Alexander on developing and implementing the tool. At the time, Kinsley was the nurse educator in the ED at Hartford Hospital.

"We were not capturing our patients who were at risk of falling because all the risk assessment tools were just so cumbersome and long. So we broke it down into the basics," Kinsley explains.

ALEXANDER AND COLLEAGUES DEVELOPED A STREAMLINED FALL RISK ASSESSMENT TOOL THAT COULD BE INTEGRATED EASILY INTO THE TRIAGE PROCESS WITHOUT SLOWING THE WORKFLOW.

For example, the resulting instrument, which Alexander and Kinsley refer to as the Kinder 1 Fall Risk Assessment Tool, identifies five risk areas, any one of which will flag a patient as being at risk for a fall when they go through triage in the ED. The risk areas include:

- patient presented to the ED because of a fall;
- age older than 70;
- altered mental status;
- impaired mobility;
- nursing judgement of fall risk.

A "yes" to any of the criteria denotes a patient as being at risk for a fall. Even if a patient does not have any of the first four risks, the triage nurse can flag that the patient is, indeed, a fall risk if he or she has any concerns.

"The other thing that is very different about this [tool] is that there is no scoring, there is no high fall risk, moderate fall risk, low fall risk," Kinsley observes. "In our minds they are all the same. If you are a moderate or a low fall risk and you fall and hit your head, you are still going to get a bleed. If you are a high fall risk and you fall and hit your head, you are going to get a bleed, so it doesn't really matter the amount of risk."

Kinsley adds that a retrospective chart audit of all the patients who had fallen showed that the risk assessment tool would likely have captured 85% of these patients if it had been applied at triage.

The risk assessment questions have been embedded in the electronic medical record so that triage nurses can complete the process quickly as part of their regular workflow process, Kinsley explains. Further, once a patient has been flagged as a fall risk, he or she remains a fall risk for their entire stay in the ED. For patients who are not deemed a fall risk, they must be reassessed every two hours to see if their status has changed.

While many people may not think of the ED as a setting where falls typically occur, it is in fact a high-risk

EXECUTIVE SUMMARY

Noting that there are far too many falls in healthcare settings, The Joint Commission (TJC) has issued a Sentinel Event Alert, telling hospitals and other providers to take steps to identify patients at risk for a fall, and implement preventive interventions. However, while most falls occur in hospitals, preventing falls in the emergency setting presents some unique challenges.

- Since 2009, TJC says it has received 465 reports of patient falls with serious injury, and more than half of these have resulted in death.
- Most fall risk assessment tools are too cumbersome and take too long to complete at triage in the ED.
- The ED at Hartford Hospital in Hartford, CT, has implemented a streamlined risk assessment tool with just five "yes or no" factors for the triage nurse to consider.
- In concert with the risk assessment tool, the hospital has implemented a series of prevention interventions, including hourly rounding, bed alarms, post-fall huddles, and a non-punitive culture for reporting falls.

area, Alexander says.

"Even if you come in and you are not at risk for falling, but you have pain and we are giving you narcotics, we could make you at risk of falling," she explains. "Actually you are pretty high risk the instant you cross the threshold of the ED because even if you are not at risk, we may do things to you that put you at risk."

Implement post-fall huddles

However, identifying fall risk is only the first step in Hartford Hospital's program to prevent falls in the ED. The second part is equally important, and involves a series of interventions aimed at making a patient's stay in the ED safe and free from falls. For instance, patients identified as at risk for a fall in triage are provided green bracelets so that it is easy for clinicians to recognize their fall status.

Also, each of the rooms in the ED has been equipped with fall alarms so that nurses don't have to search for the alarms when they have a patient wearing a green bracelet.

"That makes it very easy for each of the nurses to be successful," Alexander says.

While nurses are key players in preventing falls in the ED, it is also important to involve physicians in the program, Alexander adds.

"All the attending and resident physicians are aware of [our fall prevention efforts], so they will put up the side rails after they have performed an exam of a patient," Alexander says. "Involving them from the get-go is very, very important. It keeps the channels of communication open for feedback on how we can get better."

Another key to the effort is performing a "fall huddle" every time a patient falls in the ED.

"That is where you find out about systems issues," Alexander explains. "When someone has a fall and we perform a post-fall huddle, we try to make it as non-punitive as possible."

In the past, nurses would never call the charge nurse to report a fall, but such calls are routine now, Alexander says.

WHILE NURSES ARE KEY PLAYERS IN PREVENTING FALLS IN THE ED, IT IS ALSO IMPORTANT TO INVOLVE PHYSICIANS IN THE PROGRAM.

"When a nurse calls and reports that they have had a fall, we all go and look at it, and if they did everything they possibly could to prevent the fall, then it is a non-punitive process," she explains. "Obviously, you would have issues if someone was blatantly neglectful, but usually they are not. They just need support."

Kinsley adds that one practice that goes hand-in-hand with the fall prevention interventions is hourly rounding.

"I wish we had implemented that even sooner," she says. "It doesn't have to necessarily just be nurses performing the rounding, as long as someone is going in and logging some face time with the patient every hour."

Change the culture

While the fall prevention program is well-integrated into ED operations now, it took about a year for the nurses to buy into the approach, Kinsley recalls.

"We just kept plugging away. Danette and I were very visible on the unit, and we did lots of selling of the program," she explains. "It was very labor-intensive on our part."

However, Kinsley notes that a key turning point occurred after the fall prevention program had been in place for about eight months.

"We had a patient who had come into the ED in the very early morning because she had fallen," Kinsley says. "She was an older lady from an Alzheimer's unit."

The day shift was just coming on board, and care of the patient was being transferred from a travel nurse to the oncoming day shift nurse.

"As they were finishing up report, they heard the sound that you hear when a head hits the floor," Kinsley notes. "The patient had fallen out of bed and it turned out that no fall precautions had been put in place."

The patient eventually passed away, although it is impossible to determine whether this was the result of her first fall or the fall that occurred in the ED, Kinsley explains. Nonetheless, the incident received everyone's immediate attention.

"It just really shifted the whole culture," Kinsley adds. "That is when we saw the tide turn."

Since then, nurses have embraced the program.

"It is a matter of getting one person on the bandwagon, and then everybody else follows," Kinsley notes.

In fact, while all of the interventions have made a difference in curbing serious injuries from falls, what has worked best is the way the program has focused awareness on

the issue, Alexander explains.

"We will have a lot of falls for a variety of reasons. Sometimes they are [due to] behavioral health [reasons] where people will throw themselves on the floor. We also get a lot of intoxicated people, whether due to alcohol or other types of substances," she says. "What we have tracked over the past two or three years on our dashboard unit is whether someone has experienced a serious injury from a fall, and … that has been relatively flat."

Also, since first reporting on Hartford Hospital's ED fall prevention efforts in the summer of 2013,[1] Alexander says she has heard from other EDs that have adopted the Kinder 1 tool. She notes that now the EMS personnel who bring patients to the hospital will often put the green bracelets on patients even before they arrive.

Soon, the Kinder 1 tool will be shared with the other EDs in the hospital system, and Alexander is hoping this will provide an opportunity to conduct a formal observational study on the effectiveness of the tool. ■

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UNDERLYING INFECTIONS CITED AS POSSIBLE CAUSE OF MANY FALLS

New research suggests that underlying infections, rather than slippery floors, dementia, or other more commonly cited factors, may in fact be the root cause of many falls that lead to ED visits or hospitalizations. The provocative findings were reported in October at IDWeek, a meeting that is held jointly by the Infectious Diseases Society of America, the HIV Medicine Association, the Society for Healthcare Epidemiology of America, and the Pediatric Infectious Diseases Society.

The findings stem from a retrospective review of 14 years of electronic medical records at Massachusetts General Hospital (MGH) in Boston. The researchers, led by **Farrin Manian**, MD, a hospitalist at MGH, identified 161 patients who presented to the ED for a fall and were hospitalized for their injuries, but were later found to have a coexisting systemic infection. The most common bugs cited were urinary, bloodstream, and respiratory infections.

Manian reported that the signs of infection in these patients were often subtle. Only 20% had a fever upon their initial examination and just 44% showed signs of a systemic inflammatory response. However, the investigators noted that in many cases, both the falls and the infections were quite serious. Close to 19% of the patients experienced a fracture from their fall, and nearly 40% had bacteremia. Further, 18% of the patients died while in the hospital.

Investigators reported that signs of altered mental status were apparent in as many as 25% of the patients upon admission. However, they said only a small number of family members observed such changes before the fall. Manion suggested that providers need to be more attuned to the subtle signs of infection in patients who have fallen. Further, if family members are made aware of such signs, it may be possible to prevent falls though earlier detection.

The average age of the identified patients was 76, but the investigators noted that 18% were younger than 65, including some in their 30s. Most of the patients still lived in the community (78%). The researchers said only 9.3% of the patients came from extended-care facilities, and just 8.1% had dementia.

While this is just a single-center study, Manian is hoping to investigate the issue further through a multi-center analysis. ■

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