

INSIDE EDGE

Patient Safety, All-Cause Harm and IT: The Revolution Will Not Be Voluntary

INTRODUCTION Like many aspects of healthcare, patient safety is undergoing a transformation that is both painful and promising. Painful on at least two accounts: one, we've learned that medical errors are much worse than we previously thought, as shocking as the 1999 IOM report was; and two, getting control of these errors is grindingly difficult even for our best minds. However, because of IT, the promise of dramatically improving patient safety is real and getting closer every day. For the first time since the IOM report, we are poised to be able to systematically identify and prevent medical errors by embedding patient-safety programs in the EHR. That will eliminate the need for voluntary reporting of harm events, which misses most errors. Also, IT enables near-real-time analysis, allowing clinicians to intervene before harm occurs or mitigate it as harm can be detected in real time with IT.

Clinical decision support (CDS) has made huge strides in the last decade in identifying and preventing adverse drug interactions, medication errors and other kinds of medical errors. CDS will continue to mature and provide a bulwark for patient safety going forward. [See SI's new [CMIO/CHIO Summit report, "Managing Clinical Decision Support and Improving Workflow"](#)]. The next frontier for CDS is using analytics in the EHR for near or real-time identification of high-risk patients and imminent adverse events.

In this issue of *Inside Edge* we talk to two leading health systems in the patient-safety movement: Adventist Health System and Indiana University Health. Kicking off the discussion is David Classen, MD, of the University of Utah and Pascal Metrics, a national patient-safety expert and author. They tell us the

revolution is occurring and that it is IT-enabled. Not voluntary.

The new normal

If the 1999 Institute of Medicine (IOM) report is the epicenter of the modern patient-safety movement, the seismic vibrations from that event continue to trigger aftershocks.

"The new normal," says David Classen, MD, CMIO, Pascal Metrics and Associate Professor of Medicine, University of Utah, "is that the estimates of patient harm and death in the 1999 Institute of Medicine (IOM) report are old and very outdated. Numerous articles, including several recent IOM reports, suggest that hospital deaths are *four times worse* than we previously thought and hospital harm may be *six-to-eight times worse* than previously estimated."

Classen, an SI board member, co-authored research articles in [Health Affairs](#) and the [Journal of Patient Safety](#) citing these new IOM reports and other research which estimated that one third of all hospital patients experience harm during their stay and more than 400,000 preventable hospital deaths occur annually. "They suggest," he says of the most recent studies, "that, rather than the 65,000 to 98,000 preventable deaths a year posited in the 1999 IOM report, that there are up to 400,000. And, rather than the one million injuries there are actually six-to-eight million injuries a year."

Why the dramatic update? For starters, the 1999 IOM report relied on old studies based only on clear



David Classen, MD,
CMIO, Pascal Metrics

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cases of malpractice. Second, the newer research encompassed all death and injuries to patients—what is now called “all-cause harm.” Finally, researchers in the latter studies used newer methodology that can detect more problems. Still, both eras of research used a similar approach involving retrospective chart review by clinical experts.

All-cause harm

One of the ‘new’ research tools has been around nearly 20 years. The Institute of Healthcare Improvement (IHI) (<http://www.ihl.org/>) developed the Global Trigger Tool as a more refined retrospective method to examine all death and injuries to patients, or all-cause harm.

The Global Trigger Tool uses nurse-and-physician review similar to that used for the 1999 IOM report. “It’s a consistent approach that has matured and been updated since Harvard introduced it in 1999 as a way to determine all causes of harm to patients,” says Classen, lead author of an article on the Global Trigger Tool published in *Health Affairs* in 2011.

That article featured a study comparing the Global Trigger Tool to traditional voluntary reporting systems to measure patient safety. It found that voluntary reporting systems identified only four out of 393 patient-harm events. “Voluntary reporting misses more than 95 percent of adverse events even in advanced clinical settings—and that’s the most common approach to catching medical errors. It massively under-measures,” he says.

Still, as advanced as retrospective review of all-cause harm is to traditional—and still common—voluntary reporting, Classen asserts the most advanced thinking is to IT-enable patient safety by incorporating patient-safety surveillance into the EHR, to make identification and reporting “easy” through electronic means.

Leverage IT

“That’s the transition we’re in now,” he says. “How do health systems find new ways to leverage the EHR to protect patients? The 2011 IOM report, ‘Health IT and Patient Safety: Building Safer Systems For Better Care,’ said we should be leveraging IT to measure medical errors. We’ve been woefully negligent in that regard. It’s absolutely critical to leverage all the money we put into IT. That’s where the most innovative approaches to safety are.”

“Now we can detect and measure these events in real time—and you can intervene, mitigate or even prevent.”

One way to automate patient safety: build on infection control using real-time analytics in surveillance software to create an all-cause-harm safety-surveillance system. This “real-time safety” enables intervention at the point of care, whereas in the past safety reporting was retrospective, after-the-fact, which obviously had no benefit to the patient being harmed. “Now we can detect and measure these events in real time—and you can intervene, mitigate or even prevent,” Classen says.

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“This is a real transformation becoming real-time and proactive. However, lots of hospitals and health systems need to staff up for it. Other industries like aviation, manufacturing, finance and retail have surveillance systems to monitor safety, manufacturing defects and credit cards. Companies like Amazon use analytics to track events in real time. They’ve all paved the way for healthcare.”

RELATED RESOURCES

In addition to the articles and guidelines mentioned in the text here are some selected resources on patient safety:

Check out this *SI Teleconference*: “[We Have a Long Way to Go Yet on Patient Safety Says Gandhi, National Patient Safety Foundation](#),” Aug. 31, 2016

And, check out these CDS-related *SI Teleconferences*: “[CDS Malfunctions: Causes, Detection and Prevention](#),” Aug. 17, 2016
“[Clinical Decision Support Governance and Analysis at Texas Health Resources](#),” Sept. 28, 2016

Finally, here are a couple of informative patient-safety websites:

Hot topics from the National Patient Safety Foundation <http://www.npsf.org/?page=safetyissuesprofil>

A good comprehensive approach to patient safety can be found at the Patient Safety Network (AHRQ) <https://psnet.ahrq.gov/>

[Joint Commission Journal on Quality and Patient Safety](#) in 2013, as well as the [Journal of Patient Safety](#) article mentioned above, which Hauck also co-authored.

Hauck notes the second article (*Journal of Patient Safety*), also co-authored by Lee Adler, DO, describes, “What we learned across Adventist Health System. It identified the most common ways patients were

harmed.” Lessons from that study, along with multiple additional clinical and information technology initiatives, enabled Adventist to reduce serious harm by 67 percent from 2009 to 2012.

“How did that happen?” asks Hauck rhetorically. “From 2009 to 2010 we went live with CPOE and evidence-based order sets that had lots of built-in safety checking. We also implemented bar coding at medication administration.” The Global Trigger Tool even helped identify errors that occurred prior to admission.

Patient safety becomes reliable because it’s part of the system, he says, citing IT-enabled hospital-wide clinical initiatives at Adventist Health System that have reduced pressure ulcers, catheter-acquired infections and medication errors. “All the IT tools we’ve implemented and care collaboratives we ran helped us reduce harm in specific ways. These IT tools offer a very accurate and precise way of determining the magnitude and cause of harm.”

Anxious to test the concept

Five years ago when Classen spoke at a national conference on the value of automating triggers in the EHR, Hauck knew another door had opened on the patient-safety path. “I said, ‘If you’re looking for a health system to test these ideas, we’d be a good one.’” In late 2011 and early 2012 Adventist Health System adopted Pascal Metrics’ risk-trigger monitoring (RTM) tool, software that combs the health system’s clinical data to identify harm in near-real time. “The electronic trigger cannot totally determine if harm has actually occurred, an experienced clinician still has to verify this by chart review,” he says.

In the past four years Adventist Health System has launched a major sepsis-prevention initiative, using the [Society of Critical Care Medicine \(SCCM\) guidelines](#), initially using a paper-based tool for screening. Now in phase four of the “Surviving Sepsis” campaign, the organization is converting from the paper to an electronic form. “When the electronic tool became available it took only three or four minutes to routinely screen or to assess a patient suspected



Loran Hauck, MD,
CMO, Adventist Health System

of being in early sepsis,” he says. Currently Adventist Health System also uses the “sepsis alert” that is part of Cerner Millennium to identify patients possibly in early sepsis to be screened using the tool, and then implementing the SCCM early goal directed therapy and three-hour sepsis bundle.

Mixing CDS with NLP

Like everything else, patient safety requires interoperable solutions. “We have an Oracle Big Database. We are learning how we use Big Data to help drive our clinical agenda and outcomes measurement. Finally, how do we use our Cerner Millennium EHR in conjunction with our athenahealth ambulatory EHR in our physician-owned ambulatory practices? And our home-care EHR and long-term care EHR data for initiatives like consumer engagement, driven by a consistent brand experience? These EHRs can’t talk to each other—interoperability is a big issue,” says Hauck.

“IT tools offer a very accurate and precise way of determining the magnitude and cause of harm.”

A promising area of IT innovation for Adventist Health System: a focus on CDS for clinicians and patients. A couple of years ago Adventist

Health System began discussions with medCPU (www.medcpu.com) a New York-based, real-time CDS firm that uses natural language processing (NLP) to “scrape” the EHR for clinical information that can guide “intelligent, real-time CDS.” MedCPU resides “on top” of different EHRs to leverage the clinical knowledge from them to drive and improve patient care and outcomes. “How do we leverage IT to change the trajectory of patient care? I’m very bullish on medCPU,” he says.

In February Pittsburgh-based University of Pittsburgh Medical Center (UPMC) invested a majority interest in medCPU, whose technology Adventist Health System is launching at 11 sites in fourth quarter 2016.

Validating the belief that patient safety is a cultural and enterprise-wide effort, Hauck says Adventist Health System’s next step is to continue the evolution toward a clinically-effective and fully-integrated network in which intelligent, real-time clinical surveillance and CDS and Big Data will play important roles for patient safety, quality and efficiency.

Analytics for infection control

Indianapolis-based Indiana University Health, a 15-hospital academic health system with nearly 3,000 physicians serving the state of Indiana, has made patient safety a corporate emphasis.

“We’ve been fortunate at IU Health to have leadership



really focused on patient safety,”

says Douglas Webb, MD, medical director for infection control. “Healthcare-associated infections are a huge issue and a major priority for IU Health. We’ve been given additional resources to tackle this issue.”



Douglas Webb, MD, medical director for infection control, IU Health

The organization identified its top priorities: central line-associated bloodstream infections (CLABSI)

which occur at the site of an intravenous catheter; and clostridium difficile (C. diff), which commonly affects older adults in hospitals or in long-term care facilities typically after use of antibiotic medications, but is increasing among younger people.

“We have a team trying to identify the key areas of opportunity and why,” he says. “We’re analyzing the data to see if it’s due to the way the catheter is inserted or the maintenance. We’ve done simulation training on how to insert these central lines & maintaining them. We just completed a blitz competency of over 2,300 nurses and more than 500 physicians on proper line insertion and maintenance. We perform audits with real-time coaching and have biweekly coaching calls with sharing of helpful interventions and lessons learned. We also do real-time huddles to identify causes of infection.”

A risk-predictive model

On top of all this activity, “We explored how we might identify these events ahead of time, so we developed a risk-predictive model that we’re about to test,” Webb says.

“We pride ourselves as a very data-driven organization and are always poring over data,” says Kristen Kelley, director of infection prevention at IU Health. “However, it’s really difficult to analyze single factors isolated from the clinical data, especially in a clinical world that is multifactorial. Currently, if an event



occurs, we do a comprehensive huddle to identify gaps, key causes and why infections occurred. But that's after the event has come and gone, so it's

“We need to look at decision-supporting mechanisms, not decision-making mechanisms.”

retrospective. And one CLABSI case's root cause doesn't mean the next case's root cause will be the same. Identifying the causal factor of a single event does not necessarily lead to statistical prediction of the next, but we were treating it in that way.”

Even—perhaps especially—in a data-driven world, outside-the-box thinking is critical. A complex interplay of factors intersect catheter-associated infection of a patient: staffing, competency, hours worked, time of day, movement of the patient from her room to other locations like the OR, different people changing the dressing, patient education, patient engagement, line care on all shifts and the previous patient in the bed.

Thinking outside the box

For Kelley, that complexity often prompts her to step back from the data and think intuitively.



Indiana University Health



Kristen Kelley, director of infection prevention, IU Health

“Each of us has a sense for when something in our environment is not ok. As humans our senses are wired for observation of risk. In this situation, our data wasn't helping us to find issues or risk in the moment. So, we've been on a journey, mining our data in real time to auto-analyze it for us. In this dashboard we created, a manager can analyze his or her data in two seconds: ‘Is my bundle increasing or decreasing? Is hand hygiene up or down?’ The dashboard mines the clinical unit and is constantly analyzing the evidenced-based interventions for CLABSI prevention and informing leadership on that unit where we are improving and where we have decreasing trends that could result in increased risk for our patients. The next

step beyond this dashboard is to determine: Can we convert a database that auto-analyzes to a database that predicts someone's risk at a patient level before an event even occurs?”

Two years ago, IU Health partnered with Health Catalyst to develop the enterprise data warehouse used in the CLABSI and other patient-safety initiatives. Health Catalyst also helped the health system develop advanced analytics apps for the risk-prediction model.

Early on the risk-prediction tool—which auto-mines the EHR daily—has successfully predicted 85 percent to 90 percent of CLABSIs. IU Health developed the tool using [Joint Commission evidence-based risk factors](#) that the team configured for their EHR during the past year. “It was an incredibly exciting feat, but we are just at the beginning with little-to-no precedence for this tool. We have gleaned insight from other industries that have long used statistical prediction to predict human behavior or patterns from buying habits, stock market trends and weather forecasting,” she says.

Tony Pastorino, IU Health's executive director for decision-



Indiana University Health



Tony Pastorino, executive director for decision-support analytics, IU Health

support analytics, says cultural attitudes are an important consideration in analytics. “There's an expectation in healthcare that these analytics should be perfect. However, even if an IT tool is not 100 percent perfect, it's better having this data at these decision points than not having it. We need to look at decision-supporting mechanisms, not decision-making mechanisms.”

Don't let perfect block good

Jose Azar, MD, IU Health's medical director of quality and safety, agrees. “We expect perfection while we are less than mediocre in healthcare given the amount of unintentional harm and errors. The number is outrageous. We need to change and improve. The alternative is keeping the current status, which is not acceptable. In patient care we interpret the data whether its lab results, radiology or other diagnostic tests with a probabilistic approach. In these settings, we accept imperfect data because we use it to identify a pattern and find solutions to improve a clinical situation. Why do we use a different level of rigor





Indiana University Health



Jose Azar, MD, medical director of quality and safety, IU Health

when we are approaching a quality or safety problem? Why do we become paralyzed by good data and await perfect data before testing a change?"

He notes that other industries have used such models. "In healthcare we've been more reactive than proactive. We're good firefighters but not very good at preventing fires. This goes beyond infection."

And other industries have myriad variables too. "Especially when we look at Big Data. Imagine all the predictive factors in weather. It's very complex. CLABSI is a similar challenge with its huge number of variables. The problem has been our inability to track all these variables, but they aren't any more difficult or complex than predicting weather," says Azar.

Still, IU Health is making progress.

"We have quite a few initiatives centered on hospital-acquired harm events that are supported with analytics," says Kelley. "We are on the cutting edge. In the past six months we've experienced a 20 percent decrease in CLABSI and a 30 percent drop in harm events overall. So we are headed in the right direction."

Complex analytics, simple signals

"Our next step," she says, "is to determine how best to utilize this tool in an interdisciplinary and complex environment. Do we embed it in clinical workflow, for example? Do we build a team to support its use? How do we use it in the most impactful way to improve patient care and outcomes?"

In the next few weeks, the team is partnering with trauma service lines in a pilot to embed the tool in

their physician workflow. It will monitor the process and get feedback from frontline clinicians. "The beauty of this tool is the intuitive and easy-to-use dashboard, with a red light to alert a physician or manager to a high-risk patient, a green light for non-high-risk patients. This is the display of the analytics engine mining the EHR all day long. A simple click enables the clinician to do a quick analysis of care."

Says Webb: "We know its weakness is that 10 percent bucket of patients who acquired a CLABSI that the model didn't predict. These are the patients who may get an infection within two to three days whereby the EHR has not had time to collect much data. But it's also helped us to identify areas of risk that we weren't aware of previously such as patients coming in with infected lines. We are just at the beginning of exploring the potential here and it's an exciting time."

"We're good firefighters but not very good at preventing fires. This goes beyond infection."

Conclusion

Like most other areas of healthcare today, patient safety is at a crossroads—and IT is pointing the way. Having plateaued at traditional strategies like voluntary reporting, pioneering health systems are now taking the Big Data bull by the horns and applying new analytics models and tools to automate patient safety by embedding it in the EHR. So much for the post-EHR era.

"It's an example of healthcare IT causing a transformation," says Classen. "This is a demonstration of the clear value of analytics programs, which are tailor-made for patient safety. What's going to drive this revolution is a patient-centered care model with real-time data applied to chronic care. What does a real-time patient safety program look like? It identifies an event as it happens."

And the system responds—automatically. The revolution will not be voluntary.



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