



As Industry Automates, Adverse Events Continue to Haunt Caregivers

In response to the blight of patient harm, providers are working to harmonize cultures of safety with their I.T. efforts.

By Tracy Granzyk Wetzel

In November of 2010, the Office of the Inspector General (OIG) released a report alerting providers, patients and hospital executives there is still much room for improvement when it comes to keeping patients safe in the hospital. The report, an examination of “never events”, or serious events that should never occur in hospitals, was mandated in the Tax Relief and Health Care Act of 2006 ,

to keep Congress abreast of the quality of care Medicare dollars were purchasing.

Results from the OIG analysis, a random sample of 780 Medicare patients discharged during the month of October 2008 and representing beneficiaries across the nation, indicated 13.5 percent of patients experienced an adverse event, defined as harm to a patient resulting from medical care, and an additional 13.5

percent experienced temporary harm.

While not all adverse events were deemed “never events,” these findings compound the emotional costs for all involved, with an approximate \$324 million expenditure for the Center for Medicare and Medicaid Services (CMS) in October 2008 alone.

Physician reviewers determined 44 percent of adverse events or patient harm found, could have been prevented altogether.

Troubling research

Shortly after the OIG report was issued, *The New England Journal of Medicine* published a retrospective study by Christopher Landrigan, M.D., reviewing suspected harm in 10 randomly selected North Carolina hospitals.

Researchers applied the Institute for Healthcare Improvement (IHI) Global Trigger Tool for Measuring Adverse Events to 10 random patient records from each of the 10 hospitals every quarter, from January 2002 through December 2007.

Trigger tools are used as a means of medical record review, and the IHI tool aids in the identification of patient harm over time via 52 “triggers,” or evidence in a medical record that could represent harm (i.e. rapid response team activation, blood transfusion).

In this study, researchers defined harm as an unintended result of medical care and was evaluated from the patient’s point-of-view (i.e. would you be happy if this happened to you?).

Of the 2,341 admissions examined by reviewers in this study, 588 events of patient harm were identified, illustrating patient harm to be a common event, with little indication of improvement throughout the period examined.

These results occurred even though North Carolina hospitals had been highly engaged in national and statewide patient safety initiatives and training programs.

Beyond the harm caused to patients, hospital-acquired conditions also come with financial costs.

Costs attributed to each include in-

creased time in the hospital for the patient, as well as the monetary cost incurred to the hospital system. According to Shelley Burns, director of knowledge management at the Healthcare Management Council, a benchmarking firm that acquires cost data from hospital clients, the average cost for treating five of the most common HACs from fiscal year 2009 reports were:

- Decubitous ulcers at \$9,200 per patient;
- Postoperative pulmonary embolism and deep-vein thrombosis at \$15,500 per patient;
- Accidental punctures and lacerations at \$8,300 per patient;
- Post-operative respiratory failure at \$21,900 per patient; and
- Hospital-acquired infections at \$24,500 per patient

“Clients provided costs based on DRG data for various conditions with and without the hospital-acquired conditions,” Burns says.

For example, the average cost attributable to a decubitous ulcer was based on the difference between the cost of treating a patient who had heart surgery and developed a bedsore less the cost of treating a patient for the same heart surgery who did not develop a bedsore.

Diving into disconnect

Why does a disconnect between intent and outcomes still exist when it comes to keeping patients safe?

The often-referenced *To Err Is Human* report from the Institute of Medicine (which estimated that up to 98,000 deaths per year were caused by medical errors) is a call to arms that has been out since 1999, with an admonishing 10-year follow up highlighting the million lives lost, and billions of dollars spent due to medical errors in that 10-year period.

Yet patients continue to experience harm in alarming numbers as evidenced by the OIG findings last November.

The quality-challenged health care environment coupled with increasing costs has moved the Department of Health and

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— Christopher Landrigan, M.D.

Human Services to further action. As a result of the OIG report last November, recommendations were made that CMS and the Agency for Healthcare Research and Quality (AHRQ): 1) broaden patient safety efforts to include all types of adverse events; 2) enhance efforts to identify adverse events and; 3) that CMS should provide financial incentives to reduce adverse events.

Landrigan, associate professor of medicine and pediatrics at Harvard Medical School, relates the failure to fully implement human strategies, systemic interventions and advanced information technology systems such as computerized physician order entry, bar coding and computerized handoff tools, as possible reasons for the disconnect in outcomes and intent.

And as providers move toward EHR meaningful use milestones this year, the ever-present data on the frequency of medical error and patient harm begs for true meaningful use of information technology and human resource strategies that provide solutions to this blight on the U.S. health care system.

“Meaningful use requirements by themselves are not enough,” warns Landrigan. “The technology strategies that are put in place need support of those utilizing them or you will never get the full benefit.”

Hospitals which have nurtured a culture of safety know, that no matter how sophisticated I.T. systems are in their ability to capture and analyze data related to medical error, patient harm or a near miss, those systems are only as effective as the user’s willingness to report harm to a patient. The culture defines a health care

provider's comfort level to report voluntarily.

Cathie Furman, R.N., senior vice president of quality and compliance at Seattle-based Virginia Mason Medical Center knows I.T. and safety are interrelated. Virginia Mason, named The Leapfrog Group's Hospital of the Decade in December, is seeking to create process improvements related to quality and safety, with I.T. efforts playing a supporting role at the front lines.

"One of the things we are learning with I.T. is that it is 20 percent technology and 80 percent change management," says Furman. "If you just implement an I.T. strategy without understanding how people use it, it could be like garbage in, garbage out."

Virginia Mason has been on a 10-year journey to put the patient at the center of its improvement efforts.

Its Toyota inspired Virginia Mason Production System (VMPS) encourages every employee of the hospital to "stop the line" if they see the potential for patient harm.

As such, all 5,000 Virginia Mason employees are considered to be "safety inspectors" and are encouraged to use various communication methods (phone, online, and in person) to report a patient safety alert (PSA) whenever they witness

a system, process, or behavior with the potential to cause harm, says Jim Bender, M.D., medical director for health information.

"While VPMS is largely a human process, software tools are used to aggregate and manage PSA data," says Bender. "The VPMS comes in handy because we use it to embed our I.T. efforts into the flow of care," Furman says. "We first try to understand how practice occurs, and then look to how we can implement I.T. in the best way possible."

Bender agrees that the key to I.T. systems success is designing them in a manner that makes the most sense to the clinician at the point-of-care.

"Bringing computers into practice can be terribly disruptive," says Bender. "Clinicians are not always used to this, but we show them that the pain upfront to change is for a higher purpose—the patient. Not just meaningful use."

Bender describes the challenges of implementing new information technology as ongoing. Each new tool requires getting into the "cognitive space" of the provider, he says, knowing his job is to help them through the discomfort by developing tools smart enough to display information and alerts pertinent to the patient in the room, when it matters most to both doctor

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and patient.

"We are amassing mountains of clinical data," Bender says. "The challenge is to get information out in the right format to trigger the right care."

While many in health care are doing similar work with data and electronic records, the difference at Virginia Mason is the focus on safety work as the foundation for all their I.T. efforts.

Each year the organization has specific safety goals (i.e. medication reconciliation, minimizing over-sedation) and they develop I.T. tools that conform to these goals.

"The one way I.T. systems can help prevent errors is to make defects more visual," Furman says.

For example, CPOE has helped Virginia Mason reduce the frequency of prescription-writing defects, such as dangerous abbreviations, illegible handwriting and dosage errors, from showing up in 82 percent of orders to only .1 percent of orders over a 5-year period.

Safety by force

The CPOE system is set up so clinicians cannot leave the final screen or even submit a medication order without addressing all elements of safe medication ordering such as potential drug interactions or allergies.

"CPOE has virtually eliminated errors in the ordering process caused by problems with medication selection and confusing handwriting," adds Bender. "We are now embarking on a project to address medication administration errors by bringing bar coding to the bedside."

And while Virginia Mason has expe-

Applying Safety Indicators

AHRQ's Patient Safety Indicators (PSI) software was developed to help hospitals identify complications that could be indicative of a patient safety event. AHRQ has made the PSI software available to the public without charge.

The software can be applied to a hospital's inpatient administrative data and the results analyzed using the SAS statistical program to gain information on the number, type, and frequency of adverse events occurring locally. Go to: <http://www.qualityindicators.ahrq.gov/> for further information and to download the PSI software.

The hospital-level patient safety indicators are:

- Complications of anesthesia (PSI 1)
- Death in low mortality DRGs (PSI 2)
- Decubitus ulcer (PSI 3)
- Death among surgical inpatients with serious treatable complications (PSI 4)
- Foreign body left in during procedure (PSI 5)
- Iatrogenic pneumothorax (PSI 6)
- Selected infections due to medical care (PSI 7)
- Postoperative hip fracture (PSI 8)
- Postoperative hemorrhage or hematoma (PSI 9)
- Postoperative physiologic and metabolic derangements (PSI 10)
- Postoperative respiratory failure (PSI 11)

rienced marked improvements in medication ordering defects as a result of implementing CPOE, only 17 percent of hospitals in the U.S. have a similar system in place, according to a 2009 *New England Journal of Medicine* report by Ashish K. Jha, M.D., et al.

Two thousand miles to the east, in Ann Arbor, Mich., hospital executives at the University of Michigan Health System have been leading the way in both the implementation of information technology to identify medical error, as well as creating a culture of safety in which the capabilities of their I.T. efforts can be fully realized.

At UMHS, the identification of error is viewed as a tool to improve their system versus punish those involved.

Rick Boothman, chief risk officer for the health system, is setting the bar for a culture of safety at UHMS.

Since 2001, his team has openly engaged patients after unintended medical outcomes, and where appropriate, offered compensation to patients who were injured by a medical error while in their care.

The outcome of these efforts were pub-

lished in a 2010 *Annals of Internal Medicine* study, as Boothman and colleagues examined UMHS claims data before, and after, implementing the full disclosure program (i.e. open and honest communication around medical error) at UMHS.

Researchers linked the UMHS risk management database containing information pertaining to claims (i.e. injury, liability costs) with the clinical information and decision support services database to analyze the number of new claims, claims receiving compensation, time to resolution and related costs.

Results indicated the number of monthly claims, lawsuits and average costs related to total liability, patient compensation and non-compensation legal costs (i.e. expert witnesses, defense attorneys, filing fees) all decreased as a result of implementing the program.

While encouraging results, Boothman was hesitant to publish the data because he did not want to “fuel the perception that transparency is just claims management”.

“There is a broader belief at Michigan that we cannot improve unless we have open and honest discussions,” Boothman

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says. “People have learned a culture of silence because they were afraid of ramifications, so culture did not change.” Failing to discuss flawed systems is unethical, he contends.

Since 2002, UMHS has had a Web-based electronic reporting system available through their intranet for health system employees to report safety related occurrences.

Events such as surgical errors, misuse of medication or disruptive behavior can easily be entered into the system and reviewed by risk management.

Reports have increased from 2,400 per year to 17,000 per year since 2002. Their current tool of choice is RiskPro by RL Solutions, which monitors the safety events and close calls reported, and then generates daily, weekly and monthly reports for hospital leadership, and an annual report on patient safety metrics for the board of directors, says Boothman.

“The reporting systems are voluntary, and if you have a culture that encourages reporting, you will get more information,” says Boothman. “It still depends on the individual to actually report—to believe it is important and make the time to do it.”

Uncovering events

Vinita Bahl, director of clinical information and decision support services at UMHS, agrees that relying on voluntary reporting alone is most likely not sufficient. As a result, Bahl and her team developed a pilot program in the form of an additional reporting system utilizing billing data to identify, and then clinically evaluate, the adverse events it uncovers.

This new system, called the patient

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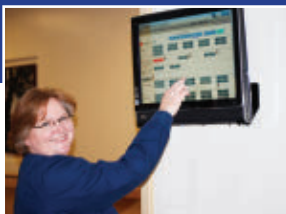
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safety indicator-case review system (PSI-CRS), supplemented the voluntary reporting of events by searching within the patient billing records for diagnoses-related group (DRG) codes, indicative of patient safety indicators developed by AHRQ (see sidebar).

Findings are sent to risk management for evaluation, and are cross-checked with the voluntary reporting system results, says Bahl.

Valid system

Events that match the voluntary reporting system are noted as captured, and events not previously reported are sent via e-mail to case reviewers for further evaluation as to the validity of the findings, and then on to the risk management department for further action where appropriate.

A link provided in the PSI-CRS generated email allows reviewers to access billing record information (i.e. diagnoses, procedure involved, treating physician) and the patient's medical record through a simple user interface.

Reviewers can garner additional information about the patient and case, read a summary of past reviews and enter comments of their own.

By providing clinicians with this additional data, potential problems were indeed uncovered, giving clinical teams an

opportunity to improve systems before a patient was harmed.

For example, it was discovered that patients at risk for blood clots during their stay were not being accurately assessed at the bedside, says Bahl.

The risk was being underestimated, and as a result, interventions aimed at improving risk assessment and prevention of blood clots for high-risk patients were implemented.

"We have the ability to look at results by specialty groups within the hospital, and while the majority of the cases are handled appropriately, there are instances like this where we have found opportunities for improvement," says Bahl.

As a result of the pilot program, Bahl and her team at UMHS developed software utilizing the billing data, which they have been using system-wide since 2008.

"We created the software because we knew we weren't the only ones experiencing these issues," says Bahl. "We found this approach to be useful and a good source of data."

The software has since been licensed to a third party, Quantros, a company which specializes in real-time, Web-based data management and decision support solutions for healthcare.

Now commercially available as Safety Insight, UMHS' technology is available to

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—Vinita Bahl

any organization wanting to capture additional layers of information about their performance related to patient safety events.

Like the UMHS pilot, Safety Insight continuously monitors inpatient billing data to identify patient safety events based on the AHRQ PSIs or hospital acquired conditions (HAC), and then generates reports to the appropriate manager for action.

The tool, a Web-based technology which includes a data processing and workflow management component, a rules engine including a library and a reporting engine, supports live streaming directly from hospital clients of HL7 v2.x and v3, as well as UB-04 hospital claims data feeds with the ability to integrate electronic health records and other patient data.

In addition to gaining knowledge around unreported safety events, the tool provides a check and balance system, giving organizations the ability to validate coding for hospital claims, and quality review teams another way to assess performance, adds Juliana Hart, director of marketing at Quantros.

Even within the culture of safety at UMHS, the need to gain further insight into performance still exists.

"This is an important step for us," says Bahl. "It's not the only step in identifying sources of events, but it is a good one. The claims data is so readily available, it makes too much sense not to use it."

Bahl's team identifies about 50 safety-related events each month through use of the software, and approximately 90 percent of those events have not been previously reported.

Of those events identified each month, approximately 12 are due to inaccurate coding, and nine are potentially prevent-



Jim Bender, M.D., is an architect of the "stop the line" safety system at Virginia Mason Medical Center.

able by healthcare providers—an opportunity for improvement that would have been missed in the past.

“It is important for us to be aware of complications and adverse events so we can understand why they are occurring,” continues Bahl. “The whole thrust behind voluntary reporting is to reduce frequency and eliminate errors. This provides a nice supplement because it alerts us to adverse events we would not have known about.”

Attention to innovation

While UMHS has been developing a culture of safety in earnest since 2001 along with the I.T. reporting platforms to support it along the way, institutions near and far have been paying close attention to the innovations.

The University of Illinois Medical Center in Chicago is once such institution, and is also crafting its own course in safety and quality.

As UIMC’s culture of safety has matured, thanks to Tim McDonald M.D., chief safety officer, and David Mayer, M.D., associate medical officer for graduate medical education, I.T. strategies have had to grow in step with their progress. “Tim and Dave have really improved the culture of safety,” says Rose Ann Laureto, CIO at UIMC. “We linked with them directly to see how best to embed information technology strategies within the safety programs.”

Laureto formed a Clinical Informatics Team at UIMC 18 months ago. Members were chosen for not only their knowledge of informatics but also their clinical expertise. One of the drivers for forming the team was to follow up on information system implementation.

“After we spend time designing and building software, and after clinicians really start using and understanding the software, it needs to be changed,” says Laureto. “We just never seem to have the time to go back and work through those situations and we need to—so the team was developed.”

Adding the safety orientation has enhanced I.T. efforts, Laureto says. “Our approach is to provide tools that assist the

providers in capturing credible clinical data in the electronic medical record,” she says.

“We utilize Cerner’s specific functionality to pull reports and decision support tools to assist users with prompts to populate data in the EHR, addressing the human element at all times.”

Laureto coaches that all of this needs to occur in an environment that is open to improvement, and one in which providers reporting events know they will be supported and each report followed up on.

McDonald and Mayer have addressed that need in ways that are setting national examples for organizations striving to develop cultures of safety.

McDonald was recently named principal investigator of a \$3 million AHRQ grant to share a “principled approach” to patient harm at nine additional hospitals in the Chicagoland area, along with co-investigator Mayer.

Locally, Mayer has found a way to incorporate reporting of near misses and unsafe conditions into resident training requirements at UIMC.

As associate medical officer for graduate medical education, Mayer says he is training a new type of doctor—one that knows only to put the patient at the center of care and one that knows reporting of medical error and near misses is a way to improve care.

“By 2012, the Accreditation Council for Graduate Medical Education will require residents to be engaged in safety and quality education which will include the reporting of hazards and risks inherent in healthcare at their institutions,” says Mayer.

At UIMC, residents are ahead of the curve, already reporting patient safety events defined as incidents, near misses or unsafe conditions related to patient care into a Web-based system as events occur.

Each report made by the resident then generates reports to the hospital’s safety and risk officer, the residency program director and, as a follow-up, references to evidence-based, best practice guidelines

“We took the data and rallied around it—no one was hung out to dry.”

—David Mayer, M.D.

and articles related to the occurrence are sent to the resident reporting the event, furthering the educational opportunity.

“The information reported back to our departments is de-identified, aggregate data,” says Mayer. “In our anesthesia department, for example, we received 17 reports over a three-month period, nine of which were due to inadequate attending supervision of the residents. We took the data to our staff meeting and rallied around it—no one was hung out to dry, the residents felt they were heard, we are all making an effort to improve and we will follow up to see if we have improved.”

UIMC has addressed these frequently encountered reporting obstacles, and has in fact moved forward on the creation of a related educational feedback and assessment software program that will not only improve the quality of its healthcare system, but train the next generation of physicians on how to be safer caregivers, shares Mayer.

“Changing to a culture of safety makes our job easier,” concurs Bill Galanter, M.D., medical director for clinical information systems. “People are willing to do a little extra to input data that makes the system more credible.”

Galanter relates he has found providers more willing to heed alerts built into I.T. systems and follow best practices generated by the EHR when they are part of a culture that supports these efforts.

“We have succeeded in creating an I.T. environment that makes it simple to input safety-related events on a Web page,” adds CIO Laureto. “Providers feel comfortable sharing what they see occurring in the hospital.” ■

Tracy Granzky Wetzel is a Chicago-based health care freelance writer.