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An Electronic Health Record–Based Real-Time Analytics Program For Patient Safety Surveillance And Improvement

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ABSTRACT Twenty years after publication of the report *To Err Is Human*, studies demonstrate persisting high levels of patient harm. Most patient safety measurement remains highly retrospective, relying on voluntary reporting and post discharge administrative coding. Progress has been limited by the lack of advances in measurement accuracy, detection sensitivity, and timely actionability. The broad adoption of electronic health records (EHRs) offers a significant opportunity to leverage digital information to improve safety measurement and management using real-time data. We developed a novel method to extract safety indicators from EHRs to identify harm and its precursors by implementing a patient safety active management system (PSAM) in hospitals within a national Patient Safety Organization (PSO). The PSAM generated validated adverse event outcomes and leveraged EHR data to develop a real-time safety predictive model. This study describes the PSAM's pilot at two large community hospitals in 2014–17. We found that the PSAM could detect harm in real time, at higher rates than current levels are detected, and that such harm could be predicted. In addition to outlining future opportunities and challenges with this EHR-enabled PSAM approach, we discuss implications and next steps for policy and practice.

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Twenty years after the publication of *To Err Is Human* by the Institute of Medicine (IOM),¹ the patient safety movement enters its third decade with some notable but slow improvements in safety. With much harm still occurring, there remains a long way to go before health care joins the ranks of other very safe high-risk industries. With the broad adoption of health information technology (IT) and the emergence of high-reliability approaches, we may be at an inflection point for more rapid improvements in patient safety.² These new developments may portend a future approach to patient safety that is very different from the current one, much of which is based on methods that were developed over forty years ago.

Current safety approaches involve measurement largely based on voluntary reporting that detects fewer than 10 percent of overall safety events. These events are often subjected to extensive root cause analyses long after they occurred, with findings that can be superficial and inaccurate, and frequently with recommendations not acted upon.^{3–9} It has been estimated that only 3–5 percent of the adverse events detected from inpatient records are reported by health care providers in hospitals.^{10–13} The use of administrative codes to detect adverse events, best demonstrated by the Hospital-Acquired Condition Reduction Program of the Centers for Medicare and Medicaid (CMS), has been shown to miss more than 90 percent of safety problems and have serious flaws in the accurate

measurement of overall safety problems across hospitals.^{2,6,7,11} Aside from the problems outlined above, the current approaches lack real-time or even timely actionability to help patients as they are being injured. Recent IOM reports suggest that patient safety problems remain very common and widespread across the continuum of care,^{6,7} with more recent studies finding that patient safety problems may lead to the deaths of more than 400,000 inpatients a year, injure another eight million inpatients, and constitute the third-leading cause of death in US hospitalized patients.^{8,9}

Broad adoption of health IT signals that future approaches to patient safety may be very different from current approaches, which are based on methods that were developed long ago. A survey by the Office of the National Coordinator for Health Information Technology found that more than 96 percent of US hospitals have implemented an electronic health record (EHR).² Ironically, most hospitals do not use these EHRs to directly measure patient harm, with the notable exception of one clinical area: infection prevention. Automated surveillance has successfully harnessed the power of EHRs to improve real-time detection of infection problems, allowing for the rapid and enhanced identification of central line-associated bloodstream infections, which has been critical in successful efforts to reduce the occurrence of these infections.²

Hospitals and health systems are moving beyond automated infection surveillance, a precursor of automated all-cause harm detection, to measure safety more broadly with real-time EHR data.¹⁴ These new approaches have been developed and implemented by health systems, EHR vendors, and other health IT vendors using advanced technologies. Further, the legal risks of collecting and analyzing huge new amounts of patient safety data have occasioned the use of federally certified Patient Safety Organizations (PSOs), established by the Patient Safety and Quality Improvement Act of 2005, which provide a legal and safe learning environment in which to collect and analyze patient safety data and provide feedback to hospitals, clinical teams, and patients without the fear of retribution.^{4,6,14} Building on the evidence above using elements from the EHR to identify harm, CMS has announced the development of a next-generation patient safety measure based on the use of EHR data.²

This article explores what the future of patient safety and quality improvement in the era of health IT might look like. We describe an initiative that used real-time EHR data; the privileged data aggregation, analysis, and feedback of a PSO; and the combination of big data and pre-

dictive analytics to create a real-time patient safety management system to detect safety problems as they occur and predict them before they happen. We evaluate how this system performed in two pilot hospitals and offer lessons from the experience to guide policy makers in this rapidly growing area of patient safety.

Study Data And Methods

This study was conducted through a federally certified PSO (Pascal Metrics), which partnered with its member hospitals and health systems to develop an automated cloud-based patient safety management system using real-time data from leading commercial EHRs. The patient safety active management system (PSAM) used a real-time analytics technology platform contained within the PSO that allowed for an interactive work flow in which users shared potentially sensitive safety data protected in the PSO environment.¹⁴ The safe learning space within the PSO is supported by the PSAM, which in turn generates the patient safety predictive score (SPS)—which was first pilot-tested in the two study hospitals within the PSO in this 2014–17 study. The PSAM has subsequently been expanded to other hospitals and health systems in the US.^{4,14}

THE PATIENT SAFETY ACTIVE MANAGEMENT SYSTEM The PSAM included functions such as surveillance, detection, classification, validation, measurement, analytics, overall management of safety events, and prediction (described below). The PSAM, hosted in a PSO technical environment, was fed real-time data from EHRs and health IT systems using standard protocols such as the internationally used HL7. The PSO applied algorithms in real time to streaming normalized data, generating standardized triggers, or signals of potential adverse events. This output was then subjected to a standardized review and clinical validation process by the PSO member hospitals^{14–16} (see the “Review Process” section in the online appendix).¹⁷

STANDARDIZED REVIEW AND CLINICAL VALIDATION PROCESS Our approach built on the Institute for Healthcare Improvement’s Global Trigger Tool approach to measuring safety through the use of standardized chart review and the use of clinical triggers.^{11,18–21} Electronic versions of the Global Trigger Tool were automated for use with all leading commercial EHRs.^{14–16,18–20} Registered nurse and physician authenticators who validated the occurrence of adverse events at PSO member hospitals consisted of those experienced in harm identification using the Global Trigger Tool manual process^{14–16,18–20} and those receiving training in this automated PSAM method. Standard operating procedures were estab-

lished for using the PSAM in a hospital or a health system.

Each day a nurse reviewer followed all of the automated positive triggers in the PSAM and determined whether a patient harm had occurred.¹⁴ Reviewers used the Institute for Healthcare Improvement's definition of *harm*: "unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death."^{21(p5)} If a harm was identified, it was classified and assigned to one of five harm categories (medication, patient care, surgery or procedure, perinatal, and health care-associated infection) and given a severity level (E-I), according to the National Coordinating Council for Medication Error Reporting and Prevention standard.²² This process took approximately five minutes of review time for every trigger found, on average. Details have been reported elsewhere¹⁴⁻¹⁶ and are also in the appendix.¹⁷

SAFETY PREDICTIVE SCORE DEVELOPMENT AND STATISTICAL METHODS We developed a predictive safety model based on data from the clinically validated adverse events documented in the PSAM in the period 2009–13 and from hospital inpatient EHR data contained within the PSO. Inpatient EHR data enabled the creation of many features that were used as machine-learning model inputs. Using feature engineering, a process that creates predictor variables for machine-learning models, we isolated risk factors for adverse events using data to guide our discovery process.²³ Data elements used included lab results, vital-sign measures, medication usage, hospital use, and movement of patients within the hospital, as described in a recent report²³ and in the appendix.¹⁷ The resulting SPS model for the prediction of the occurrence of an adverse event had the following characteristics: The C-statistic, or measurement of SPS model accuracy, was 0.9058 in the training set (used to build the initial SPS model) and 0.8806 in the validation set (used to measure the SPS model's predictive accuracy on new patient data). (A score of 1.0 would be the highest possible model accuracy.) In addition, we used a variety of statistical methods to compare populations in the analysis, as described in the appendix.¹⁷

STUDY POPULATION AND PATIENTS Two large (more than 250 beds) PSO member hospitals located in different US geographic regions participated in the study. All inpatients older than age eighteen who were admitted for more than twenty-four hours (excluding those admitted to behavioral health or rehabilitation units) were included. The PSAM was implemented at both hospitals in the period 2014–17. During this pe-

riod the SPS aspect of the PSAM was pilot-tested at one hospital for five months and at the other for nine months. This pilot-testing period formed the basis for the correlation analysis described below.

For the pilots, a web-based module displayed a list of patients on each unit, with their SPS (calculated twice per day, before each nursing shift) and a visual indicator of high, medium, and low risk of having an adverse event and an icon to indicate whether the score had increased, decreased, or remained unchanged from previous scores. The system displayed a trend line of each patient's risk over time, along with specific predictors that contributed to the score, and provided access to a screen that displayed positive triggers that fired for the patient (appendix figure 1).¹⁷ Unit charge nurses responsible for coordinating assignments and facilitating care on the units reviewed the list of SPS patients during every nursing shift.

LIMITATIONS This study had several limitations. First, pilot-testing in two community hospitals might limit the generalizability of its findings to academic, specialty, pediatric, and public hospitals.

Second, both hospitals were large community hospitals in different US regions, and each had a fully implemented EHR with extensive coded clinical documentation and a high degree of automation of all departments using the EHR—thus allowing for the evaluation of the large clinical data sets in this study. Some hospitals might not have as extensive an EHR.

Third, the SPS model included only those data elements found in a modern commercial EHR. Other data elements not routinely tracked in a modern EHR could produce a better model and could improve the effectiveness of this model to predict safety problems.

Study Results

There were 147,503 inpatient admissions in the two hospitals during the study period. Patients' demographic characteristics were similar across the hospitals, but compared to hospital A, hospital B had about 50 percent more admissions, a higher percentage of female admissions (65 percent versus 55 percent), and a lower inpatient mortality rate (1.04 percent versus 1.75 percent) (exhibit 1). During the study period, 775,416 electronic triggers were recorded, and 3,896 events met the criteria for clinical validation as an adverse event. In the study period 438,652 predictive safety scores were calculated. Exhibit 2 shows the top fifteen triggers by volume in the study population. The most common categories of triggers were general medication (66 percent)

EXHIBIT 1

Demographic characteristics of the study population in two hospitals that pilot-tested the patient safety active management system (PSAM)

Characteristic	Hospital A		Hospital B		Both hospitals	
	Number of patients	Mean	Number of patients	Mean	Number of patients	Mean
Sex						
Female	31,852	54.6%	57,709	64.8%	89,561	60.7%
Race/ethnicity						
White	50,029	85.7%	71,887	80.7%	121,916	82.7%
Black	6,512	11.2%	7,954	8.9%	14,466	9.8%
Hispanic	1,347	2.3%	6,543	7.3%	7,890	5.3%
Asian	291	0.5%	2,386	2.7%	2,677	1.8%
Age, years	— ^a	56.4	— ^b	42.1	— ^c	47.8
Length-of-stay, days	— ^a	4.6	— ^b	3.6	— ^c	4.0
Readmission	— ^a	7.34%	— ^b	5.78%	— ^c	6.40%
Mortality	— ^a	1.75%	— ^b	1.04%	— ^c	1.32%

SOURCE Authors' analysis of data for 2014–17 from the automated cloud-based PSAM of Pascal Metrics, a Patient Safety Organization (PSO). **NOTE** Hospitals A and B were large community hospitals that pilot-tested the PSAM. ^aFor the entire sample (n = 58,381). ^bFor the entire sample (n = 89,122). ^cFor the entire sample (N = 147,503).

and patient care (29 percent) (data not shown). In both hospitals, surgical triggers accounted for 1.8 percent of the total.

A total of 3,896 adverse events were documented in both hospitals combined (average: 123 events per month at each hospital). The

breakdown by severity was 46.6 percent in category E (temporary harm), 45.4 percent in category F (increased length-of-stay), 2.0 percent in category G (permanent harm), 4.6 percent in category H (life-threatening), and 1.4 percent in category I (patient death). Some patients had multiple adverse events. Overall, medication harm was the top category, followed by infections and procedural complications (exhibit 3).

We examined the correlation between triggers, adverse events, safety predictive scores, and three patient outcomes: inpatient mortality, length-of-stay, and readmission at thirty days. The correlation coefficients and *p* values for length-of-stay, mortality, thirty-day readmission, adverse events, number of triggers, and SPS measures (including SPS change and patient age) are displayed in appendix figure 2.¹⁷ Length-of-stay was significantly positively correlated with all other outcome measures (mortality, thirty-day readmission, and adverse events), trigger volume, SPS measures, and patient age. Mortality was also significantly positively correlated with all other outcome measures and trigger volume, SPS measures, and patient age, except that it was negatively correlated with thirty-day readmission. Readmission was also positively correlated with adverse events, trigger volume, SPS measures, and patient age. Trigger volume was positively correlated with adverse events, length-of-stay, mortality, and SPS measures. SPS maximum value was positively correlated with adverse events, trigger volume, mortality, readmission, and length-of-stay. SPS change was a trending measure for SPS, which was positively

EXHIBIT 2

Top 15 electronic triggers in the study population in two hospitals that pilot-tested the patient safety active management system (PSAM)

Trigger	Percent
Glucose ≥180 mg/dL in 2 consecutive values	21.3
Glucose ≥250 mg/dL	12.0
Radiology study for emboli or deep vein thrombosis	8.8
Anti-emetic administration	6.8
Restraint use	6.4
Glucose ≥250 mg/dL in 2 consecutive values	5.2
Blood urea nitrogen >2 times baseline	4.1
In-hospital stroke	3.7
Decrease in hemoglobin ≥25% within 48 hours	3.1
Vitamin K administration	2.8
Decrease in hematocrit ≥25% within 48 hours	2.7
Sepsis indicator: lactate and blood urea nitrogen	2.1
Unplanned hospital readmission within 15 days	1.4
Decrease in hemoglobin ≥25% after surgery	1.2
Platelets <50,000	1.0

SOURCE Authors' analysis. **NOTES** Blood glucose higher than 180 mg/dL is considered hyperglycemia. Antiemetics are administered in the case of patient nausea. Blood urea nitrogen is an indicator of kidney function. A decrease in hemoglobin is an indicator of possible blood loss. A decrease in hematocrit is an indicator of low red blood cell count and possible bleeding. Vitamin K administration is an indicator of an underlying problem with anticoagulation. There were 775,416 electronic triggers during the study period.

correlated with adverse events, mortality, length-of-stay, and SPS measures.

Another way to show correlation between the SPS and adverse event outcomes is to calculate the C-statistics, which are prediction accuracy measures for using the SPS to predict adverse event outcomes. For adverse events, the SPS maximum value had the highest C-statistics at hospital A (0.758) and hospital B (0.721), as well as for the two hospitals combined (0.735) (exhibit 4). For mortality, the SPS maximum value had higher C-statistics in both hospitals (0.808 at hospital A and 0.822 at hospital B), which shows that the SPS could predict patient mortality. We also noted in our analysis (data not shown) an overall decline in SPS during the patient's admission, which can be attributed to overall improvement of the patient during their hospitalization. We discuss these findings in more detail in the appendix.¹⁷

We compared mortality, readmission, and adverse event rates between patients with and without triggers using chi-square tests (see cohort comparison and tables F1–3 in the appendix).¹⁷ The mortality of the trigger cohort was 1.78 percent versus 0.00 percent in the no-trigger cohort. The thirty-day readmission rate of patients with triggers was 10.98 percent versus 0.75 percent in patients without triggers. The adverse event rate of patients with triggers was 11.14 percent versus 0.00 percent in those patients without triggers. The chi-square tests were all significant ($p < 0.0001$).

Finally, we analyzed the SPS as a precursor in time to the occurrence of the subsequent adverse event and found that the SPS moved into a high-risk category 3.53 days, on average, before the associated adverse event actually occurred.

Discussion

We developed and implemented a program in a Patient Safety Organization for real-time patient safety surveillance and improvement supported by a system called the patient safety active management system in this study. This system was built to operate on top of leading commercially available EHR systems currently in use at most US hospitals. The first focus of this study was the improved detection of safety events, and it found, on average, more than ten times more harms than those found by conventional approaches.¹⁴ Relying on real-time EHR streaming data, this approach allowed for the real-time detection of safety problems, operationally enabling interventions to help patients as these safety problems occurred. Many hospitals using this approach have developed and implemented targeted rapid-cycle safety improvement efforts

EXHIBIT 3

Top 11 adverse events documented in the study population in two hospitals that pilot-tested the patient safety active management system (PSAM)

Adverse event	No.	Percent
Medication-related bleeding	540	13.9
Medication-related glycemic events	310	8.0
Medication-related <i>Clostridium difficile</i> infection	292	7.5
Respiratory infection ^a	271	7.0
Venous thromboembolism	228	5.9
Fall with injury	219	5.6
Stage 1 or 2 pressure ulcer	176	4.5
Respiratory complications related to surgery or procedure	154	4.0
3rd or 4th degree lacerations	154	4.0
Medication-related delirium, confusion, or oversedation ^b	124	3.2
Abnormal bleeding/blood loss/hematoma following surgery or procedure	121	3.1

SOURCE Authors' analysis. **NOTE** There were 3,896 adverse events. ^aNot associated with the use of a ventilator. ^bMedications include analgesics, sedatives, and muscle relaxants.

EXHIBIT 4

Safety predictive score (SPS) performance in predicting rates of adverse events, readmissions, and mortality in the study population in two hospitals that pilot-tested the patient safety active management system (PSAM)

SPS	Hospital A	Hospital B	Both hospitals
ADVERSE EVENTS			
SPS_Max	0.758	0.721	0.735
SPS_Mean	0.737	0.698	0.713
First_SPS	0.662	0.631	0.644
Last_SPS	0.735	0.712	0.721
SPS_Min	0.642	0.610	0.621
Adverse event rate	9.40%	7.40%	8.00%
THIRTY-DAY READMISSIONS			
SPS_Max	0.674	0.715	0.704
SPS_Mean	0.668	0.697	0.689
First_SPS	0.701	0.713	0.710
Last_SPS	0.644	0.665	0.661
SPS_Min	0.653	0.651	0.651
Readmission rate	9.80%	7.40%	8.10%
MORTALITY			
SPS_Max	0.808	0.822	0.817
SPS_Mean	0.788	0.802	0.796
First_SPS	0.690	0.682	0.688
Last_SPS	0.827	0.827	0.828
SPS_Min	0.714	0.690	0.696
Mortality rate	1.60%	1.10%	1.30%

SOURCE Authors' analysis. **NOTES** The C-statistic is the correlation coefficient, which measures the strength and direction of the linear relationship between the two variables in the table—that is, the predictive accuracy of the SPS score. SPS_Max is the maximum safety predictive score for each patient during their hospitalization. SPS_Mean is the mean score; first_SPS is the first score; last_SPS is the last score; and SPS_Min is the lowest score for each patient during their hospitalization.

that have resulted in reduction of harm.^{14–16,18} This study demonstrated important linkages between patient outcomes of in-hospital mortality, length-of-stay, and thirty-day readmission and critical safety measures such as triggers, adverse events, and safety predictive scores. We found that mortality, length-of-stay, and readmission were also significantly associated with adverse events.

The use of electronic detection of safety problems is now available through EHR vendors and analytics vendors, and even with home-grown systems at various health systems. But the great challenge is that this approach has not been widely adopted. Barriers to its adoption include an entrenched safety infrastructure based around incident reporting systems, concerns about legal and reputational risk from the detection of many safety events, challenges in how to respond to this increased level of safety problems with already overburdened clinical resources, and questions about the costs and return on investment of this approach. There are published studies that address all of these perceived barriers, but the broad adoption of this approach by providers will likely require either proactive incentive programs by private and public payers or regulatory attention.^{2,4,14–16,18}

The second focus of this study was the development of predictive scores that could identify patients at risk of safety events before they occurred and across the continuum of care. The predictive analytic study in the pilot revealed that SPS can predict adverse events. Both the correlation and C-statistical analysis revealed that the SPS can also predict inpatient mortality and readmission. It was not unexpected that this score would predict readmission and mortality as well, since adverse events have been strongly predictive of both in past studies.^{14,18} Indeed, increases in safety predictive scores were predictive of length-of-stay, mortality, and adverse events. For adverse events, the maximum SPS was the best predictor; for mortality, the last SPS was the most predictive; and for readmission, the first SPS was the most predictive.

A related safety predictive analytic approach, the Rothman Index, was developed as an EHR-based acute score for predicting clinical deterioration and has been successfully implemented.²⁴ Many other approaches have also been developed to predict clinical deterioration, such as the Medical Early Warning Score, the Pediatric Early Warning Score, the Early Warning Score, the Neonatal Early Warning Score in the UK, and the Targeted Real-Time Early Warning Score for the early detection of sepsis.^{24–26} The only comparable method to the SPS approach that we could find is a new program in development

Patients may come to expect to use real-time safety information and predictive analytics in their own care.

called MySurgeryRisk that uses existing clinical data in EHRs to predict the risk for major complications and death after surgery.²⁷ However, there are many electronic safety predictive models in development that could increase the use of these types of electronic predictive scores in clinical practice.

Though we are still very early on in the development of these predictive analytics for patient safety, the pilot hospitals revealed a number of key operational findings and challenges with respect to the use of predictive analytics at the front line of care that may limit the adoption of these approaches.

First, the initial reaction of unit charge nurses at the pilot hospitals was that the SPS would help increase the general safety awareness for high-risk patients, prioritize those patients, and make nursing assignments. The SPS revealed a number of circumstances in which patients' risk of safety problems had not been adequately recognized and intervention was required, based on the predictive score. For example, it identified a group of patients with falls whose unrecognized high fall risk had not been addressed before their falls.

Second, organizations that are measuring harm with the PSAM not uncommonly find it to offer a stable, continuous electronic measure of harm that has been used in turn to measure the impact of specific safety interventions and improvements, underscoring the relevance of a "learning culture of safety" that was envisioned with the creation of PSOs.^{14–16}

Third, the PSAM was viewed by the pilot hospitals as more valuable than the SPS, which is not unexpected given the early stage of development of the field with respect to the prediction of safety problems at the front lines of care.²³

Fourth, since the SPS predicts global harm, it does not direct the users to a specific risk or set of specific interventions that should be addressed to mitigate the risk, thus limiting its applicability

in existing work flows, which was one of the concerns raised at the pilot hospitals

Fifth, many clinicians viewed the review of the score as an added burden on an already highly productivity-driven nursing process and viewed the score as a one more input out of many that nurses needed to review.

Sixth, the organizations that have been most successful with programs such as the PSAM have dedicated resources to implementation, with some early evidence of cost reductions in excess of program costs.¹⁸

Finally, based on CMS's announcement of a new EHR-based measure of harm, provider organizations are contemplating the strategic reconfiguration of their safety and quality programs as they prepare for the new CMS direction in safety measurement and improvement.²

Policy Context, Implications, And Next Steps

Our study has important implications for policy. First, it should be noted that the use of these safety measurement and predictive systems in clinical work flows is still in its infancy, as demonstrated in our pilots, and little research has been conducted about how to use this information most effectively for feedback and learning at the front line of care.

Second, ensuring the interoperability of EHR data (especially clinical documentation such as nurse and physician notes) for use by external systems will be essential for broad and deep impact across the field, without which predictive analytic learnings will be limited to silos of care.

Third, the Food and Drug Administration (FDA) has affirmed that low-risk analytic products do not need to be regulated.²⁸ However, as these new technologies are used as a “black box” at the point of care to support clinical decision making directly, additional oversight and FDA regulation might emerge.

Fourth, because the output of these systems is used to measure patient safety and risk at the

provider level, payers may find it hard to resist the temptation of using such information, which could introduce negative payment issues for providers and potential regulatory oversight for the use of this new safety data.

Last but perhaps most important, the patient's role in the use of this information is unknown. As more complex care moves to the outpatient arena, patients and their families or caregivers might be expected to review this type of information and act on it. Early results from a study supported by the Robert Wood Johnson Foundation indicate that patients can understand, value, and use this type of information,²⁵ which suggests that patients may come to expect to use real-time safety information and predictive analytics in their own care.

Conclusion

This study demonstrated the current capability to detect and predict patient safety problems using existing data from commercial EHR systems. Detection of safety problems is already being automated by both home-grown and generally available commercial solutions. Adoption has been slow to date but may be accelerated by the continued publication of evidence, ongoing regulatory action, and the emergence of the business case for patient safety within value-based care. However, the most effective approach may be financial incentives from public and private payers. In the interim, policy makers may be skeptical of the promise of predictive analytics that fail to be based on sound epidemiology, knowledgeable domain expertise, and valid adverse event outcomes. Problems in accessing high-quality data, the lack of data standards, and a shortage of experts with experience in knowing how to analyze the data effectively will become more pressing concerns as the field seeks to leverage the promise of big data, machine learning, artificial intelligence, and other advanced techniques. ■

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NOTES

- 1 Corrigan JM, Kohn LT, Donaldson MS, editors. *To err is human: building a safer health system*. Washington (DC): National Academies Press; 1999
- 2 Classen DC, Griffin FA, Berwick DM. Measuring patient safety in real time: an essential method for effectively improving the safety of care. *Ann Intern Med*. 2017;167(12):882–3.
- 3 Nance JJ. *Why hospitals should fly: the ultimate flight plan to patient safety and quality care*. Bozeman (MT): Second River HealthCare; 2008.
- 4 Kirkendall ES. Casting a wider safety net: the promise of electronic safety event detection systems. *Jt Comm J Qual Patient Saf*. 2017;43(4):153–4.
- 5 Peerally MF, Carr S, Waring J, Dixon-Woods M. The problem with root cause analysis. *BMJ Qual Saf*. 2017;26(5):417–22.
- 6 Classen DC, Munier W, Verzier N, Eldridge N, Hunt D, Metersky M, et al. Measuring patient safety: the Medicare Patient Safety Monitoring System (past, present, and future). *J Patient Saf*. 2016 Oct 20. [Epub ahead of print].
- 7 Institute of Medicine. *Health IT and patient safety: building safer systems for better care*. Washington (DC): National Academies Press; 2012.
- 8 Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ*. 2016;353:i2139.
- 9 James JT. A new, evidence-based estimate of patient harms associated with hospital care. *J Patient Saf*. 2013;9(3):122–8.
- 10 Christiaans-Dingelhoff I, Smits M, Zwaan L, Lubberding S, van der Wal G, Wagner C. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims, and incident reports? *BMC Health Serv Res*. 2011;11:49.
- 11 Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, et al. “Global Trigger Tool” shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)*. 2011;30(4):581–9.
- 12 Vincent C, Burnett S, Carthey J. *The measurement and monitoring of safety*. London: Health Foundation; 2013.
- 13 Hanskamp-Sebregts M, Zegers M, Vincent C, van Gorp PJ, de Vet HC, Wollersheim H. Measurement of patient safety: a systematic review of the reliability and validity of adverse event detection with record review. *BMJ Open*. 2016;6(8):e011078.
- 14 Sammer C, Miller S, Jones C, Nelson A, Garrett P, Classen D, et al. Developing and evaluating an automated all-cause harm trigger system. *Jt Comm J Qual Patient Saf*. 2017;43(4):155–65.
- 15 Sammer C, Hauck LD, Jones C, Zaiback-Aldinger J, Li M, Classen D. Examining the relationship of an all-cause harm patient safety measure and critical performance measures at the frontline of care. *J Patient Saf*. 2018 Feb 7. [Epub ahead of print].
- 16 Garrett PR Jr, Sammer C, Nelson A, Paisley KA, Jones C, Shapiro E, et al. Developing and implementing a standardized process for Global Trigger Tool application across a large health system. *Jt Comm J Qual Patient Saf*. 2013;39(7):292–7.
- 17 To access the appendix, click on the Details tab of the article online.
- 18 Adler L, Yi D, Li M, McBroom B, Hauck L, Sammer C, et al. Impact of inpatient harms on hospital finances and patient clinical outcomes. *J Patient Saf*. 2018;14(2):67–73.
- 19 Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized surveillance of adverse drug events in hospital patients. *JAMA*. 1991;266(20):2847–51.
- 20 Agency for Healthcare Research and Quality. Kaiser Permanente experience with automating the IHI Global Trigger Tool (text version). Rockville (MD): AHRQ; 2010 Dec.
- 21 Griffin FA, Resar RK. *IHI Global Trigger Tool for measuring adverse events*. 2nd ed. Cambridge (MA): Institute for Healthcare Improvement; 2009.
- 22 National Coordinating Council for Medication Error Reporting and Prevention. *NCC MERP index for categorizing medication errors* [Internet]. Rockville (MD): NCC MERP; 2001 [cited 2018 Oct 11]. Available from: <https://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf>
- 23 Li M, Ladner D, Miller S, Classen D. Identifying hospital patient safety problems in real-time with electronic medical record data using an ensemble machine learning model. *Int J Clin Med Inform*. 2018;1(1):43–58.
- 24 Rothman MJ, Rothman SI, Beals J 4th. Development and validation of a continuous measure of patient condition using the electronic medical record. *J Biomed Inform*. 2013;46(5):837–48.
- 25 Classen DC, Butler JM. A14: empowering patients; real-time safety e-dashboards. Paper presented at: IHI National Forum on Quality Improvement in Health Care; 2017 Dec 9–12; Orlando, FL.
- 26 Gerry S, Birks J, Bonnici T, Watkinson PJ, Kirtley S, Collins GS. Early warning scores for detecting deterioration in adult hospital patients: a systematic review protocol. *BMJ Open*. 2017;7(12):e019268.
- 27 Bihorac A, Ozrazgat-Baslanti T, Ebadi A, Motaie A, Madkour M, Pardalos PM, et al. MySurgeryRisk: development and validation of a machine-learning risk algorithm for major complications and death after surgery. *Ann Surg*. 2018 Feb 27. [Epub ahead of print].
- 28 Price WN. Regulating black-box medicine. *Mich L Rev*. 2017;116(3):2.