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'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured

ABSTRACT Identification and measurement of adverse medical events is central to patient safety, forming a foundation for accountability, prioritizing problems to work on, generating ideas for safer care, and testing which interventions work. We compared three methods to detect adverse events in hospitalized patients, using the same patient sample set from three leading hospitals. We found that the adverse event detection methods commonly used to track patient safety in the United States today—voluntary reporting and the Agency for Healthcare Research and Quality's Patient Safety Indicators—fared very poorly compared to other methods and missed 90 percent of the adverse events. The Institute for Healthcare Improvement's Global Trigger Tool found at least ten times more confirmed, serious events than these other methods. Overall, adverse events occurred in one-third of hospital admissions. Reliance on voluntary reporting and the Patient Safety Indicators could produce misleading conclusions about the current safety of care in the US health care system and misdirect efforts to improve patient safety.

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Improving patient safety continues to be a priority for both policy makers and health care providers in the United States. As a result, during the ten years since the publication of the Institute of Medicine's landmark report, *To Err Is Human: Building a Safer Health System*, there have been numerous initiatives to improve the safety of patient care in the United States.[1–4]

Several studies have reported on the often resource-intensive interventions intended to improve the safety and reliability of care in the highly fragmented US health care system.[2–4] Many studies have attempted to evaluate the safety of US health care overall. Some emphasize great progress, and others highlight how much more work is to be done. A recent study of hospitals in North Carolina showed a high rate of adverse events that has not changed over time, despite notable efforts in the state to improve the

safety of inpatient care.[5–7]

A key challenge has been agreeing on a yardstick for measuring the safety of care in hospitals.[8] Some studies have relied on the rate of adverse events based on voluntarily reported sentinel events (any unanticipated event in a health care setting resulting in serious injury or death, not related to a natural course of the patient's illness) at the national or state level. Many health care organizations have also used their own internally reported sentinel events to measure the safety of their system.[9]

This focus on sentinel events has been encouraged by the adoption of reporting patient safety "never events" (events that should not have happened; for example, deaths from blood transfusions) in several states. The Joint Commission's Sentinel Event Policy of 1996 and the Patient Safety and Quality Improvement Act of 2005 encourage further development of such volun-

tary reporting systems.[10] However, an Institute of Medicine–sponsored review noted that voluntary reporting systems miss many significant adverse events, and it called for the development of other methods for measuring patient safety.[11]

Some—including the Institute for Healthcare Improvement in its 100,000 Lives and 5 Million Lives Campaigns—have used overall and risk-adjusted hospital mortality rates, which take into account the severity of medical conditions, as global measures of patient safety.[12] Many health care organizations have also adopted a mandatory review of the records of all patient deaths as part of this approach to measuring safety.[11] However, mortality rates are crude measures of safety that focus on the most extreme events and are not suitable for evaluating the overall effect of multifaceted patient safety programs or the effect of specific interventions.

Accordingly, other measures of patient safety—such as the Agency for Healthcare Research and Quality's Patient Safety Indicators or the Utah/Missouri Adverse Event Classification (a superset of Patient Safety Indicators)—have been developed with ease of use and automated mining of administrative and financial databases in mind. Both of these measures rely on an automated review of discharge codes to detect adverse events.[13–15] The Utah/Missouri approach is more comprehensive because it uses many more diagnostic codes. Organizations, states, and the Centers for Medicare and Medicaid Services have used these measures to compare or benchmark hospitals' performance for patient safety.

Some studies have suggested that these automated measures of patient safety are neither sensitive nor specific enough to correctly identify adverse events.[16] This concern has prompted the search for more direct approaches to measuring adverse events. Such approaches generally rely on more exhaustive physician or nurse reviews of a patient's complete medical record or chart. This was the approach used in the Harvard Medical Practice Study of adverse events in hospital patients.[17] However, it is extremely labor-intensive, which limits its use.

In response to the need for a more practical and less labor-intensive approach to assessing patient safety, the Institute for Healthcare Improvement developed the Global Trigger Tool.[18] This new method has been increasingly used by hospitals in the United States and the United Kingdom (such as Ninewells Hospital near Dundee, Scotland, as described in the article by Carol Haraden and Jason Leitch, also in this issue).[19] The tool has also been used by quality improvement organizations, and by regulators such as the Department of Health and Human Services

(HHS) Office of Inspector General, which has used it in a study to estimate the incidence of adverse events in hospitalized Medicare patients.[20]

This study by the HHS Office of Inspector General has led to recommendations that the Centers for Medicare and Medicaid Services develop new detection methods for adverse events in hospitalized Medicare beneficiaries. The study has also informed ongoing work to evaluate and update national patient safety measures at the National Quality Forum, a nonprofit organization that seeks to build consensus around national performance measures for quality and disseminate them.

The Global Trigger Tool uses specific methods for reviewing medical charts. Closed patient charts are reviewed by two or three employees—usually nurses and pharmacists, who are trained to review the charts in a systematic manner by looking at discharge codes, discharge summaries, medications, lab results, operation records, nursing notes, physician progress notes, and other notes or comments to determine whether there is a "trigger" in the chart. A trigger could be a notation indicating, for example, a medication stop order, an abnormal lab result, or use of an antidote medication. Any notation of a trigger leads to further investigation into whether an adverse event occurred and how severe the event was. A physician ultimately has to examine and sign off on this chart review.[21]

In our study we evaluated the ability of these three methods (the hospital's voluntary reporting system, the Agency for Healthcare Research and Quality's Patient Safety Indicators, and the Institute for Healthcare Improvement's Global Trigger Tool) to detect the incidence of adverse events among inpatients in three leading hospitals that have invested heavily in advanced patient safety programs, initiatives, and research projects. We also compared the performance of these methods for measuring patient safety among the three hospitals. This article reports our findings.

Study Data And Methods
We evaluated the incidence of adverse events for inpatients at three hospitals, using several methods of detecting adverse events: retrospective record review (working backward from patients' medical charts) using the Institute for Healthcare Improvement's Global Trigger Tool; each hospital's voluntary sentinel event or other incident or event reporting system; and screening with the Agency for Healthcare Research and Quality's Patient Safety Indicators. We also used automated screening with the Utah/Missouri

Adverse Event Classification at one hospital.[15]

Because of our confidentiality agreements with the hospitals, we cannot identify them, but we provide additional information on key characteristics of the hospitals below.

We needed to evaluate the overall performance sensitivity and specificity, as well as the positive and negative predictive value, of the three detection methods. Thus, a physician-led local review team (see the Appendix for more detail)[22] independently conducted a complete detailed review of all hospital records for patients included in the study at one hospital (hospital A) and a review of all clinical, financial, administrative, electronic, and longitudinal health history information on those same patients.

The Global Trigger Tool is based on prior work by David Classen at LDS Hospital in Utah and the Harvard Medical Practice Study methodology for retrospective hospital chart review.[23–26] Hospital teams first used an Adverse Drug Event Trigger Tool to detect adverse drug events during an Institute Breakthrough Series Collaborative, which began in 2000 to bring together teams from hospitals and clinics to focus on specific areas of improvement.[27]

The institute and its faculty subsequently developed additional trigger tools to detect adverse events in the adult intensive care unit, in surgical and perinatal populations, and in neonatal and pediatric intensive care units.[28–30] The institute then developed the Global Trigger Tool in 2003 to detect adverse events across an entire hospital. The tool has been evaluated in terms of inter-rater reliability (the amount or degree of agreement among the raters or methods) specifically for the review approach used in this study.[31]

Our study used the Global Trigger Tool methodology in a two-stage review process, refined from the Harvard Medical Practice Study's methodology.[32] The same team of four nonphysician reviewers ("primary reviewers") and two physician reviewers ("secondary reviewers") participated in the review process for all records sampled from the three hospitals. Additional detail is available in the Appendix.[22]

We used the following definition for *harm*: "unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death."[33] Because of prior work with Trigger Tools and the belief that ultimately all adverse events may be preventable, we did not attempt to evaluate the preventability or ameliorability (whether harm could have been reduced if a different approach had been taken) of these adverse events. All events found were classified using an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention's Index for Categorizing Errors.[34]

In addition, all events were assigned to broad categories by consensus of the two secondary reviewers. Categories included medication; infection; device failure; pressure injuries; procedures; surgery; pulmonary/thromboembolism, patient falls, and anesthesia; and cardiac/myocardial infarction.

HOSPITAL SELECTION We selected three large US tertiary care centers that had well-established operational patient safety programs based on the following criteria: (1) They received external funding for patient safety research; (2) they had internal operational programs focused on improved detection of safety incidents and adverse events through patient safety reporting programs, and special tools built around advanced electronic health record systems used within all three organizations; (3) and they had received external recognition for internal patient safety initiatives through awards, publications, or involvement in national initiatives.

All three hospitals were part of large health systems. Hospital C was an academic hospital, and hospitals A and B were community-based teaching hospitals. Hospital A was located in a midsize metropolitan area in the West, hospital B was in a large metropolitan area in the Midwest, and hospital C was in a large metropolitan area in the Northeast. Hospital size ranged from 550 to 1,000 beds, and all three hospitals offered a full range of medical services, covering primary care to quaternary care.

All three hospitals were major tertiary (specialized) referral centers with significant local market share and were teaching hospitals for their respective medical schools. Each hospital received local Institutional Review Board permission for its participation in the study.

PATIENT SELECTION We randomly selected study patients from all adult (age on admission greater than eighteen years) inpatients (length-of-stay more than twenty-four hours) admitted during the period October 1–31, 2004. Medical records for study patients were administratively complete and included a completed discharge summary. A random-number generator was used corresponding to the last digit of the patient record number. Records were assigned identification numbers, and all evidence of patient identification was removed from the abstracted data. Statistical analysis was done using the statistical software Stata (version 10).

LIMITATIONS Our study was constrained by several limitations. First, the detection of adverse events by all of the methods we examined probably represents a minimum number of adverse events actually present in these hospitalizations,

based on medical record documentation alone. Because patients' hospitalizations were not reviewed in real time by direct observation, this study could not assess the actual number of adverse events. Although not an absolute gold standard, the detailed review at hospital A of all available longitudinal patient information for those patients included in the study does allow for an approximation of sensitivity (true positives), specificity (false positives), and predictive value (ability to detect) of the three methods.

Second, the hospitals selected for this review represented hospitals that had developed extensive patient safety programs, and they might not represent average hospitals across the country. Therefore, our findings may represent fewer or more adverse events than seen in other organizations.

Third, each of these hospitals is a tertiary referral center; thus, they may represent a more complex patient mix than the average hospital.

Study Results

A total of 795 patient records were reviewed from the three hospitals in the study. Exhibit 1 shows the overall demographics of the population from each hospital, for both the sample and the population from which the sample was drawn. Patients in the study sample were similar to the overall population at each hospital in terms of age, sex, acute length-of-stay, and case-mix. Average mortality of the sample was similar to that of the overall population at two of the hospitals but differed at the third.

Among the 795 patient records reviewed, 393 adverse events were detected by all three methods combined. The Global Trigger Tool methodology detected 354 adverse events (90.1 percent

of the total), the local hospital reporting systems detected 4 adverse events (1.0 percent), and the Patient Safety Indicators detected 35 adverse events (8.99 percent).

Overall, adverse events occurred in 33.2 percent of hospital admissions (range: 29–36 percent) or 91 events per 1,000 patient days (range: 89–106). Some patients experienced more than one adverse event; the overall rate was 49 events per 100 admissions (range: 43–56). Patients who experienced adverse events were older and had higher mortality, greater hospital length-of-stay, and a higher case-mix index (a measure of the characteristics of patients treated based on resource use and intensity of care) than patients without an adverse event (Exhibit 2).

Exhibit 3 shows the breakdown of adverse events detected, by severity level and event type. Medications, surgery, procedures, and nosocomial (hospital-associated) infections were most common, and the most severe events were related to surgery or a procedure. Exhibit 4 shows the number of events detected by the three methods, by severity level. The same pattern in the severity level of events detected by the various methods was also evident in the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Errors.

As described above, we also conducted a detailed review at hospital A to evaluate the sensitivity of each method (the degree to which it accurately identified patients who had truly experienced adverse events) as well as each method's specificity (the degree to which it accurately identified that patients had not experienced adverse events). Based on that review, we calculated that the Global Trigger Tool method had a sensitivity to detect patients with at least one adverse event of 94.9 percent and a specificity to

EXHIBIT 1

Demographic Profiles Of The Three Hospitals, By Overall Population And Study Sample

Demographic variables	All three hospitals		Hospital A		Hospital B		Hospital C	
	Overall	Sample	Overall	Sample	Overall	Sample	Overall	Sample
Average age (years)	53.8	52.1	50.4	50.6	58.5	54.0	52.4	52.1
Sex (percent female)	62.7%	64.3%	59.7%	58.9%	64.8%	69.6%	63.1%	66.8%
Raw mortality	1.99%	1.14%	1.00%	0.93%	2.31%	0.80%	2.18%	1.82%
Length-of-stay (days)	4.9	4.8	5.1	4.8	4.7	4.1	5.0	5.8
Case-mix index	1.52	1.37	1.61	1.50	1.42	1.35	1.54	1.23
Most common discharge DRGs (percent of all cases)								
Obstetrical[a]	20.2%	23.1%	19.1%	20.2%	19.9%	27.2%	20.8%	22.7%
Cardiovascular[b]	17.6	18.1	16.0	15.3	21.6	18.8	16.1	21.4
Musculoskeletal[c]	9.4	13.7	13.2	15.0	9.1	11.6	7.9	14.1

SOURCE Authors' analysis. **NOTES** All discharges were in October 2004. DRG is diagnosis-related group. [a]DRGs 370–5, 382–4. [b]DRGs 103–43, 515–8, 525–7. [c]DRGs 209–56, 491, 519–20, 531–2, 537–8.

detect patients with no events of 100 percent. By contrast, the Patient Safety Indicators method had a sensitivity of 5.8 percent and a specificity of 98.5 percent. The Utah/Missouri classification had a sensitivity of 46.6 percent and specificity of 90.1 percent, and the local hospital's voluntary reporting system had a sensitivity of 0 percent and a specificity of 100 percent (see the Appendix for a more detailed description).[22]

Discussion

Voluntary, sentinel event, and "never event" reporting systems, including those mandated by states and other oversight bodies, continue to be the most common method used to detect and track adverse events in most US hospitals. Our study suggests that despite sizable investments and aggressive promotional efforts by local hospitals, these reporting systems fail to detect most adverse events.[35–39] Our study adds further support to similar observations from the recent study by the HHS Office of Inspector General.[20] Hospitals that use such methods alone to measure their overall performance on patient safety may be seriously misjudging actual performance. Policy makers who support this approach for public reporting also need to understand its severe limitations.

The Agency for Healthcare Research and Quality's Patient Safety Indicators also missed most of the adverse events detected by the Institute for Healthcare Improvement's Global Trigger Tool record review method. The Utah/Missouri Adverse Event Classification also showed low true positive rates, although it still performed better than the Patient Safety Indicators.[14–16]

EXHIBIT 2

Demographic Characteristics Of Hospital Patients, By Presence Or Absence Of An Adverse Event

Demographic variable	Adverse event present	Adverse event absent
Mean age (years)[a]	58.7	49.0
Sex (percent female)[b]	61.8%	72.4%
Mortality[b]	2.36%	0.56%
Mean length-of-stay (days)[a]	7.73	3.45
Case-mix index[a]	1.78	1.18

SOURCE Authors' analysis. [a]p value calculated using two-sided t-test assuming unequal variances, $p < 0.0000001$ for all variables. [b]p value calculated using two-sided exact binomial test of independent proportions (StatExact, Cytel Software): for sex, $p = 0.1078$; for mortality, $p = 0.03069$.

Based on the local analysis at hospital A, the Global Trigger Tool method had both high sensitivity and high specificity, the Patient Safety Indicators method had very low sensitivity and high specificity, and voluntary reporting systems seemed to be very insensitive. Neither voluntary reporting systems nor the Patient Safety Indicators seemed to be better at detecting more severe events in this study, as has been reported in several other studies.

Although no accepted gold standard exists for the detection of adverse events in hospital patients, the method of local review at hospital A may be a proxy for a gold standard: It included not only the records of the inpatient admission of concern, but also all longitudinal health records and all other clinical, financial, and administrative records for each of the patients included in the study at hospital A.

The Global Trigger Tool is a well-developed,

EXHIBIT 3

Adverse Events In Three Study Hospitals Detected By All Methods, By Severity Level

Type of adverse event	Severity level					
	E	F	G	H	I	Total
Medication-related	100	46	2	2	0	150
Procedure-related (excluding infection)	67	26	5	7	4	109
Nosocomial infection	30	37	2	2	1	72
Pulmonary/VTE	8	5	2	0	1	16
Pressure ulcers	10	1	0	0	0	11
Device failure	0	6	0	0	0	6
Patient falls	2	1	0	0	0	3
Other	10	11	0	3	2	26
Total	227	133	11	14	8	393

SOURCE Authors' analysis. **NOTES** The severity level categories used here are adapted from the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Errors. This system uses categories labeled A–I, classifying events as to whether errors reach a patient and the severity of resulting harm. Error categories that reach the patient and cause harm are labeled E–I, with severity increasing from E (temporary harm that requires intervention) to I (death). The Appendix includes more detail on each of the categories; see Note 22 in text. VTE is venous thromboembolism.

EXHIBIT 4

Adverse Event Detection, By Severity Level And Hospital

	IHI Global Trigger Tool	AHRQ Patient Safety Indicators	Hospital voluntary reporting system
SEVERITY LEVEL			
E	204	23	0
F	124	7	2
G	8	1	2
H	14	0	0
I	4	4	0
Total	354	35	4
HOSPITAL			
Hospital A	161	13	0
Hospital B	92	13	3
Hospital C	101	9	1
Total	354	35	4

SOURCE Authors' analysis. **NOTES** IHI is Institute for Healthcare Improvement. AHRQ is Agency for Healthcare Research and Quality.

well-documented, and publicly available approach to the detection of adverse events in hospital patients. Its use in hospitals has been increasing, but it could increase further with appropriate guidance from policy makers.

Although the tool's approach is less resource-intensive than earlier record review approaches, the successful use of this tool still requires some resource commitments. However, review costs may decline, and the tool may become much more easily generalizable, if it can be successfully automated within commercial electronic health record systems. A health system has recently accomplished such automation of this tool.[40] The increasing adoption of electronic health records may make such adverse event detection tools more generally available, especially if policy makers incorporate the use of such tools into future meaningful-use criteria for record adoption.

A fully electronic hospital would facilitate the use of multiple parallel adverse event detection methods, including electronic health records, voluntary reporting, analysis of administrative coding (such as the Utah/Missouri classification, rather than the Patient Safety Indicators), and even the Medicare Patient Safety Monitoring System,[41] a new patient safety surveillance system. A demonstration project of such a hospital might be conducted through the new Center for Medicare and Medicaid Innovation and might help identify the true rate of harm in the US health care system.

Our study also detected far more adverse events in hospitalized patients than have been found in prior studies. Our detection levels were clearly higher than those of the Harvard Medical Practice Study, which reported inpatient adverse event rates of 3.9 percent and 2.7 percent, respectively, in New York and Utah/Colorado.[17,33,35] Our detection levels were also higher than those of comparative studies of adverse events with other methods in hospitalized patients from England, Australia, and Canada.[42–44]

Part of this difference in incidence is definitional; our study used a broader definition of *adverse events* and did not require that these events either be judged preventable or lead to major disability, as in prior studies. In addition, the severity of illness in US hospital patients has risen since the Harvard Medical Practice Study (patient samples in 1984 and 1992), which may also account for some of the difference; however, the Canadian study was much more recent.[44]

Nonetheless, despite more than a decade of focus on improving patient safety in the United States, the current rates of adverse events among inpatients at three leading hospitals are still quite high for 33.2 percent of hospital admissions for adults. That is more consistent with findings from a recent study in North Carolina hospitals[7] and from the recent HHS study on Medicare patients.[20] The true rates are likely to be higher still, given the consistent finding that direct observational studies reveal higher rates of adverse events than retrospective studies because not all adverse events are documented in the patient record.[45]

Our findings indicate that two methods commonly used by most care delivery organizations and supported by policy makers to measure the safety of care—enhanced voluntary reporting systems and the use of the Agency for Healthcare Research and Quality's Patient Safety Indicators—fail to detect more than 90 percent of the adverse events that occur among hospitalized patients. Reliance on such methods could produce misleading conclusions about safety in the US health care system and could misdirect patient safety improvement efforts.

Our results, in concert with other recent studies, suggest that despite almost ten years since the Institute of Medicine report on patient safety, rates of adverse events in hospital patients are still high.[7,20] As policy makers struggle to measure improvements in patient safety, the results of our study should help inform ongoing efforts to evaluate methods for the detection of adverse events in hospital patients. Specifically, the results could influence the work of the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality as they evaluate methods to detect patient safety problems in Medicare inpatients, as well as the ongoing work at the National Quality Forum to evaluate and develop new national measures of patient safety.

Most important, US hospitals still have an opportunity to improve patient care by reducing care-associated adverse events or harm. Sound measurement helps establish priorities, generate ideas for improvement, and evaluate whether improvement efforts work. The tools presented in this study are a step forward in the overall patient safety effort. ∎

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22 To access the Appendix, click on the Appendix link in the box to the right of the article online.

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In this issue of *Health Affairs*, David Classen and his coauthors report on a study examining different methods for tracking adverse event rates in hospitals. They conclude that the Institute for Healthcare Improvement's (IHI's) Global Trigger Tool identified up to ten times as many adverse events as did other methods—either voluntary disclosure by hospitals,

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Errata

CLASSEN ET AL., APRIL 2011, P. 585 This article contained several errors. First, in the final paragraph under "Study Results," the Patient Safety Indicators method had a sensitivity of 5.8, not 8.5 as shown. Also, in Exhibit 3, the values for "Pulmonary/VTE" in severity level I should have been 1, not 2, leading to a total of 16, not 17. These errors do not affect the article's findings and conclusions. The text and Exhibit 3 have been corrected online.

SMITH ET AL., APRIL 2011, P. 646, P. 652, P. 654 This article contained several errors. First, the fifth sentence in the abstract (p. 646) should have stated that pharmacists resolved nearly 80 percent of drug therapy problems, not nearly 83 percent. Next, Michael P. Starkowski's tenure as commissioner of the Connecticut Department of Social Services ended in April 2011. This should have been reflected in the biographical information on pp. 646 and 654. In addition, the notes to Exhibit 3 (p. 652) should have referred readers to Note 18 in text, not Note 19 in text.

PEABODY ET AL., APRIL 2011, P. 773, P. 781 Information about these authors contained an error. John Peabody is chief medical officer at Sg2. This information was omitted from his biography on p. 773 and was erroneously attributed to a coauthor on p. 781.

WYNIA ET AL., FEBRUARY 2011, P. 267 On p. 267 of this article, first paragraph under "Study Data And Methods," the word "psychologists" should be "psychiatrists."