Measuring Patient Safety: The Medicare Patient Safety Monitoring System (Past, Present, and Future)

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Abstract: The explicit declaration in the landmark 1999 Institute of Medicine report "To Err Is Human" that, in the United States, 44,000 to 98,000 patients die each year as a consequence of "medical errors" gave widespread validation to the magnitude of the patient safety problem and catalyzed a number of U.S. federal government programs to measure and improve the safety of the national healthcare system. After more than 10 years, one of those federal programs, the Medicare Patient Safety Monitoring System (MPSMS), has reached a level of maturity and stability that has made it useful for the consistent measurement of the safety of inpatient care. The MPSMS is a chart review–based national patient safety surveillance system that provides rates of 21 specific hospital inpatient adverse event measures, which have been divided into 4 clinical domains (general, hospital-acquired infections, postprocedure adverse events, and adverse drug events) for analysis. The 2014 MPSMS national sample was drawn from 1109 hospitals and includes approximately 20,000 medical records of patients admitted to the hospital (all payors) for at least 1 of the 4 conditions of congestive heart failure, acute myocardial infarction, pneumonia, and major surgical procedures as defined by the Centers for Medicare and Medicaid Services Surgical Care Improvement Project. The MPSMS is now going through a major transformation to capture additional types of adverse events and is being redeveloped as the Quality and Safety Review System (QSRS). As an example of this transformation, QSRS will electronically import electronic data, which are standardized according to the Centers for Medicare and Medicaid Services billing definitions and will be updated and evolve over time to incorporate expanded standardized data available from electronic health records. This article reviews the development of MPSMS, the strengths and limitations of MPSMS, and expected future directions in patient safety measurement, focusing on those issues that are informing the development and implementation of QSRS.

Key Words: patient safety, measurement, Medicare, policy, quality, risk management, public reporting

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The explicit declaration in the landmark 1999 Institute of Medicine (IOM) report "To Err Is Human" that, in the United States, 44,000 to 98,000 patients die each year as a consequence of "medical errors" gave widespread validation to the magnitude of the patient safety problem.[1] The Department of Health and Human Services Office of Inspector General (OIG) found in 2008 that 27% of Medicare inpatients experienced adverse events or "temporary harm events" during their hospital stay and estimated that 1.5% of the 780 Medicare hospital inpatients included in the study experienced an adverse event that contributed to their deaths.[2] The Department of Health and Human Services OIG also found that overall, 44% of the total number of 302 adverse events or temporary harm events they identified in their study were preventable. Recent reports from the IOM[3,4] and others[5,6] suggest that safety remains a major problem for the U.S. healthcare system.

The *To Err Is Human* report catalyzed a number of U.S. federal government programs to measure and improve the safety of the national healthcare system. After more than 10 years, one of those federal programs, the Medicare Patient Safety Monitoring System (MPSMS), has reached a level of maturity and stability that has made it useful for the consistent measurement of the safety of inpatient care.[5,7–10] The MPSMS is a chart review–based national patient safety surveillance system that provides rates of 21 specific hospital inpatient adverse event measures. The system employs software and trained abstractors to perform an explicit, rule-based medical record review to identify and count events in a reproducible and scalable manner. In recent years, between 18,000 and 40,000 inpatient charts have been reviewed annually, and the resulting data have provided a rich source of insight into the safety of patient care in U.S. hospitals. The MPSMS data have been used in the patient safety sections of the National Health Care Quality and Disparities Reports[9] and currently serve as the major national-level patient safety data source for the Department of Health and Human Services' Partnership for Patients initiative.[5,10,11] More than 90% of the hospital acquired conditions (HACs) measured in the national HAC rate calculated for the PfP are based on MPSMS measures.[12]

The MPSMS is the largest and most robust patient safety–focused source of clinical data abstracted from medical records available today. Table 1 provides a list of the MPSMS adverse events measures, which includes adverse drug events, selected hospital-acquired infections, selected postprocedure complications, pressure ulcers, and others.[7,8,13] Although many adverse event types usually considered as among the most frequent and important types are included, among those not included are surgical site infections and adverse drug events associated with opioids.

The MPSMS was initially developed at a time when electronic health records (EHRs) were less widespread than they are now. As such, its primary approach was manual abstraction of paper-based hospital records. The era of paper medical records is now receding, and medical records are increasingly electronic.[14] Each year, printed and screen-viewed pdf versions of electronic records are more and more common among the records reviewed by this program.[15] The MPSMS is now going through a major transformation to capture additional types of adverse events and to address some of the new realities described previously and is being redeveloped by the Agency for Healthcare Research and Quality (AHRQ) as the Quality and Safety Review System (QSRS). As

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TABLE 1. The Measures in the 2014 MPSMS

Measure Name	Domain	Period Data Available
Adverse events associated with digoxin	Adverse drug event	2004–2014
Adverse events associated with hypoglycemic agents	Adverse drug event	2004–2014
Adverse events associated with heparin	Adverse drug event	2004–2014
Adverse events associated with low molecular weight heparin and factor Xa inhibitors	Adverse drug event	2004–2014
Adverse events associated with warfarin	Adverse drug event	2004–2014
Hospital-acquired pressure ulcers	General	2004–2014
Inpatient falls	General	2005–2014
Central line–associated bloodstream infections	Hospital-acquired infection	2002–2014
Postoperative pneumonia	Hospital-acquired infection	2002–2014
Hospital-acquired antibiotic-associated *C. difficile*	Hospital-acquired infection	2004–2014
Catheter-associated urinary tract infections	Hospital-acquired infection	2005–2014
Hospital-acquired methicillin-resistant *Staphylococcus aureus*	Hospital-acquired infection	2005–2014
Hospital-acquired vancomycin-resistant enterococcus	Hospital-acquired infection	2005–2014
Ventilator-associated pneumonia	Hospital-acquired infection	2005–2014
Adverse events associated with hip joint replacement	Postprocedure	2002–2014
Adverse events associated with knee joint replacement	Postprocedure	2002–2014
Mechanical complications associated with central lines	Postprocedure	2002–2014
Postoperative venous thromboembolic events	Postprocedure	2002–2014
Postoperative cardiac events (cardiac and noncardiac surgeries)	Postprocedure	2004–2014
Adverse events associated with femoral artery puncture for catheter angiographic procedures	Postprocedure	2005–2014
Contrast nephropathy associated with catheter angiography	Postprocedure	2005–2014

an example of this transformation, QSRS will electronically import Admit, Discharge, and Transfer ADT files, which are standardized according to the Centers for Medicare and Medicaid Services (CMS) billing definitions, and will be updated and evolve over time to incorporate the structured electronic data increasingly available from EHRs.

This article reviews the development of the MPSMS, the strengths and limitations of MPSMS, and expected future directions in patient safety measurement, including specifically those issues that are informing the ongoing development and implementation of QSRS.

BACKGROUND

With the increasing interest in patient safety improvement, the demand for establishing an effective method for national patient safety measurement has increased. Historically, the major goals of MPSMS, originally developed under the auspices of the Department of Health and Human Services' Patient Safety Task Force and leadership of the CMS, were to provide an understanding of the magnitude of specific patient safety issues among the hospitalized fee-for-service Medicare population and to obtain baseline and trend data to support national Medicare patient safety improvement initiatives.[7] In April 2001, 4 distinct workgroups were recruited to build MPSMS. The CMS was appointed as the lead organization. The CMS selected Qualidigm, the Connecticut Quality Improvement Organization (QIO), to provide administrative and technical support for the project. The MPSMS Federal Agency Workgroup—including representatives from the AHRQ, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, and, after its creation in 2004, the Office of the National Coordinator for Health Information Technology, and the Veterans Health Administration—provided technical assistance for MPSMS development. Finally, a Technical Expert Panel, consisting of the Federal Agency Workgroup members, representatives of national healthcare organizations, and other national patient safety experts, guided the development process.[7,8,13,15]

To maximize cost-effectiveness and to ease the burden on hospitals of providing an additional separate medical record sample for MPSMS, MPSMS has relied on medical records collected for other CMS initiatives. Initially, from 2002 to 2007, the MPSMS sample population included hospitalized Medicare fee-for-service beneficiaries randomly selected from a subset of the Medicare Hospital Payment Monitoring Program. The system identified exposures to specific hospital healthcare delivery processes and associated adverse events along with specific patient characteristics and outcomes from inpatient medical records and Medicare Part A National Claims and Eligibility databases. These methods have been described in previous publications.[7,8] Beginning in 2009, the MPSMS was expanded to include hospitalized patients aged 18 years and older from all payers (not just Medicare), but it included only those patients who were hospitalized for 1 of the following 4 conditions: congestive heart failure, acute myocardial infarction, pneumonia, and major surgical procedures as defined by the CMS Surgical Care Improvement Project.[8] In 2009, primary coordination of MPSMS was also transferred from CMS to AHRQ. Due to the change in the sample population from 2007 to 2009, data originally collected from the Medicare Eligibility and National Claims databases, such as 30-day mortality and 30-day readmissions, were no longer available for the patient records used in MPSMS.[8,9,15] In-depth information regarding the MPSMS sample is provided in the supplemental material under the study by Wang et al.[8]

Three key principles—intent, transparency, and relevance—guide the development and ongoing analytic processes of MPSMS.[7] The MPSMS uses cost-effective (costs for chart abstraction and data analysis for this national program have been approximately US $3 million per year), well-tested, accurate, and

reliable methods to identify and count specific adverse events. Data from this large, national sample are collected from medical records using an abstraction process performed by abstractors at the CMS Medicare Clinical Data Abstraction Center (CDAC) using explicitly defined clinical questions and instructions. Although all abstractors have an excellent facility with the lexicon of inpatient records, it should be noted that in the process of explicit review, the abstractors make no clinical inferences from the record. To maintain consistency, particularly over time, abstractors are specifically instructed not to use their clinical knowledge or judgment to determine findings. For example, to establish whether a patient had a history or currently had a specific chronic illness, the abstractor must find documentation of a provider-specified diagnosis of the chronic illness in the medical record. The instructions define specific synonyms that the provider may have used in the diagnosis or the description of the adverse event (AE).[7,8,13,15]

In preparation for constructing the data collection tool, algorithms were developed to represent clinical thought processes to determine whether during the hospitalization, the patient was exposed to a specific healthcare delivery process and whether an associated adverse event had occurred. These algorithms were validated and vetted by technical experts. Based on the information required by the algorithm, a data collection tool with specific questions and instructions was developed. Questions and instructions used to guide chart abstraction without the application of clinical judgment by the abstractors were programmed into an electronic data collection software. The algorithms are the basis for analysis of the data collected. Thus, the determination of whether an exposure and an associated adverse event occurred is accomplished through a specific and explicit abstraction protocol and data analysis process.[7,8,13]

Current State

The MPSMS includes measures that were developed in 3 sequential phases from 2002 to 2005 (Table 1). The 21 measures have been divided into 4 clinical domains (general, hospital-acquired infections, postprocedure adverse events, and adverse drug events) for analysis.[8,13] In Table 2 are the results for all the MPSMS measures outlined previously for 2014. The 2014 MPSMS sample is drawn from 1109 hospitals and includes approximately 20,000 medical records of patients admitted to the hospital for at least 1 of the 4 conditions and a new complementary category of patients selected to represent all other conditions.[8] Most MPSMS publications to date have been limited to data from the 4 conditions patient record sample. Information on the use of the MPSMS in the Department of Health and Human Services (HHS) Partnership for Patients program is online on the AHRQ web site.[5] Several articles have been published recently based on MPSMS data on topics. These include articles on (1) the potential to reduce inpatient warfarin adverse events through daily international normalized ratio measurement, (2) how the rate of adverse events may be influenced by the use of a fully EHR, (3) the demographics of healthcare-associated infections, and (4) the mortality associated with adverse events.[16–20] The MPSMS data from the period since that covered by Wang et al[8] is being analyzed for a new peer-reviewed publication addressing the period from 2011 to 2014 and comparing the MPSMS data from this period to previous periods.

Lessons Learned From MPSMS

Strengths

As the program was developed from 2001 to 2007, the MPSMS team accessed and used nationally recognized lists, definitions, and descriptions as a basis for measures and algorithms to increase credibility of MPSMS measures and to maximize the ability to compare with other measure sets used for national reporting. All MPSMS measures and processes are clearly defined, and the limitations of measures and processes are openly acknowledged. The abstraction tool and data elements are reviewed annually with the goals of (1) streamlining the data collection tool and associated record abstraction time and (2) updating the questions and instructions to better reflect changes in clinical knowledge and practice. Changes are only made when considered crucial, to keep the definitions stable and retain the ability to trend data across years.[9,13]

The MPSMS data collection and analysis processes are designed to identify (1) whether a patient is subject to one of the specific healthcare delivery process exposures and (2) whether the patient experienced an associated adverse event. Some types of adverse events may have a tendency to be overestimated or underestimated by MPSMS because of the nature and limitations of the documentation contained in patient medical records. This is one of the reasons why some adverse events, such as surgical site infections, which are highly dependent on postdischarge information, were not included in MPSMS. Because of the limitations of the explicit review process and the absence of a "criterion standard" with which to determine sensitivity and specificity, a continuing goal of the abstraction tool and subsequent analyses is to provide balance, consistent sensitivity and specificity to allow reliable measurement of changes in event frequency over time.[8,15]

The explicit review process eliminates the need for review of the medical record by a physician or other clinical expert, greatly minimizing the chance of bias and subjectivity influencing the results, providing greater consistency over time, and decreasing the cost of review. When the MPSMS measures were developed from 2001 to 2005, expert physicians were employed to review the results of the abstractors' use of the MPSMS tool to identify the specific adverse events of interest, and physician inputs were used to make adjustments to the measures and improve abstractor-training materials. After implementation, determination of interrater reliability and accuracy has been the key components of MPSMS internal quality control. Accuracy is determined as the raw agreement rate of both the original abstractor and the reabstractor with adjudicated standard data. Overall, accuracy is the aggregate agreement rate across all data elements in all cases in the internal quality control sample. In previous reports, agreement rates in MPSMS ranged from 94% to 99%.[7,8] Raw agreements and Kappa statistics are used to measure reliability. The preliminary results are reported to Qualidigm and AHRQ on a quarterly basis, which then prepares an annual report on each calendar year of data that contain final results on all of the MPSMS measures, as well as summary data.[8,15]

Limitations

First, adverse event determination using MPSMS is based solely on retrospective examination of the medical record of the index hospitalization. Clearly, MPSMS has no capacity to assess adverse events that are not documented in the record (although some undocumented events and near misses are routinely recorded in hospitals' event reporting systems). Neither outpatient medical records nor records from past and subsequent hospitalizations are available. Thus, the MPSMS outcomes are solely reflective of documented care during the index hospitalization.

Second, local variability in documentation practices has always been a serious constraint to the accurate evaluation of healthcare quality and consistent identification of adverse events from medical records alone. Third, although hospitals have significant incentive to assure that the complete medical record is

TABLE 2. The 2014 MPSMS Measure Results

Measure	Exposure		Adverse Event		
	n	Rate, %	n	Rate, %	95% CI
Adverse events associated with digoxin	640	3.3	6	0.9	0.34–2.03
Hospital-acquired antibiotic-associated *C. difficile*	14,025	72	70	0.5	0.39–0.63
Adverse events associated with hypoglycemic agents	6802	34.9	596	8.8	8.1–9.19
Adverse events associated with IV heparin	1970	10.1	219	11.1	9.79–12.59
Adverse events associated with low molecular weight heparin and factor Xa inhibitor	7727	39.7	272	3.5	3.12–3.96
Adverse events associated with warfarin	2441	12.5	117	4.8	3.98–5.72
Adverse events associated with femoral artery puncture for catheter angiographic procedures	2242	11.5	47	2.1	1.54–2.78
Adverse events associated with hip joint replacements	1036	5.3	47	4.5	3.35–5.99
Adverse events associated with knee joint replacements	1520	7.8	40	2.6	1.89–3.57
Central Line-associated bloodstream infections	1485	7.6	5	0.3	0.11–0.78
Catheter-associated urinary tract infections	8015	41.2	204	2.6	2.21–2.91
Contrast nephropathy associated with catheter angiography	2646	13.6	317	11.9	10.77–13.28
Hospital-acquired methicillin-resistant *S. aureus*	19,066	97.9	12	0.06	0.03–0.11
Hospital-acquired pressure ulcers	19,475	100.0	712	3.7	3.4–3.93
Hospital-acquired vancomycin-resistant enterococcus	19,382	99.5	10	0.05	0.02–0.09
Inpatient falls	19,475	100.0	183	0.9	0.81–1.09
Mechanical complications associated with central lines	2799	14.4	92	3.3	2.66–4.02
Postoperative cardiac events for cardiac and noncardiac surgeries	5793	29.7	45	0.8	0.60–1.00
Postoperative pneumonia	5698	29.3	100	1.8	1.43–2.13
Postoperative venous thromboembolic events	5794	29.8	26	0.5	0.29–0.66
Ventilator-associated pneumonia	416	2.1	46	11	8.21–14.47

CI indicates confidence interval; IV, intravenous.

submitted because complete documentation is necessary to support patient care and accurate payment, MPSMS is still occasionally limited by incomplete medical record submissions. Fourth, MPSMS adverse event rates are based only on explicit abstraction and not an implicit clinician review. This methodology of explicit analysis produces high interrater reliability and specific criteria for identifying adverse events, but it carries with it a trade-off. No matter how well designed and defined the abstractor questions and instructions are, the abstractor will sometimes miss subtle nuances indicating the presence or absence of a hospital-acquired adverse event that might be identified through the judgment of a well-trained clinician. Fifth, MPSMS is a patient-centered surveillance system that does not explicitly consider or identify whether the events detected were the result of an error on the part of the provider, the natural history of disease, a known adverse effect of accepted treatment, or a complex system failure. As such, the degree of preventability of adverse events identified by MPSMS is not assessed. Without clinician review, the MPSMS methods can only establish an association between the healthcare delivery process and a hospital-acquired AE. Although subjective, clinician review can help assure that outcomes are associated with healthcare delivery processes described in the patient record. Thus, in most cases, MPSMS data are not sufficient for understanding root causes of adverse events. They will not reveal whether a patient death was related to an adverse event. Mortality rates "with and without" specific adverse events or any adverse event can be computed,[8] but these rates cannot be directly connected to deaths caused by adverse events, as has been done in special studies with much smaller sample sizes.[2] Finally, adverse events not on the discrete list of MPSMS topics are not detected by MPSMS methodology.

The Future of MPSMS Informed by Other Approaches to Measuring Patient Safety

Despite numerous attempts, the accurate and widely representative measurement of patient safety has been elusive. Although it is not new, the MPSMS system for producing patient safety data is capable of producing rates on 21 types of adverse event measures, as well as providing combined rates of adverse events,[8] and supporting other methods for combining events that have been used for year-to-year measurement of patient safety in the United States.[5,10,12]

Similar to MPSMS, many other patient safety reporting and measurement systems are based on information contained in patient charts, but unlike MPSMS, these depend on the administrative data that are conveniently available at low cost. Although relatively easy to implement, methods based on administrative data are known or believed to undercount adverse events.[21] These systems have also been characterized by a tendency to flag records that do not actually contain adverse events.[22] Therefore, patient safety systems based on administrative (billing) data may include false negatives and false positives that reduce their reliability.[21,23,24]

The use of present-on-admission (POA) indicators and other recent enhancements in administrative measure methodology may help make these systems increasingly useful, especially with respect to use for case finding to support quality improvement programs.[25] Although POA conditions are now identified more frequently, the use of POA does not address other factors that lead to false negatives and false positives.[25]

Another approach to patient safety measurement, "The Global Trigger Tool (GTT)" developed by the Institute for

Healthcare Improvement, has been effectively used in numerous studies to reveal many previously uncharacterized or uncounted adverse events,[2,26–28] especially adverse drug events. The GTT has been used to assess the national status of efforts to improve patient safety and has indicated that little or no improvement has occurred.[26–28] The Global Trigger Tool data have demonstrated that systems that rely on spontaneous reporting (even if legally mandated or "mandatory") or on administrative data identify only a small fraction of adverse events. For example, in the 2010 OIG study,[2] which was based on GTT data compiled by the OIG's specific methods, only 9% of cases confirmed after first being found with the GTT were identified by the Patient Safety Indicators, and a smaller fraction (1%) was reported by staff using internal, hospital-based reporting systems. Although the GTT does an excellent job of identifying problematic outcomes that seem likely to be due to inpatient care rather than a patient's underlying disease, interrater reliability has been poor. This finding is seen in the study by Landrigan et al,[26] where the external and internal reviewers had very different findings when looking at the same patient records—internal reviewers identified approximately 30% more "harms" overall than external reviewers, and nearly 50% more "preventable harms." The rates of adverse events reported by GTT-based studies range from 13.5% to 27%,[17–19] depending on whether cases with less harm are included, and from 20.7 (non-POA) per 100 admissions in the Landrigan study,[26] to 49 per 100 in 2011 study by Classen et al.[27] Limitations of the GTT also include its relatively high cost to use, because it relies on clinical experts to review patient charts and to find initial indicators of adverse events and then filter out false positives. There is also a certain amount of subjectivity introduced by using human reviewers, although they are often considered the closest one gets to a "criterion standard" for finding quality and safety issues in medical records.

Other sources of patient safety data include event reports to hospital quality or safety systems[28] or to central authorities, such as The Joint Commission,[29] the Pennsylvania Patient Safety Authority,[30] or the Department of Veterans Affairs (VA) National Center for Patient Safety,[31] which can be used for learning and for estimation of apparent changes in incidences of certain comparatively rare events. However, these sources cannot be used consistently for understanding the true incidence of adverse events overall or for comparing relative rates of events among different providers or over time. An extreme example of this limitation is The Joint Commission Sentinel Event data[29]—where more cases of wrong-site surgery (782) were reported than infection-related events (135), medication related events (approximately 600 types), or falls (439).

These reporting systems are referred to as spontaneous active event reporting systems.[32] Helmreich [33] pointed out that such types of reporting systems should not be used to determine rates, but they argue that such reporting systems are extremely valuable in identifying latent failures associated with no harm and near-miss events that might not otherwise be undetected. A further strength of such systems is the involvement of health professions in looking for and reporting patient safety threats. These reporting systems are also impacted by an organization's safety culture. Changes in reporting rates may signal changes in the safety culture either in a positive or negative manner, that is, fewer or more reports of AEs are not necessarily associated with fewer or more actual AEs.

Special information systems dedicated to acquiring and analyzing quality and safety data are another important resource. Two examples are the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) that was developed from the preceding VA NSQIP program (now renamed VASQIP) and the CDC's National Healthcare Safety Network (NHSN) that presently produces data on major classes of hospital-acquired infections (HAIs) including central-line associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, ventilator-associated events, as well as events associated with multidrug-resistant organisms and *Clostridium difficile*.[34,35] The NHSN has also moved to incorporate automated Health Level Seven International messaging for data exchange on surgical conditions and antibiotic resistance. These systems produce adverse event and other data at the hospital level and other levels (such as a state for NHSN or a healthcare system for NSQIP) with the cooperation of professionals working at the hospital level who are employed by the hospital. These systems are operated from a central location that ensures consistency in adverse events and other definitions, usage of the systems, and methods and provides training, training materials, and other services. The NSQIP data include some information related to surgical safety, such as surgical site infections, but the NSQIP has not been a source of useful data for pure surgical safety problems, such as retained surgical items, wrong-site or wrong-patient surgery, and operating room fires.[34] In recent years, the NHSN has experienced enormous growth, use, and impact on the field of healthcare-associated infection prevention. The NHSN now provides comparative benchmark data on more than 10,000 healthcare facilities, which are incorporated into local quality improvement efforts, while also providing comparative data to state health departments, CDC, and part of the CMS Quality Reporting Program.[35] The NHSN data are also used by CMS to provide data to the public via the Hospital Compare web site.[36]

For all of the advantages of MPSMS, it has the limitation of not being able to identify rare or unusual events, such as wrong-site surgeries or infant abductions, as can be done with many hospital or central event reporting systems. Unlike systems based on administrative data or NHSN, MPSMS cannot produce data on the basis of analysis of information contained in millions of charts, such as infections caused by rare but emerging pathogens. The MPSMS system is also likely to contain more "false positives" than information systems such as NHSN, which have put a special emphasis on excluding inappropriate designations of adverse events such as catheter-associated urinary tract infections.[8,35]

Although it is generally understood that there is no specific system that is perfect for measuring patient safety, it is less well understood that there is presently no single general method that can be universally applied to reliably identify all rates, risks, and hazards in patient safety. Rather, it seems that multiple complementary methods must be employed. A useful principle comes from the one used in maritime navigation, which is that one can never truly know where one is without a 3-point fix of one's position. In the process of identifying rates, risks, and hazards, multiple operational methods must be employed to truly understand (fix a position) where a facility or an organization stands with respect to patient safety. Prudent healthcare systems, hospitals, and other organizations may consider the use of multiple complementary systems (chart review, administrative data, and other information or reporting systems) and conduct triangulation of different data sources to ascertain a complete picture of their rates and risks of patient harm.[37,38]

Since the creation of MPSMS over a decade ago, much has changed in the patient safety landscape. Hospital event reporting, which is now required for accreditation and payment, has become almost universal. In addition, such event reporting has become increasingly automated through various software systems. Electronic health record systems also have been much more widely deployed, especially after the passage of the American Recovery and Reinvestment Act of 2009—from 2009 to 2013 basic EHR adoption at acute care hospitals rose from 12% to 59%.[14] These initiatives,

while representing real progress toward improving patient care and tracking quality and safety, have not been guided by uniform standards for measuring quality and safety, although fostering such common standards is an explicit goal of the HHS Office of the National Coordinator for Health Information Technology. Ironically, proliferation of multiple software systems, both EHRs and event reporting systems, has solidified in software code the many disparate ways of representing patient safety events. Although it might seem at first glance that reporting should be easier because of the greater use of electronic systems, in fact, it has not become easier, in part because of the lack of uniform standards. In the meantime, MPSMS remains as virtually the only practical way of measuring patient safety nationally using common standards (NHSN employs common standards for nationwide measurement of major HAIs; however, its data are not easily segmented into incident rates per patient for all hospitalized patients in the United States for each calendar year.).

This situation is beginning to change, as evidenced by legislation, administrative policy at HHS, and action on the part of the private sector. The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized AHRQ to establish common definitions and reporting formats, "Common Formats," for reporting on quality and safety.[39] The intention is for the formats to provide a "nucleating agent" around which other patient safety reporting systems can converge. Otherwise, the formats would be yet another competing event reporting system; and for HAIs, the formats are based on NHSN's definitions. The agency released the first version of the hospital formats in 2008 and has revised them 3 times in response to public and professional comment (The formats are available at https://www.psoppc.org/web/patientsafety.) The common formats have been adopted and used by (some) Patient Safety Organizations, which were established pursuant to the Patient Safety Act,[40] as well as other interested organizations, including software developers. The common formats have been slow to be adopted for a number of reasons, including the fact that their use is voluntary and that there is a large number of legacy systems in place.

Quality and Safety Review System

The Future of MPSMS

The AHRQ is currently developing and implementing the QSRS, a successor system to MPSMS. Similar to MPSMS, QSRS is based on chart abstraction performed by trained medical records personnel, but it has been designed in modules that are largely consistent with the common formats and to facilitate the capture of many more than the 21 specific adverse event measures captured by MPSMS. Major additions include additional adverse drug events (such as opioid adverse events), surgical site infections and numerous other types of surgical adverse events, and obstetric and neonatal adverse events. The QSRS event descriptions for healthcare-associated infections are based on CDC NHSN definitions. The contract for QSRS development was awarded in September 2012,[41] and use of QSRS in the CMS CDAC began in 2015.[42]

The QSRS is a modular, expandable, and multifunctional software platform to permit the collection, analysis, and reporting of specified patient safety and quality of care data. The initial system has the capability to support web-based medical record abstraction for surveillance of adverse events from medical records to import Admit, Discharge, and Transfer or ADT data and will be able to be updated to incorporate other structured electronic data from EHRs in the future. Structured data in EHRs, such as test results for blood glucose and international normalized ratio levels, as well as positive tests for *C. difficile* or methicillin-resistant staphylococcus aureus infections, promise to enable streamlined data acquisition and increase the accuracy of QSRS and other adverse event measurement systems.

The QSRS represents another of AHRQ's family of the common formats that are being promulgated consistent with the provisions of the U.S. Patient Safety and Quality Improvement Act of 2005.[43] The adverse event definitions in QSRS were developed to be as similar as possible to those in the common formats for event reporting. Subsequent versions of QSRS may expand on the initial focus on safety to include surveillance of a wider range of quality issues.

The goal of QSRS is to allow the capture and quantification of "all-cause harm" to the extent possible, using defined fields for a vast majority of reporting and selected text fields to capture rare and/or unanticipated events and circumstances. The QSRS will be used by CMS CDAC, where MPSMS is now employed. It could also be used at local hospitals or healthcare systems in the future, if desired. A pilot test at a private sector location is currently underway in 2016. In addition, AHRQ has funded initial studies to study the feasibility of automating QSRS where feasible.

CONCLUSIONS

Based on the findings from numerous IOM reports and other studies, patient safety remains a very serious problem for the healthcare system in the United States. Fifteen years after the IOM report *To Err Is Human* and despite multiple initiatives to improve patient safety in U.S. hospitals, it is likely that nearly a quarter of all Medicare patients still experience adverse events or temporary harm events. The IOM reports emphasize the importance of methods that can measure these types of events. As such, MPSMS is the only system yet developed that provides reliable estimates of a large set of diverse adverse events at the national level. The MPSMS has recently been put to use for this purpose by the Department of Health and Human Services as the main source of data for measuring the results of the Partnership for Patients,[12] and the interim results through 2013 and 2014 showed a 17% reduction in HACs when compared with the baseline year of 2010.[5,44] Because this system improves and evolves into QSRS, an all-cause harm measurement system, the ability to reliably measure safety, understand the areas requiring improvement, and then measure subsequent improvements will be more fully realized. This robust measurement capability is sorely needed to guide ongoing efforts to keep patients safe.

REFERENCES

1. Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press; 1999.
2. Department of Health and Human Service Office of Inspector General. Adverse events in hospitals: national incidence among Medicare beneficiaries, OEI-06-09-0009. 2010. Available at: https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf. Accessed September 25, 2016.
3. Institute of Medicine. Health IT and patient safety: building safer systems for better care. 2011. Available at: http://www.nationalacademies.org/hmd/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx. Accessed September 26, 2016.
4. National Academies of Sciences, Engineering, and Medicine. *Improving Diagnosis in Health Care.* Washington, DC: The National Academies Press; 2015.
5. 2013 Annual Hospital-Acquired Condition Rate and Estimates of Cost Savings and Deaths Averted From 2010 to 2013. Rockville, MD: Agency for Healthcare Research and Quality; 2015. AHRQ Publication No. 16-0006-EF. Available at: http://www.ahrq.gov/professionals/qualitypatient-safety/pfp/index.html.
6. Makary MA, Daniel M. Medical error-the third leading cause of death in the US. *BMJ.* 2016;353:i2139.

7. Hunt DR. Fundamentals of Medicare patient safety surveillance: intent, relevance, and transparency. In: Henriksen K, Battles JB, Marks ES, et al. Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology). Rockville: Agency for Healthcare Research and Quality; 2005.
8. Wang Y, Eldridge N, Metersky ML, et al. National trends in patient safety for four common conditions, 2005–2011. *N Engl J Med*. 2014;370:341–351.
9. National Healthcare Quality & Disparities Reports. 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/research/findings/nhqrdr/index.html. Accessed September 26, 2016.
10. Hackbarth AD, Munier WB, Eldridge N, et al. An overview of measurement activities in the partnership for patients. *J Patient Saf*. 2014; 10:125–132.
11. Partnership for patients: "it's about time", say quality expert. *Healthcare Benchmarks Qual Improv*. 2011;18:73–75.
12. Method to Estimate the Baseline 2010 PFP National Hospital-Acquired Condition Rate. HRQ Pub. No. 14-0046EF. Revised 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/pfphac.pdf. Accessed September 26, 2016.
13. Classen DC, Jaser L, Budnitz DS. Adverse drug events among hospitalized Medicare patients: epidemiology and national estimates from a new approach to surveillance. *Jt Comm J Qual Patient Saf*. 2010;36:12–21.
14. Charles D, Gabriel M, Furukawa MF. Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008–2013, *ONC Data Brief, no. 16*. Washington, DC: Office of the National Coordinator for Health Information Technology; 2014.
15. Federal Register 51648, August 18,2011. Available at: https://www.gpo.gov/fdsys/pkg/FR-2011-08-18/html/2011-19719.htm. Accessed September 26, 2016.
16. Metersky ML, Eldridge N, Wang Y, et al. Predictors of warfarin-associated adverse events in hospitalized patients: opportunities to prevent patient harm. *J Hosp Med*. 2015;11:276–282.
17. Bakullari A, Metersky M, Wang Y, et al. Racial and ethnic disparities in healthcare-associated infections in the United States, 2009–2011. *Infect Control Hosp Epidemiol*. 2014;35:S10–S16.
18. Eckenrode S, Bakullari A, Metersky ML, et al. The association between age, sex, and hospital-acquired infection rates: results from 2009–2011. *Infect Control Hosp Epidemiol*. 2014;35:S3–S9.
19. Furukawa M, Eldridge N, Wang Y, et al. Electronic health record adoption and rates of in-hospital adverse events. *J Patient Saf*. 2016. [Epub ahead of print].
20. Wang Y, Eldridge N, Metersky ML, et al. Association between hospital performance on patient safety and 30-day mortality and unplanned readmission for Medicare fee-for-service patients with acute myocardial infarction. *J Am Heart Assoc*.
21. Rosen AK, Itani KM, Cevasco M, et al. Validating the patient safety indicators in the Veterans Health Administration: do they accurately identify true safety events? *Med Care*. 2012;50:74–85.
22. Coye MJ, Milstein A, Pronovost PJ. Leading through innovation & collaboration: addressing health system change, patient safety, and quality of care. *AHRQ 2011 Annual Conference*, Bethesda, MD.
23. Rajaram R, Barnard C, Bilimoria KY. Concerns about using the patient safety indicator-90 composite in pay-for-performance programs. *JAMA*. 2015;313:897–898.
24. Winters BD, Bharmal A, Wilson RF, et al. Validity of the Agency for Health Care Research and Quality Patient Safety Indicators and the Centers for Medicare and Medicaid Hospital-acquired Conditions: a systematic review and meta-analysis. *Med Care*. 2016. [Epub ahead of print].
25. McNutt R, Johnson TJ, Odwazny R, et al. Change in MS-DRG assignment and hospital reimbursement as a result of Centers for Medicare & Medicaid changes in payment for hospital-acquired conditions: is it coding or quality? *Qual Manag Health Care*. 2010;19:17–24.
26. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med*. 2010;363:2124–2134.
27. Classen DC, Resar R, Griffin F, et al. "Global trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)*. 2011;30:581–589.
28. Stockwell DC, Bisarya H, Classen DC. A trigger tool to detect harm in pediatric inpatient settings. *Pediatrics*. 2015;135:1036–1042.
29. Joint commission Update: sentinel event statistics available online. Jt Comm Perspect. 2009;29:7.
30. Patient safety authority enables sharing of lessons learned. *Healthcare Benchmarks Qual Improv*. 2005;12:1–4.
31. Bagian JP, Lee C, Gosbee J, et al. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. *Jt Comm J Qual Improv*. 2001;27:522–532.
32. Farley DO, Haviland A, Champagne S, et al. Adverse-event-reporting practices by US hospitals: results of a national survey. *Qual Saf Health Care*. 2008;17:416–423.
33. Helmreich RL. On error management: lessons from aviation. *BMJ*. 2000; 320:781–785.
34. Tepas JJ 3rd, Kerwin AJ, Devilla J, et al. Macro vs micro level surgical quality improvement: a regional collaborative demonstrates the case for a national NSQIP initiative. *J Am Coll Surg*. 2013;21:599–604.
35. CDC NHSN web site for acute care hospital reporting: Available at: http://www.cdc.gov/nhsn/acute-care-hospital/index.html. Accessed September 26, 2016.
36. Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-12-12.html). Accessed September 26, 2016.
37. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *Qual Saf Health Care*. 2003;12(suppl 2):ii2–ii7.
38. Kilbridge PM, Classen DC. Automated surveillance for adverse events in hospitalized patients: back to the future. *Qual Saf Health Care*. 2006;15: 148–149.
39. Clancy CM. Common formats allow uniform collection and reporting of patient safety data by patient safety organizations. *Am J Med Qual*. 2010; 25:73–75.
40. West N, Eng T. Monitoring and Reporting Hospital-acquired Conditions: a Federalist Approach. *Medicare Medicaid Res Rev*. 2015;4. doi: 10.5600/mmrr.004.04.a04.
41. Available at: https://www.fbo.gov/index?s=opportunity&mode=form&id=07761e92aa412c02b98f4cb681c45744&tab=core&_cview=1. Accessed September 26, 2016.
42. Presentations by A. Buckler, N. Eldridge, and S. Terrillion at AHRQ Common Formats 2016 Software Developers Meeting, April 15, 2016. Available on-line at: https://www.psoppc.org/psoppc_web/publicpages/forDevelopersAndVendors. Accessed September 26, 2016.
43. PSO Statute. Available at http://www.pso.ahrq.gov/legislation/act. Accessed September 26, 2016.
44. CMS PfP Program Web Page. Available at: http://partnershipforpatients.cms.gov/. Accessed September 26, 2016.