

Measures of Patient Safety Based on Hospital Administrative Data. The Patient Safety Indicators

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Summary

Introduction

The longstanding cornerstone of medicine “first, do no harm” exists because of the fragility of life and health during medical care encounters, and represents the medical profession’s understanding that patient safety has always been an important part of quality health care. Recently, however, concerns and evidence have mounted about the complexities of the health care system potentially causing patient deaths and significant unintended adverse effects. With a major national interest in addressing patient safety issues, a wide spectrum of individuals and organizations are working toward developing methods and systems to detect, characterize, and report potentially preventable adverse events. These activities are crucial precursors to prioritizing areas for action and for studying the effects of approaches to reduce sources of medical error.

As part of this activity, the Evidence-based Practice Center (EPC) at the University of California San Francisco and Stanford University (UCSF-Stanford), with collaboration from the University of California Davis, was commissioned by the Agency for Healthcare Research and Quality (AHRQ) to review and improve the evidence base related to potential patient safety indicators (PSIs) that can be developed from routinely collected administrative data. For the purposes of this report, PSIs refer to measures that screen for potential problems that patients experience resulting from exposure to the health care system, and that are likely amenable to prevention by changes at the level of the system.

Reporting the Evidence

The primary goal of this report is to document the evidence from a variety of sources on potential measures of patient safety suitable for use based on hospital discharge abstract data. The approach to identification and evaluation of PSIs presented in this report serves as the basis for development of a third module for the AHRQ QI tool set (referred to as the HCUP II in previous work by the UCSF-Stanford EPC reporting on the research underpinning the refinement of the initial AHRQ HCUP QIs, available on AHRQ’s web site at <http://www.achq.gov/data/hcup/qirefine.htm>). This third module will be the *Patient Safety Indicators (PSIs)*, which focus on potentially preventable instances of harm to patients, such as surgical complications and other iatrogenic events. The two other modules are the *Prevention Quality Indicators*, based on hospital admissions that might have been avoided through high-quality outpatient care; and the *Inpatient Quality Indicators*, consisting of inpatient mortality, utilization of procedures for which there are questions of overuse, underuse, or misuse; as well as volume of procedures for which higher volume is consistently associated with lower mortality.

Purpose of the PSIs

Like the companion AHRQ Quality Indicators (QIs) screening tool set refined by the UCSF-Stanford EPC, the PSIs are a starting point for further analysis to reduce preventable errors through system or process changes. Additionally, these measures are likely to support the public mandate for aggregate statistical reporting to monitor trends over time, as planned

for the National Quality Report.

Scope of the Project

This report reviews previous studies and presents new empirical evidence for identifying potential patient safety problems based on one potentially important source of data: computerized hospital discharge abstracts from the AHRQ Healthcare Cost and Utilization Project (HCUP). Therefore, the measures considered needed to be defined using variables that are available from most state-level hospital administrative data. Data elements in these sets include International Classification of Disease, Clinical Modification (ICD-9-CM) discharge diagnosis and procedure codes; dates of admission, discharge and major procedures; age; gender; and diagnostic related group (DRG). Data from outside the hospital stay (e.g., post-hospital mortality or readmissions) were not used because most state databases do not accommodate linkages between datasets. The HCUP State Inpatient Databases (SID) is an example of such a common denominator hospital discharge dataset, and was used for the development of the AHRQ PSIs, reported here. The PSIs presented in this report therefore relate to inpatient care, and the adverse events that have either a high likelihood or at least a reasonable possibility of being iatrogenic. These two constraints – the data source and the location of care—guided the development and evaluation of a promising set of patient safety indicators.

Following from these constraints, the PSIs by necessity capture adverse events that may, but possibly are not, related to medical care. They do not capture “near misses” or other undocumented adverse events. They also do not include adverse events related to a number of important patient safety concerns that are not reliably specified using ICD-9-CM, the official codes assigned to diagnoses and procedures associated with hospital utilization in the United States. Based on previous validation work and the limitations inherent in the data source, PSIs derived from discharge data capture a mixture of adverse events, including those that are almost certainly preventable and those that current best practices and error-mitigating systems of care have not been able to prevent. However, the evidence is presented for their promise as a low-cost screen for potential quality concerns to guide further investigations with additional data gathering and information collection.

Methodology

Following the previous refinement of quality indicators described in a companion technical report from the EPC, and published by AHRQ, an evaluation framework for validity testing (i.e., face validity, precision, minimum bias, and construct validity) was applied to each candidate PSI. Specifically, a four pronged strategy to collect validation data and descriptive information included two aspects of the previous work: a background literature review, and empirical analyses of the potential candidate PSIs using the HCUP SID. In addition to these approaches of the previous project, expert coders from the American Health Information Management Association (AHIMA) were consulted, and clinical panel reviews of potential indicators were conducted based on a process adapted from the RAND organization and University of California Los Angeles (RAND/UCLA) Appropriateness Method.

Evidence from these four sources was used to modify and select the most promising indicators for use as a screening tool to provide an accessible and low-cost approach to

identifying potential problems in the quality of care related to patient safety. The methods applied provide baseline information on the ability of a fairly broad range of discharge-based PSIs to identify systematic differences across hospitals, and potentially to monitor trends on a national or regional basis.

Results

A review of previously reported measures in the literature (e.g. Complications Screening Program by Iezzoni et al, Patient Safety Indicators by Miller et al), and of medical coding manuals, resulted in identification of over 200 ICD-9-CM codes representing potential patient safety problems. Most of these codes were grouped into clinically meaningful indicators either based on previous indicator definitions or on clinical and coding expertise. Based on literature review of the published evidence related to their validity, several potential PSIs were eliminated. Because of the limited validation literature available on PSIs and complications indicators from which many PSIs were derived, the research team conducted a clinical panel review process to assess the face validity and to guide refinements to the initial definitions of the 34 most promising PSIs. Response to a questionnaire by clinicians (i.e., physicians from a number of specialties, nurses, and pharmacists) for each indicator, augmented by coding review and initial empirical testing, provided the basis for selecting the indicators expected to be most useful for screening for potentially preventable adverse events. Tables 1S and 2S summarize the strength of the evidence literature, definitions, and key findings for the set of 20 *hospital level* PSIs that are recommended for implementation as the initial AHRQ PSI set (designated Accepted indicators).

Table 1S. Strength of Evidence Literature for PSIs

Indicator	Coding	Construct Explicit Process	Construct Implicit Process	Construct Staffing
Complications of anesthesia	0	0	0	0
<i>Death in low mortality DRGs</i>	+	0	+	0
Decubitus ulcer	-	0	0	±
<i>Failure to rescue</i>	+	0	0	++
Foreign body left in during procedure	0	0	0	0
Iatrogenic pneumothorax	0	0	0	0
Infection due to medical care	0	0	0	0
<i>Postoperative hip fracture</i>	+	+	+	0
Postoperative hemorrhage or hematoma	±	±	+	0
Postoperative physiologic and metabolic derangements	-	0	0	-
<i>Postoperative respiratory failure</i>	+	±	+	±
<i>Postoperative PE or DVT</i>	+	+	+	±
Postoperative sepsis	±	0	0	-
Technical difficulty with procedure	±	0	0	0
Transfusion reaction	0	0	0	0
Postoperative wound dehiscence	0	0	0	0
Birth trauma	-	0	0	0
Obstetric trauma – vaginal delivery with instrumentation	+	0	0	0
Obstetric trauma – vaginal delivery without instrumentation	+	0	0	0
Obstetric trauma – cesarean delivery	+	0	0	0

^aLevel of evidence

(-) Published evidence suggests that the indicator lacks validity in this domain (i.e., less than 50% sensitivity or predictive value; explicit or implicit process failure rates no more frequent than among control patients).

(0) No published evidence regarding this domain of validity.

(±) Published evidence suggests that the indicator may be valid in this domain, but different studies offer conflicting results (although study quality may account for these conflicts).

(+) Published evidence suggests that the indicator IS valid, or is likely to be valid, in this domain (i.e., one favorable study).

(++) There is strong evidence supporting the validity of this indicator in this domain (i.e., multiple studies with consistent results, or studies showing both high sensitivity and high predictive value).

^b *Coding*: Sensitivity is the proportion of patients who suffered an adverse event, based on detailed chart review or prospective data collection, for whom that event was coded on a discharge abstract or Medicare claim. Predictive value is the proportion of patients with a coded adverse event who were confirmed as having suffered that event, based on detailed chart review or prospective data collection.

Construct, explicit process: Adherence to specific, evidence-based or expert-endorsed processes of care, such as appropriate use of diagnostic modalities and effective therapies. Our construct is that hospitals that provide better processes of care should experience fewer adverse events.

Construct, implicit process: Adherence to the “standard of care” for similar patients, based on global assessment of quality by physician chart reviewers. Our construct is that hospitals that provide better overall care should experience fewer adverse events.

Construct, staffing: Our construct is that hospitals that offer more nursing hours per patient day, better nursing skill mix, better physician skill mix, or more experienced physicians, should have fewer adverse events.

^c Note that when content validity is exceptionally high, as for transfusion reaction or iatrogenic pneumothorax, construct validity becomes less important.

Table 2S. Summary of Evidence for Accepted Hospital Level PSIs

Indicator name	Definition	Panel concerns of validity ^a									Empirical performance		
		Rare	Condition definition varies	Under-reporting/ screening	Adverse consequences	Stratification suggested	Unclear preventability	Heterogeneous severity	Case mix bias	Denominator unspecific	Rate (per 1000 population at risk) ^e	Standard deviation ^e	Bias detected ^b
Complications of anesthesia	Cases of anesthetic overdose, reaction, or endotracheal tube misplacement per 100 surgery discharges. Excludes codes for drug use and self-inflicted injury.		X	X						X	0.80	7.15	
Death in low mortality DRGs ^d	In-hospital deaths per 100 patients in DRGs with less than 0.5% mortality. ^c Exclude trauma, immunocompromised and cancer patients.							X			1.14	11.94	X+
Decubitus ulcer	Cases of decubitus ulcer per 100 discharges with a length of stay greater than 4 days. Exclude patients with paralysis or in MDC 9, ^d or patients admitted from a long term care facility.			X				X	X		20.5	20.7	X+
Failure to rescue	Deaths per 100 patients having developed specified complications of care during hospitalization. Exclude patients admitted from long term care facility and patients transferred to or from other acute care facility.				X	X	X	X			170.3	80.9	X+
Foreign body left during procedure	Discharges with foreign body accidentally left in during procedure per 100 discharges.	X				X				X	0.08	0.18	N/A
Iatrogenic pneumothorax	Cases of iatrogenic pneumothorax per 100 discharges. Exclude trauma, thoracic surgery, lung or pleural biopsy or cardiac surgery patients.									X	0.86	1.35	X
Infection due to medical care	Cases of secondary ICD-9-CM codes 999.3 or 996.62 per 100 discharges. Exclude patients with immunocompromised state or cancer.			X	X						1.37	1.75	X
Postoperative hemorrhage or hematoma	Cases of hematoma or hemorrhage requiring a procedure per 100 surgical discharges. Excludes obstetric admissions.					X			X	X	1.83	3.66	
Postoperative hip fracture	Cases of in-hospital hip fracture per 100 surgical discharges. Exclude patients in MDC 8, with conditions suggesting fracture present on admission.								X	X	1.12	5.94	X

5

Indicator name	Definition	Panel concerns of validity ^a									Empirical performance		
		Rare	Condition definition varies	Under-reporting/ screening	Adverse consequences	Stratification suggested	Unclear preventability	Heterogeneous severity	Case mix bias	Denominator unspecific	Rate (per 1000 population at risk) ^e	Standard deviation ^e	Bias detected ^b
Postoperative physiological and metabolic derangement	Cases of specified physiological or metabolic derangement per 100 elective surgical discharges. Exclude patients with principle dx of diabetes and with diagnoses suggesting increased susceptibility to derangement. Exclude obstetric admissions.		X								0.92	11.1	X
Postoperative PE or DVT	Cases of deep vein thrombosis or pulmonary embolism per 100 surgical discharges. Exclude obstetric patients.			X		X					6.95	12.3	X+
Postoperative respiratory failure	Cases of acute respiratory failure per 100 elective surgical discharges. Exclude MDC 4 and 5 and obstetric admissions.						X		X		2.68	5.01	X+
Postoperative septicemia	Cases of septicemia per 100 elective surgery patients, with length of stay more than 3 days. Exclude principle diagnosis of infection, or any dx of immunocompromised state or cancer, and obstetric admissions.		X		X						10.0	29.6	X+
Postoperative wound dehiscence	Cases of reclosure of post-operative disruption of abdominal wall per 100 cases of abdominopelvic surgery. Excludes obstetric admissions.								X		2.43	8.77	X
Technical difficulty with procedure	Cases of technical difficulty (e.g. accidental cut or laceration during procedure) per 100 discharges. Excludes obstetric admissions.			X			X				2.42	2.64	X+
Transfusion reaction	Cases of transfusion reaction per 100 discharges	X				X					0.01	0.06	N/A
Birth trauma – injury to neonate	Cases of birth trauma per 100 liveborn births. Excludes some preterm infants, and infants with osteogenic imperfecta.		X				X	X			9.36	31.4	N/A
Obstetric trauma – cesarean delivery	Cases of obstetric trauma (4 th degree lacerations, other obstetric lacerations) per 100 cesarean deliveries.						X		X		6.13	16.12	N/A
Obstetric trauma – vaginal delivery with instrument	Cases of obstetric trauma (4 th degree lacerations, other obstetric lacerations) per 100 instrument assisted vaginal deliveries.						X		X		203.6	142.4	N/A

Indicator name	Definition	Panel concerns of validity ^a									Empirical performance			
		Rare	Condition definition varies	Under-reporting/screening	Adverse consequences	Stratification suggested	Unclear preventability	Heterogeneous severity	Case mix bias	Denominator unspecific	Rate (per 1000 population at risk) ^e	Standard deviation ^e	Bias detected ^b	
Obstetric trauma – vaginal delivery w/o instrument	Cases of obstetric trauma (4th degree lacerations, other obstetric lacerations) per 100 vaginal deliveries without instrument assistance.						X			X		75.6	57.9	N/A

a Concerns raised by panels included the following:

Rare: Some events are relatively rare, and thus may not have adequate statistical power for some providers.

Condition definition varies: Conditions covered by this indicator include conditions for which diagnosis may be subjective, depending on the threshold of the physician. Thus patients with the same clinical state may not have the same diagnosis.

Under-reporting/screening: These conditions may not be systematically reported leading to an artificially low rate, or may be routinely screened for, leading to a higher rate in facilities that screen as compared to those that do not.

Adverse consequences: Use of these indicators may have undesirable effects, such as increasing inappropriate antibiotic use.

Stratification suggested: Indicator includes some high risk patient groups which should be stratified when examining rates.

Unclear preventability: As compared to other PSIs these conditions may be less subject to the control of the health system, and thus less preventable.

Heterogeneous severity: These indicators include codes that encompass several levels of severity of that condition that cannot be ascertained by the codes.

Case mix bias: These indicators were felt to be particularly subject to systematic bias due to the case mix of the provider. DRG and comorbidity risk adjustment may or may not adequately address the concern.

Denominator unspecific: The denominators for these indicators are less than ideal, because the true population at risk could not be identified completely clearly using ICD-9-CM codes, and thus some patients are likely included that are not truly at risk, or some patients that are at risk are not included.

^b Bias ratings are based on a series of tests of bias using DRG and comorbidity risk adjustment. Those indicators flagged with ‘X+’ demonstrated substantial bias, and should be risk adjusted. Those indicators flagged with ‘X’ also demonstrated some bias. Those without a flag did not demonstrate substantial bias in empirical tests, but may nonetheless be substantially biased in a manner not detectable by the bias tests. Those with marked with N/A did not undergo empirical testing of bias due to lack of systematic variation.

^c DRGs that are divided into “with complications and comorbidities” and “without complications and comorbidities” are only included if both divisions have mortality rates below 0.5%.

^d DRG: Diagnostic Related Group; MDC: Major Diagnostic Category

^e Rates represent the average rate of indicator for a nationwide sample of hospitals. Standard deviation is reported between providers.

Several accepted patient safety indicators were also modified into *area level indicators*, which were designed to assess the total incidence of the adverse event within geographic areas. For example, the transfusion reaction indicator can be specified at both the hospital and area level. Transfusion reactions that occur after discharge from a hospitalization would result in a readmission. The area level indicator includes these cases, while the hospital level restricts the number of transfusion reactions to only those that occur during the same hospitalization that exposed the patient to this risk. The five hospital level indicators that have area level analogs are Iatrogenic Pneumothorax, Transfusion Reaction, Infection Due to Medical Care, Wound Dehiscence, Foreign Body Left in During Procedure, and Technical Difficulty with Medical Care.

In addition to the accepted PSIs, another 17 indicators show promise, though have more concerning limitations. These were designated “experimental” and examined empirically. They performed empirically somewhat less well than the accepted indicators empirically. In addition, the concerns raised about various aspects of these indicators during the clinical panel discussions limit their potential usefulness. However, with possible further refinements to the underlying coding of data and to the indicator definitions, these indicators have the potential to measure what they purport to identify. For example, Reopening of Surgical Wound, while conceptually a useful PSI, requires further information to exclude cases that are planned during staged operations for example, and requires coding changes in order to capture only similarly serious reopening procedures.

Conclusions

This project took a four pronged approach to the identification, development and evaluation of PSIs that included use of literature, clinician panels, expert coders and empirical analyses. For the best-performing subset of PSIs, this project has demonstrated that rates of adverse events differ substantially and significantly across hospitals. The literature review and the findings from the clinical panels combined with data analysis provide evidence to suggest that a number of discharge-based PSIs may be useful screens for organizations, purchasers, and policymakers to identify safety problems at the hospital level, as well as to document systematic area level differences in patient safety problems.

Few adverse events captured by administrative data are unambiguous enough for a great deal of certainty that every case identified reflects medical error. Most adverse events identified by the PSIs have a variety of causes in addition to potential medical error leading to the adverse event, including underlying patient health and factors that do not vary systematically. Clinician panelists rated only two of the accepted indicators as very likely to reflect medical error: 1.) “Transfusion reaction” and 2.) “Foreign body left in during a procedure.” As is expected for indicators of this case-finding type, these indicators proved to be very rare with less than 1 per 10,000 cases at risk. All other accepted indicators identify adverse events which represent a spectrum of likelihood of reflecting either medical error or potentially preventable complications of care, but cannot be expected to identify only cases in these categories.

Potential Uses of PSIs

Because the PSIs are intended for use as an initial, efficient screen to target areas for further data exploration, the primary goal is to find indicators that guide those interested in quality improvement and patient safety to areas where there are systematic differences between hospitals or geographic areas. These systematic differences may relate to underlying processes or structures that an organization could change to improve patient care and safety. These errors may be attributed to human error on the part of physicians or nurses, or system deficiencies. On the other hand, the systematic differences will sometimes correspond to coding practices, patient characteristics not captured by administrative data, or other factors. These will be dead ends to some degree. In the application of these PSIs, users will be determining how well patient safety problems are identified at the level of groups of patients. Sharing experiences about application of these PSIs, researchers and health care practitioners will build on the information highlighted in this report about each indicator, as well as the set of PSIs.

At the national or state level, these indicators could be used to monitor the frequency of potential patient safety problems, to determine whether the rates are increasing or decreasing over time, and to explore large variations among settings of care. While the indicators were primarily developed at the hospital level, some were also implemented to provide an analogous area level measure, and analyses show that additional cases are in fact identified that correspond to care received at one institution, and the potentially iatrogenic complication addressed in another hospital. Clearly, the locus of control and the ability to study the potential underlying causes for an adverse event is simpler in the case of the hospital level PSIs. However, trends over time in area rates, as well as aggregations of the hospital level rates are likely to reveal points of leverage outside of individual institutions. No measure is perfect. Each is suited to its designed purpose. Methods of aggregating across groups of PSIs still need to be tested. This report provides the background for “safe” use of a tool that has the potential to guide prevention of medical error, reductions of potentially preventable complications, and quality improvement in general. Table 3S provides examples of potential uses and potentially inappropriate uses.

Table 3S. Use of patient safety indicators

User	Potential Uses	Potential Inappropriate Uses
Case-finding indicators		
Provider	Identification of events for further investigation.	Identification of cases for disciplinary action. Comparison of rates.
Public Health	Surveillance of events.	Use of indicators in formal evaluation of providers.
Research	Flagging of cases for use in research studies.	Comparison of rates.
Rate-based indicators		
Provider	Surveillance of rates for internal quality improvement investigations.	Physician-level investigation. Use of rates for disciplinary action or formal evaluation.
Public Health	Surveillance of rates. Examination of area rates over time, by region, by hospital type.	Public reporting of provider level rates.
Research	Use with other measures of quality to determine relationships of PSIs with structural, process or other aspects of care.	Use in research as a definitive measure of quality of care.

Limitations and Future Research

Many important concerns cannot currently be monitored well using administrative data, such as adverse drug events. Just as administrative data limited specific indicators chosen, the use of administrative data tends to favor specific types of indicators. The PSIs evaluated in this report contain a large proportion of surgical indicators, rather than medical or psychiatric. Medical complications are often difficult to distinguish from comorbidities that are present on admission. In addition medical populations tend to be more heterogeneous than surgical, especially elective surgical populations, making it difficult to account for case-mix. Panelists often expressed that indicators were more applicable to patient safety when limited to elective surgical admissions.

The initial validation evaluations reviewed and performed for the PSIs leave substantial room for further research with detailed chart data and other data sources. Future validation work should focus on the sensitivity and specificity of these indicators in detecting the occurrence of a complication; the extent to which failures in processes of care at the system or individual level are detected using these indicators; the relationship of these indicators with other measures of quality, such as mortality; and further explorations of bias and risk adjustment.

Enhancements to administrative data are worth exploring in the context of further validation studies that utilize data from other sources. For example, as with other quality indicators, the addition of timing variables may prove particularly useful in order to identify whether or not a complication was present on admission, or occurred during the hospitalization. While some of the complications that are present on admission may indeed reflect adverse events of care in a previous hospitalization or outpatient care, many may reflect comorbidities instead of complications. A second example area, linking of hospital data over time and with outpatient data and other hospitalizations, would allow inclusion of complications that occur after discharge, and likely would increase the sensitivity of the PSIs.

The current development and evaluation effort will best be augmented by a continuous communication loop between users of these measures, researchers interested in improving these measures, and policy makers with influence over the resources aimed at data collection and patient safety measurement.