Patient Safety Indicators: Using Administrative Data to Identify Potential Patient Safety Concerns

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Objective. To develop Patient Safety Indicators (PSI) to identify potential in-hospital patient safety problems for the purpose of quality improvement.

Data Source/Study Design. The data source was 2,400,000 discharge records in the 1997 New York State Inpatient Database. PSI algorithms were developed using systematic literature reviews of indicators and hand searches of the ICD-9-CM code book. The prevalence of PSI events and associations between PSI events and patient-level and hospital-level characteristics, length of stay, in-hospital mortality, and hospital charges were examined.

Principal Findings. PSIs were developed for 12 distinct clinical situations and an overall summary measure. The 1997 event rates per 10,000 discharges varied from 1.1 for foreign bodies left during procedure to 84.7 for birth traumas. Discharge records with PSI events had twofold to threefold longer hospital stays, twofold to 20-fold higher rates of in-hospital mortality, and twofold to eightfold higher total charges than records without PSI events. Multivariate logistic regression revealed that PSI events were primarily associated with increasing age ($p < .001$), hospitals performing more inpatient surgery ($p < .001$), and hospitals with higher percentage of beds in intensive care units ($p < .001$).

Conclusions. The PSIs provide an efficient and user-friendly tool to identify potential in-hospital patient safety problems for targeted institution-level quality improvement efforts. Until better error-reporting systems are developed the PSIs can serve to shed light on the problem of medical errors not limited solely to mortality because of errors.

Key Words. Inpatient, medical error, quality of health care statistics and numerical data, safety

BACKGROUND

The Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* estimated that 44,000 to 98,000 Americans die each year as a result of preventable medical errors and that the annual cost attributable to medical errors

may be as high as $29 billion (Kohn, Corrigan, and Donaldson 1999). This report prompted significant media attention and regulatory and legislative initiatives to better identify instances of medical errors and strategies to reduce the occurrence of medical errors. In follow-up, the second IOM report *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM 2001) further highlighted patient safety as an important goal for our health care system.

As the lead federal government agency for patient safety the Agency for Healthcare Research and Quality (AHRQ) held the first National Summit on Medical Errors and Patient Safety Research on September 11, 2000 to better outline stakeholders' interests and research priorities. At this summit Dr. John Eisenberg, director of AHRQ, likened the problem of medical errors to an epidemic and noted that we are currently in the first stages of understanding this epidemic (Eisenberg 2000). Logistically this means that research is necessary to understand the magnitude of the problem, its causes, and its burden on people.

With these considerations in mind and a definitional understanding that the term "patient safety" applies to initiatives designed to reduce hazards from contact with the health care system, our team of clinical researchers at AHRQ sought to develop Patient Safety Indicators (PSI) for identifying potential instances of compromised patient safety in the inpatient setting. Similar to AHRQ's Healthcare Cost and Utilization Project Quality Indicators (HCUP QI), the PSIs would serve as a case finding tool that relies on administrative data to identify potential patient safety events warranting institutional review and targeted quality improvement efforts (Johantgen, Elixhauser, Ball, et al. 1998). In developing the PSIs, AHRQ aimed for the desirable attributes of performance measures as jointly articulated by the American Medical Association, Joint Commission on Accreditation of Healthcare Organizations, and the National Committee on Quality Assurance and as expressed by others in the field (Hofer et al. 1997; Performance

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Measurement Coordinating Council 1999). These attributes include importance of the topic area (high priority to maximize health, financially important, potential for improvement), usefulness in improving patient outcomes (actionable by user, meaningful and interpretable to user), and careful measure design (well-defined specifications, proven feasibility, public availability). Admittedly some desirable characteristics will need to be proven with future work on the PSIs focused on documented reliability and validity. With the current paucity of measures focused on medical errors, we believed it would be useful to report our work to date while the health care community awaits development of better error-reporting systems.

In this article we describe the development of the PSIs; provide an epidemiologic description of PSI events; explore the relationship between PSI events and patient length of stay, in-hospital mortality, and hospital charges; and examine correlates of PSI events. Lastly, we describe both the ongoing and planned development work for the PSIs.

METHODS

Definition of Patient Safety

Consistent with the IOM report *To Err Is Human* (Kohn, Corrigan, and Donaldson 1999), patient safety was defined as freedom from accidental injury caused by medical care, which translates to medical errors. Such medical errors were further defined using the definition from the federal response to this report (Quality Interagency Coordination Task Force 2000): "the failure of a planned action to be completed as intended or of use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems." This definition excludes acts that did not achieve their desired outcomes (as long as that was not the result of negligence), outcomes because of the intrinsic properties of the underlying illness or additional patient comorbidities, and outcomes known to be risks of specific procedures. These excluded acts distinguish the PSIs from other indicator systems designed to detect complications of care. For example, although sepsis is clearly a complication and at times an adverse event caused by medical care, the rationale to define sepsis as a patient safety concern is limited without detailed chart review because of the unclear underlying issues such as

immunocompromised status, timing of onset, and even the definition of sepsis itself (Pronovost, Angus, and Miller 2000).

PSI Algorithm Development

The overall methodology for development of the PSIs mirrored earlier AHRQ efforts in creating the HCUP QIs and occurred in four phases to date (Johantgen, Elixhauser, Ball, et al. 1998). We undertook the venture to create the PSIs knowing that the resultant algorithms would be indicators, not definitive measures, of patient safety concerns. More specifically, we realized that the PSIs would not comprehensively identify all inpatient errors and that not all events identified would be true errors. In other words, information resulting from application of the PSIs is intended to be a useful screen to identify processes of care that warrant further evaluation.

Phase one: Evaluation of existing measures. Much work has been done in the development of administrative data algorithms to identify complications of care and adverse events. Because patient safety concerns are likely a subset of these we systematically identified and reviewed published nonproprietary code books and literature using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes regarding complications of care, adverse events, and medical negligence (Public Health Service and Healthcare Financing Administration 1997; Iezzoni, Daley, and Foley 1992; Riley, Lubitz, Gornick, et al. 1993; Rutstein, Berenberg, Chalmers, et al. 1976; Hannan et al. 1989; DesHarnais et al. 1990, Rosen, Geraci, Ash, et al. 1992; Geraci, Ashton, Kuykendall, et al. 1997; Pronovost, Jenckes, Dorman, et al. 1999; Kalish, Daley, Duncan, et al. 1995; Kravitz, Rolph, and McGuigan 1991; Bates, O'Neil, Petersen, et al. 1995; Iezzoni, Davis, Palmer, et al. 1999; Iezzoni, Daley, Heeren, et al. 1994; Iezzoni, Foley, Heeren, et al. 1992). Based on clinical judgment and knowledge of the limitations of administrative data we sought to identify potential ICD-9-CM codes suitable for patient safety indicators. For example, because of imprecision in administrative data regarding whether a condition occurred during a hospitalization or preceded the hospitalization, ICD-9-CM codes such as 53531 (Alcoholic gastritis with hemorrhage) and 42741 (Ventricular fibrillation) were excluded from consideration despite their being included in the Complications Screening Program (Iezzoni, Daley, and Foley 1992). Overall our search yielded 148 potential ICD-9-CM codes.

In addition, literature evaluating complications of care and adverse events based on chart abstraction was also reviewed to generate ideas for new adminis-

trative data–based indicators focused on patient safety problems (Brennan, Leape, Laird, et al. 1991; Leape, Brennan, Laird, et al. 1991; Leape et al. 1993; Gawande et al. 1999; Lakshmanan, Hershey, and Breslau 1986; Luft and Hunt 1986; Davis, Hoyt, McArdle, et al. 1991; Thomas, Studdert, Newhouse, et al. 1999; O'Neil, Petersen, Cook, et al. 1993; Localio, Lawthers, Brennan, et al. 1991; Brennan, Sox, and Burstin 1996; Localio, Weaver, Landis, et al. 1996; Silber, Rosenbaum, Schwartz, et al. 1995).

Phase two: Hand search of ICD-9-CM. The baseline pool of ICD-9-CM codes identified in phase one was augmented with a hand search of the entire ICD-9-CM code book (Public Health Service and Healthcare Financing Administration 1997). The decision to include a given ICD-9-CM code was based on consensus by two independent AHRQ clinical reviewers with the goal of finding those codes that could identify errors with the least ambiguity given the limitations of administrative data. This subset of new candidate codes was then added to codes identified from the literature for the next phases of PSI development.

Phase three: Inclusion and exclusion criteria. We next developed inclusion and exclusion criteria for each ICD-9-CM code to identify the appropriate risk pool of patients and narrow the events captured for each code to those most likely to represent true patient safety concerns. Based on our literature review we evaluated existing inclusion and exclusion criteria applicable to administrative data (Iezzoni, Daley, and Foley 1992; Pronovost, Jenckes, Dorman, et al. 1999; Elixhauser et al. 1998). In addition, we performed hand searches of the ICD-9-CM codes and diagnosis-related group (DRG) codes for all inclusion/exclusion conditions to augment these existing definitions with any new codes (Public Health Service and Healthcare Financing Administration 1997; *DRGs: Diagnosis Related Groups Definitions Manual* 1997).

Inclusion criteria using ICD-9-CM and DRG codes were developed to identify the following types of discharges: surgical, medical, obstetric, and live births. These inclusion criteria enabled us to focus each PSI on appropriate risk pools of patients.

Exclusion criteria were developed to identify trauma, immunocompromised status, foreign body, and cancer. These exclusion criteria were designed to eliminate cases with conditions that predispose patients to events that are similar to PSI events but are not caused by failures of medical care nor are necessarily preventable.

Based primarily on the logic underlying the Complications Screening Program (Iezzoni, Daley, and Foley 1992) we also established an inclusion criterion that stipulated whether the ICD-9-CM code must be a secondary diagno-

sis/procedure or could appear in any diagnosis/procedure field on the record. For example, codes for suture of lacerations of various body organs were only considered in the PSIs if they occurred as secondary procedures. The rationale behind this centered on trying to identify events that occurred during the hospitalization as opposed to prior to hospitalization. On the other hand, some codes for the PSIs were deemed to be eligible if the code occurred in any position in the discharge record, such as for code 9996 (ABO incompatibility reaction), because such an event is a patient safety concern regardless of whether it occurs before or during hospitalization. Furthermore, such events may well capture outpatient events that can be examined and altered by a given hospital.

Lastly, we created an inclusion criterion where only records of patients electively admitted for surgical procedures were considered. The goal of this criterion was to distinguish the medically stable patient admitted for a scheduled procedure from those patients undergoing surgical procedures while possibly not in optimal medical condition as is more likely with emergent or urgent admissions such as trauma. This was considered important because, to varying degrees, all of the PSIs capture complications of care likely caused by patient comorbidities. To implement this criterion we relied on the subjective report in administrative data labeling an admission as elective, urgent, or emergent. Use of such an elective flag to identify cases has been reported in the literature (Pronovost, Jenckes, Dorman, et al. 1999). Additionally, our pilot testing of this variable to assess reliability determined that the variable appeared to be accurately coded (e.g., only 1.8 percent of acute myocardial infarction cases were coded "elective" admission compared to 65 percent of infertility cases).

Phase four: Algorithm testing and PSI grouping. The PSI algorithms were tested using the 1996 HCUP New York State Inpatient Database (NY SID) with the primary goal of evaluating the event rates of the codes and appropriate inclusion/exclusion criteria to determine if rates were consistent with the literature on medical errors. Output from the NY SID 1996 also guided the grouping of PSI codes such that all 11 unique groups made clinical sense. In addition, we created a PSI group of only E codes from ICD-9-CM and an overall summary group of all the groups except for the E codes for a total of 13 PSI groups. The rationale for excluding the E codes from the PSI summary group was that these events are less consistently recorded, given that they are clearly denoted as "injuries due to external causes" in the ICD-9-CM and thereby may have substantial biases in terms of the events actually reported.

Analysis of PSI Events

After establishing the algorithms and groupings, we applied the PSIs to the NY SID for 1997. First, we examined the rates for each of the PSI groups. Second, we examined the relationship between PSI events and length of stay, percent in-hospital mortality, and total charges, compared to patients not experiencing a PSI event. Third, we conducted bivariate and multivariate regression analyses to examine the associations between PSI events and various patient-level and hospital-level characteristics.

Patient-level variables retrieved from the NY SID 1997 included age (up to 17 years, 18–44 years, 45–64 years, 65–74 years, and 75+ years), sex, ethnicity, and primary expected payer (Medicare, private, Medicaid, other, or uninsured).

Hospital-level variables were identified from the literature and were obtained from either NY SID 1997 data or by linkage to the American Hospital Association's (1997) Annual Survey of Hospitals Database, Fiscal Year 1997 (Manheim et al. 1992; Hartz, Krakauer, Kuhn, et al. 1989; Taylor, Whellan, and Sloan 1999; Silber et al. 1992; Allison, Kiefe, Weissman, et al. 2000). These variables were ownership (public, for profit, not for profit), teaching status (nonteaching defined as no residents, minor teaching defined as less than median ratio of residents to hospital beds for NY SID 1997, and major teaching defined as greater than or equal median ratio of residents to hospital beds for NY SID 1997), nursing expertise (number of full-time and part-time registered nurses divided by number of full-time and part-time registered nurses and licensed practicing nurses, categorized into less than median value for NY SID 1997 and greater than or equal to median value for NY SID 1997), hospital location (rural, urban), and total number of hospital beds (stratified into less than median value for NY SID 1997 and greater than or equal median value for NY SID 1997).

To examine variations among hospitals caused by the types of patients cared for we also included two variables previously used in the literature to capture hospital-level severity of illness: percent of hospital beds in intensive care (categorized into less than median value for NY SID 1997 and greater than or equal median value for NY SID 1997) and number of inpatient surgical procedures divided by total number of annual admissions (categorized into less than median value for NY SID 1997 and greater than or equal median value for NY SID 1997) (Manheim et al. 1992; Hartz, Krakauer, Kuhn, et al. 1989). Because hospitals vary in the number of ICD-9-CM diagnosis and procedure codes typically recorded on discharge records and because the PSIs rely on these codes, we also included variables to account for the median number of diagnosis and procedure codes recorded by each institution during 1997 (categorized into less than median

value for NY SID 1997 and greater than or equal median value for NY SID 1997) (Iezzoni, Foley, Daley, et al. 1992).

Multivariate logistic regression analyses were completed using all of the above patient-level and hospital-level variables as well as incorporating hospital case-mix adjustment using all-patient refined (APR)–DRG software (1999). Because the PSIs were likely to be imperfect in identifying only cases of medical errors as opposed to events reflecting patient comorbidities this adjustment for hospital case mix was necessary. To obtain the APR-DRG hospital case mix for patient severity we first applied the APR-DRG software to the discharge records and determined each individual patient's severity of illness using the APR-DRG four-point scale (class 1 = least severe, class 4 = most severe). Because the APR-DRG software relies on ICD-9-CM codes to assign severity scores we deleted those ICD-9-CM codes from the APR-DRG scoring algorithm that clearly represent in-hospital patient safety events such as Iatrogenic hypotension and Transfusion reaction. Next, for each given institution in NY SID 1997 we determined the distribution of patients among the four severity classes for 1997, that is, the percentage of each hospital's patients in class 1, class 2, class 3, and class 4.

For the multivariate logistic regression analysis the following variable categories were used as reference values: age 18 to 44 years, female sex, nonwhite ethnicity, private insurance, not-for-profit ownership, nonteaching hospital status, high nursing expertise, rural hospital location, large hospital bed size, low percentage of beds in intensive care units, low percentage of inpatient surgical volume, and percentage of patients in severity class 1.

Statistical Analysis

Nonparametric comparisons of medians for length of stay and total charges were done using the Wilcoxon rank-sum tests because these data were not normally distributed. Comparisons of percent in-hospital mortality were completed using chi-square tests, as were bivariate associations between patient-level and hospital-level characteristics and PSI events. Multivariate logistic regression analyses yielded odds ratios (OR) and 95 percent confidence intervals (CI) for experiencing a PSI event compared to not experiencing a PSI event. Analyses were done using SAS with significance level of $p < .05$ (SAS Institute, Inc. 1989).

RESULTS

Overall Rate of PSI Events

Table 1 summarizes the 13 PSI groups developed and the associated inclusion and exclusion criteria for each. Table 2 presents the rate of PSI events by PSI group for the 2,400,000 discharges in the NY SID 1997. The event rates ranged from 0.8 (foreign body left during procedure) to 84.1 (birth trauma) events per 10,000 discharge records. The ICD-9-CM E codes identified only 8.9 events per 10,000 discharge records. By pooling the first 11 individual PSI groups and excluding duplicate records at the patient level an overall event rate of 87.9 potential patient safety events per 10,000 discharges was identified.

Comparison of Outcomes Based on PSI Events

Analyses of the relationship between PSI events and median length of stay, percent in-hospital mortality, and median total charges are shown in Table 3. Across all 11 individual PSI groups, the E codes group, and the PSI summary group, discharges with PSI events had twofold to fourfold greater median lengths of stay. All PSI groups were associated with greater mortality rates except for the "foreign body left during a procedure" group. The magnitude of this increased in-hospital mortality rate ranged from twofold to 60-fold. Similarly, all PSI groups had twofold to fourfold higher median total charges.

Factors Associated with PSI Events

Bivariate associations between patient-level and hospital-level characteristics and PSI events are summarized in Table 4 for the PSI summary group. Overall there was a significant increase in the rate of PSI events with increasing age, male sex, white ethnicity, Medicare and private primary insurance, not-for-profit hospital status, major teaching status, higher nursing expertise, urban location, and higher number of hospital beds. We also found a significant association between PSI events and a higher number of hospital beds in intensive care units and higher percent of inpatient surgical procedures, both measures that potentially reflect a more severe case mix. Additionally, PSI events were significantly associ-

ated with hospitals that generally use a higher number of diagnosis and procedure codes on their discharge records.

Table 1: PSI Algorithms

Group	ICD-9-CM Codes		DX/PR Fields*	Inclusion Criteria†	Exclusion Criteria‡
Procedure for suture of laceration	2951–pharynx 3161–larynx 3341–bronchus 3343–lung 3482–diaphragm 4282–esophagus 4461–stomach 4671–duodenum 4673–small intestine 4675–large intestine	4871–rectum 4971–anus 5061–liver 5191–gallbladder 5581–kidney 5682–ureter 5781–bladder 5841–urethra 6941–uterus	2° PR	Surg Elective	T; FB
Perforation DX	5304–esophagus 5754–gallbladder	5763–bile duct 56983–intestine	2° DX	Surg Elective	T; FB; CA
Postoperative infection	99851, 99859–postoperative infection		2° DX	Surg	T; IC
Transfusion reaction	9996–ABO incompatibility 9997–Rh incompatibility	9998–other transfusion reaction	Any DX	Med and surg	T
Foreign body left during procedure	9984–foreign body accidentally left during a procedure 9987–acute reaction to a foreign substance accidentally left during a procedure		Any DX	Med and surg	T
Infection due to procedure	9993–other infection after infusion, injection, transfusion, vaccination		Any DX	Med and surg	T
Iatrogenic conditions	41511–iatrogenic pulmonary embolism and infarction 4582–iatrogenic hypotension 5121–iatrogenic pneumothorax		Any DX	Med and surg	T
Wound disruption	5461–reclosure of postoperative disruption of abdominal wound 9983–postoperative wound disruption		Any PR Any DX	Med and surg Med and surg	T; IC T; IC

Miscellaneous misadventure	9954–shock due to anesthesia 9980–postoperative shock due to procedure 9982–accidental puncture or laceration during procedure 9991–air embolism due to procedure	Any DX	Med and surg	T
Obstetric misadventure	Complications of anesthesia in labor/delivery: (66800-4–pulmonary; 66810-4–cardiac; 66820-4–central nervous system; 66880-4–other; 66890-4–unspecified) 66910–66914–shock during/following labor/delivery 66930, 66932, 66934–acute renal failure 66940-4–other complication obstetric surgical procedure 67410, 67412, 67414–disruption C section wound	Any DX	OB	T
Birth trauma	7670–subdural or cerebral hemorrhage 7676–injury to brachial plexus 7673–injury to skeleton (excludes clavicle) 7678–other specified birth trauma 7674–injury to spine 7679–unspecified 7677–injury to other cranial/peripheral nerves (excludes facial)	Any DX	Liveborns	T
E codes	E8700–E8709–accidental cut, puncture, or hemorrhage during medical care E8710–E8719–foreign body left in body during procedure E8720–E8729–failure of sterile precautions during procedure E8740–E8749–mechanical failure of instrument or apparatus during procedure E8750–E8759–contaminated or infected blood, other fluid, drug, or biological substance E8760–E8769–other and unspecified misadventures during medical care E8730–E8739–failure in dosage	Any DX	Med and surg	
PSI summary group	All groups denoted above, except E code group, with records unduplicated (e.g., if a given record has PSI event for both Transfusion reactions and Iatrogenic conditions, that record will contribute "1" to the numerator for the PSI summary group)	As defined per PSI groups	Med, surg, and liveborns	T

*DX = diagnosis; PR = procedure; 2° = secondary.

†Surg = surgical patients defined by DRGs; elective = elective admissions; med = medical patients defined by DRGs; OB = obstetric patients defined by DRGs; liveborns = live-born infants defined by DRGs and ICD-9-CM codes.

‡T = trauma; FB = foreign body; CA = cancer; IC = immunocompromised.

Table 2: PSI Events in 1997 New York State Inpatient Database

	No. of Records with PSI Event	Risk Pool for PSI Event	Event Rate per 10,000 Discharges
Procedure for suture of laceration	494	291,702	16.9
Perforation diagnosis	110	230,395	5.0
Postoperative infection	1,508	229,854	65.6
Transfusion reaction	981	2,029,357	4.8
Foreign body left during procedure	157	2,029,357	0.8
Infection caused by procedure	1,131	2,029,357	5.6
Iatrogenic conditions	7,811	2,029,357	38.5
Wound disruption	1,838	1,741,925	10.6
Miscellaneous misadventures	3,762	2,029,357	18.5
Obstetric misadventures	1,089	241,926	45.0
Birth trauma	2,097	249,259	84.1
E codes	1,953	2,185,108	8.9
PSI summary group—patient level	20,019	2,276,646	87.9

Risk pool definitions based on inclusion and exclusion criteria:
*Elective surgical discharges, excluding trauma and foreign body cases.
†Elective surgical discharges, excluding trauma, foreign body, and cancer cases.
‡Elective surgical discharges, excluding trauma and immunocompromised cases.
§Medical and surgical discharges, excluding trauma cases.
¶Obstetric discharges, excluding trauma.
**Live-born discharges, excluding trauma.
††Medical and surgical discharges.
‡‡Medical, surgical, and live-born discharges, excluding trauma.

When analyzing bivariate associations at the level of the 11 individual PSI groups additional findings surfaced with respect to patient-level characteristics. Women were more likely than men to experience a PSI event of procedures for suture of laceration during elective surgical care (20 events vs. 12 events per 10,000 discharges; $p < .001$). Black women were more likely to experience an obstetric misadventure than white women (57 events vs. 43 events per 10,000 discharges; $p < .001$). Among records with birth trauma, a greater percentage of cases had Medicaid primary insurance compared to private insurance (93 events vs. 80 events per 10,000 discharges; $p = .001$).

In terms of bivariate analyses of hospital-level characteristics birth trauma was higher in public institutions as opposed to for-profit or not-for-profit institutions (189 events vs. 36 and 69 events, respectively, per 10,000 discharges; $p < .001$). Greater nursing expertise was associated with greater rates of PSI events except for a greater rate of procedures for suture of lacerations among elective

surgery patients in institutions with lower nursing expertise (24 events vs. 15 events per 10,000 discharges; $p < .001$).

Table 3: Comparison of Outcomes for Records with PSI Events Vs. Records Without PSI Events

	Median Length of Stay (Days)			% In-hospital Mortality			Median Total Charges ($)		
	PSI	No PSI	p	PSI	No PSI	p	PSI	No PSI	p
Suture of laceration*	7	3	.0001	3.6	0.60	.001	14,051	7,456	.0001
Perforation diagnosis†	10	3	.0001	15.5	0.50	.001	22,684	6,965	.0001
Postoperative infection‡	12	3	.0001	6.0	0.40	.001	22,675	6,925	.0001
Transfusion reaction§	9	4	.0001	9.0	3.10	.001	16,784	6,381	.0001
Foreign body left§	7	4	.0001	3.8	3.10	NS	14,533	6,383	.0001
Infection due to procedure§	11	4	.0001	8.1	3.10	.001	18,323	6,381	.0001
Iatrogenic conditions§	9	4	.0001	12.9	3.10	.001	22,506	6,362	.0001
Wound disruption‡	16	4	.0001	9.5	2.30	.001	28,988	6,000	.0001
Miscellaneous misadventures§	7	4	.0001	9.6	3.10	.001	17,727	6,373	.0001
Obstetric misadventures¶	4	2	.0001	0.6	0.01	.001	6,970	3,952	.0001
Birth trauma**	2	2	.0001	1.5	0.40	.001	1,680	1,463	.0001
E codes††	6	4	.0001	6.0	3.10	.001	13,367	6,462	.0001
PSI summary group‡‡	8	4	.0001	8.9	2.80	.001	17,150	5,670	.0001

Definitions for identifying eligible group "without PSI event":
*Elective surgical discharges, excluding trauma and foreign body cases.
†Elective surgical discharges, excluding trauma, foreign body, and cancer cases.
‡Elective surgical discharges, excluding trauma and immunocompromised cases.
§Medical and surgical discharges, excluding trauma cases.
¶Obstetric discharges, excluding trauma.
**Live-born discharges, excluding trauma.
††Medical and surgical discharges.
‡‡Medical, surgical, and live-born discharges, excluding trauma.

Table 4: Bivariate Associations Between Patient and Hospital Characteristics and PSI Events for the PSI Summary Group

	No. of Records with PSI Event	Risk Pool for PSI Event	Rate*	p-value
Age (y.)				
0–17	2,697	403,390	67	
18–44	3,633	689,973	53	
45–64	4,914	452,212	109	.001
65–74	4,297	308,871	139	
75+	4,471	421,927	106	
Sex				
Male	8,646	956,967	90	.001
Female	11,369	1,319,598	86	
Ethnicity				
White	13,719	1,358,603	101	
Black	2,434	401,830	61	
Hispanic	1,156	198,539	58	.001
Asian	326	43,120	76	
Other	926	152,679	61	
Primary insurance				
Medicare	8,863	768,210	115	
Private	726	803,376	91	
Medicaid	3,121	563,290	55	.001
Other	308	34,749	89	
Uninsured	427	107,021	40	
Ownership				
Public	2,021	293,616	69	
For profit	433	65,569	66	.001
Not for profit	17,498	1,907,902	92	
Resident:bed ratio				
Nonteaching	4,162	500,065	83	
Minor teaching	3,588	408,831	88	.001
Major teaching	12,265	1,367,750	90	
Nurse expertise				
< median for NY 1997	3,885	528,139	74	.001
• median for NY 1997	16,130	1,748,507	92	
Hospital location				
Rural	801	133,229	60	.001
Urban	19,141	2,132,524	90	
Bed size				
< median for NY 1997	3,190	440,624	72	.001
• median for NY 1997	16,825	1,836,022	92	
No. of beds in intensive care units				
< median for NY 1997	8,574	1,065,926	81	.001
• median for NY 1997	11,441	1,210,720	94	

Continued

	No. of Records with PSI Event	Risk Pool for PSI Event	Rate*	p-value
No. of inpatient surgeries/total admissions				
< median for NY 1997	6,588	1,043,413	65	.001
• median for NY 1997	13,427	1,233,233	109	
Median no. of diagnosis codes by institution				
< median for NY 1997	4,312	1,448,651	30	.001
• median for NY 1997	15,703	827,995	190	
Median no. of procedure codes by institution				
< median for NY 1997	4,007	1,243,301	32	.001
• median for NY 1997	16,008	1,033,345	155	

*Per 10,000 discharges.

Unlike the other 11 PSI groups, E code events were more likely recorded for female patients (ten events vs. eight events per 10,000 discharges; $p < .001$), equally likely among Medicare insurance and private insurance (both ten events per 10,000 discharges), more likely in public institutions compared to for-profit and not-for-profit ones (11 events vs. six and nine events, respectively, per 10,000 discharges; $p < .001$), and more likely in rural hospital settings (15 events vs. nine events per 10,000 discharges; $p < .001$).

Multivariate logistic regression analysis, including APR-DRG–derived case-mix adjustment for each institution, was performed using all the variables from the bivariate analyses. Overall this model had a low predictive value with a *c* statistic of only 0.65 and a R^2 of only 0.0025, reflecting the fact that these administrative data–derived variables alone did not perform well in predicting PSI events. The variables with the greatest predictive value for experiencing a PSI event, in order, were: age 65 to 74 years (OR 2.4, CI 2.3–2.5), age 45 to 64 years (OR 1.9, CI 1.8–2.0), high percentage of inpatient surgical volume (OR 1.5, CI 1.4–1.5), age 75+ years (OR 1.9, CI 1.8–2.0), and high percentage of hospital beds in intensive care units (OR 1.3, CI 1.2–1.3).

DISCUSSION

Unlike other published measures looking at complications of care or adverse events, the PSIs were specifically created to capture those instances representing potentially preventable events that compromise patient safety. Our preliminary

analyses using the PSIs show that these events have substantial associations with outcomes such as in-hospital mortality, length of stay, and total charges.

Given the IOM report on medical errors these findings are not surprising (Kohn, Corrigan, and Donaldson 1999). Additionally, a growing pool of literature clearly supports these findings of relatively high rates of patient safety events in hospital settings. For example, one study focusing on intensive care units reported that on average there were 178 activities per patient per day, with 1.7 errors per patient per day (Donchin, Gopher, Olin, et al. 1995). A recent study focusing only on in-hospital mortality estimated that 22.7 percent of active-care patient deaths are at least possibly preventable by optimal care (Hayward and Hofer 2001).

Similar to the PSIs, prior studies that evaluated a broader category of events—usually called adverse events or complications—tend to show comparable results in terms of associations with outcomes and with patient-level and hospital-level characteristics. Because patient safety events are likely a subset of these complications these similarities are not surprising. For example, it has been reported that complications of care are associated on average with a doubling of lengths of stay and tripling of hospital charges (Kalish, Daley, Duncan, et al. 1995). As early as 1991 associations between in-hospital adverse events and teaching status and urban hospital location have been reported (Brennan, Hebert, Laird, et al. 1991). A recent study found that increasing patient age is associated with higher risk for injuries during hospitalization such as falls, nosocomial infections, and pressure sores (Rothschild, Bates, and Leape 2000).

Although it would be desirable to identify the independent effects of patient and hospital factors on PSI events, our multivariate regression analysis did not show a substantial predictive ability of these variables. This is not surprising given the limitations of administrative data both in terms of the types of variables that can be created and the likely imprecision of the PSIs to identify only cases of medical errors. Clearly many other patient-level and hospital-level factors beyond the reach of administrative data may better predict medical errors. Nevertheless, our analysis did show a significant link between PSI events and patient characteristics indicating more intense contact with medical care providers (older age) and hospitals likely to perform more surgeries and procedures that by their nature predispose a patient to medical errors.

Clearly the most significant limitation of the PSIs is their reliance on hospital administrative data. Although hospitals are not the only setting where medical errors occur, the well-developed administrative databases reflecting hospital care and the high likelihood of significant errors compared to other settings make the inpatient setting an ideal initial focus for PSI development. Nevertheless, there

are many unattractive attributes of administrative data such as limited clinical descriptions inherent in ICD-9-CM codes, concerns about coding accuracy and completeness, regional and institutional variations in coding accuracy and thoroughness, inability to perfectly risk adjust with the limited clinical information, and limited insight into the timing of events particularly with respect to onset of a condition as either during the index hospitalization or preceding the hospitalization (Schwartz, Gagnon, Muri, et al. 1999; Iezzoni 1997; Romano and Mark 1994; Weiss, Nannini, Fogerty, et al. 2000). Despite these issues administrative data remain a readily available, inexpensive, and computer-readable source of information on large populations. Overall, as with the HCUP QIs, the advantages of hospital discharge administrative data appear to outweigh the disadvantages as an initial focus for indicator development.

A second limitation of the PSIs is the relatively low number of cases identified if applied to a single institution's data. This fact re-emphasizes the appropriate use of the PSIs as a case-finding tool for patient safety improvements as opposed to a comparative tool.

Third, the PSIs are limited by likely imperfections in truly identifying only cases of compromised patient safety because of limited clinical descriptions associated with administrative data. This means that the PSIs are not intended to unambiguously measure medical errors. This imperfection likely encompasses both false positives and false negatives. Furthermore, the imperfection also encompasses cases of medical errors that are inadvertently excluded from consideration because of inclusion and exclusion criteria. For example, all of the surgically oriented PSIs rely on the subjective "elective" coding. Although this clearly strives to minimize false positives, it also limits our ability to detect patient safety events in urgent or emergent admissions. Given the primary goal of serving as a case-finding tool for further investigation, this limitation is acceptable and underscores the precautions against using the PSIs for comparative purposes. Therefore, although once any given institution applies the PSIs all cases identified may not be determined to have been preventable, the narrow focus of the PSI should maximize the number of cases identified that are preventable.

Fourth, all of the preceding limitations underlie an important fact regarding the PSIs. The PSIs are not an exhaustive list of all medical errors that can occur in the hospital setting. Instead they are a conservative list of errors amenable to detection with administrative data. Because few if any other tools currently exist to identify medical errors this conservative short list of errors can serve as a starting point for tackling the patient safety problem.

Despite these significant and unavoidable limitations of the PSIs there are clear benefits to using them. First, the PSIs will have value both cross sectionally and over time within a defined system of care for case-finding activities. The stipulation for a defined system of care would serve to minimize coding variations. Such case-finding activities would enable easy identification of patient events that may signify systems problems. Second, pending the development of better error-reporting systems, the PSIs will have value when applied broadly at the state and national levels to provide an initial assessment of the potential scope of the "epidemic" of patient safety events. Such all-inclusive analyses would minimize institutional and regional variations in administrative data. Third, the PSIs provide a tool to identify cases of medical errors that result in either morbidity or mortality as opposed to solely mortality. In part because of the limited data on medical errors many reports to date have only been able to focus on cases of patient mortality (Kohn, Corrigan, and Donaldson 1999; Hayward and Hofer 2001).

In terms of future directions for the PSIs, AHRQ is currently seeking to expand the indicator pool and conduct external validation. Under contract with AHRQ's University of California at San Francisco-Stanford Evidence-based Practice Center the PSIs as reported here will be augmented with additional potential patient safety measures from the literature and will undergo further evaluation via clinician feedback on indicator validity and usefulness as well as empirical analyses of variability in event rates. These expansion and validation efforts are currently underway, with expected project completion and public release of the PSIs as a component of the AHRQ QIs by early 2002. With the national focus on patient safety and ever-changing codes and coding practices we anticipate that the PSIs will be an evolutionary list with future refinements even beyond these initial efforts as the capabilities of administrative data change. Additionally, AHRQ is considering undertaking an effort to correlate PSI events with chart data to better quantify how precisely the PSIs identify true patient safety events and how preventable these events were. Such a project would serve to answer the first key question one should consider when using an indicator: When cases identified by an indicator are examined, can one find a set of definable and preventable processes of care known to lead to the bad outcome (Hofer et al. 1997)?

That being said and given the potential benefit of an easy-to-use tool to identify patient records at high risk of having experienced a medical error, we wanted to report our findings on the PSIs without this extensive validity work complete. One can clearly argue that implementation of the PSIs without this validation work still has one of two possible outcomes, both of which are beneficial. Either true errors will be identified or institutions will find significant needs

for improving their coding practices so that, for example, cases of elective surgery do not erroneously receive codes for suturing of lacerations.

In summary, the PSIs are a set of administrative data–based indicators that represent a possible approach to identify potential patient safety events. These indicators are intuitively easy to understand and readily applied but must be used cautiously given their reliance on administrative data. The PSIs are appropriate for internal quality improvement efforts but not for purchasing decisions, sanctioning individual institutions, or public reporting for individual institutions. Preliminary analyses of the PSIs show consistency with earlier broader measures of complications of care and reasonable numbers of cases identified, enabling institution-level quality improvement efforts and state- and national-level descriptive efforts. Overall, as the field of patient safety evolves, improved measures with better precision, validity, and reliability will likely be developed, but these efforts will inevitably require substantial time to reach fruition. In the interim and similar to AHRQ's prior efforts with the HCUP QIs, the PSIs provide a user-friendly tool for organizations interested in quality improvement efforts focused on patient safety. For indeed even today a basic tenet of medicine remains true: "There are some patients whom we cannot help; there are none whom we cannot harm (Arthur L. Bloomfield, as quoted in Strauss 1968)."

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