Validity of AHRQ Patient Safety Indicators Derived from ICD-10 Hospital Discharge Abstract Data

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Running header: Validating Patient Safety Indicators in ICD-10 Data

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Abstract

Objective: To assess if AHRQ PSIs could be used for case-findings in International Classification of Disease (ICD)-10 hospital discharge abstract data.

Methods: We identified and randomly selected 490 patients with foreign body left during a procedure (PSI 5-foreign body), selected infections (IV site) due to medical care (PSI 7-infection), post-operative pulmonary embolism or deep vein thrombosis (PSI 12-PE/DVT), post-operative sepsis (PSI 13-sepsis), and accidental puncture or laceration (PSI 15-laceration) among patients discharged from three adult acute care hospitals in Calgary, Canada in 2007 and 2008. Their charts were reviewed for determining presence of PSIs and used as the reference standard, positive predictive value (PPV) statistics were calculated to determine the proportion of positives in the administrative data was 'true positives'.

Results

The PPV for PSI 5-foreign body was 62.5% (95% confidence interval: 35.4% - 84.8%), PSI 7-infection was 79.1% (67.4% - 88.1%), PSI 12-PE/DVT was 89.5% (66.9% - 98.7), PSI 13-sepsis was 12.5% (1.6% - 38.4%) and PSI 15-laceration was 86.4% (75.0% - 94.0%) after excluding those who presented to the hospital with the condition.

Conclusion

Several PSIs had high PPV in ICD administrative data and are thus powerful tools for true positive case-finding. The tools could be used to identify potential cases from large volume of admissions for verification through chart review. In contrast, their sensitivity has not been well-characterized and users of PSIs should be cautious if using these for 'quality of care reporting' presenting rate of PSIs because under-coded data would generate falsely low PSI rates.

Key words: ICD-10, patient safety, outcome, administrative data

Introduction

Patient safety is a critical component of health care quality. Assessments of patient safety are traditionally done through chart review, survey and voluntary reporting of adverse events and medical errors(1;2). These data collection methods focus on a specific type of event, collect data from non-random and biased populations, cover limited geographic areas, or are too labor-intensive for widespread use. Therefore, researchers have paid great attention to routinely collected hospital discharge abstract administrative data for population-based studies of adverse events(3). Therefore, the Agency for Healthcare Research and Quality (AHRQ) conducted pioneering work to develop patient safety indicators (PSIs) for use with the International Classification of Disease, 9th version, Clinical Modification (ICD-9-CM) administrative data, which cover large geographic areas and are readily available and relatively inexpensive to use.

AHRQ PSIs were developed through a literature search, review of ICD-9-CM manuals, consultation with physician panels, and empirical data analyses. Over 200 ICD-9-CM codes representing potential patient safety problems were identified and 48 indicators were labeled as the most promising PSIs by the AHRQ research team. Of these, 20 hospital-level and 7 area-level PSIs were recommended by one or more multi-specialty panels as a set of 'accepted' indicators.(4) To facilitate utilization of PSIs, AHRQ developed and distributed (at no cost) SAS and SPSS software tools. The PSIs can be used to help hospitals identify potential adverse events that might need further study and also provide an opportunity to assess the occurrence of adverse events and in-hospital complications using routinely collected administrative data.

The AHRQ PSIs have been broadly used to assess the occurrence of adverse events and in-hospital complications by many international and national agencies, including Organization for Economic Cooperation and Development. Drosler et al.(5;6) analyzed hospital discharge abstract administrative data from multiple countries and found that PSI rates varied across countries. The variation in the PSI estimate could be caused by true quality of care differences or by differences in data quality.

PSIs could be used for case-finding or/and quality of care reporting. When PSIs are used for case-finding and positive predictive value (PPV) is low, chart review or investigation is required to verify the true case status after identification of cases from the administrative data. When PSIs are used to generate 'quality of care report' presenting rates, all of these four statistical parameters of validity (i.e. sensitivity, specificity, negative predictive value and PPV) should be high.

PSIs have been validated using chart data as ‘gold standard’ or ‘reference’ in the USA ICD-9-CM data only (see Appendix 1). Many countries have employed ICD-10 for coding hospital discharge abstract data.(7) However, the validity of PSIs in ICD-10 data has not been studied. Therefore, we conducted this study to estimate PPV or 'true positives' of PSIs derived from Canadian ICD-10 hospital discharge abstract data with flag of presence on admission using chart review as a reference standard.

Methods

Identify patients at risk for each of 5 PSIs from ICD-10 data

Of the AHRQ PSIs, we assessed PPV for 5 PSIs, which are likely to have high PPVs based on literature, including foreign body left during procedure (PSI 5 - foreign body), selected infections (IV site) due to medical care (PSI 7 - infection), postoperative pulmonary embolism or deep vein thrombosis (PSI 12 - PE/DVT), postoperative sepsis (PSI 13 -sepsis), and accidental puncture or laceration (PSI 15 - laceration).

Our study sample was patients discharged in the years 2007 and 2008 from all three adult acute care hospitals in Calgary, Canada, a city with a population of just over one million. Professionally trained health records coders in Calgary code up to 50 diagnosis codes and 20 procedures for each patient using ICD-10-CA/CCI (Canadian ICD-10 and Canadian Classification of Intervention)(8). One coordinator supervises and manages the coding practice at the three sites to establish a consistent approach to coding.

We developed ICD-10 PSI algorithm(9) based on AHRQ ICD-9-CM PSI definition manual as the blueprint (see ICD-10 codes in Appendix 2). PSIs in the data were defined using the ICD-10 codes in the 49 secondary diagnosis coding fields. We included patients with those ICD-10 codes. Earliest admission date was assigned to patients as the index date for those with multiple admissions in the study period. The indexed patients were stratified by the three hospitals and 50 patients were randomly selected per hospital for each PSI when there were more than 50 patients available. We aimed to review 40 patients at each hospital for each PSI, since at least 30 patients should be reviewed for calculating PPV.(10) Because PSI 5, foreign body left in during procedure, occurs rarely, we expanded the observation period for this PSI to 2006-2009 to increase the number of patients. However we did not reach the target sample size for PSI 5 and 7. An operating room procedure was defined using the code for inpatient procedure room type: '1' for main operating room, '8' for cardiac catheterization laboratory or '9' for ambulatory care operating room. Patients who underwent surgeries in the same day or emergency room were not included.

Review charts to determine presence and absence of PSIs

Corresponding patient charts for the sampled patients were located using a combination of the patient chart number and personal health number, which uniquely identifies each patient

and admission. Two chart reviewers underwent training and practice in the data extraction process using the PSI data collection tools developed by AHRQ(11). In the training session, the definition of study variables was discussed. Then the reviewers extracted data independently for evidence of PSIs through an examination of the entire chart, including the cover page, discharge summaries, pathology reports (including autopsy reports), trauma and resuscitation records, admission notes, consultation reports, surgery/operative reports, anesthesia reports, interdisciplinary progress notes, and physician daily progress notes. The reviewers followed the AHRQ definitions to determine the presence or absence of the five PSIs, and specified whether these events were present at the time of admission or arose during hospitalization. In the period of data collection, they discussed cases with uncertainty in determining conditions to ensure the consistency between them.

Statistical analysis

The ICD-10 administrative data and chart review data were linked and the linked data were analyzed using statistical software of SAS 9.2. Study populations were characterized using descriptive statistics. As mentioned above, we calculated PPV and its 95% confidence interval for each PSI recorded in ICD-10 hospital discharge data accepting the chart review data as a 'reference standard'. PPV determines the extent to which a PSI present in the ICD-10 data was also present in the chart review data. Unit of analysis is patient because one discharge abstract record and chart was assigned to each patient.

Results

A total of 490 patients were included from ICD-10 hospital discharge abstract data. There were 334 patients after excluding non-surgical patients for PSI 12 - EP/DVT and PSI 13 - sepsis (see Figure 1) and 163 patients after excluding those with PSIs present on admission. We reviewed all charts of 490 patients.

Among 334 patients, the mean age ranged from 57.9 to 67.2 years across the 5 PSIs (see Table 1). The proportion of male patients was lowest for PSI 13 - sepsis (36.6%) and highest for PSI 7 -infection (55.3%). Patients with PSI 7-infection, 12-PE/DVT, or 13-sepsis stayed in hospital 32.7, 41.3 and 43.9 days on average.

Some countries do not code whether the condition was present at admission or arose during the hospital stay. When conditions present on admission were included (see Table 2), the PPV was 35.6% for PSI 5-foreign body, 70.6% for PSI 7-infection, 79.0% for PSI 12-PE/DVT, 9.8% for PSI 13-sepsis and 90.8% for PSI 15-laceration. When conditions present on admission were excluded from the analysis, the PPV increased for PSI 5-forgein body (62.5%), 7-infection (79.1%), 12-PE/DVT (89.5%) and 13-sepsis (12.5%) but decreased for PSI 15-laceration (from 90.8% to 86.4%).

Considering some countries may not code procedures in administrative data, we evaluated the PPV among 123 PSI 12-PE/DVT patients and 117 PSI 13-sepsis patients ignoring surgical status. The PPV was 25.2% for PSI 12-PE/DVT, and 27.4% for PSI 13-sepsis. When present on admission was considered, the PPV increased to 27.0% for PSI 12-PE/DVT, and 47.1% for PSI 13-sepsis.

The reasons for misclassification of PSI conditions in administrative data varied across PSIs (see Table 3). The most common reason was that the condition was present on admission.

Discussion

Like previous PSI validation studies in ICD-9-CM data, we focused on the PPV in ICD-10 administrative data as the foremost of interest. Our study revealed that PSI PPVs in most instances are sufficiently high to support widespread use for case findings. The low PPVs for some PSIs, such as sepsis do not support utility of the PSIs for quality of care reporting for comparisons across jurisdictions.

The validity of ICD-10 data varied by PSI. PSI 5-foreign body and 13-sepsis had low PPV but PSI 7-infection, 12-PE/DVT and 15-laceration had high PPV. The high PPV for PSI 12-PE/DVT (89.5%) is supported by one US study(12) (PPV=79%), but is higher than four other US studies (PPV=22-55%).(13-16) In contrast to our finding for PSI 13-sepsis (PPV=9.8%), Romano et al.(15) reported a higher PPV for PSI 13-spesis (45%). As our finding PPV for PSI 15-laceration (PPV=90.8%), Kaafarani et al.(16) and Utter(17) et al. reported high PPV for PSI 15-laceration (91% and 85%, respectively).

Because low prevalence PSIs with reasonable precision (i.e. 95% confidence intervals) requires reviewing many charts for calculating sensitivity, all previous studies except for the study conducted by Koch et al.(18) evaluated data quality using PPV. The PPV value depends on prevalence and varies greatly across PSIs and studies. For example, the PPV for PSI 12-PE/DVT ranged from 22% to 79% across studies conducted in USA.(12-16) Koch et al.(18) compared agreement between ICD-9-CM data, National Surgical Quality Improvement Program (NSQIP) and Cardiovascular Information Registry (CVIR) in PSIs. The agreement was substantial for PSI

12-PE/DVT and poor for PSI 9-hemorrhage, PSI 11-respiratory failure and PSI 13-sepsis. Sensitivity was very low, for example 0.13% for PSI 9-hemorrhage, 1.35% for PSI 11-respiratory failure, 1.6% for PSI 12-PE/DVT and 0.13% for PSI 13-sepsis when ICD-9-CM and NSQIP were compared.

Variation in validity across PSIs is determined by factors related to physicians (i.e., chart documentation), and coders (i.e., coding guidelines and coders' practice). Coders code medical events after discharge based on chart documentation. We used chart review as our reference standard; therefore, completeness of chart documentation could not be evaluated. Physicians might not document consequences of medical care in charts, leading to under-coding in hospital discharge abstracts. In addition, coders at hospitals are allotted a specific amount of time per chart on average, for example, 30 minutes in Alberta. Thus they might focus on coding diagnoses and procedures that contribute significantly to length of stay such as PE/DVT, and ignore minor conditions such as infection or laboratory results that indicate sepsis, to follow Canada national coding guidelines. Our reviewers focused on determining the presence or absence of conditions based on all documented information in the chart, including diagnostic imaging and laboratory results. This is in contrast to general coding guidelines(8) that instruct coders to confine their coding to clinical problems, conditions, or circumstances that are identified in the record by the treating physicians as the clinically significant reason for the patient's admission, or that require or influence evaluation, treatment, management, or care. Coders do not typically code problems that do not meet these requirements, whereas the reviewers who conducted our 'reference standard' chart review included them regardless of the significance of the condition on resource use during hospitalization. Coders are instructed that when a condition is suggested by diagnostic test results, they should only code the condition if it has been confirmed by physician documentation. Our previous studies demonstrated that hospital discharge abstract data quality is not related to coders' employment status (full-time/part time and length of employment) but related to physician documentation quality.(19;20)

Excluding conditions present on admission improves PSI validity. For example, the PPV for PSI 12-PE/DVT increased from 79.0% to 89.5% from including to excluding the presence of the condition on admission. Canada has a long history of flagging timing of condition occurrence. Some US and Australian states currently have similar data elements in their discharge abstract data, and the US has recently begun coding the timing of conditions nation-wide. Timing of condition occurrence is not aimed at judging causal relationships between medical care and complications, just flagging whether the condition occurred or was diagnosed during the hospitalization. To capture complications, Japan has specified fields for coding complications in its hospital discharge data, in addition to diagnoses and procedures.

Could AHRQ PSIs derived from hospital discharge abstract data be utilized for comparing quality of care across countries and/or jurisdictions, or for monitoring system performance in an institution? Because data quality contributes to the magnitude of PSIs , data validity has to be similar across comparison groups (such as countries, regions or jurisdictions) and over time. Thus, PSIs should not be compared across jurisdictions without validation because adjustment for data validity is necessary. Our findings suggest that PSIs could be used to screen potential cases with adverse events using administration data. Confirming the presence of these events needs additional clinical information such as chart reviews. If PSIs are used for comparison, validity of data has to be adjusted/considered in the analysis.

While PSIs are used for monitoring quality of care improvement over time, the assumption of temporal consistency of data validity has to be met. Unfortunately, we did not evaluate PSI validity over time. Quan et al.(21) evaluated impact of ICD-10 implementation on data quality through chart review of 32 conditions. Canadian ICD-10 data had significantly higher sensitivity for one condition and lower sensitivity for seven conditions relative to ICD-9-CM data. The two databases had similar sensitivity values for the remaining 24 conditions. Walker(22) et al. compared coding practice between ICD-9-CM and ICD-10 and reported that the number of diagnoses coded decreased in four Canadian provinces and remained similar in other five provinces after implementation of ICD-10. Januel JM(23) et al. reported that of 36 conditions assessed in Switzerland, Kappa values for ICD-10 and chart data increased for 29 conditions and decreased for seven conditions compared with ICD-9-CM and chart data.

Our study has limitations. First, of 20 AHRQ PSIs, we intentionally evaluated five conditions that might have a high validity based on literature. Second, we used chart data as the reference standard; conditions not documented in chart were missing. Prospective data collection through clinical examination on these events should be conducted to establish near gold standard. Third, this study was conducted in one urban area; the validity of PSIs might vary by institutions or regions.

In conclusion, our study supports that PSIs could be used for case-findings in the ICD-10 hospital discharge abstract data. Even PSIs with low PPVs could be used to identify potential cases from large volume of admissions for verification through chart review. In contrast, their sensitivity has not been well-characterized because of the inherit challenges of reviewing huge numbers of charts for properly testing sensitivity. Therefore, users of PSIs should be cautious if

using these for 'quality of care reporting' presenting rate of PSIs because under-coded data would generate falsely low PSI rates.

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Competing Interests Statement:

None

Contributorship Statement:

Hude Quan: Conception and design, acquisition of data, analysis, interpretation of data, and final approval of the version to be published.

Cathy Eastwood: Acquisition of data, interpretation of data, critical revision and final approval of the version to be published.

Ceara Cunningham: Acquisition of data, interpretation of data, critical revision and final approval of the version to be published.

Mingfu Liu: Acquisition of data, analysis, interpretation of data, critical revision and final approval of the version to be published.

Ward Flemons: Conception and design, interpretation of data, critical revision and final approval of the version to be published.

Carolyn De Coster: Conception and design, interpretation of data, critical revision and final approval of the version to be published.

William A Ghali: Conception and design, interpretation of data, critical revision and final approval of the version to be published.

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Table 1. Characteristics of patients by AHRQ patient safety indictor (PSI)

	PSI 5 Foreign body left during procedure N= 45	PSI 7 Selected infections due to medical care N=85	PSI12 Postoperative pulmonary embolism or deep vein thrombosis N=43 surgery patients	PSI13 Postoperative sepsis N=41 surgery patients	PSI15 Accidental puncture or laceration N=120
Age Mean (Range)	58.0 (21.6 – 93.5)	61.7 (18.5 – 90.0)	67.2 (31.0 – 94.0)	63.9 (19.9 – 83.5)	57.9 (19.3 – 96.5)
Sex (male)	24 (53.3%)	47 (55.3%)	23 (53.5%)	15 (36.6%)	44 (36.7%)
Length of stay	14.7 (1 – 195)	32.7 (2 – 184.0)	41.3 (2 - 274)	43.9 (1 – 238)	16.2 (1. – 181)

Table 2. Positive predictive value and 95% confidence interval (95% CI) for AHRQ patient safety indicators (PSI) recorded in ICD-10 hospital discharge abstract administrative data comparing chart data

Patient Safety Indicator	Including PSIs present on admission % (n/N, 95% CI)	Excluding PSIs present on admission % (n/N, 95% CI)
PSI 5 Foreign body left during procedure	35.6% (16/45) (21.9% - 51.2%)	62.5% (10/16) (35.4% - 84.8%)
PSI 7 Selected infections due to medical care	70.6% (60/85) (59.7% - 80.0%)	79.1% (53/67) (67.4% - 88.1%)
PSI12 Postoperative pulmonary embolism or deep vein thrombosis among surgery patients	79.0% (34/43) (64.0% - 90.0%)	89.5% (17/19) (66.9% - 98.7)
PSI13 Postoperative sepsis among surgery patients	9.8% (4/41) (2.7% - 23.1%)	12.5% (2/16) (1.6% - 38.4%)
PSI15 Accidental puncture or laceration	90.8% (109/120) (84.2% - 95.3%)	86.4% (51/59) (75.0% - 94.0%)
When surgical status was ignored		
PSI12Pulmonary embolism or deep vein thrombosis among surgery and non-surgery patients	25.2% (31/123) (17.8% - 33.8%)	27.0% (10/37) (13.8% - 44.1%)
PSI13 Postoperative sepsis among surgery or non-surgery patients	27.4% (32/117) (19.5% - 36.4%)	47.1% (16/34) (29.8% - 64.9%)

Table 3. Reasons for false positives of AHRQ patient safety indicators (PSI) in ICD-10 hospital discharge abstract administrative data when the indicator of presence on admission was ignored.

PSI 5 Foreign body left during procedure N=29	PSI 7 Selected infections due to medical care N=25	PSI 12 Postoperative pulmonary embolism or deep vein thrombosis N=9	PSI 13 Post operative sepsis N=37	PSI 15 Accidental puncture or laceration N=11
18- present on admission	7- present on admission	6- present on admission	15- present on admission	4 – present on admission
8– no foreign body	11 – unrelated to medical care	2 – had DVT/PE in past	12 – urgent surgeries, having sepsis	7 –no accidental puncture or laceration
2 – for treatment purposes (e.g. packing, stitch)	5 – IV site bruised or injured, no infection	1 – no DVT/PE	6 – urgent surgeries, no sepsis	
1 – patient pulled and broke catheter	2 – conflicting documentation		2 – no sepsis	
			2 – no surgery, sepsis	

ARTICLE SUMMARY

1) Article focus

- The Agency for Healthcare Research and Quality (AHRQ) patient safety indicators (PSIs) have been broadly used to assess the occurrence of adverse events and in-hospital complications using routinely collected administrative data.
- Estimates of PSIs could be caused by true quality of care differences or by differences in data quality.
- This study estimated 'true positives' of PSIs derived from Canadian ICD-10 hospital discharge abstract data with flag of presence on admission using chart review as a reference standard.

2) Key messages

- The validity of ICD-10 data varied by PSI.
- PSIs could be used to screen potential cases with adverse events using administration data. Confirming the presence of these events needs additional clinical information.
- If PSIs are used for comparison of jurisdiction performance, validity of data has to be adjusted for and considered in the analysis.

3) Strengths and Limitations

- To our knowledge, this is the first validation of ICD-10 data in recording AHR PSIs.
- We validated 5 out of 20 PSIs.
- Chart data were used as the reference standard; conditions not documented in chart were missing.

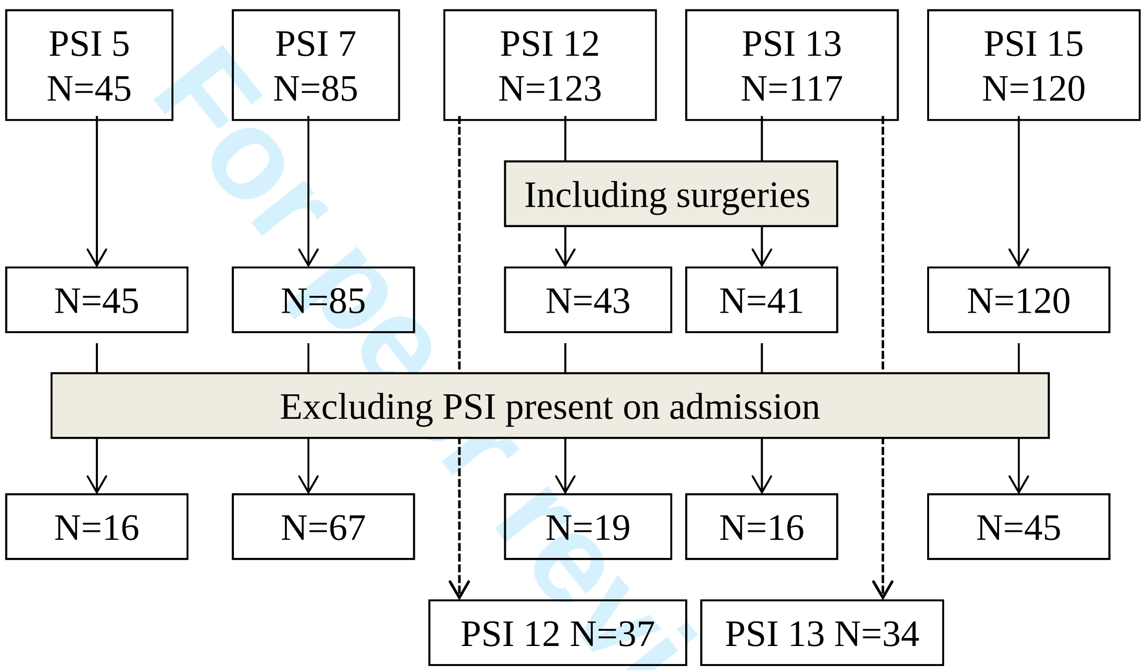

Figure 1: Sample Size by Patient Safety Indicator (PSI)

Appendix 1. Validation studies of Agency for Healthcare Research and Quality **(**AHRQ**)** patient safety indicator (PSI)

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
PSI 3: Decubitus ulcer Polancich et al.(1)	Chart review Year 2005 US	27.1% of 118	“Administrative data, when used alone, are not sufficient in measuring the true rate of hospital-acquired decubitus ulcers.”
PSI 4: Failure to rescue Hortitz et al.(2)	Chart review, 2004, US	50.7% of 2354	“This indicator may be useful internally to flag possible cases of quality failure but has limitations for external institutional comparisons.”
PSI 5: Foreign body left during procedure, Chen et al.(3)	Chart review, 2003-07, US	45% of 93	"The reported rate of foreign body events as detected by PSI 5 is low in the VA, but occurs in both surgical and medical procedures."
PSI 6: Iatrogenic Pneumothorax Sadeghi et al.(4)	Chart review Year 2006-07 US	78% of 200	“AHRQ’s iatrogenic pneumothorax indicator can serve in quality of care improvement.”
PSI 7: Infection due to medical care, Zrelak et al. (5)	Chart review, 2005-07, US	54% of 191	"PSI 7 has a low positive predictive value compared with other PSIs recently studied. Present on admission diagnoses and improved coding for infections related to central venous catheters (implemented October 2007) may improve validity."
PSI 7: Central venous catheter-related bloodstream infections, Cevasco et al.(6)	Chart review, 2003-07, US	45% of 112	"As it currently stands, PSI 7 should not be used as a pay-for-performance measure, but should be limited to use in internal quality improvement efforts."
PSI 10: Postoperative physiologic and metabolic derangement Borsecki et al. (7)	Chart review, 2002-07 US	63% of 119	"Due to its low PPV, we recommend removing diabetes complications from the indicator and focusing on AKI."

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
PSI 11: Respiratory failure Utter et al.(8)	Chart review, 2007 US	83% of 609	"A hospitalization flagged by PSI 11 is reasonably likely to represent a true postoperative pulmonary complication."
PSI 11: Respiratory failure Borzecki et al.(9)	Chart review Year 2003-07 US	67% of 112	"PRF should continue to be used as a screen for potential patient-safety events. Its PPV could be substantially improved in the Veterans Health Administration through introduction of an admission status code."
PSI 12: Postoperative venous Thromboembolism and pulmonary embolism, White et al.(10)	Chart review, 2005-07, US	79% of 573 44% of 452, for lower extremity	"Current PSI 12 criteria do not accurately identify patients with acute postoperative lower extremity DVT or PE."
PSI 12: Venous thromboembolism and pulmonary embolism, Zhan et al.(11)	Chart review, 2002-04, US	29% of 327	"ICD-9-CM codes in Medicare claims are sensitive but have limited predictive validity in identifying postoperative DVT/PE."
PSI 12: Venous thromboembolism and pulmonary embolism, Henderson et al.(12)	Chart review, 2004, US	54.5% of 112	"The VTE PSI performed well as a screening tool but generated a significant number of false-positive cases, a problem that could be substantially reduced with improved coding methods."
PSI 13: Postoperative sepsis, Cevasco et al.(13)	Chart review, 2005-07	53% of 112 41% of 164	"As it currently stands, the use of PSI 13 as a stand-alone measure for hospital reporting appears premature"
PSI 14: Postoperative wound dehiscence, Cevasco et al.(14)	Chart review, 2003-07, US	87% of 112	"This PSI is a promising measure for both quality improvement and performance measurement"
PSI 15: Accidental puncture or laceration	Chart review Year 2005-07	91% of 249	"Although PSI 15 is highly predictive of APL from a coding perspective, the

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
Utter et al.(15)	US		indicator is less predictive of APL that could be considered clinically important.”
PSI 18 and 19: Obstetric trauma 3rd or 4th degree of perineal laceration Romano et al.(16)	Chart review Year 1992-93 US	90% of 62	“Third- and fourth-degree perineal lacerations are accurately reported on hospital discharge abstracts.”
PSI 18 and 19: Obstetric trauma 3rd or 4th degree of perineal laceration, Brubaker et al.(17)	Chart review Year 2002-04 US	76.6% of 383	“Discharge coding errors are common after delivery-associated anal sphincter laceration, with omitted codes representing the largest source of errors.”
PSI 19: Postoperative hemorrhage or hematoma Borzecki et al.(18)	Chart review, 2003-07, US	75% of 112	"PHH's accuracy could be improved by coding enhancements, such as adopting present on admission codes or associating a timing factor with codes dealing with bleeding control. "
PSI 10: Postoperative physiologic and metabolic derangements PSI 11: Postoperative respiratory failure PSI 12: Postoperative pulmonary embolism or deep vein thrombosis PSI 13: Postoperative sepsis PSI 14: Postoperative wound dehiscence Romano et al.(19)	Chart data Year 2001 US	PSI 10: 63% of 62 PSI 11: 68% of 344 PSI 12: 22% of 241 PSI 13: 45% of 32 PSI 14: 72% of 274	“PSI sensitivities and PPVs were moderate. For three of the five PSIs, AHRQ has incorporated our alternative, higher sensitivity definitions into current PSI algorithms. Further validation should be considered before most of the PSIs evaluated herein are used to publicly compare or reward hospital performance.”
PSI 6: Iatrogenic pneumothorax PSI 12: Postoperative	Chart review Year 2003-07 US	PSI 6: 73% of 112 PSI 12: 45%	“Until coding revisions are implemented, these PSIs, especially pPE/DVT, should be used primarily

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
pulmonary embolus and deep vein thrombosis PSI 15: Accidental puncture and laceration Kaafarani et al.(20)		of 112 PSI 15: 85% of 112	for screening and case-finding. Their utility for public reporting and pay-for-performance needs to be reassessed."
PSI 3: Decubitus ulcer PSI 5: Foreign body left during procedure PSI 6: Iatrogenic pneumothorax PSI 7: Central venous catheter-related bloodstream infections PSI 8: Postoperative hip fracture PSI 9: Postoperative hemorrhage or hematoma PSI 10: Postoperative physiologic and metabolic derangements PSI 11: Postoperative respiratory failure PSI 12: Postoperative pulmonary embolism or deep vein thrombosis PSI 13: Postoperative sepsis PSI 14: Postoperative wound dehiscence PSI 15: accidental puncture or laceration Rosen et al.(21)	Chart review Year 2003-07 US	PSI 3: 30% of 112 PSI 5: 93% of 46 PSI 6: 73% of 112 PSI 7: 38% of 112 PSI 8: 28% of 46 PSI 9: 75% of 112 PSI 10: 63% of 119 PSI 11: 67% of 112 PSI 12: 43% of 112 PSI 13: 53% of 112 PSI 14: 87% of 112 PSI 15: 85% of 112	"Overall, PPVs were moderate for most of the PSIs. Implementing POA codes and using more specific ICD-9-CM codes would improve their validity. Our results suggest that additional coding improvements are needed before the PSIs evaluated herein are used for hospital reporting or pay for performance."
PSI 9: Postoperative hemorrhage or	National Surgical	Kappa: NSQIP vs.	"The main contributor was difference in definitions, with additional

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
hematoma PSI 11: Postoperative respiratory failure PSI 12: Postoperative pulmonary embolism or deep vein thrombosis PSI 13: Postoperative sepsis Koch et al.(22)	Quality Improvement program (NSQIP) Cardiovascular Information Registry (CVIR) Year 2009-10 US	AHRQ, 4583 PSI 9: 0.14 PSI 11: 0.30 PSI 12: 0.60 PSI 13: 0.07 CVIR vs. AHRQ, 7897 PSI 9: 0.08 PSI 11: 0.02 PSI 12: 0.55 PSI 13: 0.16	contribution from data collection and management methods. Although any of these sources can be used for their original intent of performance improvement, this study emphasizes the shortcomings of using these sources for grading performance without standardizing definitions, data collection, and management."

Appendix 2. ICD-10 diagnosis codes for AHRQ patient safety indicator (PSI)

Code	Description
Foreign body left in during procedure	
T815	Foreign body accidentally left in body cavity or operation wound following a procedure
T816	Acute reaction to foreign substance accidentally left during a procedure
Y610	Foreign object accidentally left in body during surgical and medical care: During surgical operation
Y611	Foreign object accidentally left in body during surgical and medical care: During infusion or transfusion
Y612	Foreign object accidentally left in body during surgical and medical care: During kidney dialysis or other perfusion
Y613	Foreign object accidentally left in body during surgical and medical care: During injection or immunization
Y614	Foreign object accidentally left in body during surgical and medical care: During endoscopic examination
Y615	Foreign object accidentally left in body during surgical and medical care: During heart catheterization
Y616	Foreign object accidentally left in body during surgical and medical care: During aspiration, puncture and other catheterization
Y617	Foreign object accidentally left in body during surgical and medical care: During removal of catheter or packing
Y618	Foreign object accidentally left in body during surgical and medical care: During other surgical and medical care
Y619	Foreign object accidentally left in body during surgical and medical care: During unspecified surgical and medical care
Infections due to medical care	
T80.2	Infections following infusion, transfusion and therapeutic injection
T82.7	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts
T88.0	Infection following immunization
Pulmonary embolism and deep vein thrombosis	
I26.0	Pulmonary embolism with mention of acute cor pulmonale
I26.9	Pulmonary embolism without mention of acute cor pulmonale
I80.1	Phlebitis and thrombophlebitis of femoral vein

Code	Description
I80.2	Phlebitis and thrombophlebitis of other deep vessels of lower extremities
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified
I80.8	Phlebitis and thrombophlebitis of other sites
I80.9	Phlebitis and thrombophlebitis of unspecified site
I82.8	Embolism and thrombosis of other specified veins
I82.9	Embolism and thrombosis of unspecified vein
Sepsis	
A400	Septicaemia due to streptococcus, group A
A401	Septicaemia due to streptococcus, group B
A402	Septicaemia due to streptococcus, group D
A403	Septicaemia due to Streptococcus pneumoniae
A408	Other streptococcal septicaemia
A409	Streptococcal septicaemia, unspecified
A410	Septicaemia due to Staphylococcus aureus
A411	Septicaemia due to other specified staphylococcus
A412	Septicaemia due to unspecified staphylococcus
A413	Septicaemia due to Haemophilus influenzae
A414	Septicaemia due to anaerobes
A415	Septicaemia due to other Gram-negative organisms
A418	Other specified septicaemia
A419	Septicaemia, unspecified
R578	Other shock
T811	Shock during or resulting from a procedure, not elsewhere classified
Accidental cut, puncture, perforation, or hemorrhage during medical care	

Code	Description
T812	Accidental puncture and laceration during a procedure, not elsewhere classified
Y600	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During surgical operation
Y601	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During infusion or transfusion
Y602	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During kidney dialysis or other perfusion
Y603	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During injection or immunization
Y604	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During endoscopic examination
Y605	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During heart catheterization
Y606	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During aspiration, puncture and other catheterization
Y607	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During administration of enema
Y608	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During other surgical and medical care
Y609	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During unspecified surgical and medical care

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Validity of AHRQ Patient Safety Indicators Derived from ICD-10 Hospital Discharge Abstract Data (Chart Review Study)

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Title: Validity of AHRQ Patient Safety Indicators Derived from ICD-10 Hospital Discharge Abstract Data (Chart Review Study)

Running header: Validating Patient Safety Indicators in ICD-10 Data

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ARTICLE SUMMARY

1) Article focus

- The Agency for Healthcare Research and Quality **(**AHRQ) patient safety indicators **(**PSIs) have been broadly used to assess the occurrence of adverse events and in-hospital complications using routinely collected administrative data.

- Estimates of PSIs could be caused by true quality of care differences or by differences in data quality.

- This study estimated 'true positives' of PSIs derived from Canadian ICD-10 hospital discharge abstract data with flag of presence on admission using chart review as a reference standard.

2) Key messages

- The validity of ICD-10 data varied by PSI.

- PSIs could be used to screen potential cases with adverse events using administration data. Confirming the presence of these events needs additional clinical information.

- If PSIs are used for comparison of jurisdiction performance, validity of data has to be adjusted for and considered in the analysis.

3) Strengths and Limitations

- To our knowledge, this is the first validation of ICD-10 data in recording AHR PSIs.

- We validated 5 out of 20 PSIs.

- Chart data were used as the reference standard; conditions not documented in chart were missing.

ABSTRACT

Objective: To assess if AHRQ PSIs could be used for case-findings in International Classification of Disease (ICD)-10 hospital discharge abstract data.

Design: We identified and randomly selected 490 patients with foreign body left during a procedure (PSI 5-foreign body), selected infections (IV site) due to medical care (PSI 7-infection), post-operative pulmonary embolism or deep vein thrombosis (PSI 12-PE/DVT), post-operative sepsis (PSI 13-sepsis), and accidental puncture or laceration (PSI 15-laceration) among patients discharged from three adult acute care hospitals in Calgary, Canada in 2007 and 2008. Their charts were reviewed for determining presence of PSIs and used as the reference standard, PPV statistics were calculated to determine the proportion of positives in the administrative data was 'true positives'.

Results: The PPV for PSI 5-foreign body was 62.5% (95% confidence interval: 35.4% - 84.8%), PSI 7-infection was 79.1% (67.4% - 88.1%), PSI 12-PE/DVT was 89.5% (66.9% - 98.7), PSI 13-sepsis was 12.5% (1.6% - 38.4%) and PSI 15-laceration was 86.4% (75.0% - 94.0%) after excluding those who presented to the hospital with the condition.

Conclusions: Several PSIs had high PPV in ICD administrative data and are thus powerful tools for true positive case-finding. The tools could be used to identify potential cases from large volume of admissions for verification through chart review. In contrast, their sensitivity has not been well-characterized and users of PSIs should be cautious if using these for 'quality of care reporting' presenting rate of PSIs because under-coded data would generate falsely low PSI rates.

Key words: ICD-10, patient safety, outcome, administrative data

INTRODUCTION

Patient safety is a critical component of health care quality. Assessments of patient safety are traditionally done through chart review, survey and voluntary reporting of adverse events and medical errors (1;2). These data collection methods focus on a specific type of event, collect data from non-random and biased populations, cover limited geographic areas, or are too labor-intensive for widespread use. Therefore, researchers have paid great attention to routinely collected hospital discharge abstract administrative data for population-based studies of adverse events(3). Therefore, the Agency for Healthcare Research and Quality (AHRQ) conducted pioneering work to develop patient safety indicators for use with the International Classification of Disease, 9th version, Clinical Modification (ICD-9-CM) administrative data, which cover large geographic areas and are readily available and relatively inexpensive to use.

AHRQ PSIs were developed through a literature search, review of ICD-9-CM manuals, consultation with physician panels, and empirical data analyses. Over 200 ICD-9-CM codes representing potential patient safety problems were identified and 48 indicators were labeled as the most promising PSIs by the AHRQ research team. Of these, 20 hospital-level and 7 area-level PSIs were recommended by one or more multi-specialty panels as a set of 'accepted' indicators(4). To facilitate utilization of PSIs, AHRQ developed and distributed (at no cost) SAS and SPSS software tools. The PSIs can be used to help hospitals identify potential adverse events that might need further study and also provide an opportunity to assess the occurrence of adverse events and in-hospital complications using routinely collected administrative data.

The AHRQ PSIs have been broadly used to assess the occurrence of adverse events and in-hospital complications by many international and national agencies, including Organization for Economic Cooperation and Development. Drosler et al.(5;6) analyzed hospital discharge abstract administrative data from multiple countries and found that PSI rates varied across countries. The variation in the PSI estimate could be caused by true quality of care differences or by differences in data quality.

Administrative data has possible limitations for identifying complications that represent medical error or may be at least in some way preventable. (4) First, administrative data are unlikely to capture all cases of a complication, regardless of the preventability, without false positives and false negatives. Second, when the ICD codes are accurate in defining an event, the clinical vagueness inherent in the description of the code itself may lead to a highly heterogeneous pool of clinical states represented by that code. Third, incomplete reporting may compromise the accuracy of any data source used for identifying patient safety problems, as medical providers might fear adverse consequences of “full disclosure” in potentially public records such as discharge abstracts. Fourth, the ability of these data to distinguish events in which no error occurred from true medical errors is uncertain.

Data quality is commonly evaluated using four statistical parameters. Sensitivity is a measure of the accuracy of recording presence of PSIs in administrative data when these are truly present according to reference data (i.e. gold standard). Specificity is to determine the accuracy of reporting absence of these PSIs in the administrative data when these PSIs are absent in the reference data. Positive predictive value (PPV) and negative predictive value (NPV) are to determine the extent to which PSIs present in the administrative data are also present in the reference data or the extent to which a condition absent in the administrative data are truly absent according to the reference data.

PSIs could be used for case-finding or/and quality of care reporting. When PSIs are used for case-finding and PPV is low, chart review or investigation is required to verify the true case status after identification of cases from the administrative data. When PSIs are used to generate 'quality of care report' presenting rates, all of these four statistical parameters of validity (i.e. sensitivity, specificity, NPV and PPV) should be high.

PSIs have been validated using chart data as 'gold standard' or 'reference' in the USA ICD-9-CM data only (see Appendix 1). Many countries have employed ICD-10 for coding hospital discharge abstract data(7). However, the validity of PSIs in ICD-10 data has not been studied. Therefore, we conducted this study to estimate PPV or 'true positives' of PSIs derived from Canadian ICD-10 hospital discharge abstract data with flag of presence on admission using chart review as a reference standard.

METHODS

Identify patients at risk for each of 5 PSIs from ICD-10 data

Of the AHRQ PSIs, we assessed PPV for 5 PSIs, which are likely to have high PPVs based on literature (see Appendix 1), including foreign body left during procedure (PSI 5 - foreign body), selected infections (IV site) due to medical care (PSI 7 - infection), postoperative pulmonary embolism or deep vein thrombosis (PSI 12 - PE/DVT), postoperative sepsis (PSI 13 - sepsis), and accidental puncture or laceration (PSI 15 - laceration).

Our study sample was patients discharged in the years 2007 and 2008 from all three adult acute care hospitals in Calgary, Canada, a city with a population of just over one million. Professionally trained health records coders in Calgary code up to 50 diagnosis codes and 20 procedures for each patient using ICD-10-CA/CCI (Canadian ICD-10 and Canadian

Classification of Intervention)(8). One coordinator supervises and manages the coding practice at the three sites to establish a consistent approach to coding.

We developed ICD-10 PSI algorithm(9) based on AHRQ ICD-9-CM PSI definition manual as the blueprint (see ICD-10 codes in Appendix 2). PSIs in the data were defined using the ICD-10 codes in the 49 secondary diagnosis coding fields. We included patients with those ICD-10 codes. Earliest admission date was assigned to patients as the index date for those with multiple admissions in the study period. Adverse events (e.g. pulmonary embolism) are likely coded in the index admission as adverse events. Sometimes adverse events are not coded in the index admission but could be coded as the most responsible diagnosis for a subsequent admission. We missed these cases because timing of adverse event was not recorded for the primary diagnosis. The indexed patients were stratified by the three hospitals and 50 patients were randomly selected per hospital for each PSI when there were more than 50 patients available. We aimed to review 40 patients at each hospital for each PSI, since at least 30 patients should be reviewed for calculating PPV(10). Because PSI 5, foreign body left in during procedure, occurs rarely, we expanded the observation period for this PSI to 2006-2009 to increase the number of patients. However, we did not reach the target sample size for PSI 5 and 7. An operating room procedure was defined using the code for inpatient procedure room type: '1' for main operating room, '8' for cardiac catheterization laboratory or '9' for ambulatory care operating room. Patients who underwent surgeries in the same day or emergency room were not included because our administrative data does not capture these services.

Review charts to determine presence and absence of PSIs

Corresponding patient charts for the sampled patients were located using a combination of the patient chart number and personal health number, which uniquely identifies each patient

and admission. Two chart reviewers underwent training and practice in the data extraction process using the PSI data collection tools developed by AHRQ(11). In the training session, the definition of study variables was discussed. Then the reviewers extracted data independently for evidence of PSIs through an examination of the entire chart, including the cover page, discharge summaries, pathology reports (including autopsy reports), trauma and resuscitation records, admission notes, consultation reports, surgery/operative reports, anesthesia reports, interdisciplinary progress notes, and physician daily progress notes. The reviewers followed the AHRQ definitions to determine the presence or absence of the five PSIs, and specified whether these events were present at the time of admission or arose during hospitalization. In the period of data collection, they discussed cases with uncertainty in determining conditions to ensure the consistency between them.

Statistical analysis

The ICD-10 administrative data and chart review data were linked and the linked data were analyzed using statistical software of SAS 9.2. Study populations were characterized using descriptive statistics. As mentioned above, we calculated PPV and its 95% confidence interval for each PSI recorded in ICD-10 hospital discharge data accepting the chart review data as a ‘reference standard’. PPV determines the extent to which a PSI present in the ICD-10 data was also present in the chart review data. Unit of analysis is patient because one discharge abstract record and chart was assigned to each patient. Ethics approval for this study was granted by the Conjoint Health Research Ethics Board at the University in the city in which the study took place Extra or additional information on data is available by emailing the lead author HQ.

RESULTS

A total of 490 patients were included from ICD-10 hospital discharge abstract data. There were 334 patients after excluding non-surgical patients for PSI 12 - EP/DVT and PSI 13 - sepsis (see Figure 1) and 163 patients after excluding those with PSIs present on admission. We reviewed all charts of 490 patients.

Among 334 patients, the mean age ranged from 57.9 to 67.2 years across the 5 PSIs (see Table 1). The proportion of male patients was lowest for PSI 13 - sepsis (36.6%) and highest for PSI 7 -infection (55.3%). Patients with PSI 7-infection, 12-PE/DVT, or 13-sepsis stayed in hospital 32.7, 41.3 and 43.9 days on average.

Some countries do not code whether the condition was present at admission or arose during the hospital stay. When conditions present on admission were included (see Table 2), the PPV was 35.6% for PSI 5-foreign body, 70.6% for PSI 7-infection, 79.0% for PSI 12-PE/DVT, 9.8% for PSI 13-sepsis and 90.8% for PSI 15-laceration. When conditions present on admission were excluded from the analysis, the PPV increased for PSI 5-forgein body (62.5%), 7-infection (79.1%), 12-PE/DVT (89.5%) and 13-sepsis (12.5%) but decreased for PSI 15-laceration (from 90.8% to 86.4%).

Considering some countries may not code procedures in administrative data, we evaluated the PPV among 123 PSI 12-PE/DVT patients and 117 PSI 13-sepsis patients ignoring surgical status. The PPV was 25.2% for PSI 12-PE/DVT, and 27.4% for PSI 13-sepsis. When present on admission was considered, the PPV increased to 27.0% for PSI 12-PE/DVT, and 47.1% for PSI 13-sepsis. The reasons for misclassification of PSI conditions in administrative data varied across PSIs (see Table 3). The most common reason was that the condition was present on admission.

DISCUSSSION

Like previous PSI validation studies in ICD-9-CM data, we focused on the PPV in ICD-10 administrative data as the foremost of interest. Our study revealed that PSI PPVs in most instances are sufficiently high to support widespread use for case findings. The low PPVs for some PSIs, such as sepsis do not support utility of the PSIs for quality of care reporting for comparisons across jurisdictions.

The validity of ICD-10 data varied by PSI. PSI 5-foreign body and 13-sepsis had low PPV but PSI 7-infection, 12-PE/DVT and 15-laceration had high PPV. The high PPV for PSI 12-PE/DVT (89.5%) is supported by one US study(12) (PPV=79%), but is higher than four other US studies (PPV=22-55%)(13-16). In contrast to our finding for PSI 13-sepsis (PPV=9.8%), Romano et al.(15) reported a higher PPV for PSI 13-spesis (45%). As our finding PPV for PSI 15-laceration (PPV=90.8%), Kaafarani et al.(16) and Utter(17) et al. reported high PPV for PSI 15-laceration (91% and 85%, respectively).

Because low prevalence PSIs with reasonable precision (i.e. 95% confidence intervals) requires reviewing many charts for calculating sensitivity, all previous studies except for the study conducted by Koch et al.(18) evaluated data quality using PPV. The PPV value depends on prevalence and varies greatly across PSIs and studies. For example, the PPV for PSI 12-PE/DVT ranged from 22% to 79% across studies conducted in USA(12-16). Koch et al.(18) compared agreement between ICD-9-CM data, National Surgical Quality Improvement Program (NSQIP) and Cardiovascular Information Registry (CVIR) in PSIs. The agreement was substantial for PSI 12-PE/DVT and poor for PSI 9-hemorrhage, PSI 11-respiratory failure and PSI 13-sepsis. Sensitivity was very low, for example 0.13% for PSI 9-hemorrhage, 1.35% for PSI 11-

respiratory failure, 1.6% for PSI 12-PE/DVT and 0.13% for PSI 13-sepsis when ICD-9-CM and NSQIP were compared.

Variation in validity across PSIs is determined by factors related to physicians (i.e., chart documentation), and coders (i.e., coding guidelines and coders' practice). Coders code medical events after discharge based on chart documentation. We used chart review as our reference standard; therefore, completeness of chart documentation could not be evaluated. Physicians might not document consequences of medical care in charts, leading to under-coding in hospital discharge abstracts. In addition, coders at hospitals are allotted a specific amount of time per chart on average, for example, 30 minutes in Alberta. Thus, they might focus on coding diagnoses and procedures that contribute significantly to length of stay such as PE/DVT, and ignore minor conditions such as infection or laboratory results that indicate sepsis, to follow Canada national coding guidelines. Our reviewers focused on determining the presence or absence of conditions based on all documented information in the chart, including diagnostic imaging and laboratory results. This is in contrast to general coding guidelines(8) that instruct coders to confine their coding to clinical problems, conditions, or circumstances that are identified in the record by the treating physicians as the clinically significant reason for the patient's admission, or that require or influence evaluation, treatment, management, or care. Coders do not typically code problems that do not meet these requirements, whereas the reviewers who conducted our 'reference standard' chart review included them regardless of the significance of the condition on resource use during hospitalization. Coders are instructed that when a condition is suggested by diagnostic test results, they should only code the condition if it has been confirmed by physician documentation. Our previous studies demonstrated that hospital discharge abstract data quality is not related to coders' employment status (full-time/part time and length of employment) but related to physician documentation quality(19;20).

Excluding conditions present on admission improves PSI validity. For example, the PPV for PSI 12-PE/DVT increased from 79.0% to 89.5% from including to excluding the presence of the condition on admission. Canada has a long history of flagging timing of condition occurrence. Some US and Australian states currently have similar data elements in their discharge abstract data, and the US has recently begun coding the timing of conditions nation-wide. Timing of condition occurrence is not aimed at judging causal relationships between medical care and complications, just flagging whether the condition occurred or was diagnosed during the hospitalization. To capture complications, Japan has specified fields for coding complications in its hospital discharge data, in addition to diagnoses and procedures.

Could AHRQ PSIs derived from hospital discharge abstract data be utilized for comparing quality of care across countries and/or jurisdictions, or for monitoring system performance in an institution? Because data quality contributes to the magnitude of PSIs, data validity has to be similar across comparison groups (such as countries, regions or jurisdictions) and over time. Thus, PSIs should not be compared across jurisdictions without validation because adjustment for data validity is necessary. Our findings suggest that PSIs could be used to screen potential cases with adverse events using administration data. Confirming the presence of these events needs additional clinical information such as chart reviews. If PSIs are used for comparison, validity of data has to be adjusted and considered for in the analysis.

While PSIs are used for monitoring quality of care improvement over time, the assumption of temporal consistency of data validity has to be met. Unfortunately, we did not evaluate PSI validity over time. Quan et al.(21) evaluated the impact of ICD-10 implementation on data quality through chart review of 32 conditions. Canadian ICD-10 data had significantly higher sensitivity for one condition and lower sensitivity for seven conditions relative to ICD-9-CM data. The two databases had similar sensitivity values for the remaining 24 conditions. Walker(22) et al. compared coding practice between ICD-9-CM and ICD-10 and reported that the number of diagnoses coded decreased in four Canadian provinces and remained similar in other five provinces after implementation of ICD-10. Januel JM(23) et al. reported that of 36 conditions assessed in Switzerland, Kappa values for ICD-10 and chart data increased for 29 conditions and decreased for seven conditions compared with ICD-9-CM and chart data.

Our study has limitations. First, of 20 AHRQ PSIs, we intentionally evaluated five conditions that might have a high validity. Remaining PSIs should be evaluated in future studies. Second, we used chart data as the reference standard; conditions not documented in chart were missing. Prospective data collection through clinical examination on these events should be conducted to establish near gold standard. Third, this study was conducted in one urban area; the validity of PSIs might vary by institutions or regions. Fourth, we evaluated the validity using PPV alone. Sensitivity, specificity and NPV should be assessed for all of the PSIs. The ascertainment of the sensitivity requires a large sample size and involves expensive and time consuming resources due to low prevalence rate of PSIs. Fifth, the sample sizes for certain PSIs are small and 95% confidence interval is relatively wide.

In conclusion, our study supports that PSIs could be used for case-findings in the ICD-10 hospital discharge abstract data. Even PSIs with low PPVs could be used to identify potential cases from large volume of admissions for verification through chart review. In contrast, their sensitivity has not been well-characterized because of the inherent challenges of reviewing huge numbers of charts for properly testing sensitivity. Therefore, users of PSIs should be cautious if

using these for 'quality of care reporting' presenting rate of PSIs because under-coded data would generate falsely low PSI rates.

Table 1. Characteristics of patients by AHRQ patient safety indictor (PSI)

	PSI 5 Foreign body left during procedure N= 45	PSI 7 Selected infections due to medical care N=85	PSI12 Postoperative pulmonary embolism or deep vein thrombosis N=43 surgery patients	PSI13 Postoperative sepsis N=41 surgery patients	PSI15 Accidental puncture or laceration N=120
Age Mean (Range)	58.0 (21.6 – 93.5)	61.7 (18.5 – 90.0)	67.2 (31.0 – 94.0)	63.9 (19.9 – 83.5)	57.9 (19.3 – 96.5)
Sex (male)	24 (53.3%)	47 (55.3%)	23 (53.5%)	15 (36.6%)	44 (36.7%)
Length of stay	14.7 (1 – 195)	32.7 (2 – 184.0)	41.3 (2 - 274)	43.9 (1 – 238)	16.2 (1. – 181)

Table 2. Positive predictive value and 95% confidence interval (95% CI) for AHRQ patient safety indicators (PSI) recorded in ICD-10 hospital discharge abstract administrative data comparing chart data

Patient Safety Indicator	Including PSIs present on admission % (n/N, 95% CI)	Excluding PSIs present on admission % (n/N, 95% CI)
PSI 5 Foreign body left during procedure	35.6% (16/45) (21.9% - 51.2%)	62.5% (10/16) (35.4% - 84.8%)
PSI 7 Selected infections due to medical care	70.6% (60/85) (59.7% - 80.0%)	79.1% (53/67) (67.4% - 88.1%)
PSI12 Postoperative pulmonary embolism or deep vein thrombosis among surgery patients	79.0% (34/43) (64.0% - 90.0%)	89.5% (17/19) (66.9% - 98.7)
PSI13 Postoperative sepsis among surgery patients	9.8% (4/41) (2.7% - 23.1%)	12.5% (2/16) (1.6% - 38.4%)
PSI15 Accidental puncture or laceration	90.8% (109/120) (84.2% - 95.3%)	86.4% (51/59) (75.0% - 94.0%)
When surgical status was ignored		
PSI12Pulmonary embolism or deep vein thrombosis among surgery and non-surgery patients	25.2% (31/123) (17.8% - 33.8%)	27.0% (10/37) (13.8% - 44.1%)
PSI13 Postoperative sepsis among surgery or non-surgery patients	27.4% (32/117) (19.5% - 36.4%)	47.1% (16/34) (29.8% - 64.9%)

Table 3. Reasons for false positives of AHRQ patient safety indicators (PSI) in ICD-10 hospital discharge abstract administrative data when the indicator of presence on admission was ignored.

PSI 5 Foreign body left during procedure N=29	PSI 7 Selected infections due to medical care N=25	PSI 12 Postoperative pulmonary embolism or deep vein thrombosis N=9	PSI 13 Post operative sepsis N=37	PSI 15 Accidental puncture or laceration N=11
18- present on admission	7- present on admission	6- present on admission	15- present on admission	4 – present on admission
8– no foreign body	11 – unrelated to medical care	2 – had DVT/PE in past	12 – urgent surgeries, having sepsis	7 –no accidental puncture or laceration
2 – for treatment purposes (e.g. packing, stitch)	5 – IV site bruised or injured, no infection	1 – no DVT/PE	6 – urgent surgeries, no sepsis	
1 – patient pulled and broke catheter	2 – conflicting documentation		2 – no sepsis	
			2 – no surgery, sepsis	

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COMPETING INTERESTS

None to declare.

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CONTRIBUTOR STATEMENT

Hude Quan: Conception and design, acquisition of data, analysis, interpretation of data, and final approval of the version to be published.

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Data Sharing: Hude Quan will provide aggregated statistical data, not individual and raw data.

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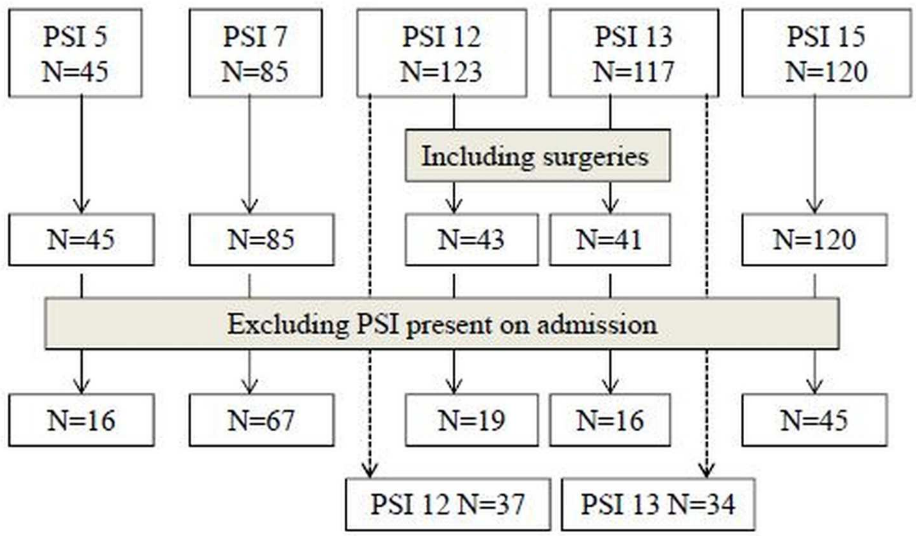

Figure 1: Sample Size by Patient Safety Indicator (PSI)

117x90mm (300 x 300 DPI)

Appendix 1. Validation studies of Agency for Healthcare Research and Quality **(**AHRQ**)** patient safety indicator (PSI)

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
PSI 3: Decubitus ulcer Polancich et al.(1)	Chart review Year 2005 US	27.1% of 118	"Administrative data, when used alone, are not sufficient in measuring the true rate of hospital-acquired decubitus ulcers."
PSI 4: Failure to rescue Hortitz et al.(2)	Chart review, 2004, US	50.7% of 2354	"This indicator may be useful internally to flag possible cases of quality failure but has limitations for external institutional comparisons."
PSI 5: Foreign body left during procedure, Chen et al.(3)	Chart review, 2003-07, US	45% of 93	"The reported rate of foreign body events as detected by PSI 5 is low in the VA, but occurs in both surgical and medical procedures."
PSI 6: Iatrogenic Pneumothorax Sadeghi et al.(4)	Chart review Year 2006-07 US	78% of 200	"AHRQ's iatrogenic pneumothorax indicator can serve in quality of care improvement."
PSI 7: Infection due to medical care, Zrelak et al. (5)	Chart review, 2005-07, US	54% of 191	"PSI 7 has a low positive predictive value compared with other PSIs recently studied. Present on admission diagnoses and improved coding for infections related to central venous catheters (implemented October 2007) may improve validity."
PSI 7: Central venous catheter-related bloodstream infections, Cevasco et al.(6)	Chart review, 2003-07, US	45% of 112	"As it currently stands, PSI 7 should not be used as a pay-for-performance measure, but should be limited to use in internal quality improvement efforts."
PSI 10: Postoperative physiologic and metabolic derangement Borsecki et al. (7)	Chart review, 2002-07 US	63% of 119	"Due to its low PPV, we recommend removing diabetes complications from the indicator and focusing on AKI."

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
PSI 11: Respiratory failure Utter et al.(8)	Chart review, 2007 US	83% of 609	"A hospitalization flagged by PSI 11 is reasonably likely to represent a true postoperative pulmonary complication."
PSI 11: Respiratory failure Borzecki et al.(9)	Chart review Year 2003-07 US	67% of 112	"PRF should continue to be used as a screen for potential patient-safety events. Its PPV could be substantially improved in the Veterans Health Administration through introduction of an admission status code."
PSI 12: Postoperative venous Thromboembolism and pulmonary embolism, White et al.(10)	Chart review, 2005-07, US	79% of 573 44% of 452, for lower extremity	"Current PSI 12 criteria do not accurately identify patients with acute postoperative lower extremity DVT or PE."
PSI 12: Venous thromboembolism and pulmonary embolism, Zhan et al.(11)	Chart review, 2002-04, US	29% of 327	"ICD-9-CM codes in Medicare claims are sensitive but have limited predictive validity in identifying postoperative DVT/PE."
PSI 12: Venous thromboembolism and pulmonary embolism, Henderson et al.(12)	Chart review, 2004, US	54.5% of 112	"The VTE PSI performed well as a screening tool but generated a significant number of false-positive cases, a problem that could be substantially reduced with improved coding methods."
PSI 13: Postoperative sepsis, Cevasco et al.(13)	Chart review, 2005-07	53% of 112 41% of 164	"As it currently stands, the use of PSI 13 as a stand-alone measure for hospital reporting appears premature"
PSI 14: Postoperative wound dehiscence, Cevasco et al.(14)	Chart review, 2003-07, US	87% of 112	"This PSI is a promising measure for both quality improvement and performance measurement"
PSI 15: Accidental puncture or laceration	Chart review Year 2005-07	91% of 249	"Although PSI 15 is highly predictive of APL from a coding perspective, the

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
Utter et al.(15)	US		indicator is less predictive of APL that could be considered clinically important."
PSI 18 and 19: Obstetric trauma 3rd or 4th degree of perineal laceration Romano et al.(16)	Chart review Year 1992-93 US	90% of 62	"Third- and fourth-degree perineal lacerations are accurately reported on hospital discharge abstracts."
PSI 18 and 19: Obstetric trauma 3rd or 4th degree of perineal laceration, Brubaker et al.(17)	Chart review Year 2002-04 US	76.6% of 383	"Discharge coding errors are common after delivery-associated anal sphincter laceration, with omitted codes representing the largest source of errors."
PSI 19: Postoperative hemorrhage or hematoma Borzecki et al.(18)	Chart review, 2003-07, US	75% of 112	"PHH's accuracy could be improved by coding enhancements, such as adopting present on admission codes or associating a timing factor with codes dealing with bleeding control. "
PSI 10: Postoperative physiologic and metabolic derangements PSI 11: Postoperative respiratory failure PSI 12: Postoperative pulmonary embolism or deep vein thrombosis PSI 13: Postoperative sepsis PSI 14: Postoperative wound dehiscence Romano et al.(19)	Chart data Year 2001 US	PSI 10: 63% of 62 PSI 11: 68% of 344 PSI 12: 22% of 241 PSI 13: 45% of 32 PSI 14: 72% of 274	"PSI sensitivities and PPVs were moderate. For three of the five PSIs, AHRQ has incorporated our alternative, higher sensitivity definitions into current PSI algorithms. Further validation should be considered before most of the PSIs evaluated herein are used to publicly compare or reward hospital performance."
PSI 6: Iatrogenic pneumothorax PSI 12: Postoperative	Chart review Year 2003-07 US	PSI 6: 73% of 112 PSI 12: 45%	"Until coding revisions are implemented, these PSIs, especially pPE/DVT, should be used primarily

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
pulmonary embolus and deep vein thrombosis PSI 15: Accidental puncture and laceration Kaafarani et al.(20)		of 112 PSI 15: 85% of 112	for screening and case-finding. Their utility for public reporting and pay-for-performance needs to be reassessed.”
PSI 3: Decubitus ulcer PSI 5: Foreign body left during procedure PSI 6: Iatrogenic pneumothorax PSI 7: Central venous catheter-related bloodstream infections PSI 8: Postoperative hip fracture PSI 9: Postoperative hemorrhage or hematoma PSI 10: Postoperative physiologic and metabolic derangements PSI 11: Postoperative respiratory failure PSI 12: Postoperative pulmonary embolism or deep vein thrombosis PSI 13: Postoperative sepsis PSI 14: Postoperative wound dehiscence PSI 15: accidental puncture or laceration Rosen et al.(21)	Chart review Year 2003-07 US	PSI 3: 30% of 112 PSI 5: 93% of 46 PSI 6: 73% of 112 PSI 7: 38% of 112 PSI 8: 28% of 46 PSI 9: 75% of 112 PSI 10: 63% of 119 PSI 11: 67% of 112 PSI 12: 43% of 112 PSI 13: 53% of 112 PSI 14: 87% of 112 PSI 15: 85% of 112	"Overall, PPVs were moderate for most of the PSIs. Implementing POA codes and using more specific ICD-9-CM codes would improve their validity. Our results suggest that additional coding improvements are needed before the PSIs evaluated herein are used for hospital reporting or pay for performance."
PSI 9: Postoperative hemorrhage or	National Surgical	Kappa: NSQIP vs.	"The main contributor was difference in definitions, with additional

Validated PSI and author	Reference standard, Year of data Country	PPV (% of N)	Conclusion made by authors
hematoma PSI 11: Postoperative respiratory failure PSI 12: Postoperative pulmonary embolism or deep vein thrombosis PSI 13: Postoperative sepsis Koch et al.(22)	Quality Improvement program (NSQIP) Cardiovascular Information Registry (CVIR) Year 2009-10 US	AHRQ, 4583 PSI 9: 0.14 PSI 11: 0.30 PSI 12: 0.60 PSI 13: 0.07 CVIR vs. AHRQ, 7897 PSI 9: 0.08 PSI 11: 0.02 PSI 12: 0.55 PSI 13: 0.16	contribution from data collection and management methods. Although any of these sources can be used for their original intent of performance improvement, this study emphasizes the shortcomings of using these sources for grading performance without standardizing definitions, data collection, and management."

Appendix 2. ICD-10 diagnosis codes for AHRQ patient safety indicator (PSI)

Code	Description
Foreign body left in during procedure	
T815	Foreign body accidentally left in body cavity or operation wound following a procedure
T816	Acute reaction to foreign substance accidentally left during a procedure
Y610	Foreign object accidentally left in body during surgical and medical care: During surgical operation
Y611	Foreign object accidentally left in body during surgical and medical care: During infusion or transfusion
Y612	Foreign object accidentally left in body during surgical and medical care: During kidney dialysis or other perfusion
Y613	Foreign object accidentally left in body during surgical and medical care: During injection or immunization
Y614	Foreign object accidentally left in body during surgical and medical care: During endoscopic examination
Y615	Foreign object accidentally left in body during surgical and medical care: During heart catheterization
Y616	Foreign object accidentally left in body during surgical and medical care: During aspiration, puncture and other catheterization
Y617	Foreign object accidentally left in body during surgical and medical care: During removal of catheter or packing
Y618	Foreign object accidentally left in body during surgical and medical care: During other surgical and medical care
Y619	Foreign object accidentally left in body during surgical and medical care: During unspecified surgical and medical care
Infections due to medical care	
T80.2	Infections following infusion, transfusion and therapeutic injection
T82.7	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts
T88.0	Infection following immunization
Pulmonary embolism and deep vein thrombosis	
I26.0	Pulmonary embolism with mention of acute cor pulmonale
I26.9	Pulmonary embolism without mention of acute cor pulmonale
I80.1	Phlebitis and thrombophlebitis of femoral vein

Code	Description
I80.2	Phlebitis and thrombophlebitis of other deep vessels of lower extremities
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified
I80.8	Phlebitis and thrombophlebitis of other sites
I80.9	Phlebitis and thrombophlebitis of unspecified site
I82.8	Embolism and thrombosis of other specified veins
I82.9	Embolism and thrombosis of unspecified vein
Sepsis	
A400	Septicaemia due to streptococcus, group A
A401	Septicaemia due to streptococcus, group B
A402	Septicaemia due to streptococcus, group D
A403	Septicaemia due to Streptococcus pneumoniae
A408	Other streptococcal septicaemia
A409	Streptococcal septicaemia, unspecified
A410	Septicaemia due to Staphylococcus aureus
A411	Septicaemia due to other specified staphylococcus
A412	Septicaemia due to unspecified staphylococcus
A413	Septicaemia due to Haemophilus influenzae
A414	Septicaemia due to anaerobes
A415	Septicaemia due to other Gram-negative organisms
A418	Other specified septicaemia
A419	Septicaemia, unspecified
R578	Other shock
T811	Shock during or resulting from a procedure, not elsewhere classified
Accidental cut, puncture, perforation, or hemorrhage during medical care	

Code	Description
T812	Accidental puncture and laceration during a procedure, not elsewhere classified
Y600	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During surgical operation
Y601	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During infusion or transfusion
Y602	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During kidney dialysis or other perfusion
Y603	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During injection or immunization
Y604	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During endoscopic examination
Y605	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During heart catheterization
Y606	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During aspiration, puncture and other catheterization
Y607	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During administration of enema
Y608	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During other surgical and medical care
Y609	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care: During unspecified surgical and medical care

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Title: Validity of AHRQ Patient Safety Indicators Derived from ICD-10 Hospital Discharge Abstract Data (Chart Review Study)

Running header: Validating Patient Safety Indicators in ICD-10 Data

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ABSTRACT

Objective: To assess if AHRQ PSIs could be used for case-findings in International Classification of Disease (ICD)-10 hospital discharge abstract data.

Design: We identified and randomly selected 490 patients with foreign body left during a procedure (PSI 5-foreign body), selected infections (IV site) due to medical care (PSI 7-infection), post-operative pulmonary embolism or deep vein thrombosis (PSI 12-PE/DVT), post-operative sepsis (PSI 13-sepsis), and accidental puncture or laceration (PSI 15-laceration) among patients discharged from three adult acute care hospitals in Calgary, Canada in 2007 and 2008. Their charts were reviewed for determining presence of PSIs and used as the reference standard, PPV statistics were calculated to determine the proportion of positives in the administrative data was 'true positives'.

Results: The PPV for PSI 5-foreign body was 62.5% (95% confidence interval: 35.4% - 84.8%), PSI 7-infection was 79.1% (67.4% - 88.1%), PSI 12-PE/DVT was 89.5% (66.9% - 98.7), PSI 13-sepsis was 12.5% (1.6% - 38.4%) and PSI 15-laceration was 86.4% (75.0% - 94.0%) after excluding those who presented to the hospital with the condition.

Conclusions: Several PSIs had high PPV in ICD administrative data and are thus powerful tools for true positive case-finding. The tools could be used to identify potential cases from large volume of admissions for verification through chart review. In contrast, their sensitivity has not been well-characterized and users of PSIs should be cautious if using these for 'quality of care reporting' presenting rate of PSIs because under-coded data would generate falsely low PSI rates.

Key words: ICD-10, patient safety, outcome, administrative data

INTRODUCTION

Patient safety is a critical component of health care quality. Assessments of patient safety are traditionally done through chart review, survey and voluntary reporting of adverse events and medical errors (1;2). These data collection methods focus on a specific type of event, collect data from non-random and biased populations, cover limited geographic areas, or are too labor-intensive for widespread use. Therefore, researchers have paid great attention to routinely collected hospital discharge abstract administrative data for population-based studies of adverse events(3). Therefore, the Agency for Healthcare Research and Quality (AHRQ) conducted pioneering work to develop patient safety indicators for use with the International Classification of Disease, 9th version, Clinical Modification (ICD-9-CM) administrative data, which cover large geographic areas and are readily available and relatively inexpensive to use.

AHRQ PSIs were developed through a literature search, review of ICD-9-CM manuals, consultation with physician panels, and empirical data analyses. Over 200 ICD-9-CM codes representing potential patient safety problems were identified and 48 indicators were labeled as the most promising PSIs by the AHRQ research team. Of these, 20 hospital-level and 7 area-level PSIs were recommended by one or more multi-specialty panels as a set of 'accepted' indicators(4). To facilitate utilization of PSIs, AHRQ developed and distributed (at no cost) SAS and SPSS software tools. The PSIs can be used to help hospitals identify potential adverse events that might need further study and also provide an opportunity to assess the occurrence of adverse events and in-hospital complications using routinely collected administrative data.

The AHRQ PSIs have been broadly used to assess the occurrence of adverse events and in-hospital complications by many international and national agencies, including Organization for Economic Cooperation and Development. Drosler et al.(5;6) analyzed hospital discharge abstract administrative data from multiple countries and found that PSI rates varied across countries. The variation in the PSI estimate could be caused by true quality of care differences or by differences in data quality.

Administrative data has possible limitations for identifying complications that represent medical error or may be at least in some way preventable. (4) First, administrative data are unlikely to capture all cases of a complication, regardless of the preventability, without false positives and false negatives. Second, when the ICD codes are accurate in defining an event, the clinical vagueness inherent in the description of the code itself may lead to a highly heterogeneous pool of clinical states represented by that code. Third, incomplete reporting may compromise the accuracy of any data source used for identifying patient safety problems, as medical providers might fear adverse consequences of “full disclosure” in potentially public records such as discharge abstracts. Fourth, the ability of these data to distinguish events in which no error occurred from true medical errors is uncertain.

Data quality is commonly evaluated using four statistical parameters. Sensitivity is a measure of the accuracy of recording presence of PSIs in administrative data when these are truly present according to reference data (i.e. gold standard). Specificity is to determine the accuracy of reporting absence of these PSIs in the administrative data when these PSIs are absent in the reference data. Positive predictive value (PPV) and negative predictive value (NPV) are to determine the extent to which PSIs present in the administrative data are also present in the reference data or the extent to which a condition absent in the administrative data are truly absent according to the reference data.

PSIs could be used for case-finding or/and quality of care reporting. When PSIs are used for case-finding and PPV is low, chart review or investigation is required to verify the true case status after identification of cases from the administrative data. When PSIs are used to generate 'quality of care report' presenting rates, all of these four statistical parameters of validity (i.e. sensitivity, specificity, NPV and PPV) should be high.

PSIs have been validated using chart data as 'gold standard' or 'reference' in the USA ICD-9-CM data only (see Appendix 1). Many countries have employed ICD-10 for coding hospital discharge abstract data(7). However, the validity of PSIs in ICD-10 data has not been studied. Therefore, we conducted this study to estimate PPV or 'true positives' of PSIs derived from Canadian ICD-10 hospital discharge abstract data with flag of presence on admission using chart review as a reference standard.

METHODS

Identify patients at risk for each of 5 PSIs from ICD-10 data

Of the AHRQ PSIs, we assessed PPV for 5 PSIs, which are likely to have high PPVs based on literature (see Appendix 1), including foreign body left during procedure (PSI 5 - foreign body), selected infections (IV site) due to medical care (PSI 7 - infection), postoperative pulmonary embolism or deep vein thrombosis (PSI 12 - PE/DVT), postoperative sepsis (PSI 13 - sepsis), and accidental puncture or laceration (PSI 15 - laceration).

Our study sample was patients discharged in the years 2007 and 2008 from all three adult acute care hospitals in Calgary, Canada, a city with a population of just over one million. Professionally trained health records coders in Calgary code up to 50 diagnosis codes and 20 procedures for each patient using ICD-10-CA/CCI (Canadian ICD-10 and Canadian

Classification of Intervention)(8). One coordinator supervises and manages the coding practice at the three sites to establish a consistent approach to coding.

We developed ICD-10 PSI algorithm(9) based on AHRQ ICD-9-CM PSI definition manual as the blueprint (see ICD-10 codes in Appendix 2). PSIs in the data were defined using the ICD-10 codes in the 49 secondary diagnosis coding fields. We included patients with those ICD-10 codes. Earliest admission date was assigned to patients as the index date for those with multiple admissions in the study period. Adverse events (e.g. pulmonary embolism) are likely coded in the index admission as adverse events. Sometimes adverse events are not coded in the index admission but could be coded as the most responsible diagnosis for a subsequent admission. We missed these cases because timing of adverse event was not recorded for the primary diagnosis. The indexed patients were stratified by the three hospitals and 50 patients were randomly selected per hospital for each PSI when there were more than 50 patients available. We aimed to review 40 patients at each hospital for each PSI, since at least 30 patients should be reviewed for calculating PPV(10). Because PSI 5, foreign body left in during procedure, occurs rarely, we expanded the observation period for this PSI to 2006-2009 to increase the number of patients. However, we did not reach the target sample size for PSI 5 and 7. An operating room procedure was defined using the code for inpatient procedure room type: '1' for main operating room, '8' for cardiac catheterization laboratory or '9' for ambulatory care operating room. Patients who underwent surgeries in the same day or emergency room were not included because our administrative data does not capture these services.

Review charts to determine presence and absence of PSIs

Corresponding patient charts for the sampled patients were located using a combination of the patient chart number and personal health number, which uniquely identifies each patient

and admission. Two chart reviewers underwent training and practice in the data extraction process using the PSI data collection tools developed by AHRQ(11). In the training session, the definition of study variables was discussed. Then the reviewers extracted data independently for evidence of PSIs through an examination of the entire chart, including the cover page, discharge summaries, pathology reports (including autopsy reports), trauma and resuscitation records, admission notes, consultation reports, surgery/operative reports, anesthesia reports, interdisciplinary progress notes, and physician daily progress notes. The reviewers followed the AHRQ definitions to determine the presence or absence of the five PSIs, and specified whether these events were present at the time of admission or arose during hospitalization. In the period of data collection, they discussed cases with uncertainty in determining conditions to ensure the consistency between them.

Statistical analysis

The ICD-10 administrative data and chart review data were linked and the linked data were analyzed using statistical software of SAS 9.2. Study populations were characterized using descriptive statistics. As mentioned above, we calculated PPV and its 95% confidence interval for each PSI recorded in ICD-10 hospital discharge data accepting the chart review data as a 'reference standard'. PPV determines the extent to which a PSI present in the ICD-10 data was also present in the chart review data. Unit of analysis is patient because one discharge abstract record and chart was assigned to each patient. Ethics approval for this study was granted by the Conjoint Health Research Ethics Board at the University in the city in which the study took place Extra or additional information on data is available by emailing the lead author HQ.

RESULTS

A total of 490 patients were included from ICD-10 hospital discharge abstract data. There were 334 patients after excluding non-surgical patients for PSI 12 - EP/DVT and PSI 13 - sepsis (see Figure 1) and 163 patients after excluding those with PSIs present on admission. We reviewed all charts of 490 patients.

Among 334 patients, the mean age ranged from 57.9 to 67.2 years across the 5 PSIs (see Table 1). The proportion of male patients was lowest for PSI 13 - sepsis (36.6%) and highest for PSI 7 -infection (55.3%). Patients with PSI 7-infection, 12-PE/DVT, or 13-sepsis stayed in hospital 32.7, 41.3 and 43.9 days on average.

Some countries do not code whether the condition was present at admission or arose during the hospital stay. When conditions present on admission were included (see Table 2), the PPV was 35.6% for PSI 5-foreign body, 70.6% for PSI 7-infection, 79.0% for PSI 12-PE/DVT, 9.8% for PSI 13-sepsis and 90.8% for PSI 15-laceration. When conditions present on admission were excluded from the analysis, the PPV increased for PSI 5-forgein body (62.5%), 7-infection (79.1%), 12-PE/DVT (89.5%) and 13-sepsis (12.5%) but decreased for PSI 15-laceration (from 90.8% to 86.4%).

Considering some countries may not code procedures in administrative data, we evaluated the PPV among 123 PSI 12-PE/DVT patients and 117 PSI 13-sepsis patients ignoring surgical status. The PPV was 25.2% for PSI 12-PE/DVT, and 27.4% for PSI 13-sepsis. When present on admission was considered, the PPV increased to 27.0% for PSI 12-PE/DVT, and 47.1% for PSI 13-sepsis. The reasons for misclassification of PSI conditions in administrative data varied across PSIs (see Table 3). The most common reason was that the condition was present on admission.

DISCUSSSION

Like previous PSI validation studies in ICD-9-CM data, we focused on the PPV in ICD-10 administrative data as the foremost of interest. Our study revealed that PSI PPVs in most instances are sufficiently high to support widespread use for case findings. The low PPVs for some PSIs, such as sepsis do not support utility of the PSIs for quality of care reporting for comparisons across jurisdictions.

The validity of ICD-10 data varied by PSI. PSI 5-foreign body and 13-sepsis had low PPV but PSI 7-infection, 12-PE/DVT and 15-laceration had high PPV. The high PPV for PSI 12-PE/DVT (89.5%) is supported by one US study(12) (PPV=79%), but is higher than four other US studies (PPV=22-55%)(13-16). In contrast to our finding for PSI 13-sepsis (PPV=9.8%), Romano et al.(15) reported a higher PPV for PSI 13-spesis (45%). As our finding PPV for PSI 15-laceration (PPV=90.8%), Kaafarani et al.(16) and Utter(17) et al. reported high PPV for PSI 15-laceration (91% and 85%, respectively).

Because low prevalence PSIs with reasonable precision (i.e. 95% confidence intervals) requires reviewing many charts for calculating sensitivity, all previous studies except for the study conducted by Koch et al.(18) evaluated data quality using PPV. The PPV value depends on prevalence and varies greatly across PSIs and studies. For example, the PPV for PSI 12-PE/DVT ranged from 22% to 79% across studies conducted in USA(12-16). Koch et al.(18) compared agreement between ICD-9-CM data, National Surgical Quality Improvement Program (NSQIP) and Cardiovascular Information Registry (CVIR) in PSIs. The agreement was substantial for PSI 12-PE/DVT and poor for PSI 9-hemorrhage, PSI 11-respiratory failure and PSI 13-sepsis. Sensitivity was very low, for example 0.13% for PSI 9-hemorrhage, 1.35% for PSI 11-

respiratory failure, 1.6% for PSI 12-PE/DVT and 0.13% for PSI 13-sepsis when ICD-9-CM and NSQIP were compared.

Variation in validity across PSIs is determined by factors related to physicians (i.e., chart documentation), and coders (i.e., coding guidelines and coders' practice). Coders code medical events after discharge based on chart documentation. We used chart review as our reference standard; therefore, completeness of chart documentation could not be evaluated. Physicians might not document consequences of medical care in charts, leading to under-coding in hospital discharge abstracts. In addition, coders at hospitals are allotted a specific amount of time per chart on average, for example, 30 minutes in Alberta. Thus, they might focus on coding diagnoses and procedures that contribute significantly to length of stay such as PE/DVT, and ignore minor conditions such as infection or laboratory results that indicate sepsis, to follow Canada national coding guidelines. Our reviewers focused on determining the presence or absence of conditions based on all documented information in the chart, including diagnostic imaging and laboratory results. This is in contrast to general coding guidelines(8) that instruct coders to confine their coding to clinical problems, conditions, or circumstances that are identified in the record by the treating physicians as the clinically significant reason for the patient's admission, or that require or influence evaluation, treatment, management, or care. Coders do not typically code problems that do not meet these requirements, whereas the reviewers who conducted our 'reference standard' chart review included them regardless of the significance of the condition on resource use during hospitalization. Coders are instructed that when a condition is suggested by diagnostic test results, they should only code the condition if it has been confirmed by physician documentation. Our previous studies demonstrated that hospital discharge abstract data quality is not related to coders' employment status (full-time/part time and length of employment) but related to physician documentation quality(19;20).

Excluding conditions present on admission improves PSI validity. For example, the PPV for PSI 12-PE/DVT increased from 79.0% to 89.5% from including to excluding the presence of the condition on admission. Canada has a long history of flagging timing of condition occurrence. Some US and Australian states currently have similar data elements in their discharge abstract data, and the US has recently begun coding the timing of conditions nation-wide. Timing of condition occurrence is not aimed at judging causal relationships between medical care and complications, just flagging whether the condition occurred or was diagnosed during the hospitalization. To capture complications, Japan has specified fields for coding complications in its hospital discharge data, in addition to diagnoses and procedures.

Could AHRQ PSIs derived from hospital discharge abstract data be utilized for comparing quality of care across countries and/or jurisdictions, or for monitoring system performance in an institution? Because data quality contributes to the magnitude of PSIs, data validity has to be similar across comparison groups (such as countries, regions or jurisdictions) and over time. Thus, PSIs should not be compared across jurisdictions without validation because adjustment for data validity is necessary. Our findings suggest that PSIs could be used to screen potential cases with adverse events using administration data. Confirming the presence of these events needs additional clinical information such as chart reviews. If PSIs are used for comparison, validity of data has to be adjusted and considered for in the analysis.

While PSIs are used for monitoring quality of care improvement over time, the assumption of temporal consistency of data validity has to be met. Unfortunately, we did not evaluate PSI validity over time. Quan et al.(21) evaluated the impact of ICD-10 implementation on data quality through chart review of 32 conditions. Canadian ICD-10 data had significantly higher sensitivity for one condition and lower sensitivity for seven conditions relative to ICD-9-CM data. The two databases had similar sensitivity values for the remaining 24 conditions. Walker(22) et al. compared coding practice between ICD-9-CM and ICD-10 and reported that the number of diagnoses coded decreased in four Canadian provinces and remained similar in other five provinces after implementation of ICD-10. Januel JM(23) et al. reported that of 36 conditions assessed in Switzerland, Kappa values for ICD-10 and chart data increased for 29 conditions and decreased for seven conditions compared with ICD-9-CM and chart data.

Our study has limitations. First, of 20 AHRQ PSIs, we intentionally evaluated five conditions that might have a high validity. Remaining PSIs should be evaluated in future studies. Second, we used chart data as the reference standard; conditions not documented in chart were missing. Prospective data collection through clinical examination on these events should be conducted to establish near gold standard. Third, this study was conducted in one urban area; the validity of PSIs might vary by institutions or regions. Fourth, we evaluated the validity using PPV alone. Sensitivity, specificity and NPV should be assessed for all of the PSIs. The ascertainment of the sensitivity requires a large sample size and involves expensive and time consuming resources due to low prevalence rate of PSIs. Fifth, the sample sizes for certain PSIs are small and 95% confidence interval is relatively wide.

In conclusion, our study supports that PSIs could be used for case-findings in the ICD-10 hospital discharge abstract data. Even PSIs with low PPVs could be used to identify potential cases from large volume of admissions for verification through chart review. In contrast, their sensitivity has not been well-characterized because of the inherent challenges of reviewing huge numbers of charts for properly testing sensitivity. Therefore, users of PSIs should be cautious if

using these for 'quality of care reporting' presenting rate of PSIs because under-coded data would generate falsely low PSI rates.

Table 1. Characteristics of patients by AHRQ patient safety indictor (PSI)

	PSI 5 Foreign body left during procedure N= 45	PSI 7 Selected infections due to medical care N=85	PSI12 Postoperative pulmonary embolism or deep vein thrombosis N=43 surgery patients	PSI13 Postoperative sepsis N=41 surgery patients	PSI15 Accidental puncture or laceration N=120
Age Mean (Range)	58.0 (21.6 – 93.5)	61.7 (18.5 – 90.0)	67.2 (31.0 – 94.0)	63.9 (19.9 – 83.5)	57.9 (19.3 – 96.5)
Sex (male)	24 (53.3%)	47 (55.3%)	23 (53.5%)	15 (36.6%)	44 (36.7%)
Length of stay	14.7 (1 – 195)	32.7 (2 – 184.0)	41.3 (2 - 274)	43.9 (1 – 238)	16.2 (1. – 181)

Table 2. Positive predictive value and 95% confidence interval (95% CI) for AHRQ patient safety indicators (PSI) recorded in ICD-10 hospital discharge abstract administrative data comparing chart data

Patient Safety Indicator	Including PSIs present on admission % (n/N, 95% CI)	Excluding PSIs present on admission % (n/N, 95% CI)
PSI 5 Foreign body left during procedure	35.6% (16/45) (21.9% - 51.2%)	62.5% (10/16) (35.4% - 84.8%)
PSI 7 Selected infections due to medical care	70.6% (60/85) (59.7% - 80.0%)	79.1% (53/67) (67.4% - 88.1%)
PSI12 Postoperative pulmonary embolism or deep vein thrombosis among surgery patients	79.0% (34/43) (64.0% - 90.0%)	89.5% (17/19) (66.9% - 98.7)
PSI13 Postoperative sepsis among surgery patients	9.8% (4/41) (2.7% - 23.1%)	12.5% (2/16) (1.6% - 38.4%)
PSI15 Accidental puncture or laceration	90.8% (109/120) (84.2% - 95.3%)	86.4% (51/59) (75.0% - 94.0%)
When surgical status was ignored		
PSI12Pulmonary embolism or deep vein thrombosis among surgery and non-surgery patients	25.2% (31/123) (17.8% - 33.8%)	27.0% (10/37) (13.8% - 44.1%)
PSI13 Postoperative sepsis among surgery or non-surgery patients	27.4% (32/117) (19.5% - 36.4%)	47.1% (16/34) (29.8% - 64.9%)

Table 3. Reasons for false positives of AHRQ patient safety indicators (PSI) in ICD-10 hospital discharge abstract administrative data when the indicator of presence on admission was ignored.

PSI 5 Foreign body left during procedure N=29	PSI 7 Selected infections due to medical care N=25	PSI 12 Postoperative pulmonary embolism or deep vein thrombosis N=9	PSI 13 Post operative sepsis N=37	PSI 15 Accidental puncture or laceration N=11
18- present on admission	7- present on admission	6- present on admission	15- present on admission	4 – present on admission
8– no foreign body	11 – unrelated to medical care	2 – had DVT/PE in past	12 – urgent surgeries, having sepsis	7 –no accidental puncture or laceration
2 – for treatment purposes (e.g. packing, stitch)	5 – IV site bruised or injured, no infection	1 – no DVT/PE	6 – urgent surgeries, no sepsis	
1 – patient pulled and broke catheter	2 – conflicting documentation		2 – no sepsis	
			2 – no surgery, sepsis	

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COMPETING INTERESTS

None to declare.

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CONTRIBUTOR STATEMENT

Hude Quan: Conception and design, acquisition of data, analysis, interpretation of data, and final approval of the version to be published.

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Data Sharing: Extra data is available by emailing hquan@ucalgary.ca.

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