Lessons learned from PSI validation and demonstration projects

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PSI Validation Pilot Methods

- Gather evidence on the criterion validity of the PSIs based on medical record review as “gold standard”
- Improve guidance about how to interpret & use the indicators, and evaluate potential refinements
- Retrospective cross-sectional study design
- Volunteer sample of 47 collaborative partners (78% nonprofit, nonreligious) plus parallel study of VA hospitals by Rosen et al.
- Sampling based on administrative data using AHRQ QI software to generate desired sample size locally (30 per hospital) and nationally (240 per PSI) from 2006-2007
- VA sampled 112 cases per PSI nationwide from 28 randomly selected hospitals (4 per hospital) from FY 2003-2007
Pilot participants (non-VA)

Total: 47
Facilitating organizations (e.g., Arizona)
Hospital systems
Individual hospitals
# Patient Safety Indicators

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
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<tr>
<td>Accidental puncture and laceration</td>
<td>Foreign body left in during procedure</td>
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<td>Iatrogenic pneumothorax</td>
<td>Postoperative Hemorrhage or Hematoma</td>
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<td>Postoperative Pulmonary Embolism or Deep Vein Thrombosis</td>
<td>Postoperative Physiologic and Metabolic Derangement</td>
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<td>Postoperative Sepsis</td>
<td>Postoperative Respiratory Failure</td>
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<td>Selected Infection due to Medical Care</td>
<td>Postoperative Wound Dehiscence</td>
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Data collection and analysis

- Each hospital identified chart abstractors (except VA did all chart abstraction centrally using VistAWeb EMR)
- Training occurred via series of webinars in early 2007 (onsite training for VA abstractors)
- Medical record abstraction tools & guidelines
  - Pretested in the Sacramento area and in VA
  - Targeted ascertainment of the event, risk factors, evaluation & treatment, and related outcomes
- Positive Predictive Values (PPV) were calculated and adjusted for hospital clustering
- Descriptive analysis of opportunities for quality improvement
PSI 15: Accidental Puncture or Laceration

- **N=249** at community hospitals
  - PPV or true events = 91% (95% CI = 88-94%)
    - 170 (75%) potentially consequential
    - 9% (n=23) false positives
      - 2% (n=5) present at admission
      - 7% (n=18) miscoded
        - 4 had disease-related lesions (perforated appendix or ischemic colon, ruptured AAA, rectovesical fistula)
        - 7 had a different complication (4 bleeding due to operative conduct, 1 surgical site infection, 1 dislodged gastrostomy tube, 1 periprosthetic fracture)
        - 7 cases had no apparent event (intentional, rule-out)

- **N=112** at VA hospitals
  - PPV = 85% (95% CI = 77-91%)
PSI 6: iatrogenic Pneumothorax

- **N=205 at community hospitals**
  - PPV = 78% (95% CI = 73-82%)
  - 11% (n=21) numerator false positives
    - 7% (n=14) present or suspected at admission (n=8 transferred in)
    - 4% (n=7) had no documentation of event (miscoded), but some with suspicion ruled out (n=3)
  - 11% (n=23) had exclusionary diagnosis or procedure (e.g., trauma, metastatic cancer)

- **N=112 at VA hospitals**
  - PPV = 74% (95% CI = 65-82%)
PSI 12: Postoperative DVT or PE

- N = 155 cases, 121 with OR procedure, at community hospitals
  - Coding perspective:
    - PPV = 84% (95% CI = 72-95%)
    - 17% (n=20) false positives
      - 10% (n=12) present at admission
      - 7% (n=8) no documentation of VTE
  - Clinical perspective:
    - PPV = 48% (95% CI = 42-67%)
    - Additional false positives (n=43) due to hospital-acquired preoperative VTE (20%), upper extremity DVT (9%), superficial/unspecified vein (6%)

- N=112 at VA hospitals
  - PPV = 43% (95% CI = 34-53%) with clinical perspective
Comparing PPV estimates with UHC sample for postoperative DVT/PE

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<thead>
<tr>
<th></th>
<th>Coding</th>
<th>Clinical</th>
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<tbody>
<tr>
<td><strong>UHC Cohort (n=450)</strong></td>
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<tr>
<td>Sensitivity</td>
<td>80% (46-100%)</td>
<td>100%</td>
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<tr>
<td>Specificity</td>
<td>99.5% (99.3-99.6%)</td>
<td>98.6% (98.6-99.2%)</td>
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<tr>
<td>Positive Predictive Value</td>
<td>72% (67-79%)</td>
<td>44% (36-52%)</td>
</tr>
<tr>
<td>Negative Predictive Value</td>
<td>99.6% (98.9-100%)</td>
<td>100%</td>
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| **VA Cohort (n=112)** |                         |                        |
| Positive Predictive Value |                        | 43% (34-53%)          |

| **AHRQ Cohort (n=121)** |                      |                        |
| Positive Predictive Value | 84% (72-95%)        | 48% (42-67%)           |

University HealthSystem Consortium cohort includes 505 flagged, randomly sampled surgical cases from 33 volunteer hospitals in 21 states; 450 cases were fully abstracted and submitted to UHC.
PSI 7: Selected Infection due to Medical Care (catheter-associated)

- **N=191 at community hospitals**
  - PPV = 54% (95% CI = 40-69%)
  - 41% (n=79) numerator false positives
    - 20% (n=38) present at admission, with no new infection (indwelling central venous catheters, AV grafts)
    - 21% (n=41) had no clear documentation of infection
    - 7% (n=12) had exclusionary diagnosis (cancer, severe malnutrition, nephrotic syndrome, other immunodeficiency)

- **N=112 at VA hospitals**
  - PPV pending
PSI 13: Postoperative Sepsis

- N=164 at community hospitals
  - PPV = 41% (95% CI = 28-54%)
  - 34% numerator false positives (ESTIMATE)
    - 17% had infection or sepsis present on admission
    - 17% had no documentation of bacteremia, septicemia, sepsis or SIRS
  - 25% did not have elective surgery (arguable)

- N=112 at VA hospitals
  - PPV = 62% (95% CI = 52-71%) preliminary
PSI 11: Postoperative Respiratory Failure

- N=609 at 18 UHC member hospitals
  - **Coding perspective:**
    - PPV = 90% (95% CI = 86-94%)
    - 4% (n=25) numerator false positives
      - 1% (n=5) present at admission
      - 3% (n=20) no documentation of acute respiratory failure
    - 5% (n=33) did not have elective surgery (n=30) or had an exclusionary diagnosis (n=3)
  - **Clinical perspective:**
    - PPV = 83% (95% CI = 77-89%)
    - Additional false positives (n=44) due to hospital-acquired preoperative respiratory failure (n=6), intubation/ventilation to protect airway or manage secretions (n=27), cardiac arrest (n=8), other (n=3)

- N=112 at VA hospitals
  - PPV = 80% (95% CI = 72-87%) with clinical perspective
Summary of PPV estimates from community hospitals

- APL, n=249
- PTX, n=205
- DVT/PE, n=121
- Selected inf, n=191
- Postop sepsis, n=164
- Postop resp failure, n=609

% cases

- % Other
- % Exclusions
- % Miscoding
- % POA
- % PPV
California Obstetric Validation Study (Romano et al.):
- Stratified random cluster sample of 1,662 records from 52 hospitals (51% vaginal)
- Sensitivity=90% (95% CI, 82-96%) and PPV=90-95%
- Adjusting for complex stratified sampling design, Sensitivity=93% (95% CI, 82-97%) and PPV=73%

Clinical research data set (Brubaker et al. 2007):
- 393 PSI-positive and 383 PSI-negative vaginal deliveries
- Sensitivity=77% (95% CI, 72-81%)
- Specificity=99.7% (95% CI, 98.5-99.4%)
- PPV could not be estimated due to the sampling design, but approximately 93% given a typical prevalence of 5%

English NHS study (Bottle and Aylin, 2008):
- 955 cases from 18 English NHS trusts
- PPV=85% (none present at admission, 15% miscoded)
Other evidence re PSI criterion validity

- **Catheter-associated BSI**
  - National Healthcare Safety Network 24 hospitals: sensitivity=9%

- **Postoperative DVT/PE**
  - Single US teaching hospital: PPV=50%, sensitivity=87%

- **Pressure ulcer**
  - UHC 32 hospitals: PPV=60% (after excluding POA) but NPV=85% (low) in high-risk cases not reported as having PU
  - Veterans Affairs: PPV=29% not excluding POA

- **Postoperative wound dehiscence**
  - Veterans Affairs 28 hospitals: PPV=88%
Implications of validation work

- Coding changes are needed to enhance PPV for some indicators
  - AHRQ proposed new codes for DVT (adopted)
  - CMS proposed new code for catheter-associated bloodstream infection (adopted)
  - New codes needed for postoperative sepsis
- “Present at admission” data will substantially improve PPV of multiple PSIs
  - New PSI software release (V4.1) “requires” POA or estimates its mean value at the hospital level
- With these changes, most PSIs should have high PPV
- Data on sensitivity (false negatives) are still needed, but preliminary data raise concerns for Pressure Ulcer and Selected Infections
Moore Demonstration Project
Goals

- Develop a collaboration with three regional hospitals in northern CA to show that it is possible to review cases flagged by PSIs in a collaborative manner.
- To provide information useful to the three participating hospitals for improving coding and quality of care in the future.
- To investigate potential safety-related events to identify specific opportunities for improvement.
Moore Demonstration Project
Methods

- Retrospective cross-sectional design
- Consecutive sampling using AHRQ QI software to generate desired sample size of up to 100 cases of at least four PSIs at each hospital (10/07-2/09)
- “Present on admission” (POA) logic was used in V3.2, March 2008 software to reduce false positives
- Each hospital identified one or more abstractors (RN or MD), who were trained individually to use the “root cause” PSI tools and guidelines
- Coordinating center (UC Davis) entered data from paper forms and identified discrepancies
- Descriptive analysis of opportunities for QI provided at meetings with key staff at each hospital
PSI 6: Iatrogenic pneumothorax Opportunities for improvement

- Watch for inadequate documentation, such as “rule out” pneumothorax without alternative diagnosis established after study (CXR or CT)
- Consider greater use of radiologic adjuncts in placement of central venous catheters, especially in the OR and ED (proven to reduce iatrogenic injuries)
PSI 7: CVC-related bloodstream infection
Opportunities for improvement

- Identify tunneled catheters that are infected at admission and code as POA
- Minimize use of femoral venous catheters, which are associated with higher rates of infection
- Remove catheters at earliest opportunity consistent with patient safety
PSI 9: Postoperative hemorrhage/hematoma
Opportunities for improvement

- Logic of indicator may sometimes capture both intraoperative and postoperative hemorrhage
- Impact of true positive cases was significant (i.e., most returned to OR), but opportunities for improvement are unclear
PSI 10: Postoperative physiologic/metabolic
Opportunities for improvement

Postoperative renal failure requiring dialysis
- Earlier recognition of renal failure may be beneficial
- Evaluate use of nephrotoxic medication, especially NSAIDs in postoperative setting
- Review ionic contrast documentation & use

Postoperative diabetic complications
- Tighter blood sugar control and monitoring in type I DM post-operatively
- Consider insulin drips instead of implanted pumps and/or SQ in the immediate postop period
PSI 11: Postoperative respiratory failure
Opportunities for improvement

- Overuse of 96.04 code when intubation was an expected part of procedure
- Two cases of oversedation leading to respiratory complications
- Reasons for re-intubation or prolonged intubations were often not documented
- Some patients could probably have been extubated earlier (and would then not have counted as respiratory failure)
- Several cases had massive blood loss which seemed to precipitate postoperative respiratory issues
PSI 12: Postoperative DVT/PE Opportunities for improvement

- Watch for inadequate documentation, such as “rule out” DVT or PE without alternative diagnosis established after study.

- More timely (day 0) use of pharmacologic prophylaxis may be beneficial, especially for perioperative patients at intermediate risk and without contraindications.

- Chronic VTE that was present on admission – new codes now available.
PSI 15: Accidental puncture or laceration

Opportunities for improvement

- Occasional overcoding of intraoperative bleeding or other routine events as accidental puncture or laceration
- Most true positive cases had extenuating circumstances, although some were probably still preventable with earlier conversion of laparoscopic to open abdominopelvic surgery, or use of Doppler ultrasound
- Hospitals with inexperienced operators performing technically difficult procedures may experience patterns of similar events
Acknowledgments

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References