Updated validation of AHRQ Patient Safety Indicators in the USA

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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)
- Sampling based on administrative data using AHRQ QI software to generate desired sample size locally (30) and nationally (240 per indicator) from 2nd quarter 2006 through 1st quarter 2007
Pilot participants

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

<table>
<thead>
<tr>
<th>PSI Rates</th>
<th>Pilot Hospitals</th>
<th>US Community Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iatrogenic Pneumothorax</td>
<td>0.95</td>
<td>0.57</td>
</tr>
<tr>
<td>Infection due to Medical Care</td>
<td>3.08</td>
<td>2.08</td>
</tr>
<tr>
<td>Postop DVT/PE</td>
<td>13.50</td>
<td>10.44</td>
</tr>
<tr>
<td>Postop sepsis</td>
<td>6.48</td>
<td>11.44</td>
</tr>
<tr>
<td>Accidental puncture &amp; laceration</td>
<td>4.51</td>
<td>3.56</td>
</tr>
</tbody>
</table>
Data collection and analysis

- Each hospital identified chart abstractors
- Training occurred via series of webinars in early 2007
- Medical record abstraction tools & guidelines
  - Pretested in the Sacramento area
  - Targeted the ascertainment of the event, risk factors, evaluation & treatment, and related outcomes
- Coordinating center (Battelle Memorial Institute) entered data from paper forms
- Positive Predictive Values (PPV) were calculated and adjusted for hospital clustering
- Descriptive analysis of opportunities for quality improvement
Accidental Puncture or Laceration

- **N=249**
  - PPV or true events = 91% (95% CI = 88-94%)
    - 170 (75%) were potentially consequential
  - 9% (n=23) were false positives
    - 7% (n=18) miscoded
      - 4 had disease-related lesions (perforated appendix or ischemic colon, ruptured AA, 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 other than normal operative/procedural conduct (intentional, rule-out)
    - 2% (n=5) POA (related to earlier episode of care)
Iatrogenic Pneumothorax

- N=205
  - PPV = 78% (95% CI = 73-82%)
  - 11% (n=21) were 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 (n=3)
  - 11% (n=23) had exclusionary diagnosis or procedure (e.g., trauma, metastatic cancer)
Postoperative DVT or PE

N = 155 cases, 121 had OR procedure

Coding perspective:
- PPV = 84% (95% CI = 72-95%)
- 17% (n=20) were false positives
  - 10% (n=12) present on 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%)
Comparing PPV estimates with UHC sample for postoperative DVT/PE

<table>
<thead>
<tr>
<th>UHC Cohort (n=450)</th>
<th>Coding</th>
<th>Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>80% (46-100%)</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.5% (99.3-99.6%)</td>
<td>98.6% (98.6-99.2%)</td>
</tr>
<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>
</tr>
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<table>
<thead>
<tr>
<th>AHRQ Cohort (n=121)</th>
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<tbody>
<tr>
<td>Positive Predictive Value</td>
<td>84% (72-95%)</td>
<td>48% (42-67%)</td>
</tr>
</tbody>
</table>

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.
Selected Infection due to Medical Care (catheter-associated)

- **N** = 191
  - PPV = 61% (95% CI = 51-70%)
  - 39% were false positive or excluded
    - 7% (n=14) had exclusionary diagnosis
    - 20% (n=39) were present on admission, with no new infection
    - 12% (n=23) had no clear documentation of infection
Postoperative Sepsis

- **N=164**
  - PPV = 41% (95% CI = 28-54%)
  - 59% were false positive or excluded
    - 17% had no documentation of bacteremia, septicemia, sepsis or SIRS
    - 17% had infection (=14%) or sepsis (=3%) present on admission
    - 25% did not have elective surgery
Other evidence re OECD patient safety indicators

- Catheter-associated BSI
  - English NHS study: PPV=79%
  - Sensitivity=9% in 24 US hospitals participating in National Healthcare Safety Network

- Postoperative DVT/PE
  - Veterans Affairs hospitals: PPV=56%
  - Single US teaching hospital: PPV=50%, sensitivity=87%
  - 8 Belgian hospitals: 54-59% PPV with 1 false negative (99.9% NPV)

- Postoperative sepsis
  - English NHS study: PPV=70%
  - 8 Belgian hospitals: 45% PPV with 25 false negatives (98.2% NPV)

- Accidental puncture or laceration
  - Veterans Affairs hospitals: PPV=86%
  - New York data linkage: sensitivity=46-80%

- Foreign body left in
  - English NHS study: PPV=52%
Summary of PPV estimates

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

% cases

- % Other
- % Exclusions
- % Miscoding
- % POA
- % PPV
Obstetric trauma

- California Obstetric Valiation 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 indicator-positive and 383 indicator-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 should be approximately 93% given a typical prevalence of 5%

- English NHS study (Bottle and Aylin, 2008):
  - 955 cases from 18 English NHS trusts sampled
  - PPV=85% (none present at admission, 15% miscoded)
<table>
<thead>
<tr>
<th>University HealthSystem Consortium Postoperative Respiratory Failure Clinical Benchmarking Project</th>
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</thead>
<tbody>
<tr>
<td>University Medical Center (Arizona)</td>
</tr>
<tr>
<td>Fletcher Allen Health Care</td>
</tr>
<tr>
<td>Harbor-UCLA Medical Center</td>
</tr>
<tr>
<td>Harborview Medical Center</td>
</tr>
<tr>
<td>University of Missouri Health Care (University Hospital)</td>
</tr>
<tr>
<td>Medical University of South Carolina</td>
</tr>
<tr>
<td>The Nebraska Medical Center</td>
</tr>
<tr>
<td>University Medical Center of Southern Nevada</td>
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<tr>
<td>The Ohio State University Medical Center</td>
</tr>
<tr>
<td>Rush University Medical Center</td>
</tr>
<tr>
<td>Shands HealthCare</td>
</tr>
<tr>
<td>UC Davis Medical Center</td>
</tr>
<tr>
<td>UC Irvine Medical Center</td>
</tr>
<tr>
<td>University of Virginia Health System</td>
</tr>
<tr>
<td>North Carolina Baptist Hospital (Wake Forest University Baptist Medical Center)</td>
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<tr>
<td>Vanderbilt University Medical Center</td>
</tr>
<tr>
<td>University of Washington Medical Center</td>
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<tr>
<td>The University Hospital at UMDNJ</td>
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UHC project methodology

Methods

- Retrospective review and documentation of 40 eligible cases from each of 18 participating hospitals
- Enrolled in reverse chronological order by discharge date (starting at 30 June 2007), proceeding back in time until the target number of cases were identified
- To avoid selection bias, cases could not be skipped or excluded unless a specific exclusion criterion was identified

Case Selection Criteria

- UHC identified postoperative respiratory failure (PSI 11) cases from the clinical database for participating hospitals, using the AHRQ PSI SAS V3.1
- Only cases that did not have a qualifying surgical procedure during the admission were excluded
### Postoperative Respiratory Failure PPV estimates

<table>
<thead>
<tr>
<th>PRF Status by AHRQ Software Version 3.1</th>
<th>PRF Status by Data Abstraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TRUE-Positive</td>
</tr>
<tr>
<td></td>
<td>Postop Resp Failure¹</td>
</tr>
<tr>
<td>Total</td>
<td>n (%)</td>
</tr>
<tr>
<td>Diagnosis code only</td>
<td>121</td>
</tr>
<tr>
<td>Procedure code only</td>
<td>308</td>
</tr>
<tr>
<td>Both code types</td>
<td>263</td>
</tr>
<tr>
<td>Total</td>
<td>692</td>
</tr>
</tbody>
</table>

¹Agreement between AHRQ software and retrospective chart review that respiratory failure (RF) diagnosis followed a qualifying surgery

²Evaluated as NOT likely PRF after retrospective chart review; additional information of following slides
Recognizing limitations

- Not all data elements of interest were available via chart review.
- We had no access to administrative data to test alternative definitions of indicators.
- Time constraints limited our ability to assess some processes of care (to minimize burden on collaborators).
- Inter-hospital variation in physician documentation and nurse abstraction.
- Volunteer sample; time periods varied slightly across hospitals.
Phase II estimates of PPV
- Foreign body left during procedure
- Postop hemorrhage or hematoma
- Postop physiologic and metabolic derangement
- Postop respiratory failure
- Postop wound dehiscence

Phase III estimates of sensitivity

Pre-piloted at 5 hospitals, now in the field at 40 additional hospital systems (>48 sites)

Phase IV will focus on pressure ulcer, selected pediatric/neonatal indicators, new version of “selected infections” (CRBSI)
Policy implications

- Coding changes are needed to enhance PPV for some indicators
  - AHRQ proposed new codes for DVT and transfusion reaction (adopted)
  - CMS proposed new code for catheter-associated bloodstream infection (adopted)

- “Present at admission” data would substantially improve PPV of multiple PSIs
  - Current PSI software has POA option
  - Next release will “require” POA

- With these changes, 4 of the 5 PSIs tested in Phase 1 should have high PPV

- Data on sensitivity (false negatives) are needed to avoid rewarding underreporting
Acknowledgments

- AHRQ project team
  - Mamatha Pancholi & Marybeth Farquhar*
- Battelle training and support team
  - Laura Puzniak & Lynne Jones**
- All of the validation pilot partners!
- References:

* Now at NQF
** No longer at Battelle
Accidental Puncture or Laceration

Characteristics of confirmed cases (N=226)

- 170 (75%) were potentially consequential
- Most of these were related to an abdominal or pelvic procedure
  - 51 (30%) enterotomy/perforation of the GI tract
  - 42 (25%) bladder injury
  - 33 (19%) dural tear
  - 27 (16%) vascular injury
- 132 (78%) involved a reparative procedure at the time of occurrence
- 19 (11%) required a return to the OR (one death)
Iatrogenic Pneumothorax

Characteristics of confirmed cases (N=156)

- 9 (6%) transthoracic needle aspiration or biopsy
- 66 (47%) central venous catheter placement
  - Only 4 used real-time ultrasonographic guidance
- 59 (40%) other invasive procedures on or near the neck or chest wall
  - 37 catheterization, pacemaker insertion
  - 3 laparoscopic procedures
  - 8 nephrectomy/renal procedures
  - 2 operations involving the spinal canal
  - 9 other procedures
- 5 (5%) mechanical ventilation
- 1 (1%) cardiopulmonary resuscitation
Characteristics of confirmed cases (n=121):

- 77 events after OR procedure
  - 14 (19%) no prophylaxis whatsoever
    - Why?: No reason 13, risk of hemorrhage 1
    - Surgery: Abdominal 5, orthopedic 6, neurosurgery 3
  - 2 (1%) cases received only aspirin
  - 11 (14%) cases received prophylaxis on day 2 or later after surgery: neurosurgery 3, major other procedures 8

- 24 events before OR procedure
  - 2 (8%) no prophylaxis whatsoever
    - Why?: No reason 2
    - Surgery: Abdominal 1, neurosurgery 1
  - 3 (12%) cases received only aspirin
Selected Infection due to Medical Care (catheter-associated)

- N=116 with new infection
  - 107 with new infection
  - 9 with new infection superimposed on POA infection

- Majority related to central venous catheters (n=72)
  - 45 cases due to non-tunneled central lines (SC, IJ, Fem)
    - Mean days from insertion to infection 6.1 femoral, 12.5 subclavian, 10.3 jugular
  - 20 cases associated with PICC lines
    - Mean 11.9 days from insertion to infection
  - 7 other/unknown central venous catheters (3 implanted)

- Other types of catheters (n=18)
  - 12 peripheral intravenous lines
  - 2 arterial lines
  - 2 endotracheal tubes
  - 1 urinary catheter
Postoperative Sepsis

- **Bloodstream (catheter-related)** = 16 cases (24%)
  - 14 received prophylactic antibiotics

- **Lungs (pneumonia, including aspiration and ventilator-associated)** = 26 cases (39%)
  - All received prophylactic antibiotics

- **UTI** = 13 cases (19%)
  - 10 received prophylactic antibiotics

- **Surgical site** = 6 (9%)
  - Antibiotic prophylaxis: 5 received (Cefazolin, IV) <1 hour prior to surgery
  - Surgery: abdominal 5, vascular 1
  - Hair removal method: 1 clipper, 5 undocumented