National and State Level Validation Efforts

Third Plenary

Co-Chairs:
Rani Jeeva, MPH, CPH
Lisa McGiffert

9:00 AM – 10:15 AM
Key Question Addressed

5. What can and should be done to improve, extend, and sustain efforts at the local, state, and national levels to validate facility-specific HAI data that are collected, analyzed, and publicly reported?
Validation: Consumer Perspective

Lisa McGiffert
Consumers Union
CMS Validation of Hospital Inpatient HAI Measures

James (Jim) Poyer, MS, MBA
Director, Division of Quality Improvement Policy for Acute Care
Quality Improvement Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Outline

• Inpatient Quality Reporting Program
  – Overview
  – HAI-related requirements

• Validation Activities
  – Objectives
  – Current methods and timeline
  – Proposed methods
  – Gaps and future plans
Hospital Inpatient Quality Reporting (IQR) Program

- Mandated by law since 2003
- Provides hospitals with financial incentive to report on quality of care delivery
- Provides consumers with data to make informed decisions about their care
- Data used for CMS Hospital Value-Based Purchasing
- Applies to hospitals paid under the inpatient prospective payment system
- Includes 72 quality measures in several domains
  - Clinical Processes of Care*
  - Healthcare-Associated Infections (HAI)*
  - Mortality and Readmissions
  - Patient experience
  - Structural Measures
  - Cost Efficiency

*Validated through medical records abstraction
Statutory Requirement – Hospital IQR Validation

• The Affordable Care Act modified Section 1886(b)(3)(B)(viii)(XI) of the Social Security Act to mandate Hospital IQR program validation
  – “The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.”
Measures Validated in Hospital IQR program

• Process of Care: AMI, Heart Failure, Pneumonia, Surgical Care Improvement Project, Emergency Department Throughput, Immunization measures

• Healthcare Associated Infection measures
Overview of CMS Hospital IQR Validation Process

- CMS randomly selects hospitals annually (currently 800) from eligible hospital list
- CMS selects targeted hospitals (e.g., hospitals failing previous annual validation)
- CMS selects medical records randomly from selected hospitals (up to 18 per quarter per hospital)
- CMS mails letter requiring hospitals to copy and return medical records to contractor
- Hospital submits medical record copies
- CMS contractor independently abstracts medical records
- CMS contractor adjudicates mismatches
- CMS computes validation score at the measure level
## HAI Measures Timelines

<table>
<thead>
<tr>
<th>Measure</th>
<th>Discharge dates reported</th>
<th>Discharge dates validated</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central line-associated bloodstream infection (CLABSI)</td>
<td>Beginning January 2011</td>
<td>Beginning January 2012</td>
<td>ICU locations only</td>
</tr>
<tr>
<td>Catheter-associated urinary tract infection (CAUTI)</td>
<td>Beginning January 2012</td>
<td>Proposed October 2012</td>
<td>ICU locations only</td>
</tr>
<tr>
<td>Surgical site infection (SSI)</td>
<td>Beginning January 2012</td>
<td>Proposed October 2012</td>
<td>Colon surgery and abdominal hysterectomy only</td>
</tr>
<tr>
<td>MRSA bacteremia, C. difficile, Healthcare personnel vaccination</td>
<td>Beginning January 2013</td>
<td>Not yet proposed</td>
<td></td>
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</table>
CLABSI Validation
(As finalized August 2011)

Objectives

• Within each hospital:
  – Estimate reliability of IQR reporting for all chart-abstracted metrics
  – Ensure it meets a minimal level of reliability (75%)

• Across all hospitals as an aggregate:
  – Evaluate predictive power of validation for ICU patients
CLABSI Validation Timeline

<table>
<thead>
<tr>
<th>Discharges</th>
<th>Validation activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1Q 2012</td>
<td>August-December 2012</td>
</tr>
<tr>
<td>• 2Q 2012</td>
<td>November-March 2013</td>
</tr>
<tr>
<td>• 3Q 2012</td>
<td>February- May 2013</td>
</tr>
<tr>
<td>• First Results</td>
<td>Summer/Fall 2013</td>
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</table>
CLABSI Validation Operations

- 800 randomly sampled hospitals
- Each sampled hospital, each quarter (Q1-Q3 2012)
  - Positive blood culture list for all ICU patients
  - Annotated to identify patients with central lines
- CMS Validation Support Contractor will
  - Check for presence of all basic qualifiers:
    - ICU patient
    - Bloodstream infection (positive blood culture results) - Isolate is:
      - A likely pathogen found at least once
      - Common skin commensal (CSC) found in two or more positive blood cultures drawn on separate occasions
    - Central line
  - Review and remove duplicates to identify candidate CLABSI (unique patient episodes of care)
  - Random sample of 3 candidate CLABSI
CLABSI Validation
Sample Size

• 800 hospitals randomly sampled
• 3 candidate CLABSIs per hospital per quarter
• Total
  – 7,200 candidate CLABSIs
CLABSI Validation

• CMS Clinical Data Abstraction Center (CDAC) Contractor
  – Requests copies of records from hospitals
    ▪ Hospital sends CDAC copies of requested charts
  – Abstracts hospital
    – For candidate events, determines if any CLABSI events occurred
    – For other records, identifies any candidate CLABSIs and determines if any CLABSI events occurred

• Validation Support Contractor
  – Provides CDC with information for all candidate events
  – Checks to see if candidate events were reported to NHSN
  – Reviews/adjudicates mismatches between hospital and CDAC
  – Scores each case as 1/1 for matches; 0/1 for mismatches
IQR and NHSN: Alignment Challenges

NHSN = infection events

IQR = hospital admissions

- Multiple events may occur during one admission
  IQR only selects events occurring in discharge quarter
- IQR does not validate central line days
Proposed Changes for Next Year Candidate Cases

- Hospitals identify candidate CLABSIs, CAUTIs and SSIs
- Candidate CLABSI: proposed same definition
- Candidate CAUTI
  - similar to candidate CLABSI
  - positive urine culture lists for ICU patients
- Candidate SSI:
  - Identified for Medicare beneficiaries from claims for index and readmissions within 30 day to same hospitals
Proposed Changes for Next Year Sample Size and Scoring

- 400-600 hospitals annually
- Random sample of 12 candidate HAIs per hospital per quarter
- Separate score for HAIs and clinical process of care measures
- Charts sampled for clinical process of care will not be abstracted/scored for CLABSI
Read and comment on the rule online at [http://www.regulations.gov](http://www.regulations.gov). Search for “CMS-2012-0052-0001”
Future Challenges

- New measures (MRSA, CDI)
- SSI readmissions for other than Medicare patients and to hospitals other than index hospital
- Submission through electronic health records, including device days
Questions not Related to Proposals?

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• Nancy Sonnenfeld:
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CDC Support for Valid HAI Data and Lessons Learned from State Validation

Kathryn E. Arnold, MD
Medical Officer
Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention
HAI Data Validation is Important

• Concerns about uneven data quality
  – Always important, now more than ever
• Need for training on all levels
• Validation findings help guide training
• Credible data are vital for prevention, public reporting, and incentivizing improvements in clinical performance
CDC Supports Valid NHSN Data

• User Support Team
• Training
  – Web-based (www.cdc.gov/nhsn/training.html)
  – CDC-hosted and professional meeting venues
  – State validation work
• Refining NHSN
  – Business rules reduce opportunities for data entry error
    Built-in analyses explore data quality
  – Consultation with partners to modify NHSN methods and definitions
2009 ARRA* Grants to States

- Few states received resources with their state reporting mandates
- CDC administered ARRA grants
  - CDC-funded PHAs to support state programs
  - All states: one position to develop and implement HAI prevention plan, advisory group
  - 31 states: money for surveillance (+/- validation)
  - 27 states: prevention collaboratives
- ARRA funding provided short-term validation resources to many states

* American Recovery and Reinvestment Act
States as Validation Laboratories

• States created innovative approaches and tools
• Central Line-Associated Bloodstream Infection (CLABSI):
  – Structure of sampling frame
  – Numerator sampling approaches
    • (Targeted, Lot Quality Assurance, Probability)
  – Checklists
  – Denominator methods surveys
  – Risk-factor (location mapping) investigations

• Surgical Site Infection (SSI):
  – Data linkage to enrich sampling frame (procedures) for SSI
  – In house and post-discharge case-finding surveys
  – Risk-factor audits in access database
Lessons Learned from State Validation

- Under-reporting is common (but not universal)
  - CLABSI Sensitivity as low as 48%

- Over-reporting is rare
  - CLABSI Specificity at least 90%

- Therefore, validation has to look for what’s missing
- This is harder than validating what’s reported
Lessons Learned from State Validation

- **Sampling frame design may be important for efficiency**
  - SSI validation with un-enriched sampling frame (surgical procedures) changes reporting in only 1-2% of charts
  - SSI validation with enriched sampling frame (surgical procedures linked to high-risk ICD-9-CM discharge codes) changes reporting in 13 to 40% of charts
  - Error rate varies by procedure, and was particularly high for colon procedures

Lessons Learned from State Validation

- Reporting can improve with validation and training
  - Serial annual CLABSI audits in NY 2007-2009*
    - Adult and pediatric ICU agreement from 92% to 94%
    - NICU agreement from 89% to 95%

- Validation must be ongoing
  - Every year there is turnover in the healthcare workforce
    - Those who track HAIs
    - Those who must prevent HAIs
  - Every year a new cohort of patients is at risk
SSI Ever (Externally) Validated, as of 2012

Dots: SSI Mandate by 2012
CLABSI Ever (Externally) Validated, as of 2012

Dots: CLABSI Mandate by 2012
Expected (External) State CLABSI Audits after 2011

Dots: CLABSI Mandate by 2012
CDC Validation Guidance and Toolkit

- Developed by adaptation of state protocols and tools, and study of survey methodologies
- To be vetted with states at Council of State and Territorial Epidemiologists (CSTE) Meeting, June 2-7
- Goals
  - Share resources, tools, and lessons learned
  - Outline strategic options for
    - Efficient data quality improvement
    - Periodic comprehensive review
  - Seek consensus on elements of national standards
- Plan to share after state input
- Ever-green document
CDC Support for CMS Validation

- Integrates existing CMS validation program and NHSN definitions
  - Borrows many aspects of state validation
CMS CLABSI Validation 2012 and After

(Dots: CLABSI Mandate by 2012)
### State and CMS Validation are Complementary, but Not the Same

<table>
<thead>
<tr>
<th></th>
<th>State</th>
<th>CMS</th>
</tr>
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<tbody>
<tr>
<td><strong>Approach</strong></td>
<td>Differs state-by-state</td>
<td>Nationwide probability sample</td>
</tr>
<tr>
<td><strong>Constrained by</strong></td>
<td>Statute (access to data), and resources</td>
<td>Statute (scope), resources, and existing infrastructure</td>
</tr>
<tr>
<td>** Validates**</td>
<td>Cases; denominator methods; risk adjustment variables</td>
<td>Cases</td>
</tr>
<tr>
<td><strong>Sampling</strong></td>
<td>Hospitals, locations, pathogens often targeted; sample varies</td>
<td>All IPPS hospitals, at least every 4 years; small sample each facility</td>
</tr>
<tr>
<td><strong>Primary goals</strong></td>
<td>Improve surveillance practice; train reporters; optimize data quality, all levels</td>
<td>assure compliance; validate accuracy of metric; motivate internal improvement</td>
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Vision for the Future

- **Ongoing validation is essential**
- **CDC, CMS, and states have a great beginning, with complementary approaches**
  - Need to continue and expand validation
  - Hope for integrated requirements and infrastructure
  - Continue to benefit from state innovations
    - Need to identify state validation resources
  - Continue to work toward nationwide participation
  - Periodic comprehensive look at facility level surveillance
State Level Validation: Results and Lessons Learned from California

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Slides Not Available
Questions & Answers

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