



American Recovery and Reinvestment Act
Epidemiology and Laboratory Capacity (ELC)
for Infectious Disease Program
Healthcare-Associated Infections (HAIs)
Grantee Meeting

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NHSN Data Validation



Objectives

- Background and need
- Objective of validation study
- Validation methods
- Review of validation work that has been done
- Discussion





Background and Need for Validation



- NHSN serves multiple purposes: infection control, national-level surveillance, prevention research, state-level public reporting
- Data collection from a sample of U.S. healthcare facilities enables valid estimation of adverse events among patients and healthcare workers



Objective of HAI Validation Study



- Determine the accuracy of reporting
 - Cases meet NHSN criteria for infection?
All aspects of NHSN reporting protocols met?
 - Under- or over-reporting?
 - Cases complete?



Review of Methodology



- Selection of facilities
- Creation of chart sampling framework within the facility
- Selection of patient charts for review
- Abstraction of charts
- Analysis and use of the data



Selection of Facilities



- Comprehensive
- Sample
 - Random
 - Convenience based on desire or capacity to evaluate
 - Use random number generator to choose every n th facility until reach desired number of facilities



Selection of Facilities



- Sample (continued)
 - Proportional/stratified random
 - Representative of all facilities
 - Bed size
 - Urban/rural
 - Public/private
 - Number of admit/pt days
 - Case mix (type of ICU or operation)



Selection of Facilities



- Sample (continued)
 - Based on rate of interest
 - High and low outliers
 - Based on a pre-determined criterion
 - Range of expected ratios of positive blood cultures to reported bloodstream infections
 - Stratify facilities by the factors of interest and randomly choose



Chart Sampling Framework



- Include all reported HAI and a pre-determined number of patients without HAI
- Simple random sample
- Stratified sample
 - May be determined by mandated reporting
 - CLABSI in certain types of ICU
 - SSI for selected operations
 - May be influenced by prevalence of infections in certain locations



Selection of Patient Charts for Review



- Determine study timeframe that will yield a sufficient sample size
- Select charts from list of eligible patients during the study timeframe

Ex: If validating CLABSI in ICU, source of eligible patients

- ICU patient logs
 - Microbiology lab reports of positive blood cultures
- Billing records of patients who had central catheter



Abstraction of Charts



- Blinded
- Trained chart reviewers
 - Ideally, each chart should have 2 independent reviews
 - Expert supervisor
- Use standardized data collection form/data entry screen



Analysis of the Data

- Assume that the retrospectively detected cases represent “truth”
- Match the abstracted cases to those reported (orgID, patID, DOB, gender)
- Calculate sensitivity, specificity, positive predictive value, negative predictive value



HAI Validation Example



Truth*

	Truth*	
	HAI (+)	No HAI (-)
ICP detected HAI (+)	115	17
ICP detected without HAI (-)	18	700

*Determined by retrospective chart review



Accuracy Measure Terms

Positive Predictive Value



	HAI (+)	Without HAI (-)
Test (+)	True positives	False positives
Test (-)	False negatives	True negatives

Sensitivity

Specificity

Negative Predictive Value





Accuracy Measure Terms



Sensitivity: The proportion of positive test results among all positives (probability of a positive test among patients with disease)

$$\text{sensitivity} = \frac{\text{number of true positives}}{\text{number of true positives} + \text{number of false negatives}}$$



Accuracy Measure Terms



Specificity: The proportion of negative tests among all negatives (probability of a negative test among patients without disease)

$$\text{specificity} = \frac{\text{number of true negatives}}{\text{number of true negatives} + \text{number of false positives}}$$



Accuracy Measure Terms



Positive Predictive Value : The proportion of positives among all positive tests (probability of a positive among patients testing positive for disease)

$$\text{Positive Predictive Value (PPV)} = \frac{\text{number of true positives}}{\text{number of true positives} + \text{number of false positives}}$$



Accuracy Measure Terms



Negative Predictive Value : The proportion of negatives among all negative tests (probability of a negative among patients testing positive for disease)

$$\begin{array}{l} \text{Negative} \\ \text{Predictive} \\ \text{Value} \\ \text{(NPV)} \end{array} = \frac{\text{number of true negatives}}{\text{number of true negatives} + \text{number of false negatives}}$$



HAI Validation Example



	HAI (+)	No HAI (-)
ICP detected positive (+)	115	17
ICP detected negative (-)	18	700

$$\text{Sensitivity} = \frac{115}{115 + 18} = .865$$

$$\text{Specificity} = \frac{700}{700 + 17} = .976$$

$$\text{PPV} = \frac{115}{115 + 17} = .871$$

$$\text{NPV} = \frac{700}{700 + 18} = .975$$



Uses of the Data



- Unreported cases should be reviewed with facility to determine why they went undetected and be corrected
- Same for reported cases found to not meet criteria
- Data elements not reported according to NHSN protocols should be reviewed with facility and corrected



Other Considerations

- Experience of chart reviewers
 - IP with ≥ 5 years experience (more for expert supervisor)
 - Training in NHSN protocols
 - Demonstrate consistency in case finding from chart review
- IRB, HIPAA
- Confidentiality
- Data security



- New York
- Connecticut
- South Carolina
- Tennessee



- Assess reliability and consistency of surveillance definitions
- Evaluate current surveillance methods to detect infections
- Assess risk factors
- Ascertain prevention strategies
- Provide on-site education



Data checks



- Computerized data validation scan
 - Clean colon procedures
 - Outpatient CABG procedures
 - Colon surgery duration less than 30 minutes or more than 15 hours
- Discuss with hospitals
- Hospitals verify or correct data



New York



Audits - 2008

- Audits conducted in 163 (90%) of 182 hospitals
 - 131 NICU charts with positive blood cultures
 - 891 Adult/Peds ICU charts with + blood cultures
 - 462 CABG surgery patient records
 - 1911 Colon surgery patient records
 - 1578 Hip surgery patient records
 - 4973 Total charts reviewed



CLABSI Record Selection

- Limited to one of each type of ICU
 - Adult
 - Peds
 - NICU
- Selected charts from laboratory records of positive blood cultures
 - Minimum of 5 records without MRSA from each ICU
 - Minimum of 3 records with MRSA-positive blood



SSI Record Selection



- Central office
 - Stratified random sample of records
 - For each type of procedure
 - 4 SSI cases
 - 8 Not a SSI
- HAI regional staff
 - Given list of records
 - Unaware of SSI status



Enter New Audit Data

Add New Surgical Chart Review

Add New NICU CLABSI Chart Review

Add New Adult/Pediatric ICU Chart Review

Trauma: Disagree Explain Other (explain):

Emergency: Disagree Explain: Other (explain):

Scope: Disagree Explain

Multiple Procedures Disagree MultProcExp: Other (explain):

Meet criteria for an NHSN SSI
When Detected: Extent of SSI Disagree

Die: Disagree

Organism 1: Organism 2: Other:

Diabetes Comments:

***COLON ONLY** Diverticulitism Comments: Surgery a result of C.Diff infection?

***HPRO ONLY** HPRO type: Disagree: Other (explain):

Weight lbs 0 Weight kg 0 Weight n/a Height in 0 Height cm 0 Height n/a

BMI 0 BMI n/a

After completing ALL operative procedure chart reviews open the reveal file and complete the following questions



Hospital vs. HAI Program Adult/Pediatric ICU CLABSIs



	Number of Differences	Number of Charts	Percent Differences
Admission date	0	891	0
Date of Birth	0	891	0
Gender	0	891	0
CLABSI	53	891	5.9
ICU Type	7	98	7.1



2007 and 2008 Adult/Pediatric ICU Audits

	Percent Different 2007	Percent Different 2008
Met criteria for SSI		
Hospital=Yes, Reviewer=No	4.0	1.3
Hospital=No, Reviewer=Yes	1.2	4.6
ICU type	4.2	7.1



Comparison: Hospital Report and HAI Program Colon Surgery - 2008

	Number of Differences	Number of Charts	Percent Different
Admission date	1	1911	0.05
Discharge Date	2	1911	0.1
Gender	7	1911	0.4
General anesthesia	12	1762	0.7
Date of Birth	16	1911	0.8
SSI*	22	1762	1.1
Procedure date	22	1911	1.2
Trauma	32	1762	1.8
NHSN Procedure*	56	1911	2.9
Depth of Infection	59	1762	3.3
When Detected	69	1762	3.9
ASA score*	74	1762	4.2
Primary Closure*	94	1911	4.9
Emergency	90	1762	5.1
Scope	133	1762	7.6
Wound Class*	188	1762	10.7
Procedure Duration*	249	1762	14.3
Multiple Procedure	366	1762	20.8

New York State data reported as of April 8, 2009

* Affects risk-adjusted rate



Colon Audits 2007 vs. 2008



	Percent Different 2007	Percent Different 2008
Met criteria for SSI		
Hospital=Yes, Reviewer=No	7.9	0.7
Hospital=No, Reviewer=Yes	2.8	0.7
Not NHSN Procedure	3.2	2.9
ASA score	8.6	4.2
Not Primarily Closed	4.4	4.9
Wound Class	17.8	10.7
Procedure Duration	52.5	14.3

New York State data reported as of April 8, 2009



Hospital Report vs. HAI Program

Depth of Colon Surgical Site Infection

Depth of Infection According to Reviewer #, (ROW%), (COL%)	Depth of Infection Reported by the Hospital				
	None	Superficial Incisional	Deep Incisional	Organ Space	Total
None	1338 (99.1) (99.1)	6 (0.4) (2.8)	4 (0.3) (4.5)	2 (0.2) (1.8)	1350 (76.6)
Superficial Incisional	8 (3.9) (0.6)	192 (93.7) (90.6)	5 (2.4) (5.6)	0 (0) (0)	205 (11.6)
Deep Incisional	3 (3.5) (0.2)	8 (9.4) (3.8)	69 (81.2) (77.5)	5 (5.9) (4.5)	85 (4.9)
Organ Space	1 (0.8) (0.1)	6 (4.9) (2.8)	11 (9.0) (12.4)	104 (85.3) (93.7)	122 (6.9)
Total	1350 (76.6)	212 (12.0)	89 (5.1)	111 (6.3)	1762

New York State data reported as of April 8, 2009



Validation Challenges NY

- Transition from paper to electronic patient record
- Each hospital has different system
- Systems within a single hospital often not integrated
- Password protection issues

Even with focus on limited variables, chart review took 30 min – 1 hour for each record



Connecticut



Connecticut: Methods

October 1 – December 31, 2008

- > 400 charts, all patients with positive blood culture (micro reports) in all participating ICUs from 30 acute care hospitals
- On-site hospital visits by trained IP
 - Retrospective, blinded chart audit
 - Interview IP to assess collection of denominator data



Connecticut: Results

Revealed during audit	REPORTED TO NHSN		
	Infected	Not Infected	TOTAL
Infected	23	26	49
Not Infected	4	423	427
TOTAL	27	449	476

- 49 HAI CLABSIs identified by CT HAI Program
 - Infection rate of 3.58 per 1000 CLDs
- 27 CLABSIs total had been reported to NHSN
 - Infection rate of 1.97 per 1000 CLDs



Connecticut

Reasons for Inconsistencies

- Misunderstanding about NHSN surveillance or term definitions
 - Clinical vs. surveillance definitions
 - Collection of central line days and patient days
- Future Plans
 - Additional training
 - Repeat data validation for 4th quarter of 2009
 - Conduct annual data validation audits



Validation of Denominator Data

- Central line days and patient days
 - Visit locations where denominators are collected -- interview to determine methodology
 - Review monthly report form to identify gaps in daily counts



South Carolina



Chart review

- 1955 charts reviewed
- 94% overall agreement with data entered into the NHSN.
- Almost 90% of errors due to:
 - Incorrect surgery duration
 - Incorrect surgical wound class
 - Use of an “endoscope” or not
 - ASA score



CLABSI Validation

- 156 Charts and/or IP documentation reviewed to confirm CLABSI
 - 1 not a CLABSI—secondary to an infection
 - 13-correct criteria not applied
 - 5-organism entered as recognized pathogen instead of skin organism
 - 5-organism entered as skin organism instead of recognized pathogen
 - 2-IP used 2007 criteria instead of 2008 criteria
 - 1- organism entered as other organism instead of recognized pathogen



Resources

- Successful studies depend on dedicated staff
- Costs of validation not well-established



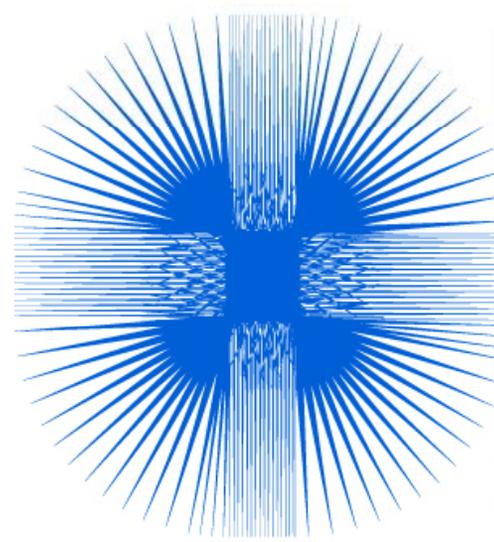
Thank you!

- New York:
 - Rachel Stricof, Carole Van Antwerpen, Valerie Haley
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- Connecticut
 - Richard Melchreit, Lauren Backman, Richard Rodriguez
- Tennessee
 - Marion Kainer



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