Protocol for Validation of Mandatory Reporting of Central Line-Associated Bloodstream Infections, 2012

INTRODUCTION

Objectives

1. Determine the sensitivity and specificity of central line associated blood stream infections among a sample of eligible Oregon hospitals.
2. Validate estimation of denominator data among a sample of eligible Oregon hospitals, and provide feedback.
3. Estimate coefficient of underreporting among a sample of eligible Oregon hospitals, and provide feedback.
4. Validate CDC 2012 CLABSI Toolkit and provide feedback to CDC.
5. Compare different methods of CLABSI identification and their relative estimation of CLABSI rates; specifically, validation by blood culture, CLABSI event, and patient chart.
6. Validate NHSN location attribution
7. Validate events reported to NHSN vs mandated state reporting

Background

Healthcare-associated infections (HAI) contribute to patient morbidity and mortality, the rising cost of health care, and are the target of patient safety improvement initiatives (Scott 2009, Yokoe 2008, Klevens 2007). Adherence to infection prevention bundles prevents central line-associated bloodstream infections (CLABSIs), and consists of proper hand hygiene, sterile insertion, hub scrub, and prompt line removal (Shannon 2006, IDSA CLABSI Guidelines 2009). Many healthcare facilities and private and government payers now consider the degree of infection prevention bundle adherence to be a useful process measure for determining best practice patient care.

The National Healthcare Safety Network (NHSN) was established to provide voluntary surveillance of central line associated blood stream infections (CLABSIs) to be used for individual facility reporting and process improvement (Edwards 2009). Since 2009, the Oregon HAI Program has used the NHSN to perform mandatory HAI reporting and track patient safety outcome measures, including CLABSIs (Oh 2012).

While a health care facility performs internal validation to ensure consistency, an external, neutral evaluator such as the state public health department performs external validation to confirm data quality, assess reliability and accuracy, measure sensitivity and specificity, and calculate standardized infection ratios (SIR) to compare facilities. Findings from state validations confirm the need for external validation of any mandatory reporting system. The Connecticut Department of Public Health conducted a validation project of ICU CLABSIs from 30 acute care

hospitals during the fourth quarter of 2008; 52% of NHSN events had not been reported (Backman 2010). In the 2009 Oregon HAI program validation study, external reviewers agreed with hospitals on CLABSI status in 782 (96%) of 817 bacteremia episodes. Ultimately, 16 of 86 (18.6%) CLABSIs were not been reported by hospitals to NHSN (under-reporting); 6 were episodes were reported incorrectly by the hospitals to NHSN (over-reporting) (Oh et al. 2012). Hospital and external reviewer sensitivities were 72% and 60%, respectively; arbitration often revealed more information not available to external reviewers at the time of the audit. In 2013 October, Oregon Public Health Division's (OPHD) Healthcare-associated Infections Program received funding to complete validation using a newly created 2012 Centers for Disease Control and Prevention (CDC) NHSN CLABSI Validation Toolkit.

CDC NHSN Toolkit uses the CLABSI event as the unit of analysis. For example, the selected blood culture is used only as a proxy for one clinical event to be reviewed. During the 2012 OPHD validation of 2009 data, the health department used a positive blood culture as a proxy to review an entire medical record for all potential CLABSI events. However, this method differs from how Infection Preventionists initially determine CLABSI status, that is, by using the positive blood culture as the unit of analysis. The retrospective nature of validation and time constraints make identification and review of events rather than individual blood cultures more efficient.

Differing methods could affect validation. Review of unique positive blood culture results permits rapid record review using a line listing; review of an entire event requires an expanded medical chart abstraction. In turn, more complex methods could require more complex data collection. Our 2012 ICU CLABSI validation of Oregon healthcare facilities is structured to compare these methods. Using different units of analysis, we sought to determine if there were significant estimation differences of Oregon CLABSI rates between blood culture-based vs event-based validation reviews; we consider complete review of medical charts to be the gold standard. Secondary outcomes are sensitivity and specificity, facility-level rates, inter-rater reliability, difference in resources, data collection, and time.

METHODS

Facility Selection

In accord with the 2012 CDC CLABSI Toolkit we exported reported ICU CLABSI results from all eligible Oregon hospitals (excluding long term acute care hospitals) that reported to NHSN during 2012 (N = 41). Facilities were divided into 3 strata: above the median standard infection ratio (SIR) (N = 14); SIR greater than zero but less than the mean SIR (N = 14); and no reported SIR (N = 13). Only 19 facilities had a calculated standard infection ratio (SIR).

We obtained a targeted sample of 18 facilities by ordering facilities within the strata and using a rotating selection from the highest to the middle tertiles until 18 were obtained. An additional

facility (5% of remaining) without a reported SIR was chosen from the middle and lower tertiles using a random number generator.

We made two changes to CDC methods: (1) we retained all 19 facilities with a calculated SIR; and (2) we chose a 20% sample of facilities without a reported SIR (N = 4) instead of 5%. We determined that a review of only 1 critical access facility was insufficient representation, given that Oregon has many rural hospitals who manage central catheters. This produced a total of 23 facilities.

Positive blood culture line lists from selected facilities

We mailed a formal letter to each selected facility's Infection Preventionist (IP), CEO, and laboratory manager requesting a list of positive, ICU-attributed blood cultures collected on January 1–December 31, 2012; we also made courtesy phone calls to IPs to introduce the project. ICU-attributed blood cultures were defined as positive blood cultures collected during ICU admission, or within 48 hours of ICU discharge. Per NHSN definitions, only positive blood cultures attributable to adult, pediatric, or neonatal ICUs were considered. All facilities complied with our data request.

Medical chart selection using positive blood cultures

Positive blood cultures were sampled to determine medical charts for review. A unique medical record was defined by the same medical record number (MRN) and admission date; all blood cultures from a unique medical record were considered together.

From the line list of positive ICU blood cultures provided by each hospital, we created a validation line list for each hospital with up to a total of 20 unique medical records with reported CLABSIs, and up to 40 unique records with unreported candidate CLABSIs (e.g., positive blood cultures). If the facility had a neonatal ICU, we created the validation list with up to 30 ICU and 10 neonatal ICU records. The unreported CLABSIs were selected from the screening sample as follows: (1) by targeted pathogens and NICU site; (2) by targeted pathogen and other ICU site; (3) other pathogens and NICU site; and (4) other pathogens and other ICU site. Targeted pathogens include *Candida spp., Torulopsis spp., Enterococcus spp., Staphylococcus aureus, coagulase-negative staphylococcus, Klebsiella spp., E. coli or Pseudomonas spp.*

During the medical chart review, we reviewed up to a total of 20 unique medical records with reported CLABSIs and up to 40 unique medical records with unreported candidate CLABSIs (up to 10 from NICU).

Sample size

Based upon results from the 2009 Oregon CLABSI review, OPHD identified 86 true positives out of 817 positive blood cultures reviewed (CLABSI prevalence, 10.5%). Hospitals reported 76

CLABSIs (9.3%). Thus, to we would need to review at least 123 charts to detect a similar frequency of events with a 95% confidence interval (Open Epi Version 3.01).

Data collection

A letter was mailed to the CEO, Lab Manager, and Infection Preventionist at selected facilities to request a line list of positive, ICU-attributed blood cultures collected between January 1 and December 31, 2012, to be sent to OPHD in Excel format by secure-email.

Requested variables included:

- Facility NHSN ID
- Hospital contact information
- Date of report
- Medical record number
- Name
- Sex
- Date of birth
- Hospital admission and discharge dates associated with blood culture
- Laboratory acquisition number
- Specimen collection date and time
- NHSN attributed unit or location
- Organism species and genus
- Site and source of blood culture (e.g., central line, etc)
- CLABSI status

Once OPHD received the blood culture lists, unique records (MRN + admission date) were identified. Positive blood cultures not reported as CLABSIs were sampled as follows to create the validation list: (1) by targeted pathogens and NICU site; (2) by targeted pathogen and other ICU site; (3) other pathogens and NICU site; and (4) other pathogens and other ICU site. Reported CLABSIs were added to the final validation list, but abstractors were blinded to whether or not the selected record was reported to NHSN as a CLABSI.

Medical record abstraction tool

A retrospective, standardized medical chart review was performed for each medical chart on the validation list (see Appendix) by one of two trained abstractors. Each selected unique medical record underwent three levels of CLABSI validation: (1) *selected blood culture*; (2) *selected infection event* which includes the selected blood culture; and (3) *selected unique medical record* (MRN + date of admission).

We diverged from the CDC CLABSI Toolkit in our method of chart review. Per the original CDC CLABSI Toolkit, the protocol called for a pre-review to identify up to 20 charts with a

central line, after which the charts would be exchanged between abstractors, and the MRAT tool used (p 22, Toolkit). Instead, we reviewed all 40 using only the logic model in the MRAT. If the selected blood culture was not eligible, we did not review it further. However, we did review the entire medical chart for other positive blood cultures to increase our sensitivity to identify unreported CLABSIs. Because of the way most EMRs are constructed, it is very easy to rapidly review all positive blood cultures (e.g., for the outcome) in a selected patient admission; it is more labor intensive to identify if, when, and where a central line was in place (e.g., the risk factor). In addition, following the CDC Toolkit would have led to repeat chart reviews, first to see if the patient had a central line, and second to determine if the selected blood culture met eligibility criteria. Because "present on admission" was not precisely defined in 2012 (e.g., the first 48 hours after admission), most positive blood cultures *were* present on admission, and did not warrant further review. We believe that our adaptations of the method increased sensitivity without increasing effort.

We followed the CDC CLABSI Toolkit medical record abstraction tool (MRAT) to evaluate each *selected blood culture, selected event*, and *selected medical record*. For the *selected blood culture,* Sections 3–5 were skipped and replaced with a selected blood culture review with similar questions as the original Sections 3–5. For the *selected event*, this was reviewed per the original CDC Toolkit protocol. To review *additional* positive blood cultures in the *selected medical record,* we developed a rapid screening tool. Potential CLABSI events identified by the screening tool were reviewed using the MRAT. In this way, each method could be reviewed independently.

Record reviews were performed during on-site visits, unless facility and OHA determined that remote electronic medical record review or CD-ROM copies were equivalent. Each abstractor reviewed half of the charts at a site, and was available for consultation. Difficult cases were summarized and discuss with the CDC support staff (Katie Arnold and Kathy Bridson) to determine final NHSN attribution.

Selected blood culture review

During record review, each abstractor followed the 2012 MRAT to determine whether or not the selected blood stream infection (BSI) was present on admission, was caused by a pathogen or ≥1 matching common commensals, occurred in an eligible ICU location, and in the presence of a central line. If a central line was present at the time of an ICU BSI, abstractors determined whether the BSI was attributable to a primary source using CDC 2012 NHSN HAI Surveillance Protocol criteria (e.g., CLABSI, PNEU1, etc). If the BSI could not be attributed to another source, it was recorded as an ICU CLABSI. Tennessee criteria were used to assist with NHSN HAI classification (CDC CLABSI Toolkit 2012).

Selected infection event

Selected blood culture events were reviewed as per the original CDC Toolkit instructions. This event sometimes included several positive blood cultures. A final determination of the event was made according to NHSN criteria, as above.

Selected unique medical record

After review of the selected blood culture and event, as above, abstractors reviewed the remainder of the unique medical record for other positive blood cultures. Additional positive blood cultures were screened for ICU CLABSI eligibility using a rapid screening tool. If they were eligible (not present on admission, contained a pathogen or ≥1 common commensal, occurred in the ICU in the presence of a central line), they were reviewed using the same MRAT tool.

Reasons for hospitals incorrectly reporting CLABSIs

Records not reported as CLABSIs or those incorrectly reported as CLABSIs were reviewed at arbitration to determine factors which contributed to incorrect reporting (e.g., incorrect location, alternative source, etc).

Denominator data validation

A CDC 2012 standardized surveillance validation survey was administered to the IP staff at each facility. Surveys were administered face-to-face during site visits, or at a mutually convenient time in-person or by telephone if remote electronic medical record review performed. Topics included how the staff determines denominators (e.g., central line days, patient days) and numerators (e.g., CLABSI events), methods of internal validation, resolution of uncertain cases, and NHSN data entry. Three months of denominator data (patient days and central line days during October, November, and December 2012) were requested from each facility to compare to reported NHSN counts. The interviewer verified NHSN locations and health care facility characteristics (total bed size, ICU bed size, and medical school affiliation). Additionally, the interviewer (GB) asked about the facility's progress implementing the new state rule on interfacility transfer.

Inter-rater reliability

We calculated inter-rater reliability between the two main reviewers (VC and GB). The two main reviewers reviewed 20 of the same selected charts at the three largest hospitals (Legacy Good Samaritan, Providence St Vincent's, and OHSU) during in the early, middle, or late phases. At each inter-rater reliability review, discrepancies were reviewed and corrected.

A kappa statistic (Fleiss, for paired raters) of overall inter-rater reliability were calculated comparing the final determination of OHA reviewers and combined facility reporters.

Cost and time

We arranged with facilities to review up to 60 records from facility specific lists of positive blood cultures. We consulted travel maps to minimize travel time. When such methods are available and considered equivalent, we will use remote electronic medical record review, mailed CD-ROMs, or other methods to reduce travel time and costs. The abstractor recorded the start and stop time of each part of the record abstraction (for the selected event and additional events).

Analysis and Follow-Up

Completed MRATs and surveys will be reviewed for completeness and entered into an OPHD electronic database. A summary and post-validation analysis was prepared by OPHD and shared with the participating facilities. Any discrepancies will undergo group adjudication between OPHD and the facility (infection prevention staff, infectious disease staff) in a follow up phone call; CDC consultation will be requested in unresolved cases.

Staff training

All OPHD staff is trained to conduct HIPAA-compliant public health work. In addition, reviewers were trained in NHSN validation techniques through required webinars, case reviews, and review of Patient Safety Component Manual.

Binders containing 2012 NHSN criteria, 2012 Tennessee criteria, and the expanded list of common commensals were provided to each reviewer.

Data management and security

All identifiable data collected as a part of this study was kept confidential. During reviews, line lists, surveys, interviews, and standardized abstraction forms were kept in locked briefcases and in the possession of a study staff member at all times until return to OPHD. At OPHD, they were kept in locked file cabinets maintained by study staff. Collected data were entered into a password-protected internal OPHD database accessible only to study staff. Two years after the data validation project has ended, all confidential information will be destroyed.

Data analysis and reports (Kelly et al., 2008)

The purpose of this grant is to evaluate the 2012 CDC CLABSI Toolkit, provide feedback to the project manager, validate Oregon NHSN ICU CLABSI data, identify unreported CLABSIs, provide facility feedback, and report on our findings.

Data obtained from record abstraction will be matched electronically to cases reported into NHSN by medical record number, date of birth, gender, and collection date.

A CLABSI case is defined as a bloodstream infection occurring in a patient admitted to an ICU or NICU (or within 48 hours of discharge) occurring in the presence of a central catheter without other indentified source. A central line catheter is an intravascular device placed in a major artery or vein emanating from the heart.

An NHSN CLABSI case is defined as a unique entry into the NHSN database by MRN, date of birth, gender, and collection date. CLABSI cases reported by the hospital into NHSN will be compared to the true CLABSI cases determined by OPHD retrospective analysis.

Final CLASBI classifications will be as follows:

(1) True positives: reported to NHSN by hospital and confirmed by OPHD review;

(2) True negatives: not reported to NHSN by hospital and not identified by OPHD review;

(3) False positives: reported to NHSN by hospital and not confirmed by OPHD review; and

(4) False negatives: not reported to NHSN by hospital but identified by OPHD review.

The primary outcome of this study is to determine the percent under-reporting in Oregon and by facility by using different units of analysis: blood culture, event, or medical chart.

Secondary outcomes are (1) sensitivity and specificity of CLABSI reports in Oregon and by facility; (2) estimated rate of CLABSI in Oregon and by facility; (3) kappa between facility and OPHD reviewers; (4) differences by method in time and data collection resources.

Sensitivity and specificity of CLABSI reports among Oregon hospitals will be determined as follows:

Estimated rates of CLABSI in Oregon (and by facility) will be as follows:

Estimated kappa statistic between facilities and OPHD reviewers will be as follows:

X^2 tests will be used to compare sensitivity of CLABSI reporting. X^2, Student t, Fisher exact, and Wilcoxon Rank tests will be used to compare CLABSI cases that were correctly reported with those that were not reported by hospitals. All analyses will be conducted in STATA 13.0 (College Station, TX).

Use of project data

Project data will inform Oregon CLABSI surveillance and the CDC 2012 CLABSI Toolkit. For the former, facility validation on accuracy and completeness of CLABSI surveillance will be shared with each facility and in aggregate state-wide.

Ongoing feedback will be provided to CDC about the validation toolkit during each phase and as a summary report. Specifically, OPHD will provide feedback on the targeted sampling, sampling methodology, medical record abstraction tool, inter-rater reliability, denominator validation and survey. In a final report, we will provide a detailed summary of findings, sampled results, including inter-rater reliability, sensitivity, specificity, positive predictive value, and negative predictive value.

In addition to providing feedback on sampling by proxy using a positive blood culture to define an event, we will evaluate the relative reliability of review of only positive blood cultures and entire medical records.

Interim observations and recommendations

Because all facilities had difficulty identifying positive blood cultures attributable to the ICU but drawn within 48 hours of ICU discharge, we recommend that future validation studies not request positive blood cultures in this time period. In addition, ICU location was a key variable to obtain from facilities because it allowed our research assistant to choose only those positive blood cultures attributable to a validated NHSN ICU location.

Two facilities had initial difficulty retrieving 2012 positive blood cultures from their data system. At least one facility performed a manual review. We also discovered a systematic underreporting bias in another facility: because of a difference between Oregon reporting requirements and Centers for Medicaid and Medicare Services (CMS), some of the hospital's NHSN-mapped ICU locations were not discoverable by the health department; only 8 of the 18 ICU CLABSIs reported to CMS during 2012 were known to OPHD.

We altered the method of chart review from the original CDC 2012 CLABSI Toolkit. See above section on medical chart abstraction for further details and rationale.