Protocol for Validation of Mandatory Reporting of Central Line-Associated Bloodstream Infections, 2009

INTRODUCTION

Objective

The objectives of the Oregon Public Health Division Acute and Communicable Disease Prevention Program (ACDP) in validating the mandatory reporting of central line associated bloodstream infection (CLABSI) data are to:

1. Determine the reliability and consistency of surveillance definitions,
2. Evaluate current surveillance methods used to detect infections,
3. Assess completeness of reporting to the Centers for Disease Control (CDC) National Healthcare Safety Network (NHSN), and
4. Based on the findings of this exercise, provide guidance to hospitals on surveillance definitions, reporting methods, and use of NHSN.

Background

Healthcare-associated infections (HAI) are a significant cause of morbidity and mortality. They are among the top ten leading causes of death in the US, accounting for an estimated 1.7 million infections and 99,000 deaths in hospitals alone in 2002 [i]. The annual cost to hospitals for these HAI was recently estimated at $33 billion. [ii] HAI are not limited to acute care hospitals, but have also been reported in same day surgical centers, dialysis facilities, outpatient ambulatory clinics, and in long-term care facilities, such as nursing homes and rehabilitation facilities.[iii] Hospital stays for methicillin-resistant *Staphylococcus aureus* (MRSA) have more than tripled since 2000 and increased nearly ten-fold between 1995 and 2005.[iv] The CDC's Emerging Infections Program (EIP) invasive MRSA surveillance system estimated that 94,360 invasive MRSA infections occurred in 2005, resulting in 18,650 deaths. [v]

In 2007, the Oregon state legislature passed House Bill 2524 with the intent of creating a mandatory HAI reporting program. The Oregon HAI Reporting Program initially published rules on July 1, 2008, and the National Healthcare Safety Network (NHSN) was chosen as the reporting system to be used for inpatient HAI outcome measures. [vi] Quarterly inpatient reporting to NHSN began January 1, 2009 and includes central line-associated bloodstream infections (CLABSI) in ICUs and three surgical site infections (SSI): coronary artery bypass graft surgery with both chest and graft incisions (CBGB); coronary artery bypass graft surgery with chest incision only (CBGC); and knee prosthesis procedures (KPROs). These infection types were selected based on their public health importance and measurability.

Need for Validation

A method to validate data must be considered in any mandatory reporting system to ensure that HAIs are being accurately and completely reported. In 2008, the New York State Health (NYS) Department reported on their CLABSI data validation process [vii]Their findings indicated that the hospitals reported inconsistent infection data because they interpreted the HAI case definitions differently. Of the 168 CLABSI cases identified by the NYS HAI validation study, 43 (25.6%) had

not been reported by the hospitals to NHSN. Of the 921 non-CLABSI cases identified by the NYS HAI validation study, 44 (4.8%) had been reported by the hospitals to NHSN as a CLABSI case.

More recently, the Connecticut Department of Public Health conducted a validation project of all CLABSI reported from ICU patients of thirty acute care hospitals in the fourth quarter of 2008. Of the 49 CLABSI cases identified by the Connecticut DPH validation study, 26 (53.1%) had not been reported by the hospitals to NHSN. Of the 427 non-CLABSI cases identified by Connecticut DPH, 4 (.09%) had been reported by the hospitals to NHSN as CLABSI cases.

METHODS

Facility selection

In February-April 2010, ACDP staff pilot tested validation methods at a sample of acute care facilities. A brief report on this pilot included analysis of the data collected with a focus on the time and other resources required, challenges encountered in accessing laboratory data, and issues presented by interactions with stakeholders. Based on the findings of this pilot, OPHD modified the validation protocol in April-May 2010. The validation will be implemented in all Oregon acute care facilities with ICUs between June 2010 and September 2011.

Selection of patients within hospitals

A list of eligible patients within each qualifying Intensive Care Unit will be determined by obtaining microbiology laboratory records of those ICU patients who had a culture positive for a bloodstream infection, up to 48 hours after ICU discharge, during the study period. The study period for the pilot project will be January 1 – December 31, 2009; depending on the findings of the pilot project and the expected number of cases, a shorter study period may be selected for larger hospitals.

A random sample from the list of eligible patients will be selected. Depending on the expected number of cases, the size of the hospital, and the reported number of cases, a minimum number of patient charts that yields a sample of sufficient size will be identified, and charts will be sampled accordingly.

Sample size

Our expected sample size is based on the findings of Connecticut DPH's 2008 validation study, which identified 49 true positive CLABSI out of 476 bloodstream infections (CLABSI prevalence of 10.3% among blood culture- positive patients) and found that hospitals had reported 27 CLABSI (5.7% of blood culture-positive patients). To detect a difference of 20% (between reported positive and true positive CLABSI) at significance level 0.05 and 80% power, we anticipate a total minimum sample size of 59 medical records.

To examine the potential of false positives we will examine records for all reported CLABSI at each facility. We will also randomly sample 60 records that were not classified as CLABSIs in order to identify false negatives. Both lists will be combined and randomly sorted so that validators are blind as to which cases were reported as CLABSIs. As the pilot project demonstrated that realistically 17 records was the maximum per day per person and he maximum number of validators is 4, due to practicality a maximum of 68 records will be reviewed for any facility (one full day with

4 validators). If a facility has less than 68 records with positive cultures then all records will be reviewed.

Data collection

A letter will be mailed to the Laboratory director of Hospital laboratories in which they will be asked to provide lists of patients admitted to the ICU during the study period who also had a culture positive for a bloodstream infection up to 48 hours after ICU discharge. We will also request that the following information for each culture be included in the laboratory reports sent to OPHD ACDP:

- Hospital Name (for epidemiology)
- Hospital number: unit or medical record number (for hospital identification & de-duplication)
- Date of Birth (for hospital identification, epidemiology & de-duplication)
- Sex (for epidemiology)
- Collection date (for de-duplication)
- Patient Unit Location on collection date (for validation)
- Site/source of blood collection: ie. Central line, antecubital/peripheral, catheter tip, etc. (for inclusion/exclusion criteria)
- Date and time found positive (for validation)
- Species of isolate (s) (for validation)

Once the list of laboratory reports has been received by ACDP, the medical records department will receive a letter requesting that the medical records of eligible patients be made available. Some facilities have electronic medical records and a special password might be needed to access the patient's record. This issue will be resolved at the time the facility is notified of the data validation project. It is anticipated that the chart reviews will occur between June 2010 and September 2011.

A retrospective chart review methodology will be used. The chart abstractor(s) will be blinded as to whether a healthcare associated infection was present or not, and whether the case was reported to NHSN. Medical records and hospital admission data will be reviewed using a standardized form (appendix A) to determine if a central line-associated bloodstream infection occurred within the study timeframe, whether the infection was hospital associated and related to an admission in an eligible ICU, and which NHSN criteria were used to meet case definition. If it is determined that a central line was in place on the date of the positive blood culture, then the audit will continue, and NHSN data and supplemental information will be collected. All definitions used for determining the presence of an infection will follow the CDC NHSN Surveillance Protocol[viii].

Analysis and Follow Up

Any discrepancies found by the validators will be discussed in a follow up phone call or in person meeting. The meeting will be composed of infection control faculty at the audited facility, including relevant infection preventionists and infectious disease physicians as well as OPHD validation staff, including validators as well as a physician with infectious disease experience. Any questionable case that needs clarification regarding NHSN eligibility will be reviewed with CDC NHSN for final determination of meeting NHSN CLABSI case criteria. Data from the standardized data collection form will be entered into an electronic database at OPHD ACDP.

Validation of denominator data

Collection of patient-days and central line-days for calculation of Blood Stream Infection (BSI) rates requires the daily counting of patients in the ICU and the ICU patients with $\geq$ 1 central line of any type. Two options will be employed to determine whether the denominator data are collected correctly. They include:

1. A visit to the ICU participating in the surveillance to review who, what time of day, and how lines are counted;
2. A review of the monthly report forms where staff collects daily counts of new patients and lines. During this review there may be qualitative evidence whether these data are collected daily or not. The absence of records for any length of time used to count line days (daily logs should be available for at least the current or past month) is suggestive of inappropriate surveillance practices.

Using a standardized questionnaire, HAI staff will interview the Infection Preventionist or the ICU staff member with reporting responsibilities.

Staff training

At the pilot sites, medical record review will be performed by ACDP staff or contractors, who have, at a minimum completed self-directed training in NHSN data entry, management, and analysis through webinar sessions (all required modules) and review of the Patient Safety Component manual.

Data management and security

All information and identifiers (both electronic and hard copy) will be kept confidential. During the on-site hospitals visits and chart reviews, validation data will be abstracted onto standardized reporting forms. Paper copies of abstracted data will be kept in locked briefcases and not left unattended in vehicles. In situations in which ACDP staff are unable to return to the Portland State Office Building on the same day as the data are collected, all hard copies will be sent via US mail to ACDP. Once returned to ACDP, all paperwork will be maintained in locked file cabinets in ACDP. The data that are gathered on these forms will be entered by ACDP staff into a secure electronic database, which is password-protected. Two years after the data validation project has ended, all confidential information will be destroyed.

Data analysis and reports

The data from the validation study will be electronically matched to the dataset containing the NHSN CLABSI cases reported by the respective hospital for the same time period. The variables that will be used to match the cases are medical record number, date of birth and gender. The NHSN CLABSI cases reported by the hospital surveillance system will be compared to the true CLABSI cases determined by the retrospective analysis. The dataset match will yield cases that fall into 4 categories:

1. Cases reported by hospital to NHSN and identified by ACDP staff as CLABSI cases (“true positives”)
2. Cases not reported by hospital and ruled out as CLABSI cases by ACDP staff (“true negatives”)

3. Cases reported by hospital to NHSN but ruled out as CLABSI cases by ACDP staff ("false positive")
4. Cases not reported by the hospital but identified as CLABSI cases by ACDP staff ("false negatives")

Use of project data

The purpose of the data validation project is to monitor the accuracy of data submitted by hospitals to NHSN, and assess the hospital's surveillance system and use of NHSN definitions. Any unreported case(s) will be analyzed individually to determine why the case(s) went undetected and what action is necessary to correct the problem. ACDP staff will review and follow-up with each hospital that have been identified as having reported data inaccuracies or data irregularities. Cases determined to have been reported but not meeting NHSN criteria will also be reviewed and discussed with hospital surveillance personnel to correct any misinterpretation of criteria. The reviews with hospital staff will serve to provide on-site education on the definitions, surveillance mechanisms and use of NHSN. The final report on this validation study will present all facilities' data in aggregate form.

Participants

ACDP Participants:
Ann Thomas, MD, MPH, Principal Investigator
Paul Cieslak, MD, MPH, Infectious Disease Consult for project
Zintars Beldavs, MS, HAI Research Coordinator
Margaret Cunningham, MPH, HAI Epidemiologist
John OH, MD, MPH, EIS Officer
Steve Moore, Public Health Nurse
Jennifer Tujo, Infection Preventionist

Appendix A

Date of Hosp Adm: _____ **Hosp Disch/Exp Date:** _____ **Adm Unit:** _____

ICU Adm Date(s)/Time(s): _____ **ICU Disch Date(s)/Time(s):** _____

MR #: _____ **Age:** _____ **Sex:** _____ **Previous Admission:** _____

Admitting Diagnoses:

Discharge / Final Diagnoses:

Signs/ symptoms of infection:

Central line present at time of (+) culture? ☐ YES ☐ NO
Pt in ICU at time of (+) culture or <48h prior**? ☐ YES ☐ NO**
If YES to both, complete "NHSN criteria for LCBI" section below.

NHSN CRITERIA for LCBI (Laboratory-confirmed bloodstream infection)

☐ Criterion 1

Patient has a recognized pathogen cultured from one or more blood cultures (□ y □ n) **AND**
organism cultured from blood is not related to an infection at another site (□ y □ n) .

☐ Criterion 2

Patient has at least one of the following signs/ symptoms:
□ fever (>38º C), □ chills, or □ hypotension, **AND**
symptoms and positive laboratory results are not related to an infection at another site (□ y □ n) , **AND**
common skin contaminant* is cultured from **two or more** blood cultures drawn on separate occasions (□ y □ n).

☐ Criterion 3

Patient <1 yr old has at least one of the following si/s:
□ fever (>38ºC), □ hypothermia (<37º C), □ apnea, or
□ bradycardia, **AND**
common skin contaminant* is cultured from two or more blood cultures drawn on separate occasions (□ y □ n).

*Common skin contaminants include

- diphtheroids (*Corynebacterium* spp.)
- *Bacillus* (not *B. anthracis*) spp.
- *Propionibacterium* spp.
- coagulase-negative staphylococci (including *S. epidermidis*)
- *Aerococcus* spp.
- *Micrococcus* spp.
- *viridans* group streptococci

UNDERLYING CONDITIONS: check all that apply

□ DM
□ CHF
□ CAD
□ any cancer
□ other immunosuppressive condition

Notes:

Reporting instructions:

a. Purulent phlebitis confirmed with a positive semi-quantitative culture of a catheter tip, but with either negative or no blood culture, is considered a CVS-VASC, not a BSI.
b. Report organisms cultured from blood as BSI–LCBI when no other site of infection is evident.

Notes:

1. Hypotension is defined as below 90/60, recorded as hypotension in record, **or** other signs strongly indicate hypotension on record.
2. Bradycardia (for criteria 3) is defined at below 100 in infants, recorded as bradycardia, or other signs strongly indicate bradycardia on record.
3. Two draws must be within 2 days and same organism for 2 and 3.

	Central Line Type	Location of Placement (ER, OR, etc)	Date Placed	Time Placed	Date Discontinued	Time Discontinued
CL#1						
CL#2						
CL#3						
CL#4						

BLOOD CULTURES:

DATE	TIME	SITE	ORGANISM

OTHER CULTURES:

DATE	TIME	SITE	ORGANISM

TEMPERATURE AND WBC

Date	Temp	WBC		Date	Temp	WBC

Blood Pressure and Heart Rate if Below Criteria

Date	Time	BP	HR

Does this case meet NHSN case definition for CLABSI attributable to ICU? □ YES □NO

Notes:

CASE AUDITED BY: _____ DATE: _____
Reviewed with facility staff (name and title): _____ DATE: _____

Was case entered by hospital into NHSN?___ Yes ___ No NHSN EVENT ID # : _____
If not, explain: _____

[i] Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating healthcare-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160-166.

[ii] Scott R, Douglas. The direct medical costs of healthcare-associated infections in US hospitals and the benefits of prevention. March 2009. http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf

[iii] Thompson ND, Perz JF, Moorman AC, et al. Nonhospital healthcare-associated hepatitis B and C virus transmission: united States, 1998-2008. Ann Intern Med 2009;150:33-9.
[iv] Elixhauser A and Steiner C. Infections with methicillin-resistant Staphylococcus Aureus (MRSA) in U.S. hospitals, 1993–2005. AHRQ Healthcare Cost and Utilization Project Statistical Brief 2007; 35:1-10.
[v] Klevens RM, Morrison MA, Nadle J, et al. Invasive methicillin-resistant *Staphylococcus aureus* infections in the US. JAMA 2007;298:1763-1771.
[vi] 7 The text of HB 2524 can be accessed at: http://www.oregon.gov/OHPPR/docs/HCAIAC/Reporting/HB_2524.pdf
[vii] New York State Hospital-Acquired Infection Reporting System: Pilot Year-2007. Report June 30, 2008.
[viii] 13. The Centers for Disease Control, National Healthcare Safety Network (NHSN) Manual. http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/NHSN_Manual_PatientSafetyProtocol_CURRENT.pdf