Validation of the surveillance and reporting of central line-associated bloodstream infection data to a state health department

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Background: The primary goal of health care-associated infection reporting is to identify and measure progress towards achieving the irreducible minimum number of infections. Assessing the accuracy of reporting data using independent validation is critical to this goal. In January 2008, all 30 acute care hospitals in Connecticut began mandatory reporting of central line-associated bloodstream infections (CLABSI) to the National Healthcare Safety Network (NHSN) system.

Methods: A state nurse epidemiologist performed a blinded retrospective chart review for NHSN-reported CLABSI based on positive blood cultures from October to December 2008.

Results: Of 476 septic events, 48 met the NHSN CLABSI definition, of which 23 (48%) had been reported to NHSN. Concordance of non-CLABSI events was 99% sensitive. Components of the case definition that were a source of misinterpretation included the following: NHSN surveillance definition of primary and secondary bacteremia (45%), CLABSI rules (19%), CLABSI terms (10%), and differentiation between laboratory-confirmed bloodstream criterion 1 (recognized pathogen) and criterion 2 (skin contaminant) (13%).

Conclusion: The validation study identified >50% underreporting of CLABSI, most related to misinterpretation of components of the NHSN definition. Continued validation and training will be needed in Connecticut to improve completeness of reported health care-associated infection data and to assure that publicly reported data are valid.

Key Words: Health care-associated infections; central line-associated bloodstream infections; data validation; National Healthcare Safety Network Surveillance system.

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Increasing public awareness of health care-associated infections (HAIs) has led to a call for measurement and public disclosure of health care infection rates in the United States.[1] Many states have passed laws requiring reporting of facility-specific HAI data to state health departments.[2,3] Currently, 29 states have implemented state-mandated HAI public reporting systems, and that number is expected to grow.[4] Through the US Department of Health and Human Resources, competitive grants funded by the American Recovery Act are available for all states to create or expand state-based HAI prevention and surveillance efforts.[5]

Many of the states that have established mandatory HAI reporting systems have chosen to use the US Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).[6,7] Through the use of the NHSN, the CDC has created a data infrastructure that allows hospitals to voluntarily collect and input data using a uniform set of surveillance definitions and to compare their HAI rates with benchmarks derived from the data submitted by all participating hospitals. NHSN participation requires health care facilities to make a commitment to follow the NHSN data collection protocols and training requirements.

The NHSN system requires trained and knowledgeable infection preventionists (IP) with dedicated time to conduct HAI surveillance. Ever-increasing complexities of the role and the scope of IP responsibilities have led to the increasing challenges of prioritizing work flow, enhancing skills, and maintaining competencies.[8] Gathering all the information needed to risk adjust and calculate infection rates and make them potentially comparable across hospitals requires substantial time and resources to compare hospital data. Even

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subtle differences in the interpretation of the case definitions can introduce measureable variation in HAI rates. Although the CDC is expanding its training and user support for the NHSN, feedback from NHSN participants indicates ongoing misinterpretation of the sometimes complex surveillance definitions.[9] Recently, the New York State Health Department reported on their central line-associated bloodstream infections (CLABSI) data validation process.[10] Their findings indicated that the hospitals reported inconsistent infection data because they interpreted the HAI case definitions differently and have now integrated ongoing validation audits into their New York State Health Department HAI program activities.

In Connecticut, a statewide HAI reporting system was mandated in 2006 with the 30 acute care hospitals required to formally enroll in the NHSN system and begin reporting data in 2008 on the NHSN CLABSI module from 1 intensive care unit (ICU) in each hospital. Four of these hospitals had previously participated in the NHSN for more than 5 years. Initial NHSN training included NHSN webinar training followed by a Connecticut Department of Public Health (DPH) HAI training program for IP staff 8 months after the CLABSI reporting began. To determine the reliability and consistency of the application of NHSN surveillance definitions to CLABSI reporting in Connecticut, a validation study was conducted on data collected during the fourth quarter of 2008 after all initial training was complete.

METHODS

Retrospective validation of CLABSI

From January 2009 through April 2009, a retrospective medical record review and a standardized interview with IP staff were conducted at the 30 Connecticut acute care hospitals to identify health care-associated central line infections in ICU patients. A list of blood cultures from the ICU patients reported positive from October 1, 2008, through December 31, 2008, was used to select the medical records for review. CDC definitions and NHSN methodology were used for conducting the surveillance for hospital-associated CLABSI.[5,11] A CLASBI was defined as a hospital-associated, primary bloodstream infection (BSI) in a patient who had a central line in place within the 48-hour period before the development of a BSI and was not related to an infection at another site (Table 1). The reviewer, an NHSN-trained nurse microbiologist (L.B.) with 9 years experience in infection control surveillance in National Nosocomial Infection Surveillance System hospitals (NNIS; the precursor to NHSN), performed the primary chart review and was blinded to the infection report status of the patient. All identified and reported CLABSI cases were also reviewed by an NHSN-trained hospital epidemiologist with 35 years experience (R.G.). The study received ''Exempt Status'' review from the DPH Internal Review Board on December 11, 2008.

The medical record of each selected patient was reviewed, and clinical data and laboratory and radiology reports were examined to determine whether a CLABSI occurred within the study time frame, whether the infection was hospital-associated and related to an admission in an reporting ICU, and which NHSN criteria were used to meet the case definition. If it was determined that a central line was not in place on the date of the positive blood culture, the patient was excluded from further review. Data collected included demographic, risk factor, clinical, treatment, and central line insertion maintenance practices. All positive blood cultures that occurred either while patients were in the ICU (or within 48 hours after transfer from it) were subcategorized as a CLABSI, a secondary BSI, a primary BSI, or a contaminant, using NHSN surveillance definitions. The agreement between a CLABSI assessed to be present by the reviewers and those entered into the NHSN database was determined. Discrepant cases were discussed with the hospital IP, and possible reasons for misclassifications were recorded.

Validation of surveillance denominator data

The NHSN methodology for the collection and reporting of central line denominator data requires the daily counting of patients in the ICU and of ICU patients with $\geq$ 1 central line of any type.[6] The reporting of patient-days and central line-days is used for the calculation of CLABSI rates and device utilization rates. In every hospital, the IP responsible for the reporting of surveillance denominator data was interviewed using a data collection form that included questions on the process for collecting central line data, methods of surveillance, interpretation of case definitions, and use of central line prevention practices.

Data analysis

Patients with positive blood cultures were determined to either have a CLABSI or No-CLABSI. All CLABSI or No-CLABSI cases were designated as concordant or discordant depending on the agreement between the reviewers and the hospital-reported NHSN cases. Using the reviewers' classification of infection as the ''gold standard,'' the sensitivity, specificity, positive predictive value and the negative predictive value of the CLABSI surveillance data submitted to the NHSN by hospitals were determined. Reasons for failure to recognize a CLABSI, or to falsely report one, were identified and classified according to which components of the case definition were misinterpreted. Surveillance data were stored in a secure server

Table 1. National Healthcare Safety Network criteria for defining laboratory-confirmed bloodstream infection criteria 1 and 2 and clinical sepsis

	LCBI criterion 1	LCBI criterion 2	CSEP criterion*
Age	Any age, including ≤1 yr	Any age, including ≤1 yr	Only used for: Neonates <30 daysInfants <12 mo
Signs and symptoms	None	Pt has at least 1: Fever (>38°C), chills, hypotension	Pt has at least one:Fever (>38°C rectal), hypothermia (<37°C rectal), apnea, or bradycardia
Pathogen	Recognized pathogen	Common skin contaminant	No culture or no growth
Number of positive blood cultures	One	Two or more	Blood culture not done
Physician clinical diagnosis	Not allowed	Not allowed	Physician institutes treatment for sepsis

LCBI, laboratory-confirmed bloodstream infection; *CSEP*, clinical sepsis; *Pt*, patient.
*Although a valid NHSN definition during the study, effective January 1, 2010, CSEP is no longer a NHSN criterion.

Table 2. Comparison of central line associated bloodstream infections reported by Connecticut hospitals and the Connecticut Health Department reviewers

	CT hospital reports to the National Healthcare Safety Network		
CT DPH reviewers	**CLABSI**	**No-CLASBI**	**Total**
CLABSI	23	25	48
No-CLABSI	4	424	428
Total	27	449	476

CLABSI, central line-associated bloodstream infections; *CT*, Connecticut; *CT DPH*, Connecticut Health Department.

database, and statistical analysis was performed with SAS statistical software, version 9.1 (SAS Institute Inc, Cary, NC).

RESULTS

CLABSI chart review

DPH conducted medical record reviews over a 35-day time period in 30 adult ICUs and 3 pediatric ICUs. A total of 770 positive blood cultures from 410 patients (395 adult and 15 pediatric) were reviewed. Of the total number of positive blood cultures, 476 septic events were identified. For the adult ICU patients, 158 patients (40%) had a central line in place at the time of the positive blood culture, and, of those, 43 (28%) met NHSN criteria for a CLABSI. For the pediatric ICUs, 14 patients (93%) had a central line in place, and, of those, 3 (21%) met the NHSN criteria for a CLABSI. Two adult patients had 2 separate HAI CLABSI events, resulting in a total of 48 CLABSI in 46 patients.

Of the 48 hospital ICU-associated CLABSI identified in the chart review (Table 2), 23 (48%) had been reported to NHSN by hospitals as a CLABSI, yielding a sensitivity for hospital NHSN reported CLABSI of 48%. Twenty-five of the 48 infections (52%) had not been reported to NHSN.

The majority of the information recorded by hospitals as a non-HAI was consistent with the reviewers. Of the 428 No-CLABSI events identified, there was agreement on 424 (99%) of the events identified by the hospital NHSN reports, yielding a specificity of 99%. There was disagreement on 4 No-CLABSI cases that had been reported as CLABSIs to NHSN but were identified by the reviewers as either a secondary bacteremia or attributed to a hospital location other than an ICU and therefore not a reportable infection. The overall positive predictive value for the hospital reports was 85%, and the overall negative predictive value was 94%. The 48 HAI CLABSIs identified by the reviewers yielded an overall infection rate of 3.51 per 1,000 central line-days (medical ICU, medical-surgical ICU, pediatric ICU infection rates of 5.52, 2.83, 4.19 per 1,000 central line-days, respectively), 78% higher than the infection rate of 1.97 per 1000 central line-days reported by the hospitals to the NHSN during the study time frame (medical ICU, medical-surgical ICU, pediatric ICU infection rates of 2.60, 1.82, 1.40 per 1,000 central line-days, respectively).

Thirteen (43%) hospitals were responsible for the 25 infections not reported and 4 (13%) hospitals for the false positives. Of those hospitals that had misidentified the hospital-associated CLABSI, 3 were experienced NHSN hospitals before the state reporting mandate. Experienced NHSN hospitals missed the identification and reporting of 40% of the discordant CLABSI cases.

CLABSI surveillance criteria

The discordant cases were reviewed against the concordant infections to determine whether 1 of the 2 surveillance criteria for CLABSI had been a particular

Table 3. Results of the Connecticut Health Department validation audit of central-line associated bloodstream infections by the National Healthcare Safety Network CLABSI Surveillance Criteria

	Connecticut Health Department Validation Results		
	Concordant CLABSI (n = 23), n (%)	Discordant CLABSI (n = 25), n (%)	Total CLABSI (N = 48), n (%)
LCBI criterion 1	15 (65)	19 (76)	34 (70)
LCBI criterion 2	8 (35)	6 (24)	14 (30)
CSEP*	0	0	0
Total	23 (100)	25 (100)	48 (100)

CLABSI, central-line associated bloodstream infections; *CSEP*, clinical sepsis; *LBCI*, laboratory-confirmed bloodstream infection.
*Although a valid National Healthcare Safety Network definition during the study, effective January 1, 2010, CSEP is no longer a National Healthcare Safety Network criterion.

problem: laboratory-confirmed BSI, criteria 1 (LCBI 1), also known as the ''Recognized pathogen'' category requiring only 1 positive blood culture with no clinical signs or symptoms, or criteria 2 (LCBI 2), also known as the ''Common skin contaminant'' that requires 2 or more blood cultures drawn on separate occasions and at least 1 sign or symptom: fever (>38°C), chills, or hypotension. However, there was little difference in the classification of surveillance definitions for the CLABSI reported between the reviewers and the NHSN hospital reports (Table 3). The DPH and NHSN reports identified 65% and 76%, respectively, of the CLABSIs as (LCBI 1). Within the discordant LCBI criteria 1 category, 53% of the CLABSIs met the case definition based on 1 positive blood culture. Almost one third of the concordant and discordant CLABSIs were identified as LCBI criteria 2 (LCBI 2).

CLABSI microbiologic data

The overall distribution of bacterial pathogens between the concordant and discordant infections was not statistically different ($P > .05$). Of those pathogens associated with CLABSI LCBI 1, 47% of the microorganisms were *Enterococcus* sp, with vancomycin-resistant enterococcus (VRE) accounting for 24%. Twenty-four percent of the LCBI 1 pathogens were *Staphylococcus aureus* with methicillin-resistant *Staphylococcus aureus* accounting for a small percentage of the infections (5%). The only microorganism identified in LCBI 2 was *Staphylococcus epidermidis*, accounting for 32% of the infections.

CLABSI central line data

Of the 23 concordant CLABSIs identified by the hospitals and the reviewers, the average length of time for presence of a central line was 20.8 days. Of the central line sites present at the time of infection, 35%, 26%, 30%, and 9% were femoral, jugular, peripherally inserted central catheter, and subclavian lines, respectively. Compared with these, the 25 discordant CLABSIs only differed by the average length of time for the presence of a central line (8.5 days).

Table 4. Application and interpretation of discordant central line-associated bloodstream infection cases by National Healthcare Safety Network surveillance definition category

	Connecticut Health Department Validation Results		
Area of misinterpretation	Discordant LCBI 1 (n = 19) n, (%)*	Discordant LCBI 2 (n = 6) n, (%)*	Over-reported CLABSI (n = 4) n, (%)
1. Surveillance vs clinical definition	12 (56)	2 (20)	2 (50)
2. LCBI 1 vs LCBI 2	1 (5)	3 (30)	0
3. CLABSI rules†	2 (10)	4 (40)	0
4. CLABSI terms‡	2 (10)	1 (10)	1 (25)
5. Not identified	4 (19)	0	1 (25)
Total	21 (100)	10 (100)	4 (100)

LCBI, Laboratory-confirmed bloodstream infection; *LCBI 1*, recognized pathogen category requiring only 1 positive blood culture; *LCBI 2*, common skin contaminant category requiring 2 or more blood culture drawn on separate occasions.
*Cases involved more than 1 area of misinterpretation.
†CLABSI rules are defined as "Minimum Time Period Rule, Patient Transfer Rule, Location of Attribution Rule, Two or more Blood Culture Rule, Sameness of Organism Rule, 80% Rule."
‡CLABSI terms are defined as "Types of Central Lines, Location of Devices, and Definition of Infusion."

Misinterpretation of CLABSI surveillance components

The reviewers identified several areas where the IPs experienced difficulties in interpretation of the NHSN CLABSI definition. These results are summarized in Table 4. Of the 19 LCBI 1 discordant cases, only 2 involved more than 1 area of misinterpretation, whereas 4 of the 6 LCBI 2 cases involved multiple areas. In many of the discordant cases, 63% LCBI 1, 33% LCBI 2, and 67% over-reported; the IPs had problems distinguishing between a primary CLABSI and secondary case of BSI. In 50% of the LCBI 2 cases and 33% of the over-reported cases, the IPs were uncertain how to interpret the positive microbial culture and identification of LCBI 1 (recognized pathogen) and LCBI 2 (skin contaminant). A third area of misinterpretation involved the knowledge of the ''CLABSI Rules'': surveillance definitions of time periods and hospital locations used to determine a CLABSI.[6] Problems applying these ''Rules'' such as the ''Minimum Time Period Rule, the Patient

Transfer Rule, the Location of Attribution Rule, the Two or more blood cultures drawn on separate occasion Rule, the Sameness of Organism Rule and the 80% Rule'' most commonly occurred among the LBCI 2 discordant cases with many IPs not understanding the Minimum Time period rule. Previously, many IPs have used 48 hours as the time interval before onset of infection. Misclassification using the definition of a primary BSI related to the presence of a central line or ''CLABSI Terms'' (ie, infusion, types of central lines, location of devices) was minimal, involving only 10.5% of the LCBI 1 cases. Surprisingly, in 21% of the discordant LCBI 1 cases, there was no apparent reason for the misidentification of the CLABSI, other than there was a lapse in the surveillance system, and the case was not reported.

Collection of central line-day and patient-day data

As part of the data validation review, IP staff in all 30 hospitals were interviewed to evaluate the hospital's methods for conducting HAI surveillance. Although there are various data sources that hospitals may use for the collection and monitoring of HAIs, the most frequently reported case detection method from all 30 hospitals was follow-up of positive blood cultures (100%), followed by ICU rounds with unit staff (60%). One third of the hospitals reported using an electronic clinical data reporting system.

Hospital IP staff were also interviewed to determine whether consistent methods and definitions were applied to the collection of patient-days and central line-days. The interviews identified that, in 80% of the hospitals, someone other than the IP collects the daily patient-day and central line-day counts. In those hospitals with other staff collecting patient-/central line-day data, 20% could not report what time of day the data were collected, and 20% could not tell how patients with multiple lines were counted. In 3 hospitals, the staff that collected central line data were not able to identify the types of central lines.

DISCUSSION

The findings of this study suggest that there were under- and over-reporting of central line-associated infections to the national surveillance system. This variation in reporting accuracy was similar to what the New York health department found.[10] Although an important potential reason for having a less than fully sensitive surveillance system is that participants may fear the consequences of detecting high infections rates,[12] these results show that the main reason for underreporting was the misinterpretation of surveillance definitions. In this data validation review, the discrepancies in diagnosing CLABSI were related to several areas regarding the misinterpretation of NHSN definitions.

The first area of misinterpretation involved the NHSN surveillance definition versus the clinical definition. In this category, IP and physicians were uncertain regarding the interpretation of the NHSN primary and secondary bacteremia definition. Many of the discordant cases (55%) involved the clinical diagnosis of secondary bacteremia in the absence of a documented HAI at another site. During the structured interviews with IP staff, it was identified that, in many of the hospitals (50%), the infectious disease (ID) specialist, although not trained in NHSN surveillance and methodology, made the final decision on identifying and reporting a CLABSI. In addition, a review of the NHSN surveillance protocol for case finding does not specifically address the strict application of surveillance definitions over clinical judgment in differentiating primary and secondary bacteremias. Perhaps it should, which would help support the IP decision to report CLABSIs.

The second area of misinterpretation involved the differences between the NHSN criteria for LCBI criteria 1 and 2, accounting for 16% of the missed CLABSIs. Explanations for underreporting and misclassifying infections were related to uncertainty on what microbial pathogens are considered a NHSN-defined recognized pathogens or common skin contaminant microorganisms. NHSN has provided a limited list of what they consider to be recognized pathogens or common skin contaminants. A comprehensive list of the NHSN-defined pathogens and contaminants could be very useful and eliminate much of the uncertainty for the IPs.

The third area of misinterpretation involved the ''NHSN CLABSI Rules.'' Many of the misclassified CLABSI cases (24%) involved 1 or more misinterpretations of what could be viewed by IPs as minor, insignificant rules. Surprisingly, the majority of the CLABSI cases involved the proper application of at least 1 of these ''minor'' NHSN rules. Several hospitals reported that positive blood cultures drawn in the Emergency Department were not investigated for HAI infection because it was assumed that the infection was ''Present on Admission.'' The Minimum Time Rule and Location of Attribution Rule were the NHSN surveillance criteria that needed to be correctly interpreted and applied for case finding in Emergency Department-drawn blood cultures. For NHSN case finding, review of both the microbiology reports and patient charts is essential, although the NHSN protocol for case finding does not emphasize this detail. In addition, several discordant cases involved misapplication of the ''Two or More Blood Culture Drawn on Separate Occasion Rule'' to LCBI 2 case findings.

The fourth area of misinterpretation involved the ''NHSN CLABSI Terms: the definition and types of

central lines.'' Despite appearing to be straightforward definitions, the discordant cases in this category (12%) highlighted the variations in interpretations of these definitions, among them, classification of central lines. It became clear after discussion with IP staff that the types of central lines are not well defined, an important consideration for case finding and the collection of denominator data.

In the final group of discordant cases (19%), no obvious reason was identified for missing the CLABSIs. Theses cases might have been missed because of weaknesses in case finding or may have been a reporting oversight because of increasing demands on the IP's time.

Despite the fact that all the hospitals received baseline NHSN and DPH training and that several were experienced NHSN hospitals, these findings illustrate the limitations of the current level of NHSN training and complexity of surveillance definitions. A recent study on the reproducibility of the NHSN CLABSI definition in ICUs showed that overall concordance with the gold standard was 57%, and the reproducibility of the LCBI 1 case definition was relatively poor, with agreement on 52.8% of the cases.[13] A case definition that can be easily applied by IP staff and supports the differentiation between primary and secondary causes of BSI must be developed to ensure accurate and reproducible numerator data.

This study also highlights the need for enhanced training of all IP staff involved in the surveillance and reporting of HAI. Specific educational modules focusing on the complex areas of the definitions, along with the credentialing of staff, similar to the education modules developed for tuberculosis outreach workers, may improve the reliability and consistency of the data.[14] Recognizing the importance of such training, a recent California Department of Public Health law requires that all physicians designated as hospital epidemiologists or infection control committee chairpersons receive formal training and credentialing by the (CDC), the Society for Healthcare Epidemiologists of America, or some other recognized professional organization in infection surveillance, prevention, and control.[15] The law also requires an official training program for IP professionals and other hospital staff.

An important question raised during this study is whether the NHSN LCBI 1 surveillance definition is able to accurately differentiate between bacterial contamination of the catheter, bloodborne seeding from a distant focus, and clinically significant infections. The LCBI 1 definition requires only 1 positive blood culture, no clinical signs or symptoms, and the absence of a documented HAI at another site. Of the 34 LCBI 1 cases identified in this review, 62% met the case definition based on 1 positive blood culture. Determining the likelihood of a true bacteremia can be challenging. To differentiate transient bacteremia from contamination, several studies recommend that at least 2 sets of blood cultures be obtained at the same time.[16] The presence of only 1 positive set among at least 2 sets drawn at the same time or from several cultures drawn over a period of time may be indicative of bacterial contamination or transient bacteremia. Additional research is necessary to strengthen the scientific basis for the acquisition of health care-associated pathogens, in particular, effective strategies for the detection of CLABSIs and for the differentiation of CLABSI from other bacteremias.

This study has several important limitations. The ''gold standard'' for comparison was based in part on the interpretation of the definitions by 2 individuals: an experienced and NHSN-trained IP and an experienced and NHSN-trained hospital epidemiologist. A different team of validators might have interpreted some information differently. This study raises questions about the accuracy of denominators used to calculate rates but was not designed to systematically determine central line-days.

CONCLUSION

A validation study conducted over 3 months found more than 50% misclassified CLABSI in Connecticut, despite all hospitals having participated in NHSN training and using the same written case definitions. Agreement in the classification and reporting of no-CLABSI was 99%. As more states implement mandatory reporting of HAIs, it is important for the accuracy of the reporting systems to be fully evaluated and that states have a validation component to their HAI program. With the projected growth of the NHSN, it is essential that future trainings consider the problems identified through this validation study. Enhanced NHSN instructions, definitions, and trainings will likely contribute substantially to improved data quality. It is important that state HAI reporting systems include ongoing validation audits and continuous training for all surveillance personnel.

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