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Major article

Validation of the surveillance and reporting of central line-associated bloodstream infection denominator data

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Background: While the main focus of validating central line-associated infections (CLABIs) has been applying strict definitions to identify cases, assessing the denominator counts has received less attention. This study evaluates the accuracy of the reporting of CLABSI denominator patient-day (PD) and central line-day (CLD) counts to the National Healthcare Safety Network (NHSN) system in one state.

Methods: The Connecticut Department of Public Health (CT DPH) performed a blinded retrospective chart review on the collection of CLABSI PD and CLD on 9 selected days during the fourth quarter of 2009 from 23 acute care hospitals.

Results: Overall, 1,988 intensive care unit patient charts were reviewed. Comparison of hospital and CT DPH counts identified over-reporting by 300 PD (17.2%) and 200 CLD (21.7%) with 17 hospitals (74%) collecting data manually. PD manual collection methods were more accurate than electronic methods ($P < .01$). For CLD, there was no significant difference in collection method ($P > .05$). Wednesday PD counts were more accurate than Monday ($P < .05$) or Saturday ($P < .05$). For CLD counts, there was no significant difference among the 3 days ($P > .05$).

Conclusion: Our results provide some evidence for the prerequisite internal validation of denominator data by hospitals before reporting to the national surveillance system.

Improving patient safety and health care quality through the elimination of health care-associated infections (HAIs) has become a national goal.[1,2] The use of reported HAI data and rates, including central line-associated bloodstream infections (CLABSI), are used by state and federal health agencies, consumers, and health insurers to evaluate, compare, and rate the relative safety and quality of hospitals.[3,4] As the demand for HAI data increases, the challenge is ensuring the reliability and validity of HAI detection and reporting. To date, 32 states mandate public reporting of HAI rates in some capacity with Medicare participating health care facilities in all 50 states using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) surveillance system for their reporting requirements.[5,6] In Connecticut, a state-mandated HAI reporting system was implemented in 2006 with the 30 acute care hospitals required to enroll in the CDC NHSN system and begin reporting data in 2008 using the NHSN device-associated module: CLABSI.[7]

Although monitoring rates of HAIs is an important quality improvement measure, the majority of publicly reported CLABSI rates have not been independently audited to ensure data quality, accuracy, and completeness.[8] Infection data that have not been validated can often yield misleading results and unreliable estimates of HAIs. Independent audits of medical records, including one performed by the Connecticut Department of Public Health (CT DPH), have demonstrated under-reporting of the true incidence of CLABSIs.[9,10]

While the main focus for validating outcome measures for the NHSN CLABSI or device-associated modules has been the application of strict definitions to clearly identify cases (numerator), validating the denominator to identify patients at risk has received less attention. NHSN CLABSI numerator (cases or events) and denominator (patient-days [PD] and central line-days [CLD]) data are used to calculate HAI incidence density rates, device utilization rates,

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and standardized infection ratios.[8] A patient care unit with an erroneous higher count of CLD would have a lower CLABSI rate as the denominator increased. Collection of PD/CLD data is labor intensive with NHSN requiring daily counts. Recent studies have examined the use of electronic medical records to automate device-day collection and methods to simplify device-day collection.[11-13] Increasingly, infection preventionists (IPs) are using hospital electronic databases to capture these denominator data with the intention of simplifying the resource-intensive process.[14] Whereas NHSN considers manual collection as the gold standard, data collected electronically may be used if it is compared from the same time frame with the data collected manually and if the values are within ± 5% of each other.[15] To determine further the reliability and consistency of the application of NHSN surveillance definitions to CLABSI reporting in Connecticut, a validation study of the collection of PD and CLD was conducted on data from the fourth quarter of 2009.

METHODS

Selection of patients for review: Sampling

All 30 acute care hospitals in CT that report CLABSI data to NHSN were asked to provide a list of patients, having received intensive care unit (ICU) care, on 9 randomly selected days during the fourth quarter of 2009. Additionally, the IPs were asked to provide the time of day that the denominator data were chosen by the hospital to be counted, how the data were obtained by manual or electronic collection methods, the procedure and persons responsible for manual data collection (ie, unit secretary, charge nurse, intravenous team, unit nurse, or other), the source of electronic data (ie, electronic medical record, electronic surveillance system, administrative database, customized information technology [IT] system, or other), and whether the IP had conducted a 1- to 3-month comparison of manually collected with electronically captured denominator data. The 9 selected days, including 1 Saturday each month, were as follows: October 12, 14, 17, 2009; November 9, 11, 14, 2009; and December 14, 16, 19, 2009. Because of limited validation resources and the importance of auditing all CT hospitals, the sample of 9 days was chosen. The study qualified for Institutional Review Board exemption because the data collection is permitted under CT state law as public health reporting.

Validation of CLABSI surveillance denominator data

From October 2010 through June 2011, a retrospective medical record review was conducted at the 30 CT hospitals to determine PD and CLD counts. The validation team consisted of 2 CT DPH team members: an experienced IP (L.A.B.) and an IP in training (G.N.).

The medical record of each selected patient was reviewed, and the ICU admission and transfer data were examined to determine whether the patient was present in the ICU at the assigned collection time, otherwise known as a *PD*. If it was determined that the patient was in the ICU, the clinical data were reviewed to reveal whether and what type of central line was in place at the assigned collection time. The number of PD and CLD were tallied for each of the selected days for each hospital. The validation team members were blinded to the patients' PD or CLD status that were counted and reported to NHSN by the hospital IP.

Upon completion of the denominator validation chart reviews, the hospitals were asked to provide CT DPH with the number of PD and CLD reported to NHSN on each of the selected days, referred to as *hospital PD* and *CLD*. Agreement between the CT DPH counts and those reported by the hospitals was determined. After the review, discrepant numbers and denominator collection methods were discussed with each hospital's IP to determine the source of discordance.

NHSN surveillance for PDs and CLDs

NHSN hospitals follow a standard protocol and case definitions for monitoring CLABSIs.[15,16] The NHSN methodology for the collection and reporting of central line denominator data requires the daily counting of patients (PD) and of patients with > 1 central line (CLD) of any type. The NHSN instructions for recording the number of patients in the patient care area(s) under surveillance state that, for each day of the month selected, at the same time each day, the number of patients should be recorded. NHSN requires tallying the daily counts and reporting a monthly total. The NHSN criterion also defines the Summary Data Rules: the procedure for comparing electronic data with manual collection.[15] Summary or denominator data that are collected electronically may be used if the electronic data are within ± 5% of the number obtained by doing the calculations manually. If more than 5% discrepant, an evaluation of the discrepancies and methods to address them must be discussed with the hospital IT department.

Data analysis

Using the CT DPH review as the reference or gold standard, the accuracy of the PD and CLD CLASBI denominator data reported to NHSN by hospitals were determined. For each hospital, the absolute difference (plus or minus) between the CT DPH counts and the hospital reported counts for each of the selected days was calculated, as well as a total summary count. The acceptable limits of the NHSN Summary Data Rule (± 5%) were calculated for each hospital using the CT DPH counts and then compared with each of the hospital reported counts. In addition, days of the week and method of data collection were analyzed. Pearson χ^2 tests were used to compare the PD and CLD counts between CT DPH and the hospital reported counts. 95% Confidence intervals (CI) were calculated and are shown in the tables. Data analyses were performed by Minitab statistical software (Minitab 16 Statistical Software 2010; Minitab, Inc, State College, PA [Available from: http://www.minitab.com]).

RESULTS

Chart reviews were conducted over a 9-month period in 30 adult and 3 pediatric ICUs. Data from 7 hospitals (6 adult and 2 pediatric ICU) were excluded because the NHSN reported that PD and/or CLD data for 1 or more of the 9 selected days were no longer available.

A total of 1,988 ICU patient charts was reviewed. Of the total number of charts reviewed, 1,748 patients were identified by CT DPH as being present in the ICU at the assigned collection time (1,748 summary PD count), and, of them, 922 had a central line in place (922 CLD) (Table 1). The CT DPH central-line utilization rate was 53% (922/1,748).

Denominator counts

Overall, the hospitals reported 1,988 patients to NHSN (1,988 summary PD count), and, of those, 966 had a central line in place (966 CLD) (Table 1). This resulted in over-reporting PD by 240 (13.7%) and an over-reporting of CLD by 44 (4.8%). By comparing each hospital daily count with the CT DPH daily count, the actual difference or absolute count between CT DPH and the hospitals was 300 PD (17.2%) and 200 CLD (21.7%). On some days, hospitals reported a higher count than CT DPH and, in others, a lower count.