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.

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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 CLABSI 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.

Table 1
Comparison of the central line-associated bloodstream infection patient-day and central line-day counts as reported by Connecticut hospitals and the Connecticut Department of Public Health reviewers

	CT DPH counts, n	CT hospital counts, n	Comparison of total CT DPH and CT hospital counts, n (%) [95% CI]	Comparison of daily CT DPH and CT hospital counts, n (%) [95% CI]
Patient-days	1,748	1,988	240 (13.7) [12.2-15.4]	300 (17.2) [15.4-19.0]
Central line-days	922	966	44 (4.8) [3.5-6.4]	200 (21.7) [19.1-24.5]

CT DPH, Connecticut Department of Public Health.

Table 2
Comparison of the central line associated bloodstream infection patient day and central line day counts by collection method reported by Connecticut hospitals and the Connecticut Department of Public Health reviewers

Collection method (number of hospitals)	CT DPH counts, n	CT hospital counts, n	Comparison of total CT DPH and CT hospital counts, n (%) [95% CI]	Comparison of daily CT DPH and CT hospital counts, n (%) [95% CI]
Patient-days*				
Electronic (10)	757	900	143 (18.9) [16.2-21.9]	167 (22.1) [19.2-25.2]
Manual (13)	991	1,088	97 (9.8) [8.0-11.8]	133 (13.4) [11.4-15.7]
Total (23)	1,748	1,988	240 (13.7) [12.2-15.4]	300 (17.2) [15.4-19.0]
Central line-days†				
Electronic (7)	216	265	49 (23.0) [17.3-28.9]	57 (26.0) [20.6-32.8]
Manual (16)	706	701	5 (0.7) [0.2-1.6]	143 (20.3) [17.4-23.4]
Total (23)	922	965	44 (4.8) [3.5-6.4]	200 (21.7) [19.1-24.5]

CT DPH, Connecticut Department of Public Health.
*Patient-days count of manual versus electronic method = ($\chi^2(1) = 15.80$, $P < .01$).
†Central line-days count of manual versus electronic method = ($\chi^2(1) = 2.30$, $P > .05$).

However, the net absolute count was higher than the count reported to NHSN.

Collection method for manual and electronic data

Among the 23 hospitals, 17 reported collecting either PD and/or CLD data by manual means. Hospitals reported that the manual collection was performed by a nursing supervisor (35%), ICU nurse (23.5%), unit secretary (23.5%), IP (12%), or intravenous team (6%). Eleven hospitals reported using an electronic system to collect PD and/or CLD. Of those, one-third reported using a customized IT system and one-third an electronic health record such as Meditech (Meditech 6.0 Electronic Health Record, Meditech, Westwood, MA). Almost 20% used an administrative database, and 1 (9%) identified a software system. None of the hospitals reported using a commercial electronic surveillance system.

Denominator counts by collection method

In evaluating the absolute PD counts by method of data collection, 13 of the 23 hospitals (57%) used manual methods to collect the PD (Table 2). Among these hospitals, CT DPH reported 991 PD with the hospitals over-reporting an additional 133 PD for a PD count discrepancy of 13.4%. Five (38%) of the 13 hospitals were within 5%. Of the 10 hospitals using electronic databases to report PD, 167 PD were over-reported for a rate of 22.1%, with 1 of the 10 hospitals within the 5% NHSN rule. For PD counts, manual methods of collection were more accurate than electronic methods ($\chi^2(1) = 15.8$, $P < .01$).

In assessing the absolute CLD counts by data collection method (Table 2), 16 of the 23 hospitals (70%) used manual methods to collect the CLD. CT DPH reported 706 CLD with the hospitals reporting an additional 143 CLD for a manual CLD count discrepancy of 20.3%. Of the 7 hospitals using electronic systems to obtain CLD counts, all were outside the ± 5% NHSN rule. These hospitals reported an additional 57 CLD for an over-reporting of 26%. For CLD, there was no significant difference in accuracy between manual and electronic methods of data collection ($\chi^2(1) = 2.3$, $P > .05$).

Denominator counts by ± 5% NHSN rule

In comparing the absolute PD counts for each hospital with the CT DPH review, 5 (22%) of the 23 hospitals were within the ± 5% NHSN rule. For these 5 hospitals, CT DPH reported 397 PD and found 7 discrepancies resulting in over-reporting by 1.8% (95% CI: 0.7%-3.6%). All of these 5 hospitals collected the data by manual methods. Among the 18 hospitals reporting outside the recommended 5% NHSN range, CT DPH reported 1,351 PD with 293 (21.7%, 95% CI: 19.5%-24.0%) PD count discrepancies reported to NHSN by the hospitals. There was no significant difference in PD discrepancies by the method of data collection ($\chi^2(1) = 0.1$, $P > .05$). The 8 hospitals using manual methods over-reported PD counts by 21.2% (95% CI: 18.0%-24.7%). The 10 hospitals using electronic sources over-reported PD counts by 22.1% (95% CI: 19.2%-25.2%).

For absolute CLD counts, none of the hospitals were within the ± 5% NHSN rule. The manual collection method, used by 16 hospitals, resulted in significantly less over-reporting of CLD (20.3%, 95% CI: 17.4%-23.4%) compared with the 7 hospitals that electronically counted and over-reported by 26.4% (95% CI: 20.6%-32.8%). Among the 23 hospitals reporting outside the recommended 5% NHSN range, there was no significant difference in CLD discrepancies by method of data collection ($\chi^2(1) = 2.3$, $P > .05$).

Denominator counts by day of the week

Data collected by selected days of the week during the validation period were analyzed (Table 3). On Wednesday, 85 (13.4%) absolute PD counts were over-reported compared with CT DPH. There was no significant difference between Monday and Saturday with CT DPH reporting 559 and 557 PD, respectively, with a rate of over-reporting by 19.3% and 19.2%, respectively. The PD counts performed on Wednesday were significantly more accurate than on Monday ($\chi^2(1) = 5.42$, $P < .05$) and Saturday ($\chi^2(1) = 5.23$, $P < .05$).

For absolute CLD counts, there was no significant difference among the 3 data collection days ($\chi^2(2) = 1.06$, $P > .05$). On Mondays, CT DPH obtained a CLD count of 293 with hospitals over-reporting 71 CLD for a rate of 24.2%; on Wednesdays, CT DPH counted 312 CLD with hospitals over-reporting 65 CLD for a rate of

Table 3
Comparison of the central line associated bloodstream infection patient day and central line day counts by collection day of the week reported by Connecticut hospitals and the Connecticut Department of Public Health reviewers

Day of the week	CT DPH counts, n	CT hospital counts, n	Comparison of total CT DPH and CT hospital counts, n (%) [95% CI]	Comparison of daily CT DPH and CT hospital counts, n (%) [95% CI]
Patient-days*				
Monday	559	647	88 (15.7) [12.8-19.0]	108 (19.3) [16.1-22.8]
Wednesday	632	689	57 (9.0) [6.9-11.5]	85 (13.4) [10.9-16.4]
Saturday	557	652	95 (17.0) [14.0-20.4]	107 (19.2) [16.0-22.7]
Total	1,748	1,988	240 (13.7) [12.2-15.4]	300 (17.2) [15.4-19.0]
Central line-days†				
Monday	293	319	26 (8.9) [5.9-12.7]	71 (24.2) [19.4-29.6]
Wednesday	312	317	5 (1.6) [0.5-3.7]	65 (20.8) [16.5-25.8]
Saturday	317	330	13 (4.1) [2.2-6.9]	64 (20.2) [15.9-25.0]
Total	922	966	44 (4.8) [3.5-6.4]	200 (21.7) [19.1-24.5]

CT DPH, Connecticut Department of Public Health.
*Patient-days count for Wednesday versus Monday = $(\chi^2(1) = 5.42, P < .05)$ or Saturday = $(\chi^2(1) = 5.23, P < .05)$.
†Central line-days count for Monday, Wednesday, or Saturday = $(\chi^2(1) = 1.06, P > .05)$.

20.8%; and, on Saturdays, the CT DPH CLD count was 317 with 64 CLD over-reported for a rate of 20.2%.

Internal hospital validation of denominator data

Use of IT systems was common among a majority of the hospitals. Of the hospitals collecting PD or CL days electronically in 2009, none reported conducting the NHSN recommended practice of comparing manual and electronic data collected during the same period and comparing to see whether the margin of error was within ± 5%. One hospital reported a comparison review before implementation of NHSN reporting in 2008. Moreover, no hospitals reported conducting manual data checks either.

Response from CT hospitals to denominator data results

Each of the hospitals received a report summarizing the validation results of the ICU denominator data for their hospital. One hospital reported a minor discrepancy in the CT DPH CLD and requested a corrected report. The majority of the IPs who responded to their validation reports indicated that they "were not surprised with the results"; "never thought about the denominator counts"; "care but are too busy to look at the counts"; and "knew the counts were wrong and that this report provides the evidence to effect change."

DISCUSSION

This is the first detailed study to assess the accuracy of CLABSI denominator data using independent validation. Results of this study had several notable findings. First, the findings of this study suggest that there was over-reporting of CLABSI denominator data to the NHSN surveillance system. Second, we found that use of electronic data sources for determination of PDs and CLDs was common practice, used for the former in almost 50% of hospitals. Third, we found that only 1 hospital had attempted to validate the electronic method they used to determine PD and CLD despite NHSN manual instructions. Fourth, we found that use of electronic methods usually resulted in over-counts of PD and of CLDs, with an average over-count rate of 22.1% and 26%, respectively. Fifth, we also found use of manual counting methods to be inaccurate with hospitals over-counting PDs by 13.4% and CLDs by 20.3%. Finally, the PD counts performed on Wednesday were significantly more accurate than on Monday or Saturday, but, for CLD, there was no significant difference in accuracy among the 3 data collection days. Our results provide some evidence for the prerequisite internal validation of denominator data by hospitals before reporting to the national surveillance system.

The results of this study show that one of the foremost reasons for the over-reporting of both PD and CLD was the reliance on electronic data that had not been confirmed by manual methods. Whether obtained from administrative files or abstracted from medical records, the vital elements to include in standardizing methods for the electronic capture of PD and CLD incorporates defined data fields including specifications of values, format, and data requirements; data extraction and search capabilities; systematic data reviews including manual system checks; and IT support and staff training.[11] A 2009 survey among California hospitals revealed that only 35% of the IP programs had help with data management and even fewer (13%) had statistical help.[17] These data suggest that, before electronic data sources are used for reporting patient and device days, proper capture for counting the data and a reliable comparison with manual methods must occur for the data to be considered dependable and accurate. It is anticipated that electronic health technology systems will grow significantly with the incentives provided under the American Recovery and Reinvestment Act of 2009.[18]

The results of this study also showed that, although more reliable, the manual method for collection of denominator data also resulted in over-counts. Manual collection of device-days is time-consuming and prone to error.[11] Gathering these data involves varying degrees of judgment and interpretation. Misunderstanding of the definition of a central line and misinterpretation of the protocol for obtaining PD and CLD counts at the same time each day, as well as missing or implausible data such as PD or CLD not counted, the number of PD greater than the number of patient beds or the number of CLD greater than the number of PD, were reported by the IPs as possible reasons for miscalculation of the denominator data. A systematic approach for manual data checks must be developed to identify and resolve unexpected discrepancies and ensure quality data.

Both methods of denominator data collection resulted in over-counts, with the manual method more error prone than was initially envisaged. Possible explanations include that limited resources in infection prevention results in competing priorities that do not necessarily allow the IP to constantly focus on data and the source of data. The data are difficult to collect and time-consuming and may not rank high on an individual's infection prevention efforts. When the CT IPs were presented with the report of the validation results, many responded that they were "not surprised with the over-counts" or "knew the counts were wrong," suggesting they did not have time to investigate and validate the source of data prior to NHSN reporting. Regardless of the system—people

(manual) or electronic—the central issue is equipping IPs with the necessary infection surveillance and reporting tools and resources. Two nationwide surveys of HAI prevention practices in US hospitals in 2005 and again in 2009 showed that the average level of dedicated IP staffing had not changed between these time periods.[19] Training initiatives have focused more on the accurate detection and reporting of CLASBI events and less on surveillance practices to collect denominator data.[20] In a 2010 survey, 16% of IPs responded that one of the challenges they face in reporting CLASBIs to NHSN for the new regulations introduced by the Centers for Medicare and Medicaid is collecting denominator data.[21]

Because staffing levels, particularly on weekends, have been associated with increased errors in the type and quality of medical care, 3 different days of the week, including Saturday, were chosen to audit the denominator collection process.[22] Results of the data collected by selected days of the week showed that the PD counts performed on Wednesday were significantly more accurate than Monday or Saturday, but, for CLD counts, there was no significant difference among the 3 data collection days. Although studies are underway to simplify the collection of denominator data with once weekly sampling, the method of choice must be independently validated.[23]

The over-reporting of denominator data, as shown in this study, can result in the under-reporting of the actual CLABSI rate. The CLABSI rate is determined by dividing the number of CLABSIs, which is the numerator, by the number of CLDs, which is the denominator.[8] The legitimacy of the CLABSI rate requires the validity of both the numerator and denominator counts. The clinical implications of the public reporting of inaccurate CLABSI rates include the cautious interpretation of trends in health care, exaggerated assessments and conclusions of quality improvement initiatives for the prevention of CLABSIs, and inaccurate use of the metric to verify the effectiveness of targeted funding for HAI prevention.

This study has several limitations including the fact that a small number of sample days were selected. An optimal sample size would have been 2 to 3 times larger. Furthermore, because of the small sample size of both the numerator and denominator counts, the significance of the over-reporting of the denominator counts on the CLASBI rates was not determined. Additionally, documentation of any kind is user dependent and as such has the potential for error. Despite the limitations, the results can be used to resolve discrepancies and devise data collection systems compliant with NHSN standardized data collection methods leading to more accurate CLABSI rates.

CONCLUSION

A validation study that was conducted on the collection of CLABSI PD and CLD on 9 selected days during the fourth quarter of 2009 found that 200 PD (17.2%) and 300 CLD (21.7%) were over-reported to NHSN. The use of electronic systems to report denominator data to NHSN resulted in an over-reporting of PD by 22.1% and CLD by 26.0%. Manual counts, although more sensitive, resulted in over-count of PDs and CLDs by 13.4% and 20.3%, respectively.

Although PD counts performed on Wednesday were significantly more accurate than on Monday or Saturday, for CLD, there was no significant difference in accuracy among the 3 data collection days of the week. With the ever increasing mandates for the public reporting of HAIs, the need for more timely, efficient, and reliable methods of HAI surveillance intensifies. Capitalizing on the advances and availability of health care data in electronic form has the potential to support these surveillance requirements, yet the data in this study suggest that a prerequisite, standardized strategy for the validation of the denominator data by hospitals before reporting to the national surveillance system is needed to enhance the efficiency of HAI detection, reporting, and accuracy of rates.

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