The Association of State Legal Mandates for Data Submission of Central Line–Associated Bloodstream Infections in Neonatal Intensive Care Units with Process and Outcome Measures

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Objective. To determine the association between state legal mandates for data submission of central line–associated bloodstream infections (CLABSIs) in neonatal intensive care units (NICUs) with process and outcome measures.

Design. Cross-sectional study.


Methods. State mandates for data submission of CLABSIs in NICUs in place by 2011 were compiled and verified with state healthcare-associated infection coordinators. A web-based survey of infection control departments in October 2011 assessed CLABSI prevention practices, ie, compliance with checklist/bundle components (process measures) in ICUs including NICUs. Corresponding 2011 NHSN NICU CLABSI rates (outcome measures) were used to calculate standardized infection ratios (SIRs). Association between mandates and process and outcome measures was assessed by multivariable logistic regression.

Results. Among 190 study NICUs, 107 (56.3%) were located in states with mandates, with mandates in place 1–3 years in 52 (49%). More NICUs in states with mandates reported ≥95% compliance to at least 1 CLABSI prevention practice (52.3%–66.4%) than NICUs in states without mandates (28.9%–48.2%). Mandates were predictors of ≥95% compliance with all practices (odds ratio, 2.8; 95% confidence interval, 1.4–6.1). NICUs in states with mandates reported lower mean CLABSI rates in the ≤750-g birth weight group (2.4 vs 5.7 CLABSIs/1,000 central line–days) but not in others. Mandates were not associated with SIR <1.

Conclusions. State mandates for NICU CLABSI data submission were significantly associated with ≥95% compliance with CLABSI prevention practices, which declined with the duration of mandate but not with lower CLABSI rates.

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Reduction of central line–associated bloodstream infections (CLABSIs) has been a focus of patient safety initiatives nationwide over the past decade.1,2 As these efforts have succeeded in reducing CLABSIs in both adult and pediatric populations,3-5 it now becomes important to sustain these gains and share successful strategies. Monitoring adherence to healthcare-associated infection (HAI) prevention practices and mandatory submission of HAI data have been used to sustain institutional commitment to this end. The 2012 Centers for Disease Control and Prevention (CDC)/Association of State and Territorial Health Officials combined HAI prevention policy tool kit recommends public reporting of HAI data,6 and many states have enacted statutes requiring mandatory CLABSI data submission.7 The association of these mandates for HAI data submission with process and outcome measures for CLABSI prevention in pediatric settings has not been well described. We assessed whether the presence of a state mandate for submission of neonatal intensive care unit (NICU) CLABSI data was associated with compliance with CLABSI prevention policies and/or CLABSI rates reported to CDC’s National Healthcare Safety Network (NHSN). We hypothesized that NICUs in states with legal mandates to submit CLABSI data would report greater compliance with CLABSI prevention practices and lower CLABSI rates than NICUs located in states without such mandates.

Methods

Parent Study Design

This analysis of NICUs was a component of a larger multicenter effort, the Prevention of Nosocomial Infections and...
Cost Effectiveness Refined (PNICER-R01NR010107) study, which assessed the impact of intensity of infection control processes on device-associated and organism-specific HAI rates in all types of intensive care units across the United States. Nonveteran hospitals that were enrolled in NHSN were eligible to participate in PNICER. Only sites that had a NICU within their hospital and conducted NICU CLABSI surveillance in 2011 were eligible to be included in this current analysis. The NHSN, CDC’s national public health surveillance system monitors HAIs using standardized definitions based on clinical and laboratory data rather than on International Classification of Diseases, Ninth Revision, codes. Eligible hospitals completed the survey described below and agreed to join the PNICER NHSN Research Group. Hospitals joining the PNICER NHSN Research Group provided the study team access to their device-associated infection rates. All procedures were reviewed and approved by institutional review boards (IRBs) at Columbia University Medical Center, CDC, and the RAND Corporation.

Survey of NICUs

An online survey10,11 was sent to eligible hospitals to be completed by the director or manager of the hospital’s infection prevention and control department. The survey included questions about NICU-specific policies and practices related to central line (CL) insertion and maintenance, ie, checklist use at CL insertion, monitoring hand hygiene, use of maximal barrier precautions, choice of optimal catheter insertion site, and assessment of daily line necessity. Respondents were asked to provide the percentage compliance recorded for each practice during the last monitored period categorized as all of the time (95%–100%), usually (75%–94%), sometimes (25%–74%), rarely or never (<25%), don’t know, or no monitoring performed.11 The survey also inquired whether the NICUs were neonatal critical care level II/III or level III as classified by NHSN.12

The hospitals in this analysis all reported NICU-specific CLABSI rates and central line–days (CL-days) to NHSN for all 12 months in 2011 and stratified CLABSI rates by birth weight (BW) groups (<750, 751–1,000, 1,001–1,500, 1,501–2,500, and >2,500 g). The NHSN annual survey was used to obtain hospital characteristics including geographic location and NICU characteristics including the number of beds and NICU level. The standardized infection ratios (SIRs) for each participating NICU were calculated using publicly available NHSN BW-specific CLABSI rates for 2011.13

State Mandates for Reporting CLABSI Data

To determine whether HAI data submission was required, pertinent HAI laws (state statutes, administrative regulations, and other administrative requirements) were systematically reviewed for all US states, the District of Columbia, and Puerto Rico. For those states and territories that required NICU CLABSI data submission, the year that reporting NICU CLABSI data was first required was recorded. State HAI coordinators were identified based on the CDC state-based HAI prevention website (http://www.cdc.gov/hai/state-based/index.html) and were contacted to confirm the accuracy of information and, when necessary, to clarify data submission requirements. HAI coordinators were contacted in February 2013, and all responses were received by the end of March 2013.

Participation in State-Level NICU CLABSI Collaboratives and Comprehensive Unit-Based Safety Program (CUSP)

In order to adjust for other factors that could influence statewide NICU CLABSI practices, we assessed participation in statewide NICU CLABSI reduction collaboratives and the Agency for Healthcare Research and Quality Comprehensive Unit-Based Safety Program (AHRQ CUSP) initiative. To locate published reports of statewide NICU CLABSI collaboratives prior to 2012, we searched PubMed for English-language studies published from January 1996 to December 2012 using the keywords “CLABSI” or “NICU.” These were combined using the Boolean “AND” with 1 of 7 other terms (“collaborative,” “state,” “network,” “quality improvement,” “surveillance,” “bundles,” and “perinatal”). Publicly available data were assessed from AHRQ to determine state participation in AHRQ CUSP.14 Online searches for AHRQ and PubMed were conducted in August 2013.

Statistical Analysis

The characteristics of study NICUs located in states with and without data submission mandates for NICU CLABSIIs were compared using χ2 tests. Bivariate analyses using ANOVA and χ2 tests were used to compare process measures (proportions of NICUs with ≥95% compliance to CLABSI prevention practices) and outcome measures (mean CLABSI rate and mean SIR) between NICUs with data submission mandates and those without.

Following bivariate analysis, we constructed 3 separate multivariable logistic regression models. In the first 2 models, we tested the association of having a mandate for NICU CLABSI data submission in 2011 with 2 process measures (≥95% reported compliance to all CLABSI prevention practices or ≥95% compliance to at least 1 prevention practice). In the third model, we tested the association of the presence of a mandate for NICU CLABSI data submission with an outcome measure (SIR <1 for 2011). All multivariable models used logistic regression and likelihood ratio tests to determine the significance of additional independent variables. NICU size, NICU level, geographic region, hospital medical school affiliation, and hospital ownership were adjusted for in the regression analysis. In addition, all NICUs in states with an existing NICU CLABSI collaborative prior to 2012 or those participating in AHRQ CUSP were assumed to have participated in these efforts for the analysis and adjusted for in the analysis.
As secondary analyses, we (i) incorporated clustering by state in the above models to allow for unmeasured state-level dependence and check robustness of any significant findings, (ii) described variation in process and outcome measures among NICUs stratified by the number of years since data submission was first required (0, 1–3, >3 years) and using the Cochrane-Armitage test for trend, and (iii) computed associations between the process and outcome measures to help better interpret results of the above regression analysis. An \( \alpha \) value of .05 was predetermined as the level of significance. All analyses were conducted using SAS (ver 9.3; SAS Institute).

**RESULTS**

**State Legal Mandates for NICU CLABSI Data Submission**

During the time being studied, 21 states had mandates for data submission for NICU CLABSIs; 3 of these states (TN, TX, AR) were located in the South. Fifteen states (CA, CO, DC, IL, ME, MD, MA, MO, NH, NJ, NY, PA, RI, TN, WA) had data submission requirements prior to 2011; the first began in 2005, and 6 states implemented CLABSI data submission requirements in 2011 (AR, DE, HI, OR, TX, UT). Only 2 states with mandates for NICU data submission implemented in 2011 did not participate in NHSN surveillance.

**Study NICUs**

Of the 870 NICUs that participated in NHSN surveillance in the last quarter of 2011, 190 (21.8%) were included in this analysis as they completed the PNICER survey and provided access to their CLABSI rate data. These NICUs contributed 356,305 CL-days and 541 CLABSIs. Over half of study NICUs (\( n = 107, 56.3\% \)) were located in states (\( n = 16 \)) with data submission mandates. NICUs in states with and without data submission mandates for CLABSIs did not differ significantly in NICU size, NICU level, hospital ownership, or hospital medical school affiliation. NICUs in the southern region were less likely to have CLABSI data submission mandates compared to NICUs from other regions of the United States (Table 1).

**Participation in CLABSI Collaboratives and CUSP**

Three states had published reports of statewide NICU CLABSI collaboratives conducted prior to October 2011.1,4,15,16 Two states had both NICU CLABSI collaboratives and data sub-
mission mandates and contributed 33 (17.3%) study NICUs, while 1 state with a collaborative had no data submission mandate and contributed 8 (4.2%) study NICUs. Seven states participating in AHRQ CUSP\textsuperscript{14} contributed 23 (12.1%) study NICUs with data submission mandates and 17 (8.9%) study NICUs without mandates (Table 1).

### Mandates and Prevention Practices

Depending on the specific prevention practice, 52%–66% of NICUs in states with mandates reported \( \geq 95\% \) compliance versus 29%–51% of NICUS from states without mandates as shown in Table 2. The smallest difference between the 2 groups of NICUs was for reporting \( \geq 95\% \) hand hygiene compliance, which was low in both groups. More NICUs in the mandatory reporting group reported compliance with all 5 practices (44% vs 25%) and reported \( \geq 95\% \) compliance with more practices (median 4 vs 2). Similar proportions of NICUs in states with and without mandatory reporting reported compliance with 2 (5% vs 6%), 3 (7% vs 5%), and 4 (14% vs 14%) practices. More NICUs located in states with data submission mandates reported \( \geq 95\% \) compliance with all prevention practices compared to NICUs located in states without mandatory data submission requirements (36.4% \( [n = 39] \) vs 16.8% \( [n = 14] \), respectively; \( P = .002 \)).

### Mandates and Infection Rates

NICUs in states with mandates reported lower mean CLABSI rates in the \( \leq 750\)-g BW group when compared with NICUs in states without mandates (2.4 vs 5.7 CLABSIs/1,000 CL-days, respectively) but did not report lower overall rates or lower rates in the other BW groups. NICUs with data submission mandates had a lower SIR compared to NICUs without data submission mandates, but this difference was not statistically significant (Table 2). There were no significant differences in NICU characteristics or CL utilization between the 2 groups of NICUs when stratified by BW (data not shown).

### Multivariable Analysis

In multivariable logistic regression models (adjusted for NICU size, NICU level, geographic region, hospital medical school affiliation, hospital ownership, and participation in state-level collaborative and AHRQ CUSP), being located in a state with a NICU CLABSI data submission mandate was significantly associated with reporting \( \geq 95\% \) compliance for all infection prevention practices assessed and for reporting \( \geq 95\% \) compliance with at least 1 of these practices as shown in Table 3. When clustered by state, reporting \( \geq 95\% \) with all prevention practices and with at least 1 practice remained

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**Table 2. Process and Outcome Measures in Neonatal Intensive Care Units with and without Mandatory Reporting Requirements (Bivariate Analysis)**

<table>
<thead>
<tr>
<th>Process measures (( \geq 95% ) compliance)</th>
<th>Mandatory reporting, ( n = 107 )</th>
<th>No mandatory reporting, ( n = 83 )</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of checklist at insertion</td>
<td>57 (53.3)</td>
<td>28 (33.7)</td>
<td>.007</td>
</tr>
<tr>
<td>Hand hygiene</td>
<td>67 (62.6)</td>
<td>42 (50.6)</td>
<td>.1</td>
</tr>
<tr>
<td>Use of maximum barrier precautions</td>
<td>71 (66.4)</td>
<td>40 (48.2)</td>
<td>.02</td>
</tr>
<tr>
<td>Choice of optimum catheter site</td>
<td>66 (61.7)</td>
<td>30 (37.3)</td>
<td>.01</td>
</tr>
<tr>
<td>Maintenance bundle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment of daily necessity</td>
<td>56 (52.3)</td>
<td>24 (28.9)</td>
<td>.001</td>
</tr>
<tr>
<td>All components</td>
<td>39 (36.4)</td>
<td>14 (16.8)</td>
<td>.002</td>
</tr>
</tbody>
</table>

**Outcome measures**

<table>
<thead>
<tr>
<th>Total events/CL-days</th>
<th>Mandatory reporting, ( n = 107 )</th>
<th>No mandatory reporting, ( n = 83 )</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean CLABSI rate/1,000 CL-days, g</td>
<td>1.2</td>
<td>1.6</td>
<td>.2</td>
</tr>
<tr>
<td>( \leq 750 )</td>
<td>2.4</td>
<td>5.7</td>
<td>.05</td>
</tr>
<tr>
<td>751–1,000</td>
<td>1.7</td>
<td>2.7</td>
<td>.1</td>
</tr>
<tr>
<td>1,001–1,500</td>
<td>1.3</td>
<td>1.2</td>
<td>.9</td>
</tr>
<tr>
<td>1,501–2,500</td>
<td>0.8</td>
<td>0.9</td>
<td>.9</td>
</tr>
<tr>
<td>( &gt;2,500 )</td>
<td>0.8</td>
<td>0.3</td>
<td>.3</td>
</tr>
</tbody>
</table>

**Standardized infection ratio**

| Mean ± SD/median                             | 1.6 ± 4.7/0.2                     | 2.7 ± 7.1/0.3                     | .2  |

**Note.** Data are no. (%) unless otherwise indicated. CLABSI, central line–associated bloodstream infection; CL-days, central line–days; SD, standard deviation.
Table 3. Association of Presence of Mandatory State Reporting of NICU CLABSI Rates with Process and Outcome Measures in Multivariable Logistic Regression

<table>
<thead>
<tr>
<th>Parameter</th>
<th>SE</th>
<th>Odds ratio (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥95% compliance with all prevention practices</td>
<td>1.1</td>
<td>0.4</td>
<td>2.8 (1.4–6.1)</td>
</tr>
<tr>
<td>≥95% compliance with at least 1 prevention practice</td>
<td>0.8</td>
<td>0.3</td>
<td>2.2 (1.2–4.3)</td>
</tr>
<tr>
<td>Outcome measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standardized infection ratio &lt;1</td>
<td>0.3</td>
<td>0.4</td>
<td>1.3 (0.6–2.6)</td>
</tr>
</tbody>
</table>

Note. Values are adjusted for neonatal intensive care unit (NICU) size, NICU level, location, medical school affiliation, hospital ownership, and participation in a statewide collaborative and comprehensive unit-based safety initiative. CI, confidence interval; SE, standard error.

Significantly associated with presence of a mandate (odds ratio [OR], 3; 95% confidence interval [CI], 1.6–5.4; P < .01; and OR, 2.2; 95% CI, 1.2–3.9; P = .01). Being located in a state with data submission mandates was not a significant predictor of SIR <1 (Table 3).

Association of Duration of Mandate with Process and Outcome Measures

Significantly fewer NICUs in states with mandates for ≥3 years reported ≥95% compliance with prevention practices than those in states with more recent mandates (Table 4). There was a significant trend for reporting ≥95% compliance with more recent mandates (P = .02). The number of years that data submission mandates were in place was not associated with lower overall CLABSI rates or SIR <1 (Table 4).

Association between Process and Outcome Measures

NICUs reporting ≥95% compliance with all prevention practices had SIR <1 more often than NICUs with <95% compliance, although this difference was not significant (81.1% vs 67.0%, respectively; P = .06).

Discussion

To our knowledge, this is the first study analyzing the association of data submission mandates for NICU CLABSI rates with CLABSI prevention practices and CLABSI rates in the pediatric population. In this national sample of NICUs, we demonstrated a significant association between data submission mandates for CLABSI and reporting ≥95% compliance with selected process measures. Implementation of data submission mandates has engendered concerns about diverting resources from infection prevention efforts toward satisfying data submission requirements. This study demonstrates that it is possible to report high levels of compliance with CLABSI prevention practices while simultaneously satisfying mandatory data submission requirements.

However, in this study, the association of data submission mandates with the outcome measures of CLABSI rates and SIR appears more complex. Lower overall rates and lower SIRs were noted in NICUs in states with data submission mandates, but this association was significant only for infants ≤750 g at birth. Potential explanations of these findings could be relatively low compliance in NICUs with and without state mandates; overall low CLABSI rates, particularly in higher BW groups; and an inadequate sample size to detect a difference. In addition, thanks to the long-standing interest in CLABSI reduction efforts nationally in NICUs, it is possible that the presence of data submission mandates could have had only a small effect on CLABSI rates. Corroborating our findings, studies from adult populations have hitherto not shown a consistent effect of mandatory reporting on CLABSI rates.

This study has limitations. The study sample represented less than 25% of total NHSN NICUs and may not be generalizable nationally. Association does not imply a causal effect, and whether data submission mandates are merely a
surrogate marker for other statewide CLABSI reduction efforts is not discernible with our cross-sectional methodology. Though we adjusted for participation in state collaboratives and the CUSP initiative, participation in interstate or regional collaborations such as the Vermont Oxford Network was not accounted for. We did not have access to NICU-level participation in collaboratives, and all NICUs in a state were assumed to have participated. The mandate was considered to have a similar effect on all NICUs within a state. Self-reported compliance and rates were used as process and outcome measures, and concerns about institutional variability in these measures, in terms of both measurement and reporting, have been raised previously. Our methodology cannot determine whether these findings reflect more institutional attention to infection control practices in the setting of a state data submission mandate versus “gaming” the system. There is heterogeneity in the legal requirement for CLABSI data submission across states that was not addressed, as we considered only the presence of mandatory data submission requirements and did not analyze other variations in provisions of HAI laws (eg, public reporting, use of facility identifiers, and risk adjustment). Finally, any effects of the Hospital Inpatient Quality Reporting Program that was initiated in 2011 were not examined as part of the analysis, although children’s hospitals are exempt from this provision and the majority of study NICUs were located in children’s hospitals.

In conclusion, in this national study of NICUs, we demonstrated a significant association between data submission mandates for CLABSI and higher reported compliance with CLABSI prevention practices. This association appeared to wane with duration of the mandate and highlights the importance of further work to reassess this association, particularly in states where mandates have been in place for a longer duration of time. NICUs in states with data submission mandates also reported lower CLABSI rates, though this association was statistically significant only for infants whose BW was \( \leq 750 \) g. Further studies could examine these effects longitudinally with larger samples; such studies have important ramifications for designing optimal strategies to reduce and report HAI.

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