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The Association of State Legal Mandates for Data Submission of Central Line-associated Blood Stream Infections in Neonatal Intensive Care Units with Process and Outcome Measures

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Abstract

Objective—To determine the association between state legal mandates for data submission of central line-associated blood stream infections (CLABSIs) in neonatal intensive care units (NICUs) with process/outcome measures.

Design—Cross-sectional study.

Participants—National sample of level II/III and III NICUs participating in National Healthcare Safety Network (NHSN) surveillance.

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 i.e. compliance with checklist and bundle components (process measures) in ICUs including NICUs. Corresponding 2011 NHSN NICU CLABSI rates (outcome measures) were used to calculate Standardized Infection Ratios (SIR). The association between mandates and process/outcome measures was assessed by multivariable logistic regression.

Results—Among 190 study NICUs, 107 (56.3%) NICUs were located in states with mandates, with mandates in place for 3 or more years for half. More NICUs in states with mandates reported

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≥95% compliance to at least one 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 (OR 2.8; 95% CI 1.4–6.1). NICUs in states with mandates reported lower mean CLABSI rates in the <750gm birth-weight group (2.4 vs. 5.7 CLABSIs/1000 CL-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 but not with lower CLABSI rates.

Background

Reduction of central line–associated blood stream 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, 4,5] 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 state mandate for submission of neonatal intensive care units (NICU) CLABSI data was associated with CLABSI prevention policy compliance and/or CLABSI rates reported to CDC's National Healthcare Safety Network [NHSN]) in a sample of NICUs in the U.S. 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 ICUs across the U.S.[8] Non-veteran 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 ICD-9 codes.[9] 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 (IRB) at Columbia University Medical Center, CDC, and the RAND Corporation.

Survey of NICUs

An online survey [10,11] was sent to eligible hospitals to be completed by the director or manager of the hospital's infection prevention and control (IP&C) department. The survey included questions about NICU-specific policies and practices related to central line (CL) insertion and maintenance, i.e., 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 if 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 CL-days to NHSN for all 12 months in 2011 and stratified CLABSI rates by birth weight (BW) groups (≤750, 751–1000, 1001–1500, 1501–2500, and >2500 grams). 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 (SIR) 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 U.S. states, the District of Columbia, and Puerto Rico. For those states and territories that required NICU CLABSI data submission, the year that data submission was first required i.e. when hospitals first had to start reporting NICU CLABSI data, 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 (CUSP) Program

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, PubMed was searched 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 the AHRQ CUSP program.[14] Online searches for AHRQ and PubMed were conducted in August 2013.

Statistical Analysis

Characteristics of study NICUs located in states with and without data submission mandates for NICU CLABSIs were compared using chi-squared tests. Bivariate analyses using ANOVA and chi–squared 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, three separate multivariable logistic regression models were constructed. In the first two models, we tested the association of having a mandate for NICU CLABSI data submission in 2011 with two process measures (≥95% reported compliance to all CLABSI prevention practices or ≥95% compliance to at least one 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.

As secondary analyses we i) described variation in process and outcome measures seen with number of years since data submission began by stratifying NICUs by the number of years (0, 1–3 years, >3 years) since data submission was first required by NICUs and by using a Cochrane-Armitage test for trend and ii) computed associations between the process and outcome variables to help better interpret results of the multivariable regression analysis. An alpha of 0.05 was predetermined as the level of significance. All analyses were conducted using SAS (Ver 9.3; SAS Institute, Cary, NC)

Results

State Legal Mandates for NICU CLABSI data submission

During the time being studied, 21 states had mandates for data submission for NICU CLABSIs with only 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 central line days and 541 events. 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 U.S. (Table 1).

Participation in CLABSI Collaboratives and CUSP Program

Three states had published reports of statewide NICU CLABSI collaboratives conducted prior to October 2011.[4, 15,16] Two states had both NICU CLABSI collaboratives and data submission mandates and contributed 33 (17.3%) study NICUs, while one state with a collaborative had no data submission mandate and contributed 8 (4.2%) study NICUs. Seven states participating in AHRQ CUSP [14] contributed 23 (12.1%) study NICUs with data submission mandates and 17 (8.9%) study NICUs without mandates (Table 1).

Mandates and Prevention Practice

Depending on the specific prevention practice, 52% to 66% of NICUs in states with mandates reported ≥95% compliance, versus 29% to 51% of NICUS from states without mandates as shown in Table 2. Reporting > 95% compliance with hand hygiene was low in both groups. More NICUs in the mandatory reporting group reported compliance will all 5 practices (36% versus 17%), and reported ≥95% compliance with a larger number of practices (median of 4 versus 2). Similar proportions of states with and without mandatory reporting reported compliance with 2, 3 and 4 practices (5% vs 6%, 7% vs 5%, 14% vs. 14%). In the bivariate analysis, the smallest difference between the two groups of NICUs was for ≥ 95% hand hygiene compliance as show in Table 2. More NICUs located in states with data submission mandates reported ≥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=0.002).

Mandates and Infection Rates

NICUs in states with mandates reported lower mean CLABSI rates in the <750 gm birth-weight group (2.4 vs 5.7 CLABSIs/1000 CL-days) but not overall nor in the other birth-weight groups. NICUs with data submission mandates had a lower SIR compared to the NICUs without data submission mandates, but this difference was not statistically significant (Table 2).

Multivariable analysis

In multivariable logistic regression analysis, being located in a state with a NICU CLABSI data submission mandate was significantly associated with reporting ≥95% compliance for all infection practices assessed and for reporting ≥95% compliance with at least one prevention practice as shown in Table 3. Being located in a state with data submission mandates was not a significant predictor of SIR <1 (Table 3). All models were adjusted for NICU size, NICU level, geographic region, hospital medical school affiliation, and hospital ownership

Association of Years of Mandates with Process and Outcome Measures

Significantly fewer NICUs in states with mandates for >3 years had >95% compliance with prevention practices than those in states with more recent mandates (Table 4). There was a significant trend documented for reporting ≥ 95% compliance with more recent mandates (p=0.02). The number of years that data submission mandates were in place was not associated with lower overall CLABSI rates or SIR <1 (Table 4, p= 0.8).

Association between process and outcome measures

NICUs with ≥ 95% compliance with all prevention practices, reported SIR < 1 more often, though not significantly (81.1% versus 67.0 % p =0.06.

Discussion

To our knowledge, this is the first study analyzing the association of data submission mandates for NICU CLABSIs and compliance 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 CLABSIs and reporting ≥95% compliance with selected process measures. Implementation of data submission mandates has engendered concerns about diverting resources from infection prevention efforts towards satisfying data submission requirements.[17, 18] This study demonstrated 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. Though lower overall rates and SIR were noted in NICUs in states with data submission mandates, and lower rates were noted in NICUs, which reported higher compliance, this association was only significant for infants ≤ 750 grams at birth. A potential explanation of this finding could be the overall low CLABSI rates in higher BW groups, and a sample size inadequate 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. In addition reported compliance in both groups was low which could have contributed to us not observing an effect in infection rates. Corroborating this finding, studies from adult populations have hitherto not shown a consistent effect of mandatory reporting on CLABSI rates.[19]

This study has limitations. The sample represented less than 25% of the total NHSN national sample 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 as having participated. The mandate was considered as having a similar effect within all NICUs within a state, which may have led to bias. 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.[20] Our methodology cannot determine if 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 [7] that was not addressed, as we only considered the presence of mandatory data submission requirements and did not analyze other variations in provisions of HAI laws (e.g. public reporting, facility identifiers, use of 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, though children's hospitals are exempt from this provision and contributed to the majority of study NICUs.

In conclusion, in this national study of NICUs, we demonstrated a significant association between data submission mandates for CLABSIs and higher reported compliance with CLABSI prevention practices. This association appears to wane with duration of the mandate and enforces the importance of further work to reassess this association after mandates are in place for a longer duration. NICUs in states with data submission mandates also reported lower CLABSI rates, though this association was not statistically significant. Further studies could examine these effects longitudinally with larger samples; such studies have important ramifications for designing optimal reporting strategies for HAIs.

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Table 1

Characteristics of NICUs in states with and without mandatory reporting requirements for CLABSI (bivariate analysis)

Variables	Mandatory Reporting (n=107)	No Mandatory Reporting (n=83)
	n (%)	
NICU characteristics		
Level II/III NICU	57 (53.2)	46 (55.4)
Level III NICU	50 (46.7)	37 (44.6)
NICU size (beds)		
≤15	25 (23.4)	18 (21.7)
16–30	57 (53.3)	54 (65.1)
31–45	19 (17.8)	6 (7.3)
≥46	6 (5.6)	5 (6.0)
Medical School Affiliation		
Teaching	72 (67.3)	51 (61.5)
Non-Teaching	35 (32.7)	32 (38.6)
Ownership		
For Profit/Other	18 (16.8)	22 (26.5)
Not for profit	89 (83.2)	61 (73.5)
Children's Hospital		
Yes	97 (90.7)	79 (95.2)
No	10 (9.4)	4 (4.8)
Location*		
Northeast (9 states & Washington, DC)	41 (38.3)	5 (6.0)
Midwest (12 states)	30 (28.0)	6 (7.2)
South (17 states)	14 (13.1)	40 (48.1)
West (11 states)	21 (19.6)	31 (37.3)
Other (HI, AK, PR)	1 (0.93)	1 (1.2)
Presence of Statewide Collaborative prior to 2011*	33 (30.8)	8 (9.6)
Location in state included in CUSP*	23 (27.7)	17 (15.9)

* $p<0.001$

Table 2

Process and outcome measures in NICUS with and without mandatory reporting requirements (bivariate analysis)

	Mandatory Reporting (n=107)	No Mandatory Reporting (n=83)	p
Process measures (≥ 95% compliance)	**n(%)**		
Use of checklist at insertion	57 (53.3)	28 (33.7)	0.007
Insertion Bundle			
Hand Hygiene	67 (62.6)	42 (50.6)	0.1
Use of maximum barrier precautions	71 (66.4)	40 (48.2)	0.02
Choice of optimum catheter site	66 (61.7)	30 (37.3)	0.01
Maintenance Bundle			
Assessment of daily necessity	56 (52.3)	24 (28.9)	0.001
All components	39 (36.4)	14 (16.8)	0.002
Outcome Measures			
Total Events/Central Line days			
Mean CLABSI rate/1000 CL-days			
Overall	1.2	1.6	0.2
*≤750 g**	2.4	5.7	0.05
751–1000 g	1.7	2.7	0.1
1001–1500 g	1.3	1.2	0.9
1501–2500 g	0.8	0.9	0.9
>2500 g	0.8	0.3	0.3
Standardized Infection Ratio			
Mean (± SD)/Median	1.6 (±4.7)/0.2	2.7 (±7.1)/0.3	0.2

Table 3

Association of presence of mandatory state reporting of NICU CLABSI rates with process and outcome measures in multivariable logistic regression*

	Parameter	SE	Odds ratio 95%CI	p
Process Measure				
≥95% compliance with all prevention practices	1.1	0.4	2.8 (1.4–6.1)	0.005
≥95% compliance with at least one prevention practice	0.8	0.3	2.2 (1.2–4.3)	0.01
Outcome Measure				
Standardized Infection Ratio (SIR<1)	0.3	0.4	1.3 (0.6–2.6)	0.5

*Adjusted for NICU size, NICU level, location, medical school affiliation, hospital ownership and participation in a statewide collaborative and/or CUSP initiative

Table 4

Variation of process and outcome variables with number of years of mandatory state reporting

Mandatory state reporting (years)	NICU n (%)	≥95% compliance with at least one component n (%)	≥95% compliance with all components n (%)	SIR<1 n (%)	Mean (Median) CLABSI rate/1000 CL-days
None	83(43.7)	46 (55.4)	14 (16.8)	56 (67.4)	1.6 (0.9)
1–3 years	55 (28.9)	41 (74.5)*	23 (41.8)*	43 (78.2)	1.0 (0.7)
> 3 years	52(27.4)	37 (71.2)	16 (30.7)	37 (71.2)	1.4 (0.7)

* $p < 0.05$