The Art and Science of Infusion Nursing

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Innovative Use of Existing Public and Private Data Sources for Postmarketing Surveillance of Central Line-Associated Bloodstream Infections Associated With Intravenous Needleless Connectors

ABSTRACT

The Centers for Medicare and Medicaid Services (CMS) Hospital Compare central line-associated bloodstream infection (CLABSI) data and private databases containing new-generation intravenous needleless connector (study NC) use at the hospital level were linked. The relative risk (RR) of CLABSI associated with the study NCs was estimated, adjusting for hospital characteristics. Among 3074 eligible hospitals in the 2013 CMS database, 758 (25%) hospitals used the study NCs. The study NC hospitals had a lower unadjusted CLABSI rate (1.03 vs 1.13 CLABSIs per 1000 central line days, $P < .0001$) compared with comparator hospitals. The adjusted RR for CLABSI was 0.94 (95% confidence interval: 0.86, 1.02; $P = .11$).

Key words: Centers for Medicare and Medicaid Services (CMS) Hospital Compare, central line-associated bloodstream infections (CLABSIs), Food and Drug Administration (FDA), Healthcare Infection Control Practices Advisory Committee (HICPAC), intravenous device, intravenous needleless connectors (NCs), postmarket surveillance, private-public partnership, Section 522, Federal Food, Drug, and Cosmetic Act

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The Food and Drug Administration Amendments Act of 2007 mandated the US Food and Drug Administration (FDA) to develop methods to obtain access to disparate data sources and to validate methods for the establishment of a post-market risk identification and analysis system to link and analyze medical device safety data from multiple sources.[1,2] As a pilot, the Mini-Sentinel Initiative has established the Sentinel System Architecture for pooling patient-level data from various sources, including billing, drug prescription/dispensing, and other data captured by health or insurance plans, and health care providers.[3,4]

Although much medical product use information can be gathered at the patient level through billing and other sources, medical devices widely used in the process of patient care, such as intravenous (IV) devices, usually are not billed at the patient level. These devices are an integral part of patient care, which potentially can be associated with risk of severe adverse events, such as IV device-associated bloodstream infections (BSIs). Section 522 of the Federal Food, Drug and Cosmetic Act authorizes the FDA to require manufacturers to conduct postmarketing surveillance of class II or class III devices, if their failure would be reasonably likely to have serious adverse health consequences.[5] Following the recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC)[6] related to positive displacement needleless connectors (NCs), the FDA issued a 522 postmarketing surveillance order to all manufacturers of positive displacement NCs in September 2010, possibly considering this a class effect.

The Centers for Medicare and Medicaid Services (CMS) publicly report hospital outcome comparison data, including central line-associated bloodstream infection (CLABSI) rates.[7] The CLABSI data reported by CMS Hospital Compare are collected through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).[8] The CDC is responsible for conducting health care-associated infection (HAI) surveillance and for developing HAI prevention guidelines. Acute care hospitals are required to report CLABSI rate data and selected other HAI data through the CDC's NHSN to receive payments from CMS. The CLABSI measure applies to patients treated in acute care hospitals, including adult, pediatric, neonatal, and Medicare and non-Medicare patients. Given its comprehensiveness, it is conceivable that the CMS Hospital Compare database may provide timely information on CLABSIs associated with the use of a given IV device.

The objective of this analysis was to evaluate the possibility of monitoring hospital-acquired CLABSI rates potentially associated with IV NC use by linking the publicly reported CMS hospital CLABSI data and IV NC use data from a private source, the study NC. CLABSI rates in hospitals using the study NC versus hospitals using other IV NCs were compared.

METHODS

Data Source

The CMS Hospital Compare data reported in 2013 (FY 2012) were downloaded from the CMS Web site.[7] The CMS data included hospital identification number, name, address, central line days, number of CLABSI episodes, and NHSN standardized infection ratio (SIR) by hospital. Also downloaded from the CMS site were hospital characteristics (ie, bed size, intern-resident-to-beds [IRB] ratio, and CMS geographic region category, rural/urban status).[9] The 2 CMS data sets were merged to create 1 CMS data set.

Merging CMS and IV Device Use Databases

All hospitals with 1 or more central line days in the CMS data set were merged with the MaxPlus Positive Displacement Connector (the study NC) client database (CareFusion, San Diego, CA) during the corresponding period to identify hospitals using the study NCs (study NC hospitals) versus those not using the study NCs (comparator hospitals). The study NC is a new generation of NC with new patient safety engineering design features.

Statistical Analysis

The distribution of hospital characteristics of the study NC versus comparator hospitals was compared. The unadjusted CLABSI rates and the NHSN SIRs in the CMS database were aggregated by the study NC versus comparator hospitals. The NHSN SIR is calculated for specific types of patient care locations, such as medical intensive care units (ICUs) and surgical ICUs at the hospital level.[7] Using the random intercept Poisson regression approach,[10,11] 2 models were fit to estimate the relative risk (RR) for CLABSIs associated with the use of the study NC versus other NCs (comparators): (1) adjusting for the care locations according to the NHSN data, ie, the ratio of SIRS (study NCs/comparator NCs); and (2) adjusting for hospital IRB, bed size, rural/urban status, and geographic region, in addition to the care locations. The CDC HICPAC review[6] and the FDA-recommended methods[12] were used to compute a noninferiority margin, allowing comparison against both an RR of 1.0 and a noninferiority margin of 1.23.

Sensitivity Analysis

Since only the device order data from the manufacturer of the study NC was available, the exclusivity of study NC use at each facility was not certain. Two sensitivity analyses were conducted: (1) restricting facilities to those that ordered the study NCs every month (high-frequency facilities); and (2) restricting facilities to those that were

at the top quartile of normalized volume intensity (high-volume intensity facility), which was defined as total number of the study NCs ordered during the study period divided by total number of hospital beds.

RESULTS

Descriptive Statistics

Overall, 3074 hospitals in the CMS Hospital Compare database reported central line days ≥ 1 during FY 2013 (Table 1). Among them, 758 hospitals used the study NCs, accounting for 25% (758/3074) of the hospitals. The study NC hospitals were more likely to be major teaching hospitals (larger IRB) ($P < .0001$), urban ($P < .0001$), and with a larger number of beds ($P < .0001$) than comparator hospitals.

The study NC hospitals accounted for 30% (2 923 859/9 887 264) of central line days and 28% (3017/10 864) of total CLABSI episodes (Table 2). The study NC hospitals had a lower unadjusted CLABSI rate (1.03 per 1000 central line days [3017 CLABSIs/2 923 859 central line days]) compared with comparator hospitals (1.13 per 1000 central line days [7847 CLABSIs/6 963 405 central line days], $P < .0001$). The NHSN CLABSI SIR was 0.51 (95% confidence interval [CI]: 0.49, 0.53) for the study NC hospitals versus 0.57 (95% CI: 0.56, 0.58) for comparator hospitals.

RR of CLABSI of the Study NC Versus Comparators

Compared with comparator hospitals, the study NC hospital CLABSI RR was 0.91 (95% CI: 0.83, 0.98; $P = .02$), adjusting for care location only. After further adjusting for hospital characteristics, the multivariable CLABSI RR of the study NC hospitals was 0.94 (95% CI: 0.86, 1.02; $P = .11$) (Table 3). Both care location-adjusted RR and full care location- and hospital characteristics-adjusted RR demonstrated that the upper limit of the 95% CIs were well below the noninferiority margin of 1.23, meeting the statistical criterion of noninferiority. The Poisson multivariable model also revealed that bed size and IRB were not significantly associated with CLABSI risk, but urban location and some geographic regions were significantly associated with higher CLABSI risk.

Sensitivity Analysis

Figure 1 summarizes the RR and 95% CIs for CLABSI in the study NC hospitals. The overall RR (95% CI) was 0.94 (0.86, 1.02). For hospitals that ordered the study NCs for all 12 months, the RR (95% CI) was 0.95 (0.85, 1.06). For hospitals in the top quartile of volume intensity, the RR (95% CI) was 0.88 (0.77, 1.02). Thus, results of the hospitals with the highest order frequency or volume intensity were consistent with the overall result.

DISCUSSION

The FDA is under legal mandate to establish a postmarket surveillance system for monitoring FDA-regulated medical product safety by linking existing electronic databases from government agencies, private health or insurance plans, and industry.[1,2] Device manufacturers are required to provide postmarketing safety surveillance data. Considerable effort has been expended in integrating patient-level data from the government-initiated programs. The FDA Mini-Sentinel Initiative is 1 such pioneering approach to aggregate large patient-level data sets from various sources intending to monitor the safety of pharmaceutical products in the postmarketing setting.[3,4] However, some FDA-regulated devices, such as IV NCs, are used extensively during the acute care process, but typically are not billed at the patient level. To monitor potential adverse events, ecological data analysis using linked public and private data sources at the hospital level may be a practical and less burdensome approach for both the FDA and industry. The analysis here demonstrates that such an approach might be worth further investigation.

CMS data offer the most current and comprehensive data on CLABSI incidence and standardized CLABSI outcome measures across all eligible hospitals in the United States. For the first time, the 2013 CLABSI report included the number of observed and expected CLABSIs, and central line days, in addition to the SIRs in the previous report.[6] Because such detailed nationwide CLABSI data were not available for public access previously and because CLABSI rates in association with positive displacement NCs are of general interest to the FDA, the CDC, and the clinical community,[13] it is timely and reassuring from the perspective of patient safety that the CLABSI rate associated with the use of the study NC, a newer-generation positive displacement NC, was not elevated and that it met the criterion of statistical noninferiority.

The advantages of using publicly reported outcome data include (1) there is no sampling bias, because all reporting hospitals are included; (2) there is no potential conflict of interest compared with data collected by manufacturers themselves; (3) these are the most current CLABSI data with minimal lag time; (4) the comparison is concurrent, which eliminates potential bias inherent to pre-post period study designs; (5) the CLABSI surveillance data are collected, using the CDC's NHSN definition, by hospital infection preventionists prospectively rather than through a retrospective review; and (6) it has potential societal benefit to limit the cost burden of surveillance, which, in turn, may reduce overall costs associated with health care.

TABLE 1

Characteristics of Hospitals Using the Study NC Versus Comparators' NCs

Hospital Characteristics	Study NC Hospitals		Comparator Hospitals		*P* Value
	n	%	n	%	
Total number of hospitals	758	100	2316	100	
Intern-residence-to-bed ratio					< .0001
0	440	58.0	1595	68.8	
> 0 and ≤ 0.25	228	30.1	513	22.2	
> 0.25 and ≤ 0.6	59	7.8	110	4.7	
> 0.6	26	3.4	66	2.8	
Urban/rural status					< .0001
Rural	162	21.4	723	31.2	
Urban	591	78.0	1561	67.4	
Bed size					< .0001
< 100	139	18.3	675	29.1	
100-300	423	55.8	1200	51.8	
> 300	196	25.9	441	19.0	
CMS region					.0004
Virgin Islands (VI)	0	0.0	1	0.0	
New England (CT, MA, ME, NH, RI, VT)	42	5.5	107	4.6	
Mid-Atlantic (NJ, NY, PA)	85	11.2	275	11.9	
Southern Atlantic (DC, DE, FL, GA, MD, NC, SC, VA, WV)	104	13.7	446	19.3	
East North Central (IL, IN, MI, OH, WI)	155	20.4	357	15.4	
East South Central (AL, KY, MS, TN)	50	6.6	204	8.8	
West North Central (IA, KS, MN, MO, ND, NE, SD)	59	7.8	166	7.2	
West South Central (AR, LA, OK, TX)	98	12.9	287	12.4	
Mountain (AZ, CO, ID, MT, NM, NV, UT, WY)	48	6.3	156	6.7	
Pacific (AK, CA, HI, OR, WA)	117	15.4	301	13.0	
Puerto Rico (PR)	0	0.0	16	0.7	

Abbreviations: CI, confidence interval; CMS, Centers for Medicare and Medicaid; NC, needleless connectors.
US Postal Service abbreviations: AK, Alaska; AL, Alabama; AR, Arkansas; AZ, Arizona; CA, California; CO, Colorado; CT, Connecticut; DC, District of Columbia; DE, Delaware; FL, Florida; GA, Georgia; HI, Hawaii; IA, Iowa; ID, Idaho; IL, Illinois; IN, Indiana; KS, Kansas; KY, Kentucky; LA, Louisiana; MA, Massachusetts; MD, Maryland; ME, Maine; MI, Michigan; MN, Minnesota; MO, Missouri; MS, Mississippi; MT, Montana; NC, North Carolina; ND, North Dakota; NE, Nebraska; NH, New Hampshire; NJ, New Jersey; NM, New Mexico; NV, Nevada; NY, New York; OH, Ohio; OK, Oklahoma; OR, Oregon; PA, Pennsylvania; PR, Puerto Rico; RI, Rhode Island; SC, South Carolina; SD, South Dakota; TN, Tennessee; TX, Texas; UT, Utah; VA, Virginia; VI, Virgin Islands; VT, Vermont; WA, Washington; WI, Wisconsin; WV, West Virginia; WY, Wyoming.

There are limitations to using hospital-level data. It would be ideal if all devices could have unique device identifiers (UDIs) that could be tracked at the patient level. However, the UDI is currently required only for class III medical devices. For widely used IV devices, such as NCs, it does not seem likely that UDIs will be mandated any time soon. Therefore, patient-level capture of this type of device use may not be feasible at this time or in the near future. There is a possibility that hospital-level data analysis may not adequately adjust for patient risks when risk stratification is limited to hospital characteristics. However, CDC's NHSN data have shown that care units, such as ICUs, are 1 of the most important risk factors for CLABSI.[7] The analysis here went beyond the NHSN care location stratification, further adjusting for hospital characteristics. It found that the urban location and certain geographic regions were associated with higher CLABSI risk, while bed size and teaching status were not. There is an advantage to gathering data at the hospital level because

TABLE 2
Descriptive Statistics

Hospital Characteristics	Study NC Hospitals (n = 758)					Comparator Hospitals (n = 2316)				
	Central Line Days	Observed CLABSI, n	Observed CLABSI Rate /1000 Central Line Days	NHSN Expected CLABSI, n	Observed/ Expected Ratio (95% CI)	Central Line Days	Observed CLABSI, n	Observed CLABSI Rate /1000 Central Line Days	NHSN Expected CLABSI, n	Observed/ Expected Ratio (95% CI)
Total	2 923 859	3017	1.03	5888	0.51 (0.49, 0.53)	6 963 405	7847	1.13	13 795	0.57 (0.56, 0.58)
Bed size										
< 100	57 769	56	0.97	90	0.62 (0.47, 0.79)	233 749	175	0.75	366	0.48 (0.41, 0.55)
100-300	845 016	730	0.86	1439	0.51 (0.47, 0.54)	2 264 368	2362	1.04	3962	0.60 (0.57, 0.62)
> 300	2 011 591	2226	1.11	4344	0.51 (0.49, 0.53)	4 433 238	5285	1.19	9418	0.56 (0.55, 0.58)
Intern-residence-to-bed ratio										
0	776 605	655	0.84	1313	0.50 (0.46, 0.54)	2 246 091	2185	0.97	3803	0.57 (0.55, 0.60)
> 0 and ≤ 0.25	1 186 591	1189	1.00	2318	0.51 (0.48, 0.54)	2 681 679	2847	1.06	5221	0.55 (0.53, 0.57)
> 0.25 and ≤ 0.6	639 153	778	1.22	1496	0.52 (0.48, 0.56)	1 109 482	1477	1.33	2520	0.59 (0.56, 0.62)
> 0.6	321 510	395	1.23	761	0.52 (0.47, 0.57)	926 153	1338	1.44	2251	0.59 (0.56, 0.63)
Rural/urban status										
Rural	123 988	107	0.86	203	0.53 (0.43, 0.63)	320 277	237	0.74	509	0.47 (0.41, 0.53)
Urban	2 791 971	2906	1.04	5672	0.51 (0.49, 0.53)	6 623 754	7599	1.15	13 256	0.57 (0.56, 0.59)
CMS geographic region										
Virgin Islands (VI)						366	2	5.46	1	3.64 (0.41, 8.77)
New England (CT, MA, ME, NH, RI, VT)	126 228	146	1.16	270	0.54 (0.46, 0.63)	240 242	276	1.15	480	0.57 (0.51, 0.64)
Mid-Atlantic (NJ, NY, PA)	362 613	446	1.23	763	0.58 (0.53, 0.64)	1 008 833	1272	1.26	2063	0.62 (0.58, 0.65)
Southern Atlantic (DC, DE, FL, GA, MD, NC, SC, VA, WV)	419 041	498	1.19	849	0.59 (0.54, 0.64)	1 669 069	1920	1.15	3371	0.57 (0.54, 0.60)
East North Central (IL, IN, MI, OH, WI)	583 960	546	0.93	1146	0.48 (0.44, 0.52)	930 108	968	1.04	1866	0.52 (0.49, 0.55)
East South Central (AL, KY, MS, TN)	181 791	244	1.34	356	0.69 (0.60, 0.77)	544 239	731	1.34	1103	0.66 (0.62, 0.71)
West North Central (IA, KS, MN, MO, ND, NE, SD)	207 011	174	0.84	408	0.43 (0.37, 0.49)	364 482	321	0.88	744	0.43 (0.39, 0.48)
West South Central (AR, LA, OK, TX)	422 860	421	1.00	855	0.49 (0.45, 0.54)	842 791	946	1.12	1588	0.60 (0.56, 0.63)
Mountain (AZ, CO, ID, MT, NM, NV, UT, WY)	158 979	176	1.11	322	0.55 (0.47, 0.63)	480 469	443	0.92	913	0.49 (0.44, 0.53)
Pacific (AK, CA, HI, OR, WA)	461 376	366	0.79	919	0.40 (0.36, 0.44)	840 621	873	1.04	1587	0.55 (0.51, 0.59)
Puerto Rico (PR)						42 185	95	2.25	81	1.17 (0.94, 1.41)

Abbreviations: CI, confidence interval; CLABSI, central line-associated blood stream infection; CMS, Centers for Medicare and Medicaid; NC, needleless connector; NHSN, National Healthcare Safety Network.
US Postal Service abbreviations: AK, Alaska; AL, Alabama; AR, Arkansas; AZ, Arizona; CA, California; CO, Colorado; CT, Connecticut; DC, District of Columbia; DE, Delaware; FL, Florida; GA, Georgia; HI, Hawaii; IA, Iowa; ID, Idaho; IL, Illinois; IN, Indiana; KS, Kansas; KY, Kentucky; LA, Louisiana; MA, Massachusetts; MD, Maryland; ME, Maine; MI, Michigan; MN, Minnesota; MO, Missouri; MS, Mississippi; MT, Montana; NC, North Carolina; ND, North Dakota; NE, Nebraska; NH, New Hampshire; NJ, New Jersey; NM, New Mexico; NV, Nevada; NY, New York; OH, Ohio; OK, Oklahoma; OR, Oregon; PA, Pennsylvania; PR, Puerto Rico; RI, Rhode Island; SC, South Carolina; SD, South Dakota; TN, Tennessee; TX, Texas; UT, Utah; VA, Virginia; VI, Virgin Islands; VT, Vermont; WA, Washington; WI, Wisconsin; WV, West Virginia; WY, Wyoming.

TABLE 3

Poisson Regression Model Results

Variables	Central Line Days	Observed CLABSI, n	Observed CLABSI Rate/1000 Central Line Days	NHSN Expected CLABSI, n	Relative Risk (95% CI)	*P* Value
Study NC vs comparator hospitals						
Study NC	2 923 859	3017	1.03	5888	0.94 (0.86, 1.02)	.1147
Comparators	6 963 405	7847	1.13	13 795	Reference	
Bed size						
< 100	291 518	231	0.79	456	Reference	
100-300	3 109 384	3092	0.99	5401	1.00 (0.85, 1.17)	.9899
> 300	6 444 829	7511	1.17	13 762	0.90 (0.76, 1.07)	.2315
Intern-residence-to-bed ratio						
0	3 022 696	2840	0.94	5116	0.91 (0.78, 1.06)	.2360
> 0 and ≤ 0.25	3 868 270	4036	1.04	7539	0.87 (0.75, 1.01)	.0594
> 0.25 and ≤ 0.6	1 748 635	2255	1.29	4016	0.97 (0.82, 1.15)	.7173
> 0.6	1 247 663	1733	1.39	3011	Reference	
Urban vs rural status						
Urban	9 415 725	10 505	1.12	18 928	1.28 (1.10, 1.48)	.0011
Rural	444 265	344	0.77	712	Reference	
CMS geographic region						
Virgin Islands (VI)	366	2	5.46	1	10.38 (1.73, 62.43)	.0106
New England (CT, MA, ME, NH, RI, VT)	366 470	422	1.15	751	1.20 (0.95, 1.53)	.1306
Mid-Atlantic (NJ, NY, PA)	1 371 446	1718	1.25	2826	1.46 (1.22, 1.76)	< .0001
Southern Atlantic (DC, DE, FL, GA, MD, NC, SC, VA, WV)	2 088 110	2418	1.16	4219	1.35 (1.13, 1.61)	.0010
East North Central (IL, IN, MI, OH, WI)	1 514 068	1514	1.00	3011	1.12 (0.93, 1.34)	.2195
East South Central (AL, KY, MS, TN)	726 030	975	1.34	1459	1.46 (1.19, 1.80)	.0003
West North Central (IA, KS, MN, MO, ND, NE, SD)	571 493	495	0.87	1152	Reference	
West South Central (AR, LA, OK, TX)	1 265 651	1367	1.08	2443	1.28 (1.06, 1.54)	.0102
Mountain (AZ, CO, ID, MT, NM, NV, UT, WY)	639 448	619	0.97	1234	1.03 (0.83, 1.27)	.7806
Pacific (AK, CA, HI, OR, WA)	1 301 997	1239	0.95	2505	1.13 (0.94, 1.36)	.1879
Puerto Rico (PR)	42 185	95	2.25	81	2.54 (1.65, 3.91)	< .0001

Abbreviations: CLABSI, central line-associated blood stream infection; CMS, Centers for Medicare and Medicaid; NC, needleless connectors; NHSN, National Healthcare Safety Network.

US Postal Service abbreviations: AK, Alaska; AL, Alabama; AR, Arkansas; AZ, Arizona; CA, California; CO, Colorado; CT, Connecticut; DC, District of Columbia; DE, Delaware; FL, Florida; GA, Georgia; HI, Hawaii; IA, Iowa; ID, Idaho; IL, Illinois; IN, Indiana; KS, Kansas; KY, Kentucky; LA, Louisiana; MA, Massachusetts; MD, Maryland; ME, Maine; MI, Michigan; MN, Minnesota; MO, Missouri; MS, Mississippi; MT, Montana; NC, North Carolina; ND, North Dakota; NE, Nebraska; NH, New Hampshire; NJ, New Jersey; NM, New Mexico; NV, Nevada; NY, New York; OH, Ohio; OK, Oklahoma; OR, Oregon; PA, Pennsylvania; PR, Puerto Rico; RI, Rhode Island; SC, South Carolina; SD, South Dakota; TN, Tennessee; TX, Texas; UT, Utah; VA, Virginia; VI, Virgin Islands; VT, Vermont; WA, Washington; WI, Wisconsin; WV, West Virginia; WY, Wyoming.

these data do not contain sensitive patient-specific information. It may be more feasible to link across data sources, which may encourage broad participation from the private sector. The linked hospital-level data would provide a valuable source of information for the FDA and industry to monitor the postmarket safety of devices that are not captured at the patient level.

This study did not have access to other private data sources regarding types of IV NCs used by the comparator hospitals, so the exclusivity-use status of the study

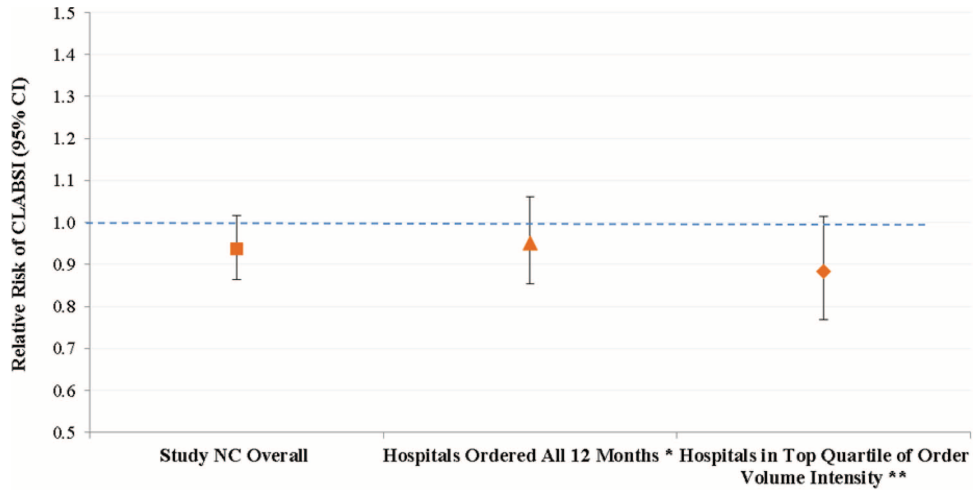

Figure 1 Adjusted relative risk (95% CI) for CLABSI by the study NC order frequency and volume intensity. All models adjusted for CDC NHSN classification of care units (MICU, SICU, etc), CMS classification of hospital bed size, teaching status, rural/urban status, and geographic locations. *Order frequency: number of months the study NCs were ordered during the 12-month study period. **Volume intensity: total number of study NCs ordered during the study period divided by total number of hospital beds.
Abbreviations: CDC, Centers for Disease Control and Prevention; CI, confidence interval; CLABSI, central line-associated bloodstream infection; CMS, Centers for Medicare and Medicaid Services; MICU, medical intensive care unit; NC, needleless connector; NHSN, National Healthcare Safety Network; SICU, surgical intensive care unit.

device was uncertain. In this study's sensitivity analysis, consistent results were found when hospitals were restricted to those with the highest order frequency and those with the highest bed size-normalized volume intensity. Furthermore, because hospitals using comparator NCs had significantly higher unadjusted CLABSI rates, the potential misclassification of mixed-device use by the study NC sites would bias the study finding toward the null hypothesis, which is unfavorable to the study device.

The study's primary objective was to explore the possibility of potential partnership of the public and private sector to establish a nationwide system for the FDA to query and pick up possible early warning signs of adverse events, such as CLABSI elevation potentially associated with certain NCs. If all manufacturers were to participate in the effort by providing lists of their clients who purchased their devices in a given time period, the FDA could determine the exclusive versus nonexclusive status for each facility. The CLABSI data then could be aggregated into exclusive versus mixed-device use categories, while maintaining anonymity of business-client relationships. This linked and aggregated CLABSI monitoring and early-warning sign system could be near real time and accomplished at a relative low cost to both the FDA and industry.

CONCLUSIONS

The CMS data are current, comprehensive, and representative of all US acute care hospitals in bed size, teaching status, rural status, and geographic locations. Effort may be expanded to encourage industry to participate in the FDA initiatives by providing the FDA access to hospital-level device use data. This government and private-sector partnership may enable the FDA to electronically monitor nationwide device safety signals with a practical and minimum-burden approach. This analysis demonstrated that the study device was not associated with elevated CLABSI, as it demonstrated statistical noninferiority. Linking publicly reported hospital-level outcome data with private data sources for postmarket surveillance of IV devices that are not typically captured at the patient level might be an approach worthy of further study.

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