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**ABSTRACT**

Central line-associated bloodstream infections (CLABSIs) can result in increased morbidity and mortality and billions of dollars of costs per year to institutions and patients. Fluctuating availability of manufacturers' supplies of intravenous (IV) solutions have created issues for health systems in which policy and procedures have been examined regarding extended hang time for IV solutions. This article examined the relationship between extended hang times of nonadditive IV solutions and incidence of CLABSIs in intensive and general practice inpatient units in a quaternary care setting. The incidence of CLABSIs with extended hang times of up to 96 hours, of nonadditive IV solutions, has demonstrated that significant changes in CLABSIs were not evident.

**Key words:** catheter-related infections, central line-associated bloodstream infections, CLABSI, cross infection, equipment contamination, hospital-acquired infection, infection, infusions, intravenous, time factors

Hospitals can use hundreds of thousands of intravenous (IV) solution bags per day depending on patient census and acuity. If manufacturer production interruptions occur and trigger supply shortages of small- or large-volume infusates, the subsequent supply of either size IV bag can also be affected. Supply issues of sodium chloride and dextrose IV solutions have occurred intermittently dating back to 2013, when manufacturers began notifying US hospitals that they might begin experiencing delivery delays.[1,2]

Periodic shortages of IV solutions were exacerbated in the summer of 2017 when quality-related production interruptions occurred at B. Braun Medical. Several months later, in September of 2017, Hurricane Maria caused power interruptions and damage to Baxter International manufacturing plants in Puerto Rico. These situations left 2 of the 3 major IV solution suppliers unable to meet market demands and caused critical supply issues for US health care institutions in early 2018.[1-3] The national shortage of IV solutions in 2018 prompted many health care administrators and supply officers to search for options to meet the IV fluid needs of patients. Subsequently, many health care institutions have had to revise policies and procedures related to how IV solution administration is managed.

This retrospective research study examined changes in the incidence of central line- associated bloodstream infections (CLABSIs) after IV solution administration policy and procedure revisions were triggered by IV solution shortages. The study took place at an 887-bed, quaternary care hospital located in the Midwestern United States, where IV solutions were obtained from 3 US manufacturers (Baxter International, B. Braun Medical, and Hospira Inc) via a distributor. The staff was notified via email by the chief nursing officer (CNO) when the procedural change to extend hang times would begin for nonadditive IV solutions and the reasons for this change. It was also announced at the monthly patient care services meeting where attendance is required by all nurse managers and nursing leadership personnel. Clinical nurse staffing in intensive care units (ICUs) and general practice units (GPUs) remained consistent before and after the intervention, as did patient census.

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## BACKGROUND

CLABSIs are grouped under the umbrella of hospital-acquired infections (HAIs), which can cause significant morbidity and mortality and billions of dollars of expense each year.[4] In a systematic review by Zimlichman et al,[5] estimated costs per CLABSI were $51,505 per patient and $2.02 billion annually (converted to today's dollars), an 18.9% share of all HAIs. The US Department of Health and Human Services has made it a priority to reduce HAIs in patients, although no specific guidelines or standards of practice are evident regarding hang times of nonadditive IV solutions from the Centers for Disease Control and Prevention (CDC).[6] The *Guidelines for the Prevention of Intravascular Catheter-Related Infections* were developed in collaboration with professional organizations representing various health care disciplines.[7] However, these and other organizations have not provided specific directives for managing hang times of nonadditive IV solutions.[6-8]

Although other studies have examined patient safety related to lengthening hang times of IV administration sets, few have examined the relationship between extending the hang times of nonadditive IV solutions beyond 24 hours and the incidence of CLABSIs. Investigators who tested IV solutions for growth found no incidence of microbial colonization in IV fluids after 24-hour hang times.[9] To evaluate whether solutions were contaminated before use, Brock-Utne et al[10] randomly tested stock IV solution bags (Hospira Inc, Lake Forest, IL) and noted that no microbial growth was evident. Other authors have explored tangentially related issues, such as strategies to decrease CLABSIs after a spike in incidence,[11] as well as negative and positive aspects of central catheters, and best evidence to avoid CLABSIs.[12] Others reported on the establishment of a vascular access team and provided guidance to decrease central line usage and incidence of CLABSIs.[13] In 2019, Shang et al[14] examined staffing and its relationship to all HAIs, including urinary tract infections, bloodstream infections, and pneumonias. Their findings indicated that short staffing was related to incidence of HAIs.[14] In summary, factors related to IV solutions and incidence of CLABSIs have been explored, but no studies were found that directly examined the relationship of CLABSI incidence to IV solution hang times of >24 hours and up to 96 hours. The purpose of this study was to test the hypothesis that there would be no change in the inpatient incidence of CLABSIs in ICU or GPU populations when nonadditive IV solution hang times were extended. The study aim included identifying the incidence of CLABSIs before and after the time period when IV hang times were extended.

## METHODS

The study protocol was reviewed and approved by the hospital institutional review board before project implementation. A retrospective chart review was completed on a convenience sample of 2967 inpatients who were admitted from mid-September 2017 through mid-February 2018.

### Data Collection

The data were abstracted electronically and included the variables: length of stay, CLABSI incidence, diagnoses, gender, IV type and IV hang time in hours, patient care unit, and patient age at admittance. No formal tools or questionnaires were used to drive the data abstraction process, but the researchers and a nurse practice expert met with the data abstractor several times before and during data abstraction to discuss the aims of the study, define and clarify the variables of interest, and address related issues. Data were collected for the comparison and intervention groups over a 2.5-month time period. The comparison group included ICU and GPU patients who received nonadditive IV solutions before the policy change. After a 2-week delay following the policy change, data collection began for the intervention group that included ICU and GPU patients who received the same type of nonadditive solutions. The 2 weeks between policy change and the beginning of the intervention period allowed time for the clinical nursing staff to transition to the revised policy.

Nonadditive IV solutions included 0.9% sodium chloride, dextrose, or lactated Ringer's solution that are hung for the purpose of keeping a vein open (KVO) for fluid volume replacement or for periodic IV-push medication administration. Patients in the ICUs had at least 1 nonadditive IV solution for the purpose of KVO for IV medication administration or for fluid volume replacement if needed. Patients on GPUs frequently had nonadditive IV solutions for fluid replacement, KVO, or IV medications. The standard of care for patients with central catheters remained consistent throughout the course of the study for both the intervention and comparison groups. The CDC definition of CLABSI was used at the study site to define and track the incidence of CLABSIs.[15]

### Statistical Analysis

For the power characteristics of the analyses, an infection rate of 0.5% was assumed in the comparison group so that, with the given sample size, a change to $\geq$1.5% could be detected in the intervention group with 80% power and a 2-sided $\alpha$ level of 0.05. Sample data were analyzed using SAS, version 9.4 (SAS Institute, Inc, Cary, NC). For the analyses, nominal variables were examined for differences between groups using a $\chi^2$ test. Continuous variables were analyzed using the *z* tests.

## RESULTS

The ages of patients within the total sample of 2967 patients ranged from 15 to 101 years. The mean age in the comparison group was 54.46 $\pm$ 18.82 years, and the mean age in the intervention group was 53.16 $\pm$ 19.06 years. Women composed 59.76% (n = 1773) of the total sample,

**TABLE 1**

## Cross-tabulations: Gender by Group Membership

| | Group | | | | | |
|---|---|---|---|---|---|---|
| | Intervention | | Comparison | | Total | |
| Gender | N | % | N | % | N | % |
| Male | 774 | 40.3 | 420 | 40.1 | 1194 | 40.2 |
| Female | 1145 | 59.7 | 628 | 59.9 | 1773 | 59.8 |
| Total | 1919 | 100 | 1048 | 100 | 2967 | 100 |

and men composed 40.24% (n = 1194) of the total sample (Table 1).

The comparison of the mean length of stay found that the comparison group (7.43 ± 8.08 days) was longer than the intervention group (6.71 ± 7.13 days; $P = 0.01$). This difference was statistically significant ($Z = 2.46$). The average total IV hours did not differ significantly between the comparison group (n = 757; 45.10 ± 31.06 hours) and the intervention group (n = 1376; 44.68 ± 28.34 hours). IV hours were not consistently recorded in all patient charts, and these missing data in some patient records account for the decreased sample sizes when examining total IV hours in the comparison and intervention groups (Table 2).

The number of infections were compared between the intervention and comparison groups after a retrospective review of patient records. Based on this review, 5 infections (0.27%) were found in the intervention group, and 2 (0.20%) were found in the comparison group (Table 3). Because of the small number of infections in the 2 groups, statistical testing for differences was not conducted.

Although not a specific aim of the study, the admitting diagnoses were obtained for the study participants. Because of the myriad of diagnoses, with many patients having multiple comorbidities, an inclusive list was not completed. Instead, the 3 most noted diagnoses in the 2 groups were determined. Common to both groups was the diagnosis of sepsis. In the intervention group, 9 participants (13.6%) in the ICU and 28 (42.4%) in the GPU groups were diagnosed with sepsis. The comparison group had 4 (6.1%) in the ICU and 25 (37.9%) in the GPU with this diagnosis. No other admitting diagnoses were common among the 4 groups. Table 4 presents these diagnoses for the intervention and control groups by ICU and GPU.

## DISCUSSION

The study identified incidences of CLABSIs before and after the time period when IV hang times were extended up to 96 hours. Five infections (0.27%) were found in the experimental group and 2 (0.20%) in the comparison group, indicating that increased hang time did not contribute to higher infection rates. Clinically, this research provided supportive evidence for health care administrators and providers who are concerned about the safety of extending IV hang times and are seeking guidance to support policy changes. This study

**TABLE 2**

## Comparison of Patient-Related Variables

| Hospital-based variables | N | M | SD | Minimum | Maximum | Z value |
|---|---|---|---|---|---|---|
| Length of stay | | | | | | |
| Comparison | 1048 | 7.43 | 8.08 | 1.00 | 72.00 | 2.46[a] |
| Intervention | 1919 | 6.71 | 7.13 | 1.00 | 71.00 | |
| Age at admittance | | | | | | |
| Comparison | 1048 | 54.46 | 18.82 | 16.00 | 101.00 | 1.86 NS |
| Intervention | 1919 | 53.16 | 19.06 | 15.00 | 98.00 | |
| IV hours | | | | | | |
| Comparison | 757 | 45.10 | 31.06 | 1.30 | 234.47[b] | −0.26 NS |
| Intervention | 1376 | 44.68 | 28.34 | 1.03 | 219.65[b] | |

Abbreviations: IV, intravenous; NS, not significant.

[a] $P \leq .05$.

[b] Patients were hospitalized for >1 week and had >1 IV. According to hospital policy, no single IV was hung for >96 hours, and the totals here reflect total number of hours with an IV.

**TABLE 3**

## Cross-tabulations: Number of CLABSIs by Group Membership

| | Group | | | | | |
|---|---|---|---|---|---|---|
| | Intervention | | Comparison | | Total | |
| CLABSIs | N | % | N | % | N | % |
| Infection – no | 1914 | 99.7 | 1046 | 99.8 | 2960 | 99.8 |
| Infection – yes | 5 | 0.3 | 2 | 0.2 | 7 | 0.2 |
| Total | 1919 | 100 | 1048 | 100 | 2967 | 100 |

Abbreviation: CLABSI, central line-associated bloodstream infection.

examined what other researchers have not by comparing the incidence of CLABSIs between increased hang times of nonadditive IV solutions (up to 96 hours) and the standard of care (hang times of ≤24 hours). The findings demonstrated that significant changes in the incidence of CLABSIs were not evident. As a result, the current study provides support to change the standard of care for hanging IV solutions up to 96 hours in ICU and GPU practice settings.

## STRENGTHS AND LIMITATIONS

The sample size of this study, 2967 patients, drawn from both GPU and ICU practice settings, was large enough to be generalizable to similar adult practice unit populations. One limitation of the study is that there may have been more emphasis on infection control or safe IV management after the intervention versus before the intervention. The change to 96 hours for IV hang time was announced by the CNO to unit leadership and was based on shortages of solutions. The reasoning was made evident with emphasis on safe techniques, which was standard practice. CLABSIs have also been tracked in hospital-wide meetings on a daily basis for the last 5 years. Data about patient admission and discharge diagnoses were collected with the intent of identifying patients who were more likely to develop CLABSIs. However, the abstracted data revealed that many patients had multiple diagnoses and, in total, >3900 different diagnoses combinations were attributed to the sample, which precluded additional analyses.

**TABLE 4**

## Admitting Diagnoses

| Group | Admitting Diagnosis | Number |
|---|---|---|
| ICU – intervention | Sepsis | 9 |
| GPU – intervention | | 28 |
| ICU – comparison | | 4 |
| GPU – comparison | | 25 |
| Remainder of diagnoses were specific to group | | |
| Diagnosis by CLABSI | | |
| ICU – intervention | Candidal sepsis | 1 |
| | Diffuse large B-cell lymphoma | 1 |
| GPU – intervention | Bloodstream infection | 2 |
| | Antineoplastic chemotherapy | 1 |
| ICU – comparison | Postsurgical malabsorption | 1 |
| GPU – comparison | Hypertensive heart and chronic kidney disease | 1 |

Abbreviations: CLABSI, central line-associated bloodstream infection; GPU, general practice unit; ICU, intensive care unit.

## CONCLUSION AND IMPLICATIONS FOR POLICY

Considering this study's findings, in which increased hang times of nonadditive IV solutions did not appear to contribute to increased incidence of CLABSIs, current hospital policy should reflect the safety of hanging nonadditive IV solutions for a period of up to 96 hours. Based on these results, the policy for IV solution hang times was changed permanently at the hospital where the study was implemented. Lengthened hang times of IV solutions would also synchronize with recommended hang times and replacement of IV tubing administration sets (96 hours)[7,8] and minimize the risk of potential contamination that can occur when IV delivery systems are unnecessarily broken to change solutions. Nonadditive saline or dextrose IV solutions were evaluated in this study with participants from both ICUs and GPUs. This methodology contributes to the generalizability of policy changes in similar health center populations.


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