Reducing Bloodstream Infections in Pediatric Rehabilitation Patients Receiving Parenteral Nutrition

abstract

OBJECTIVE: To report our quality improvement efforts to reduce total parenteral nutrition (TPN)-associated bloodstream infections, and the results of those efforts, during the period including the first quarter of 2004 through the third quarter of 2010.

METHODS: A variant on failure modes and effect analysis and existing guidelines were used to develop and modify interventions. Effectiveness of the interventions was assessed by using a graphical depiction of interrupted time-series data on TPN-associated infections per 1000 TPN-days, aggregated across quarters within intervention periods.

RESULTS: Although initial interventions yielded limited reductions in infection rates, it was not until the implementation of a multifaceted “maintenance intervention bundle” that rates strongly responded. After this key intervention revision, the TPN-associated infection rate decreased between implementation in the first quarter of 2008 from 26.1 to 4.8 per 1000 TPN-days during the 8 quarters comprising the first quarter of 2008 through the fourth quarter of 2009. The final addition of an alcohol-swab cap resulted in a reduction of rates to 0 for the first three-quarters of 2010.

CONCLUSIONS: Our evidence suggests that iterative design/redesign of interventions using failure modes and effect analysis has directly reduced TPN-associated bloodstream infections. Pediatrics 2011;128: e1273–e1278

AUTHORS: Frank Vincent Castello, MD, Anne Maher, MS, CIC, and Gregory Cable, PhD, MPA

Medical Department, Children’s Specialized Hospital, New Brunswick, New Jersey

KEY WORDS: central line–associated bloodstream infection, total parenteral nutrition, failure modes and effect analysis, maintenance intervention bundle

ABBREVIATIONS

CLABSI—central line–associated bloodstream infection
TPN—total parenteral nutrition
NACHRI—National Association of Children’s Hospitals and Related Institutions
CSH—Children’s Specialized Hospital
FMEA—failure modes and effect analysis
MIB—maintenance intervention bundle

Dr Castello and Ms Maher made substantial contributions to conception and design, drafting and revising the article, and acquiring the data and were part of the team involved in final approval of the manuscript; Dr Cable made substantial contributions to the design, analysis and interpretation of the data, and drafting and revising the article, and Dr Cable was part of the team involved in final approval of the manuscript:

www.pediatrics.org/cgi/doi/10.1542/peds.2010-3617
doi:10.1542/peds.2010-3617

Accepted for publication Jun 22, 2011

Address correspondence to Frank Vincent Castello, MD, Children’s Specialized Hospital, 200 Somerset St, New Brunswick, NJ 08901. E-mail: fcastello@childrens-specialized.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Copyright © 2011 by the American Academy of Pediatrics

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.
Central line–associated bloodstream infection (CLABSI) has been recognized as a serious and costly patient safety issue. One recent analysis of >1.3 million admissions revealed an additional cost of $19,643 (in constant 2006 dollars) associated with hospital-acquired bloodstream infections. Catheter-related bloodstream infections and their clinical sequelae have been estimated to cost between $36,000 and $50,000 per infection. Evidence-based guidelines for prevention of CLABSI are based primarily on studies of ICU populations rather than pediatric patients. Little information is available regarding long-term infection rates of patients who receive total parenteral nutrition (TPN) in an acute rehabilitation setting. To assist in the establishment of a baseline infection rate for this population and develop strategies to ameliorate rates, we contacted the National Association of Children’s Hospitals and Related Institutions (NACHRI) to help create a benchmarking group among the specialty hospital members.

Children’s Specialized Hospital (CSH) is a 60-bed pediatric rehabilitation hospital that has >500 admissions per year and serves children primarily affected by brain injury, spinal cord dysfunction and injury, and complications of premature birth, including a small population of children diagnosed with short-gut syndrome, intestinal atresia, or failure to thrive and require TPN. Patients have central lines in place on admission, and CSH does not insert or remove these lines. These young patients are particularly vulnerable to contracting CLABSI because of the length of time that the central lines remain in place. Review of the hospital’s infection-surveillance data in 2004 revealed that 70% of CLABSIs occurred in inpatients who were receiving TPN, and the rate was 38.5 infections per 1000 TPN-days. Further analysis of the 2004 data revealed that 7 infections occurred in the 3 patients who received TPN at CSH that year. Although all 3 patients were successfully treated, the infections were costly interruptions to their clinical progress.

The purpose of our quality improvement project was to reduce the incidence of CLABSI in patients who receive TPN. This article documents our quality improvement process and the results associated with our interventions, which were written following Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines.

METHODS

Intervention Design/Redesign

To address the specific problem of TPN infections, CSH created a task force with the goal of reducing the incidence of CLABSI in this vulnerable group. The task force was led by the CSH medical director and infection preventionist and included additional representatives from the medical department, as well as nurses, nurse educators, pharmacists, and therapists. Although there are benchmarks for CLABSIs and guidelines for their prevention in acute care, extant literature provided little guidance for prevention in a rehabilitation setting. Consequently, the task force decided to identify the unique problems and potential solutions in this context by using a process-analysis methodology, failure modes and effect analysis (FMEA), which permitted the determination of areas of breakdown potential in TPN processes, and the selection and implementation of customized interventions to prevent bloodstream infections.

FMEA is a process-analysis methodology that typically includes review of the process, identification of potential “failure modes” or breakdown points, assignment of a risk priority number based on risk, severity and detection of failure modes, prioritization of failure modes for action, and actions to reduce or eliminate high-risk failure modes. In applying FMEA to this process at CSH, each step in the pharmacy and nursing processes for TPN administration was examined in detail using flow diagrams. Those processes are depicted as they existed at the initiation of this effort in Figs 1 and 2. Using a consensus process, the task force estimated severity ratings and probability of occurrence for each potential breakdown point, which in turn were used to estimate individual hazard ratings (ie, severity × probability of occurrence). The following priority breakdown points were identified: hand hygiene; spiking of bags; line priming; and connection to extension. Detection of failure modes was not included in our FMEA process, because it assumes controls in the process such

![FIGURE 1](TPN process for pharmacy. QA indicates quality assurance; HEPA, high-efficiency particulate air.)
The process as each patient on TPN received TPN was instituted. By reviewing admission of each patient who received care with care providers before the duty at all times to oversee TPN-line least 1 of these nurses would be on TPN lines. The expectation was that only core team members would access setup occurred. The intent was that an accidental disconnection of the TPN process to be followed when interruptions during setup and when an accidental disconnection of the setup occurred. The intent was that only core team members would access TPN lines. The expectation was that at least 1 of these nurses would be on duty at all times to oversee TPN-line care. A thorough review of the TPN process with care providers before the admission of each patient who received TPN was instituted. By reviewing the processes as each patient on TPN was admitted, the staff could focus on their responsibilities, which in turn would increase the likelihood that the interventions were implemented with fidelity to the intervention design. This component was essential, because the hospital encounters a relatively low volume of patients who receive TPN, and weeks often pass between such admissions.

The third component was the education/reeducation of all therapy disciplines regarding infection risks associated with TPN lines. The purpose of the education was to reduce the likelihood that therapists would accidentally disconnect lines during therapies and would immediately report any line disconnections while taking appropriate ameliorating steps. Finally, the fourth component of the intervention was revision of and training for use of antiseptics. Although antiseptic soap was not readily available in patient rooms where TPN was administered, alcohol gel had recently been installed. Staff were required to sanitize their hands with alcohol gel before all line access. In addition, 2% chlorhexidine was to be used as the skin antiseptic in the dressing kit, because it has a broader antiseptic spectrum than the iodine product previously used.10

Finally, the task force instituted a program of continuous evaluation of TPN team competency, which included audits of antiseptic and disinfecting processes. This process specifically entailed repeated, systematic assessment of staff adherence to the protocols. All clinical components of the initial intervention were instituted in May 2005.

Late in 2007, the hospital moved to a new building in which the configuration of the nursing units did not include an enclosed medication room for priming TPN lines. This circumstance made implementation of the existing intervention more difficult and entailed some reengineering of this component of the intervention. Consequently, the task force reviewed current infection-prevention strategies in the acute care literature and developed a maintenance intervention bundle (MIB).10 The MIB included priming of TPN-administration sets in the pharmacy sterile hood, use of sterile gloves and masks for line access, and use of chlorhexidine for line disinfection before entry. The task force developed a checklist that included all of the aseptic nursing practices. Managers and supervisors used the checklist to observe staff periodically and monitor compliance with the MIB. Nurse educators trained pharmacists to prime lines and conducted sessions for all nurses to educate them regarding the revised TPN-administration protocols. The implementation plan included tracking of “infection-free line-days” and providing feedback to staff. The revised intervention that featured the MIB component was implemented during the first quarter of 2008. Finally, during 2008 and 2009 the task force examined additional ways of augmenting the MIB and settled on adding an alcohol-swab cap. This device is a plastic cap with a foam pad saturated with 70% isopropyl alcohol inside of it. It is attached to the intravenous valve and serves to disinfect the valve between medication administrations.11
the cap was implemented during the first quarter of 2010.

**Data Analysis**

To assess the effectiveness of the interventions, we used an interrupted time-series design in which data on TPN-associated CLABSIs per 1000 TPN-days were aggregated across quarters within intervention periods; there were 6 pre-intervention quarters serving as a baseline period. The data were aggregated in this manner because of the low number of TPN admissions. Data were collected through chart review of patients on TPN by a single infection preventionist and were reviewed by the infection preventionist for evidence of CLABSI according to Centers for Disease Control and Prevention criteria. Definitions of measurements and modes for collecting and processing blood cultures were unchanged during the study period. Patients on TPN, and the period during which each was on TPN, were identified by the pharmacy department. Graphical depictions of rate change after the interventions were used to assess intervention effects. A \(\chi^2\) test was used to assess the difference between the pre/post-MIB intervention at \(\alpha = .05\).

**RESULTS**

Twenty-seven patients were included in this analysis: 13 patients (average age: 51 months) in the pre-MIB group and 14 patients (average age: 52.8 months) in the post-MIB group (Tables 1 and 2). Seven of 13 patients (54%) in the pre-intervention group were noted to have short-gut syndrome, and 6 of 14 patients (43%) in the post-intervention group had short-gut syndrome. Figure 3 shows the CLABSI rates per 1000 TPN-days, the number of patient associated infections, and the total number of TPN-days during the baseline and intervention periods from the first quarter of 2004 to the third quarter of 2010. TPN-associated infection rates decreased from baseline to the period after the interventions that were the result of the FMEA process (33.5–26.5 per 1000 TPN-days), although the rate was stable across several quarters. Consequently, the task force reviewed the available evidence regarding the implementation of patient associated infections, and the total number of TPN-days during the baseline and intervention periods from the first quarter of 2004 to the third quarter of 2010. TPN-associated infection rates decreased from baseline to the period after the interventions that were the result of the FMEA process (33.5–26.5 per 1000 TPN-days), although the rate was stable across several quarters. Consequently, the task force reviewed the available evidence regarding the implementation

**TABLE 1** Characteristics of Patients on TPN

<table>
<thead>
<tr>
<th></th>
<th>Baseline and Pre-MIB Intervention ((n = 13))</th>
<th>Post-MIB Intervention ((n = 14))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mo</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>51</td>
<td>52.8</td>
</tr>
<tr>
<td>Range</td>
<td>3–196</td>
<td>9–204</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male, (n)</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Female, (n)</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td><strong>Diagnosis: short-gut syndrome, (n) (%)</strong></td>
<td>7 (54)</td>
<td>6 (43)</td>
</tr>
</tbody>
</table>

**TABLE 2** Number of Patients, Associated Infections, and TPN-Days Before and After Implementation of the MIB

<table>
<thead>
<tr>
<th></th>
<th>Baseline and Pre-MIB Intervention</th>
<th>Post-MIB Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients, (n)</strong></td>
<td>16</td>
<td>22</td>
</tr>
<tr>
<td><strong>Infections, (n)</strong></td>
<td>23</td>
<td>2</td>
</tr>
<tr>
<td><strong>TPN-days</strong></td>
<td>813</td>
<td>808</td>
</tr>
</tbody>
</table>

\(P < .01\) for pre-intervention versus post-intervention infections per TPN-day.

**FIGURE 3**

Effect of interventions on CLABSI rates per 1000 TPN-days from the first quarter of 2004 to the third quarter of 2010. Note that patients might be counted twice in adjacent periods. The total number of unique patients was 23. Q indicates quarter.
of the interventions and identified a few likely causes of the stable TPN-associated CLABSI rates. The task force found that changes in nursing staffing and TPN-administration times likely affected the ability to maintain a core team for care of central lines. The task force also found that the implementation audits were incomplete; audits had focused on hand hygiene to the exclusion of other aspects of nursing care of the lines, thus diminishing our ability to assess the fidelity with which the intervention was being implemented. Finally, as described previously, CSH revised the intervention to feature the MIB component, which was implemented during the first quarter of 2008 (results are shown in Fig 3). After the revised intervention, the TPN-associated infection rate decreased between implementation in the first quarter of 2008 from 26.1 to 4.8 per 1000 TPN-days during the 8 quarters aggregated comprising the first quarter of 2008 through the fourth quarter of 2009. Finally, the data in Fig 3 and Table 2 show the effect of the MIB and swab-cap intervention; the number of infections after the MIB/swab-cap intervention diminished precipitously. Subsequent to implementation of the swab cap, no TPN-associated CLABISIs have been recorded.

DISCUSSION

The purpose of this quality improvement project was to reduce the incidence of CLABISIs in our patients who receive TPN. Our evidence suggests that the interventions have directly reduced the number of these infections. During this process, we have found that the FMEA approach was an essential framework for determining and reassessing the TPN process flow and infection risks for the pediatric rehabilitation patient receiving TPN. FMEA led us to empirically based adjustments of interventions, which included the adoption and customization of published infection-prevention strategies for maintenance of central lines, which our evidence suggests was effective in providing improved patient care.

This quality improvement intervention study is limited in some ways regarding our ability to rule out all other explanations for the decline in rates, as well as our ability to generalize our findings. First, we were not able to conduct a randomized controlled trial, which we believe is inappropriate in this context given the unacceptable risk posed by our high infection rates (in addition, of course, to being impractical in one institution). The interrupted time-series design we used is subject to a well-known threat to internal validity in which influences external to those of the intervention activities could have affected the rate of infections at the same time that the interventions were implemented, termed “history” threats to internal validity. Because of the presence of a large number of time periods in our series in which we had no TPN admissions, we were unable to use associated statistical modeling techniques (eg, interrupted time series with Box-Jenkins modeling), which would have enhanced our ability to make stronger causal claims through statistical controls. Consequently, we are not able to completely rule out the possibility that history effects occurred concomitantly with the initial intervention and each revision and enhancement to the initial intervention.

Nonetheless, for a number of reasons we believe that our interventions were largely responsible for reducing the number of infections. First, although one can never completely rule out the possibility that outcome-relevant, undetected (or undetectable) changes in the patient composition could have occurred over time and thus increased the likelihood of temporal selection bias, we partially addressed this potential problem by documenting the similar composition of the patients regarding demographic variables. Important for our causal assertion is that the critical diagnostic variable (short-gut syndrome) was similar before and after the MIB. Second, the clinical theory undergirding our intervention activities is consistent with the mechanism by which CLABISIs occur, and the interventions were implemented rapidly and with a high level of fidelity. Also, the context in which the interventions were implemented was highly controlled, which reduced the likelihood that any strong forces outside of the MIB could have occurred unobserved. In this context, strong forces might specifically include undetectable changes over time in the patients on TPN admitted during the study that could reduce the likelihood that they would get a CLABSI, regardless of the effectiveness of the intervention, as mentioned earlier.

As a purely logical matter, any unmeasured, external forces would have had to occur at the exact time (or nearly so) of implementation of each intervention enhancement for any of them to confound the effects implied by the intervention. Moreover, because unmeasured external forces could plausibly increase or reduce rates, the unmeasured rate-reducing forces would have to have been stronger than rate-increasing forces, which again would have had to occur contiguously with our interventions to produce the results presented here, which we consider highly improbable. Finally, history threats to internal validity are more plausible when interventions are expected to result in gradual rather than abrupt effects. In our study, the initial intervention and each enhancement were implemented rapidly and resulted in immediate reductions in rates.
Although our results reflect outcomes at a single institution at a specific interval in time, we believe that the effects of our interventions are highly reproducible within our institution going forward and within other similar institutional contexts. The key process-related components of our success—convening a multidisciplinary task force comprising clinical leaders and staff, the use of the FMEA process to identify the specific areas that were felt to be of greatest concern to maintaining a sterile procedure, and conducting periodic auditing and specific feedback to the clinical staff on the number of infection-free days—are all portable.

REFERENCES

12. Montgomery VL, O’Flynn J, Zink K, Bryant KA, Campbell D. Characteristics of catheter-related bloodstream infections (CR-BSI) occurring in a pediatric intensive care unit (PICU) after implementation of an insertion bundle [abstr]. Presented at: 5th World Congress on Pediatric Critical Care; June 24–28, 2007; Geneva, Switzerland
Reducing Bloodstream Infections in Pediatric Rehabilitation Patients Receiving Parenteral Nutrition
Frank Vincent Castello, Anne Maher and Gregory Cable
*Pediatrics* 2011;128;e1273; originally published online October 24, 2011; DOI: 10.1542/peds.2010-3617
Reducing Bloodstream Infections in Pediatric Rehabilitation Patients Receiving Parenteral Nutrition
Frank Vincent Castello, Anne Maher and Gregory Cable
Pediatrics 2011;128;e1273; originally published online October 24, 2011;
DOI: 10.1542/peds.2010-3617

The online version of this article, along with updated information and services, is located on the World Wide Web at:
/content/128/5/e1273.full.html