

Improving Hospital Infant Safe Sleep Compliance by Using Safety Prevention Bundle Methodology

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BACKGROUND AND OBJECTIVES: Sudden unexpected infant death often results from unsafe sleep environments and is the leading cause of postneonatal mortality in the United States. Standardization of infant sleep environment education has been revealed to impact such deaths. This standardized approach is similar to safety prevention bundles typically used to monitor and improve health outcomes, such as those related to hospital-acquired conditions (HACs). We sought to use the HAC model to measure and improve adherence to safe sleep guidelines in an entire children's hospital.

METHODS: A hospital-wide safe sleep bundle was implemented on September 15, 2017. A safe sleep performance improvement team met monthly to review data and discuss ideas for improvement through the use of iterative plan-do-study-act cycles. Audits were performed monthly from March 2017 to October 2019 and monitored safe sleep parameters. Adherence was measured and reviewed through the use of statistical process control charts (p-charts).

RESULTS: Overall compliance improved from 9% to 72%. Head of bed flat increased from 62% to 93%, sleep space free of extra items increased from 52% to 81%, and caregiver education completed increased from 10% to 84%. The centerline for infant in supine position remained stable at 81%.

CONCLUSIONS: Using an HAC bundle safety prevention model to improve adherence to infant safe sleep guidelines is a feasible and effective method to improve the sleep environment for infants in all areas of a children's hospital.

Sudden unexpected infant deaths (SUIDs) are the number 1 cause of postneonatal mortality and accounted for 3607 infant deaths in the United States in 2016.¹ SUIDs are comprised of the following categories: sudden infant death syndrome, accidental suffocation and strangulation in bed, and unknown.² The American Academy of Pediatrics (AAP) recommends all parents receive education on how to create a safe sleep environment for their infant and that newborn nurseries (NBNs) and NICUs "model the SIDS risk-reduction recommendations

from birth."² However, unsafe sleep practices during hospital stays result in injuries and deaths every year, suggesting that the AAP recommendations are not always followed in the newborn period.^{3–7}

Hospital-acquired conditions (HACs) are "conditions that a patient develops while in the healthcare setting while being treated for something else [and] cause harm to patients."⁸ HAC safety prevention bundles are evidence-based guidelines that have been promulgated by the Children's

abstract

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Hospitals' Solutions for Patient Safety (SPS) and include bundles to prevent conditions such as catheter-associated urinary tract infections (CAUTIs). These bundles provide detailed elements for team members to follow to prevent each HAC. Data from SPS and others reveal that when safety prevention bundle adherence reaches and remains at 80% or higher, measured by using auditing tools, compliance is considered to be complete and the risk of HACs decreases or the HACs no longer occur.^{9,10} Continued monitoring of high bundle adherence has been revealed to enhance safety over time.¹⁰ Sleep-related deaths in the hospital and after discharge could be considered hospital-acquired if unsafe sleep practices were modeled during an infant's hospital stay, as 1 study has revealed that effective hospital education for newborns can impact postdischarge behavior.¹¹

Many institutions have shown that quality improvement (QI) projects can improve safe sleep compliance in NBNs and NICUs.¹²⁻¹⁵ However, it is also important that children's hospitals incorporate safe sleep elements into their entire inpatient infant population for a number of reasons:

1. Caregivers may not have received or absorbed the proper education at the time of delivery;
2. Many inpatients aged <1 year have a history of prematurity, and studies have revealed that these medically fragile infants are at higher risk of death from SUID^{16,17};
3. AAP recommendations regarding safe sleep apply through the entire first year of life, and hospitals can continue to reinforce concepts and reeducate parents about the risks of unsafe sleep; and

4. Despite ongoing public health efforts, declining deaths related to SUID have plateaued.¹⁸

Although previous studies have revealed that QI methodology can positively impact safe sleep in a hospital setting,¹⁹⁻²² the inclusion of an HAC standardized bundle takes an evidence-based approach that "ties the changes together into a package of interventions that people know must be followed for every patient, every single time."²³ In addition, HAC bundles become part of the safety culture of a hospital and are reviewed on a regular basis by hospital and departmental leadership, whereas other QI projects might fall off the radar once the project is over.

On the basis of the methodology advocated by SPS, we sought to increase adherence to safe sleep practices for all infants across an entire children's hospital from 9% to at least 80% over a 2-year period using an HAC bundle model, an approach that has not been reported previously.

METHODS

Study Setting

Penn State Children's Hospital is a tertiary care, academic, pediatric hospital in Southcentral Pennsylvania, with 114 inpatient beds, including a 42-bed NICU. There are 2100 deliveries per year, and the NICU has ~600 admissions per year. This QI project was aimed to improve safe infant sleep practices in the following units: NICU, general inpatient, hematology and oncology, peri-anesthesia, PICU, pediatric intermediate care, and maternity and NBN.

This project was approved as exempt by the Penn State College of Medicine Institutional Review Board.

Interventions

The hospital safe sleep committee (a team of physicians, registered nurses, occupational therapists, and child life specialists) began meeting in July 2016 to update the existing safe sleep policy to reflect coverage beyond the NICU and the maternity ward and to create elements of the HAC bundle, which are detailed in the measures section below.

Members of the safe sleep committee audited a convenience sample of admitted infants (aged <1 year) each month from March 2017 through October 2019 (no data collected June 2017), ensuring representation from each unit and from day and evening shifts. Audit methodology (direct observation of compliance with HAC bundle elements) was the same across units and shifts. The goal was to audit at least 30 infants per month on the basis of the minimum subgroup size common guideline for p-charts.²⁴

Interventions were chosen by team members during multidisciplinary team meetings. Four key time points and/or interventions across the study period were (1) nursing education on the HAC bundle, and the updated policy was completed in August 2017; (2) the HAC bundle and policy were both implemented on September 15, 2017; (3) nursing councils began to share audit data in March 2018; and (4) peer-to-peer bundle checklist reviews during registered nurse shift handoff (by using a reference card listing the bundle elements), and electronic medical record (EMR) addition to create a nursing task to provide parent safe sleep education (triggered automatically by admission order for a patient aged <1 year), were implemented in March 2019. A key component of both the bundle and policy included health care providers' role modeling safe sleep practices. Ongoing education was provided to various entities

throughout the organization, including faculty, volunteers, and nursing staff.

Although there was constant iterative learning from monthly audit reports, other notable education interventions during the study period included the following: (1) September 2017: education to parents through updating newborn video instruction and increased exposure to appropriate safe sleep modeling; (2) March 2018: safe sleep committee members visited nursing unit councils to share audit data; and (3) February 2019: subject matter expert training by guest speakers from the University of Pennsylvania as part of a Pennsylvania Department of Health grant to improve safe sleep in Pennsylvania (Pennsylvania Safe Sleep Program) and distribution of new parent education brochures with clear pictures of safe and unsafe sleep practices.

Measures

In addition to overall compliance (compliance with all measures combined), there were 3 outcome measures that were tracked over the study period: infant in supine position, head of bed flat, and sleeping space free of extra items. We also included the process measure of caregivers having received safe sleep education, which was recorded in the EMR by the nurses after completion. Medical exceptions to supine and flat sleep position included airway compromise (including Pierre-Robin sequence), congenital malformation, life-threatening gastrointestinal reflux, palliative care, respiratory distress, and other, which were specified by the ordering provider. Only patients with medical exceptions were excluded from data reporting.

Analysis

All data are categorical and therefore statistical control charts

(p-charts) were used to measure progress on the above measures. Charts were created with QI-Charts version 2.0.23 (Scoville Associates, Austin, TX, 2009). Rules used for identifying special cause were (1) a single point outside control limits, (2) a run of ≥ 8 points in a row above or below the centerline, and (3) 6 consecutive points increasing or decreasing.²⁴

RESULTS

Eighteen percent of eligible patients were audited (average of 53 audits per month and an average 293 eligible admissions per month). Overall compliance with all 4 measures was low in the beginning of our quality initiative (9%), and there was a centerline shift to 36% after implementation of the updated policy and HAC bundle (Fig 1). Further special-cause variation was noted in the context of further QI efforts in January and July 2019, with centerline shifts to 53% and 72%, respectively. The infant in supine position measure (Fig 2) stayed relatively constant over the entire study period, with no centerline shift (81%). Keeping the

head of bed flat (Fig 3) had a starting centerline of 62%, with special-cause variation in April 2018 coincident with sharing of audit data, leading to a centerline shift to 80% and a further centerline shift in October 2018 to 93%. Maintaining a sleep space free of extra items began with a centerline of 52% and shifted to 81% in April 2018, concurrent with sharing of audit data (Fig 4). The process measure of caregivers receiving safe sleep education increased from 10% to 66% to 84% during the study period (Fig 5), with the first special-cause variation occurring when nursing education was rolled out in August 2017 and the second special-cause variation occurring in February 2019, which was not immediately preceded by a major intervention. Although there was variation among individual units, the trends were all similar, and thus we present aggregate hospital data only.

DISCUSSION

Our study reveals that it is possible to use the HAC safety prevention bundle model and apply it to safe sleep to improve adherence to the

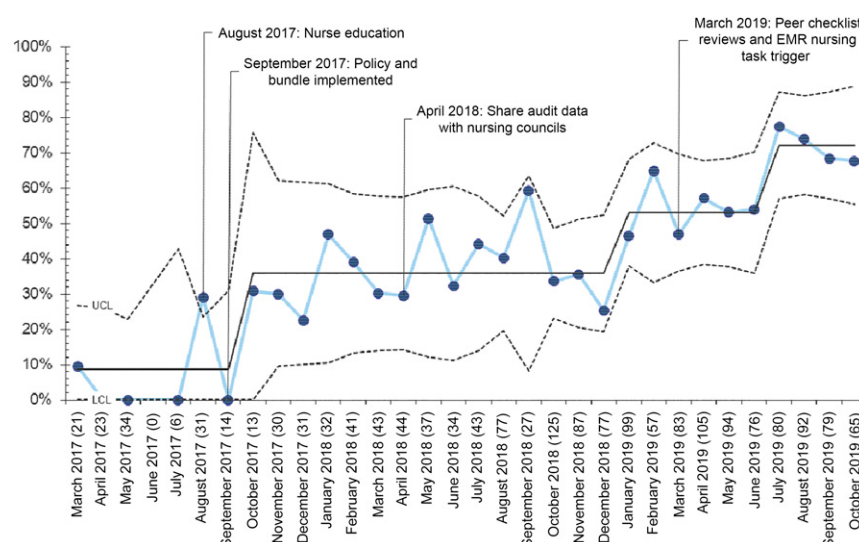


FIGURE 1

Statistical process control chart revealing monthly overall compliance with all 4 safety measures combined. LCL, lower control limit; UCL, upper control limit.

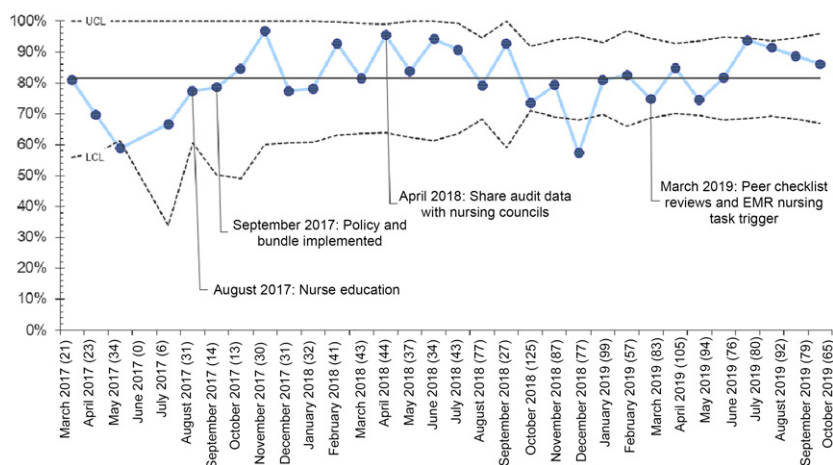


FIGURE 2

Statistical process control chart revealing monthly compliance with the infant in supine position measure. LCL, lower control limit; UCL, upper control limit.

bundle of AAP guidelines for all hospitalized infants. Safe sleep recommendations should be followed by both staff and family every time an infant who does not have a medical exception enters a children's hospital. Consistent modeling of appropriate practices will reinforce safe sleep standards for families once they return home, with the potential to save lives.¹¹ Evidence-based safety prevention bundles have been revealed to be effective ways to help mitigate harmful events, such as HACs, that can develop in a medical setting.^{25–28}

HAC bundles are traditionally used for conditions that have the potential to cause harm when a patient intersects with the health care system. These conditions are more common in, but not exclusive to, the hospital setting. Typical HAC conditions lend themselves to be counted in a binary fashion, such as, “Was this infection due to an indwelling catheter or central line?” Although the risk of unsafe sleep is not often thought of as a risk due to a hospital-related condition, the process of implementing safety bundle methodology was useful for

increasing adherence with the different AAP-defined measures. In our study, we use audits and run charts to measure failure to adhere to the prevention bundle, as opposed to the traditional HAC (eg, CAUTI), which measures audits but also actual clinical events that occur because of failure to adhere to the prevention bundle. Having clearly defined bundle elements, instructions on how to perform these elements, and knowledge that they were being measured helped improve our compliance. In addition, adding peer-to-peer bundle checklist reviews with a ready reference of the bundle helped to improve staff knowledge and engagement with safe sleep practices. The above measures enabled us to strive to the audit goal of >80% adherence revealed to decrease traditionally measured HACs.^{9,10}

Applying the principle of an HAC bundle to safe sleep presents some challenges because there are many components to a safe sleep environment.² In a hospital setting with a wide variety of patients, from typical newborns to infants with complex medical needs, developing scoring criteria to capture all of these elements was challenging because there are potentially many exceptions to the AAP policy because of the medical conditions of a patient. By measuring some of the individual safe sleep elements, we were able to get a clearer picture of compliance and opportunities for improvement than would have been possible by simply calculating overall compliance.

The measurement parameter infant in a supine position was well established at the start of our quality initiative and was maintained at a high rate of compliance throughout the QI initiative (Fig 2). This is the one variable we measured that did not reveal improvement. This may be

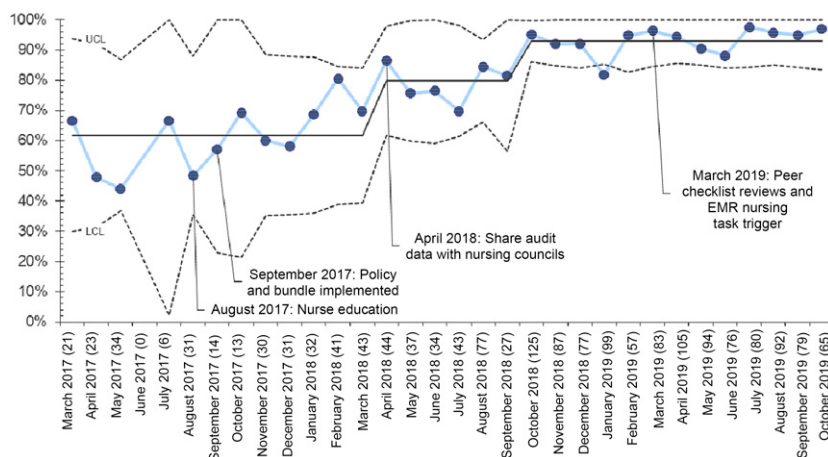


FIGURE 3

Statistical process control chart revealing monthly compliance with keeping the head of the bed flat. LCL, lower control limit; UCL, upper control limit.

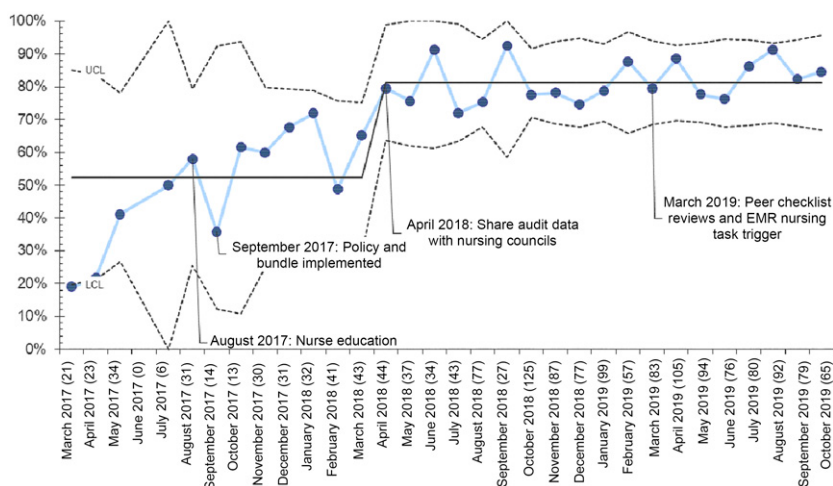


FIGURE 4

Statistical process control chart revealing monthly compliance with maintaining sleep space free of extra items. LCL, lower control limit; UCL, upper control limit.

expected given the focus of the 1994 AAP Back to Sleep campaign was to place all infants to sleep on their back. This message continues to be taught today as part of the safe sleep message; it is reassuring to see our high rate of compliance. However, we should continue to strive to achieve 100% compliance to this measure.

Keeping the head of the bed flat appeared to be the metric that is most challenging for many hospitalized patients. At our institution, it was

common to slightly elevate the head of newborn bassinets before this intervention. This antiquated practice was found to be supported by nurses and medical providers despite evidence and recommendations to the contrary.²⁹ There is no evidence that infants have more reflux if the head of the bed is flat, and the AAP policy clearly states that the sleeping surface should be flat.² Through our education efforts, we were able to reveal improvement in this metric (Fig 3).

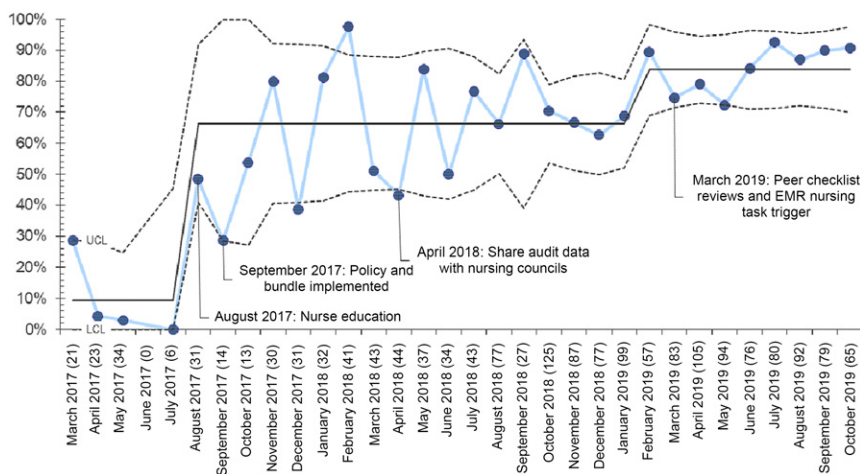


FIGURE 5

Statistical process control chart revealing monthly compliance with caregivers receiving safe sleep education. LCL, lower control limit; UCL, upper control limit.

At baseline, adherence to sleeping space free of extra items was lower than the infant in a supine position measure and was an area for which ongoing education and reminders were needed (Fig 4). Avoiding loose bedding in the sleep environment is especially important for infants outside of the NBN because 1 study revealed that infants aged ≥ 4 months more often succumb to SUID from rolling into objects, whereas younger infants die more often from bed-sharing.³⁰

Providing and documenting parent education was identified to be the bundle element with greatest opportunity for improvement early in the project (Fig 5). Staff roles in providing consistent and standard education and modeling to families was crucial to the success of this project. Shared monthly compliance data reports, provision of new parent education pamphlets, and creation of a reminder task in the EMR all helped to improve compliance.

We encountered some unique barriers in implementing our HAC bundle to units outside of the NBN and NICU. Designing a process for appropriate medical exceptions to the safe sleep bundle was the most significant challenge. Initially, the ordering provider documented one of the following medical exceptions to supine and flat sleep position when appropriate: airway compromise (including Pierre-Robin sequence), congenital malformation, life-threatening gastrointestinal reflux, palliative care, respiratory distress, and other. Anecdotally, we found that life-threatening gastrointestinal reflux became overused for many infants who seemingly had typical infant reflux. Consistent guidelines that defined life-threatening reflux were missing, which had 2 important consequences. First, an exception card was placed in the infant's bed

noting that the child had a life-threatening condition when most of them did not. This notation caused increased parental anxiety, which was expressed to hospital staff. Second, staff were modeling poor safe sleep for the parents when the decision to list an exception was often made arbitrarily. In 2018, the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition released guidelines recommending “not to use positional therapy (ie, head elevation and lateral and prone positioning) to treat symptoms of GERD in sleeping infants.”²⁹ As a result of our experience, we have since removed life-threatening reflux as an option; however, in those rare truly severe circumstances, providers can still list it under other.

Although many medical exceptions listed were related to supine flat positioning, auditors reported that once this particular exception was selected, the remainder of the guidelines were often ignored. For example, if a child has had spinal surgery, keeping them flat on their back is not practical nor advisable, and thus it is reasonable to place a medical exception for supine positioning. However, we often found that even if an exception was made that required prone positioning, the infant’s sleep environment would become unsafe from loose bedding and extra items in the crib. We subsequently clarified our medical exception rule so that it applied only to positioning and that the other components of the bundle, namely, sleep space free of bedding and nonmedical objects, still had to be followed.

A final barrier was resistance from providers and staff to implementation in older infants. Although the AAP policy and our institutional policy all stated that safe sleep guidelines should be

continued through 1 year of age, many staff and providers were not adherent once the infant was rolling over independently and certainly once the infant could sit up independently. These concerns required repeated reinforcement.

Our study included a number of limitations. First, we tried to standardize the audit process but found there were some situations for which scoring the compliance on the audit was not clear, primarily occurring in units outside of the NBN. Ultimately, there was a degree of subjectivity as to how an auditor scored the patient’s sleep environment. This problem could be mitigated in the future by periodically conducting group reviews or photograph reviews to increase interobserver reliability. Second, the success of HAC prevention bundles is commonly revealed through reduction of cases, such as fewer CAUTIs and central line-associated bloodstream infections. The outcome from implementing a safe sleep HAC bundle, namely, prevention of unsafe sleep injuries or deaths, would be extremely difficult to evaluate. However, the same evidence-based approach to prevention that is the basis for all HAC methodology (HAC avoidance) was used in this study. Third, the fact that the medical exceptions were provider driven, and did not have standard definitions (eg, what constitutes respiratory distress), may mean that more patients were excluded from our study than needed to be. In future analyses, it would be instructive to include a process measure of the number and type of medical exceptions granted. Finally, this was a single-center study at an academic children’s hospital, and thus our experience may not be generalizable to other centers.

Embedding safe sleep into the hospital QI priorities as one of our Children’s Hospital’s HACs will be helpful for long-term sustainability, as will the EMR audit alerts. Further research would be valuable to understand if the improved in-hospital rates of safe sleep translate to increased compliance in the infant’s usual sleeping space once discharged from the hospital.

CONCLUSIONS

Many infant deaths attributed to unsafe sleep practices have preventable risk factors. It is important that any time an infant aged <1 year enters the inpatient hospital system, staff adhere to AAP standards for safe sleep and parents observe and are repeatedly educated about these standards. Using an HAC safety prevention bundle approach, we have shown we can increase the adherence to infant safe sleep guidelines throughout an entire children’s hospital.

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ABBREVIATIONS

AAP: American Academy of Pediatrics
CAUTI: catheter-associated urinary tract infection
EMR: electronic medical record
HAC: hospital-acquired condition
NBN: newborn nursery
QI: quality improvement
SPS: Solutions for Patient Safety
SUID: sudden unexpected infant death

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