An Evidence-Based Infant Safe Sleep Program to Reduce Sudden Unexplained Infant Deaths

NICU nurses lead an effort to standardize practice and educate caregivers.

ABSTRACT

Objective: The purpose of this project was to design, implement, and evaluate a safe sleep program for expectant mothers and the families of infants discharged from our hospital’s neonatal intensive care unit (NICU). It was prompted by the sleep-related deaths of two infants in the community, both of whom had been discharged from our NICU.

Methods: A six-member interdisciplinary team comprising nurses, a physician, an occupational therapist, and a respiratory therapist developed a safe sleep program in an effort to identify and implement evidence-based safe sleep practices for infants in the NICU. The team examined the literature on sleep-related death and safe sleep practices, consulted with colleagues in NICUs at nearby hospitals and clinics, and conducted an audit of practices related to putting infants to sleep in the NICU. The initiative included the use of infant sleep sacks, the development of a clinical practice guideline to promote safe sleep, and the delivery of standardized discharge education for caregivers in the NICU and safe sleep classes for expectant mothers and caregivers in the community. The team educated NICU staff on the new practice guideline in November and December 2014, and implemented the clinical intervention in January 2015.

Results: Random unit audits showed that prior to implementation of the safe sleep program, NICU nurses had followed safe sleep practices only 20% of the time; after implementation, however, safe sleep practices were followed an average of about 90% of the time. In-hospital and community-oriented evidence-based teaching on safe sleep practices and environments was associated with no sleep-related infant deaths after discharge from our NICU in calendar year 2015.

Conclusion: A multifaceted safe sleep program offers many benefits to both the NICU and its patients. The implementation of a standardized safe sleep program provides an enormous opportunity to improve the health and well-being of the community. All hospitals that care for mothers and infants should adopt a safe sleep program.

Keywords: infant mortality, neonatal intensive care unit, safe sleep, sudden infant death syndrome, sudden unexplained infant death

According to the Centers for Disease Control and Prevention (CDC), approximately 3,500 sudden unexplained infant deaths (SUIDs)—deaths among infants younger than one year that have no immediate, obvious cause—occur in the United States each year. The three most commonly reported types of SUID are sudden infant death syndrome (SIDS), accidental suffocation or strangulation in bed, and death due to an “unknown cause,” which were responsible for 44%, 25%, and 31% of infant deaths, respectively, in 2014. The CDC defines SIDS as “the sudden death of an infant less than 1 year of age that cannot be explained after a thorough investigation is conducted, including a complete autopsy, examination of the death scene, and a review of the clinical history.” The CDC also notes that SIDS is the leading cause of death in infants one to 12 months of age, and that in 2014...
roughly 1,500 infants died of SIDS. The purpose of this article is to show how a nurse-led clinical and educational safe sleep program can improve outcomes for infants and their families and caregivers.

Background

In Philadelphia, where our hospital is located, there were 487 infant deaths in 2009 and 2010; 89 (18%) were sleep-related SUIDs. Among these, analyses found only 10 (11%) of the infants had been in a fully safe sleep environment.

The CDC and the American Academy of Pediatrics (AAP) define a safe sleep environment as one in which the infant is put to sleep on her or his back and that has:

- a firm, flat sleeping surface with a fitted sheet.
- no pillows.
- no blankets or toys.
- no loose bedding.

Of the 89 above-mentioned SUIDs, 34 (38%) were from accidental suffocation, and of these, 24 (71%) were caused by inanimate objects. The majority of the 89 infant deaths were attributed to unsafe sleep practices and environments (for example, bed sharing, loose bedding, prone positioning, elevated head of bed, infants surrounded by soft objects, and environments that promoted infant overheating). SUID risk was also associated with prematurity, race, and socioeconomic status.

Safe infant sleep is a national health concern. In 2011 the AAP Task Force on SIDS published a policy statement and a technical report, both entitled “SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment.” Both are widely used in public health campaigns and educational materials and are considered the most comprehensive and reliable recommendations on safe sleep. The authors emphasized that neonatal intensive care unit (NICU) providers should educate caregivers and model safe sleep practices “as soon as the infant is medically stable and significantly before the infant’s anticipated discharge.”

In August 2012, a nearby children’s hospital ED reported that two sleep-related deaths had occurred in infants who had been discharged from our NICU. These deaths were due to suffocation or an unsafe sleep environment; but, as in many sleep-related infant deaths, the exact cause of death in each case could not be determined. At the time, our NICU had no formal guidelines regarding safe sleep practices; and in discussion of practice standards with colleagues in other Philadelphia hospitals, we found no hospital-based neonatal safe sleep programs. These factors limited our ability to model best practices for families and caregivers, who had little knowledge of safe sleep practices at home.

Preintervention practices. Before we started the safe sleep program, our practice of putting infants to sleep in the NICU had been inconsistent. Data collected during preintervention random unit audits in February and March of 2014 showed that, on average, our nursing staff was modeling safe sleep practices only 20% of the time. In addition, the sleep environment for infants in our NICU wasn’t safe because extra or loose blankets had been placed over infants, heads of cribs were elevated, positioning devices were used in cribs, and infants had been put to sleep on their side or stomach (see Figure 1). Moreover, postdischarge phone calls to parents revealed unsafe sleep practices at home: seven of 14 parents surveyed were cosleeping with their baby, three placed objects in the infant’s crib, and eight put infants to sleep on a nonflat surface.

After learning of the two deaths of infants discharged from our unit, NICU clinical nurses recognized that family members’ lack of knowledge of safe sleep practices and environments was a modifiable
risk factor that could be affected by education and modeling of safe sleep practices. After thoroughly reviewing the literature and the AAP’s expanded recommendations for infant safe sleep, we thought that our NICU could vastly improve safe sleep practices for all of its patients.

Our main objective was to implement a clinical and educational safe sleep program for expectant mothers and the families and caregivers of the infants in our level IIIb NICU—a 36-bed Magnet-designated tertiary care center. We also sought to have our hospital partner with community organizations (including the Maternity Care Coalition; the March of Dimes; and the Helen O. Dickens Center for Women’s Health, an outpatient clinic serving low-income and at-risk women throughout Philadelphia) to increase safe sleep awareness and provide educational resources. Our long-term goal was to reduce sleep-related deaths among infants discharged from our NICU.

**METHODS**

Two of us (MF and NC) initiated the formation of a six-member interdisciplinary team to create a safe sleep program for the NICU. The team comprised three nurses (including WZ), a physician (the NICU medical director), an occupational therapist, and a respiratory therapist. In the last quarter of 2012 preplanning began, followed by two years of preparation for the implementation of the intervention.

**Design.** We used a bundle approach to design the project (for more on the use of “bundles” in quality improvement initiatives, see www.ihi.org/resources/Pages/ImprovementStories/WhatIsaBundle.aspx). The bundle included purchasing infant sleep sacks; creating a unit-based clinical guideline to promote safe sleep practices; creating standardized caregiver discharge education; and providing outreach education sessions in the community during women’s prenatal visits.

**Figure 1.** Instances of Unsafe Sleep Conditions (N = 216) Noted on Preintervention Random NICU Audits, February and March 2014

The bars represent the number of instances of unsafe conditions. The most frequently noted unsafe condition was loose bedding/extra blankets (n = 57), and the least frequently noted was developmental products (n = 7). The data points on the curve represent the cumulative percentage each unsafe condition is of the total number of unsafe conditions (N = 216). For example, loose bedding/extra blankets (n = 57) represents 26.4% of the total number of unsafe conditions; hats (n = 53) plus loose bedding/extra blankets (n = 57) represent 50.9% (or 110) of the total number of unsafe conditions, and so on.
Sleep sacks and funding. Our interdisciplinary team formed a partnership with a vendor that manufactures sleep sacks and makes them available to hospitals and families through low-cost programs. The sleep sacks we used in the NICU were provided for the cost of shipping, which the hospital covered; the sleep sacks we ordered for caregivers to take home were provided through grants from the March of Dimes and Penn Medicine (of which our hospital is a part) and private donations from parents.

Clinical practice guideline. The clinical guideline was formulated based on the recommendations of the AAP Task Force on SIDS, evidence-based literature, and the clinical experience of the NICU interdisciplinary team members.

While formulating the guideline, the team discussed the then current practice of putting hats on infants when putting them to sleep in the NICU (knit hats were provided by the hospital and also by family members). The practice of putting hats on infants to keep them warm while they slept had been common in both the hospital and the community for decades, but we discovered little evidence to support this. The AAP policy statement, for example, does not address the use of hats during sleep. So we contacted Rachel Y. Moon, MD, of the AAP Task Force on SIDS for further clarification on this issue. According to Moon, “Head covering in general has been associated with SIDS, and it is yet unclear whether the risk of head covering is due to the baby’s overheating, entanglement in bedding, covering of the face, or other factors” (e-mail communication, October 2014). We then agreed that hats could lead to overheating or suffocation, and that as soon as an infant has stable vital signs, has gained weight, and is moved to an open crib the hat should be removed.

To determine infants’ ability to remain normothermic (an axillary temperature of 97.6°F to 100.4°F)

### Highlights of the Clinical Practice Safe Sleep Guideline

- The infant should be supine when in an open crib.
- Exceptions can be made for prone positioning of infants with a physician’s order who have airway obstruction issues (for example, Pierre Robin syndrome, laryngomalacia), gastroesophageal reflux, or other nonroutine medical needs (for example, neonatal abstinence syndrome, phototherapy, iv access lines that are difficult to position). These infants should be routinely reevaluated for supine positioning closer to the time of discharge.
- Soft materials such as pillows, quilts, comforters, toys, stuffed animals, and loose bedding should not be placed in the infant’s sleeping environment.
- “Boundaries” or “barriers” made from blanket rolls are potential sources of airway obstruction and entrapment, and should not be used with infants in an open crib. The occupational therapist should assist nurses in developing an individualized plan for each infant to help with developmental needs and positioning.
- Open cribs must be level and flat.
- A physician’s order is required for the head of an infant’s crib to be raised.
- Sitting devices, such as car safety seats, strollers, swings, and infant carriers are not recommended for routine sleep. If an infant falls asleep in a sitting device, she or he should be moved to a crib or other appropriate flat surface as soon as it’s practical.
- The infant should be normothermic (an axillary temperature of 97.6°F to 100.4°F) without a hat for at least 24 hours during the temperature weaning process in the Isolette before being placed in an open crib. Wearing a hat while sleeping can place an infant at risk for overheating and sleep-related death.
- The infant should be placed in a sleep sack when put in an open crib. If the infant is unable to maintain body temperature in the normothermic range, add a layer of clothing under the sleep sack, if possible. If the infant’s axillary temperature remains low (< 97.6°F), place her or him in an Isolette “on skin temperature control” (set so that the infant’s skin temperature controls the air temperature); continue to monitor the infant per unit protocol.
- An infant should be swaddled in a sleep sack with hands to mouth and lower extremities in a flexed and slightly abducted position.
without a hat, we decided to collect data specifically regarding infants’ transition to an open crib environment. If the data showed that the majority of infants were unable to sustain normothermia without a hat, the team would reevaluate that portion of the clinical practice guideline. It’s important to note that our criteria for weaning from an Isolette to an open crib remained the same during the intervention: the neonate had to

- have stable vital signs and a consistent weight of 1,500 grams or more
- show weight gain over the previous three to five days
- have no bath within 24 hours of moving to an open crib
- tolerate being weaned from the warmer air temperature in the Isolette

For more on the final clinical practice guideline, see Highlights of the Clinical Practice Safe Sleep Guideline.

Caregiver education and nursing documentation. Prior to this program, the discharge nurse provided safe sleep education to caregivers approximately 72 hours before the infant’s discharge, in the form of two National Institutes of Health (NIH) handouts and a discussion of safe sleep practices. Caregivers were then required to sign a document stating that they had received safe sleep education. However, NICU nurses did not perform this process uniformly or consistently.

In designing the intervention, we wanted to standardize family and caregiver safe sleep education practices. We now require caregivers to watch a 10-minute educational video on safe sleep produced by the National Institute of Child Health and Human Development’s Safe to Sleep campaign (for this and other materials from the campaign, go to www.nichd.nih.gov/sts/news/videos/Pages/default.aspx). The video helps to standardize the safe sleep message, showing ways to reduce the risk of SIDS and other sleep-related infant deaths. The primary caregiver still signs documentation stating that safe sleep education has been provided; however, NICU nurses are now required to sign and date when they receive the signed documents. The nurses provide education on safe sleep practices and environments, model best practices, and give real-time feedback to caregivers as they practice placing the infant in an open crib. At discharge, we provide

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**Figure 2.** Percentage of NICU Infants in a Safe Sleep Environment Based on Pre- and Postintervention Random Unit Audits

[Graph showing percentage of infants in a safe sleep environment over time]
a sleep sack so caregivers can continue safe sleep practices at home.

It’s important to note that although we changed our practices for putting infants to sleep, NICU discharge criteria did not change. The criteria are still the following:

- The infant must be at least four pounds.
- The infant must have a consistent weight gain.
- The infant must be normothermic in an open crib.
- The infant must be receiving nutrition by mouth.
- The infant must exhibit no apnea or bradycardia for five days.
- All discharge education must be completed.

Community outreach education. One of us (NC) led an effort to gather a group of NICU nurses to create the content for safe sleep classes for expectant mothers and caregivers in the community. These were held at the Dickens Center, and the nurses partnered with a perinatal social worker and a lactation consultant to coordinate the sessions. The one-hour classes were held on the third Tuesday of each month for approximately one year. Content included didactic presentations, group discussions, and hands-on activities to illustrate principles of basic newborn care and safe sleep and the prevention of shaken baby syndrome. Typically, 20 to 40 people, often pairs of expectant women and their mothers, attended each session. Attendees received folders containing the safe sleep educational materials, a sleep sack, and children’s books.

Implementation of the safe sleep program. In November and December 2014, the interdisciplinary team members created a staff education program to disseminate the new information and practice changes to all NICU staff. The unit’s medical director and assistant medical director were charged with educating the medical team via in-service sessions in faculty meetings and via email. The nursing staff provided in-service education to all NICU staff. The in-services included a PowerPoint presentation, a demonstration of safe sleep practices, a review of the new NICU guideline, and time for questions. The education focused specifically on

- the incidence of sleep-related deaths nationally, regionally, and locally.
- high-risk populations and specific risk factors seen in our NICU.
- the importance of modeling safe sleep practices for families and caregivers.
- the new NICU safe sleep clinical guideline, with emphasis on major practice changes such as removal of hats and the use of sleep sacks.
- revitalized education for parents and other caregivers.

The nurses on the interdisciplinary team delivered the education sessions daily on both day and night shifts over a two-month period to ensure that all RNs, certified nursing assistants, social workers, secretaries, case managers, and respiratory therapists received it.

Measures. To assess the safe sleep program, our team measured a number of processes and outcomes. First, we tracked the creation of a safe sleep environment in the NICU, which was measured through in-unit audits performed two to three times a month on all infants in open cribs. These in-unit audits are ongoing. We also audited the in-service records to measure the percentage of staff that received the safe sleep education. Data on staff nurses’ compliance with the caregiver education, including showing the NIH safe sleep video and obtaining the signed documents, were collected in random chart audits over a six-month period. Also, for two months after we initiated the safe sleep program, NICU nurses made follow-up phone calls to caregivers of recently discharged infants to discuss the sleep environment at home. Lastly, in an attempt to capture the outcome of putting infants to sleep without hats, we measured how many infants failed to transition to an open crib because of hypothermia (an axillary temperature of 97.6°F or less) over a six-month period.

RESULTS

Before implementing the safe sleep program in January 2015, NICU nurses had followed safe sleep practices only 20% of the time. Before we learned what constitutes a safe sleep environment, several of our standard sleep-related practices were not supported by evidence, including elevating the head of the crib and using multiple blankets and a hat. Within six months of implementing the safe sleep program, random unit audits showed that NICU nurses and other members of the health care staff were modeling safe sleep approximately 90% of the time (see Figure 2). Infants who were noted in the audits as not being in a safe sleep environment were usually sleeping prone or swaddled in more than one blanket. At the time of these audits, our “safe sleep champions”—nurses who had received safe sleep education and agreed to serve as educational resources for other staff members—provided immediate reeducation on safe sleep environments to any clinical nurse who wasn’t following the new clinical practice guideline. We found that nurses were more likely to place infants who had a diagnosis of neonatal abstinence syndrome in a prone sleeping position to help alleviate withdrawal symptoms (such as loose stool, gas, and regurgitation). We also saw infants who were
swaddled in more than one blanket when the sleep sacks were in low supply (because they were being laundered or were on back order). No infants were noted to be in an unsafe environment because they were wearing a hat.

From March to August 2015, one of us (WZ) conducted random chart audits of 30 infants to review compliance with safe sleep discharge documentation. We found 100% compliance with the parent education forms (affirming that they’d viewed the NIH video) and signed SIDS documents (affirming that the family had received safe sleep education). However, this audit did not capture the content of the discharge nurse’s verbal instructions to the families.

One of us (MF), with the assistance of another clinical nurse, made follow-up phone calls to families recently discharged from the NICU to assess the infant’s home sleeping environment. Many parents and caregivers in our population move frequently, don’t have telephones, or change phone numbers often, so we were able to contact only five out of 25 caregivers. According to the data collected, the greatest impact of the safe sleep program on the home sleep environment was the use of a flat sleeping surface and the avoidance of cosleeping, which all five families reported.

From February through May 2015, 253 infants were discharged from the NICU. Four of these (1.6%) failed to wean to an open crib on their first try. For the purpose of our data collection, a failed open crib wean was defined as hypothermia (an axillary temperature of 97.6°F or less) that required returning to the Isolette within 48 hours of the transition to an open crib.

The success of the safe sleep program in terms of reducing the SIDS rate in Philadelphia is difficult to measure. However, from the beginning of the intervention in January 2015 through to the end of the calendar year, there were no sleep-related infant deaths in the community among patients discharged from our NICU.

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DISCUSSION
Implementing our standardized safe sleep program limited the variation in how nurses were putting in-fants to sleep and improved safe sleep in the NICU. Our staff nurses were modeling evidence-based safe sleep practices approximately 90% of the time after the intervention was begun. In addition, caregivers’ knowledge of safe sleep practices was modifiable through education and modeling. Contrary to what we had previously thought—and to current nursing practice at many other institutions—we found that hats are not necessary to achieve normal thermoregulation in infants in the NICU; and with data to back up the practice change, we were successful in changing the unit’s culture. We believe that this is an important finding that other institutions would do well to examine, and we are continuing to monitor the results of this practice to ensure that it contributes to a safer sleep environment for infants in the NICU. Institutional and unit-based leadership supported our safe sleep program, which was further strengthened by interdisciplinary collaboration in creating the clinical practice guideline and the staff nurses’ acceptance of the new practice changes.

As noted, after staff education on the safe sleep program, we achieved an average of 90% compliance with modeling safe sleep practices; although several random unit audits showed 100% compliance, we have not been able to sustain this. Ultimately, our goal is that all infants sleep in a safe environment while they’re patients in our NICU. Currently, when a staff nurse or other provider recognizes an unsafe sleep environment, a member of our interdisciplinary team addresses it with the clinical nurse, and reeducation on the importance of maintaining a safe sleep environment takes place immediately. In addition, if a family member or caregiver places an infant in an unsafe sleeping environment, the NICU nurses provide real-time feedback and education.

At an August meeting to review the NICU’s progress and examine the barriers to achieving 100% compliance with safe sleep practices, new strategies were
developed to address the obstacles to achieving our goal. We also discussed revitalizing the program of follow-up phone calls to gain better insight into caregivers’ practices and the home sleep environment. The team is also working to expand its membership, and to include more safe sleep champions who can contribute to follow-up and reeducation efforts.

Limitations. Our NICU discharges approximately 700 to 800 infants per year. The task of monitoring all those former patients would require resources far beyond what our hospital can supply, so it is difficult to say with any certainty how much our practice changes have affected community SUID and SIDS rates. The Pennsylvania Child Death Review Program publishes SUID and SIDS data annually, but it takes three years to collect, analyze, and publish each year’s data. Data that reflect the results of our program will not be included in its reports until 2018, so we will not know until then whether or how much our program affected the rates of SUID and SIDS in Philadelphia. In addition, there are methodological limits on our ability to collect data on sleep-related deaths among infants discharged from our NICU: we track only those infants who are brought to the ED of the neighboring children’s hospital within 30 days of discharge and are unable to obtain data on infants cared for in other facilities. This limitation highlights the need for comprehensive registries of infant sleep-related deaths on the regional, state, and national levels. Such registries would allow for better tracking and sharing of data and would have the potential to more clearly highlight the successes of standardized safe sleep programs.

Additional limitations of our intervention were the low rate at which we were able to complete follow-up phone calls to caregivers and, therefore, a lack of data on our program’s impact on home sleep environments. In most cases, the phone numbers we had were incorrect or no longer in service. Furthermore, we hadn’t designated a specific person on our interdisciplinary team who would be responsible for making the calls, so team members made them when they could, not necessarily when it would have been best for caregivers.

Conclusions. Our multifaceted safe sleep program offers an enormous opportunity to improve the health and well-being of the Philadelphia community and the nation at large. Standardization of safe sleep practices, clear guidelines, and robust education—including following these practices in the NICU and modeling them for caregivers—have had a strong impact on safe sleep practices in our hospital and have the potential to dramatically improve infant care at home. Our intervention has now been sustained for more than 18 months, and NICU staff nurses continue to follow safe sleep practices more than 90% of the time. We have added safe sleep education to new nurses’ and residents’ orientation, and members of the interdisciplinary team continue to provide reeducation on an as-needed basis when an unsafe sleep environment is identified. We are currently working to expand the safe sleep program to the newborn nursery to improve the care of a greater number of infants and families (approximately 4,500 births per year). We are also working toward achieving a Gold Champion National Safe Sleep Hospital Certification from Cribs for Kids (see www.cribsforkids.org). Penn Medicine’s fundraising efforts now provide ongoing support for the safe sleep program, ensuring that every infant discharged from the NICU receives a sleep sack for home use.

Institutions that develop a safe sleep program can have an enormous impact on the communities they serve. More institutions should develop a program of standardized safe sleep practices and education to help reduce, from approximately 3,500 each year, the number of infant sleep-related deaths nationwide.

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