

Application of a Risk Management Framework to Parent Sleep During Skin-to-Skin Care in the NICU

Ashley M. Weber, Yamile C. Jackson, Mason R. Elder, Sarah L. Remer, Nehal A. Parikh, Jennifer J. Hofherr, Kristin C. Voos, and Heather C. Kaplan

Correspondence

Ashley M. Weber, PhD, RN, College of Nursing, University of Cincinnati, 310 Proctor Hall, 3110 Vine St., Cincinnati, OH 45221. ashley.weber@uc.edu

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ABSTRACT

As NICU staff work to increase the frequency, duration, and comfort of skin-to-skin care (SSC) sessions, barriers to implementation are frequently encountered. Safety concerns are often raised when parents fall asleep during SSC intentionally or unintentionally. We present a risk management framework that we use in clinical practice to address risk related to parent sleep during SSC. Our approach is based on the steps of the Risk Management Life Cycle, which include the following: establish context, identify risk, analyze risk, respond to risk, and monitor and adapt response to risk. Clinicians may use this framework in clinical practice to manage risks related to prolonged SSC, specifically when parents relax and fall asleep during SSC.

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Ashley M. Weber, PhD, RN, RNC-NIC, is an assistant professor, College of Nursing, University of Cincinnati, Cincinnati, OH.

Yamile C. Jackson, PhD, PE, PMP, is an ergonomics, safety, and risk engineer and the Chief Executive Officer, Nurtured by Design, Sugar Land, TX.

Mason R. Elder, BSN, RN, is a staff nurse, neonatal intensive care unit, Cincinnati Children's Hospital Medical Center, Cincinnati, OH.

Sarah L. Remer, BS, is a medical student, School of Medicine, Case Western Reserve University, Cleveland, OH. • the practice of placing an infant upright on a parent's bare chest so that the infant's bare skin is in direct contact with the parent's bare skin. Decades of research evidence support the use of SSC in clinical practice (Conde-Agudelo & Díaz-Rossello, 2016; Furman, 2016). However, it is typically only practiced in short, interrupted durations in NICUs in the United States (Weber et al., 2018). Frequently cited barriers to longer and more frequent SSC sessions include lack of knowledge, training, and clear implementation guidelines, which are often discussed in the context of serious and legitimate concerns for patient safety (Smith et al., 2017). Risks that have been associated with SSC include accidental falls (Feldman-Winter et al., 2016), sudden unexpected postnatal collapse (Shipstone et al., 2017), and dislodgement of equipment or unplanned extubation (Al-Shehri & Binmanee, 2021; Kenaley et al., 2020). These risks contribute to additional barriers that affect SSC implementation, such as stopping SSC when the parent

shows signs of sleepiness.

kin-to-skin care (SSC), or kangaroo care, is

Sleep during SSC sessions can be an important, restorative intervention for parents (Angelhoff et al., 2018). Parents of hospitalized preterm inreported increased relaxation and enhanced sleep with SSC in a qualitative study (Edéll-Gustafsson et al., 2015). Although authors of systematic reviews reported poor parent sleep outcomes outside of the context of SSC (Haddad et al., 2019; Marthinsen et al., 2018), few researchers have addressed the use of SSC to improve outcomes related to parent sleep. Conversely, numerous researchers have shown that infants sleep more deeply during SSC (Bastani et al., 2017; Charpak et al., 2017; van den Hoogen et al., 2017; Wang et al., 2021), which is vital to brain development (Uchitel et al., 2021). Parent and infant coregulatory sleep is critical for infant sleep development (Barbeau & Weiss, 2017; van den Hoogen et al., 2017), short- and long-term infant growth (Mahmoodi et al., 2016), and behavioral and emotional health outcomes for infants and parents (Levy et al., 2016; Mahmoodi et al., 2016; van den Hoogen et al., 2017). Finally, the recently

1

(Continued)



As parents engage in more comfortable, prolonged, and less interrupted skin-to-skin care sessions, the need for a systematic strategy to manage risks becomes imperative.

published Standards on Infant and Family Centered Developmental Care in the Intensive Care Unit (Browne, Jaeger, Arvedson, et al., 2020; Browne, Jaeger, Kenner, and Gravens Consensus Committee, 2020) assert that "parents should be allowed to fall asleep during Kangaroo Care when safety measures are in place" (Phillips et al., 2020, Standard 1, Skin-to-Skin Contact: Competency 1.10, para. 10).

Although significant risks are associated with parent sleep during SSC, effective risk management strategies can help organizations overcome safety barriers and implement uninterrupted SSC (Weber et al., 2020). Risk management is defined as a dynamic process of identifying, analyzing, and eliminating or mitigating risks that threaten an organization and the achievement of its objectives (High Level Group for the Modernisation of Official Statistics & Modernisation Committee on Organisational Framework and Evaluation, 2017). When sleeping in SSC, two elements of safety are inhibited: the hands of the parent, which can no longer contain the infant, and the parent's attention. Alternative safety interventions, such as frequent monitoring by another adult who is not involved in SSC, should be used. Another key safety intervention is the use of an SSC safety device, a wrap that helps a caregiver properly position and hold an infant during SSC. It is critical to use devices whose manufacturers explicitly state that the device supports sleeping; otherwise, the infant may be dropped.

Although we focus on parent sleep in this article, it is important to note that additional situations and infant characteristics may increase risk during SSC sessions and transfers. The purpose of this article is to present a risk management framework that can be used in NICUs to address safety risks related to parent sleep during SSC. Various terms, stages, and processes have been used interchangeably to describe the Risk Management Life Cycle (Becker, 2004; Häring, 2015; Lavanya & Malarvizhi, 2008; Project Management Institute, 2019). We organize this article into the following steps of this cycle: establish context, identify risk, analyze risk, respond to risk, and monitor and adapt response to risk. Building on our prior work, we describe how NICU staff can apply a risk management framework to increase the safety of frequent and prolonged SSC sessions and use risk management concepts to inform policies and practices to effectively manage risks surrounding parent sleep during SSC. We conclude with recommendations for future research and quality improvement surrounding SSC, patient safety, the promotion of safe sleep practices, and restorative sleep.

A Risk Management Approach to Parent Sleep During SSC

For successful implementation of an SSC program in a hospital environment, program goals need to align with the organizational practices of the hospital and must have support from every stakeholder (Weber & Harrison, 2019). Strategies and policies should be in place to increase SSC rates and reduce the potential risks to patients, families, staff, and the organization. In this article, we focus on methodologies to manage risks associated with parent sleep during SSC, regardless of the hospital policy about sleep.

Risk management is complicated and widely used in health care to manage risks related to patient safety, emergency preparedness, clinical research, and mandatory federal regulations (High Level Group for the Modernisation of Official Statistics & Modernisation, 2017). We do not present an exhaustive explanation of the risk management process; rather, we suggest an approach using an exemplar of the Risk Management Life Cycle to identify, analyze, control, and monitor risks to keep patients safe during SSC and respond to the needs of the infant, parents, the health care team, and hospital administration (see Figure 1).

Defining Risk

A risk is defined as an event or condition with a given likelihood of happening and the possibility of positive consequences (i.e., opportunities) or negative consequences (i.e., threats). A risk has two components: the event itself and the probability or likelihood of the event occurring (Becker, 2004; Häring, 2015; Lavanya & Malarvizhi, 2008; Project Management Institute, 2019). For example, one risk would be that an infant may extubate during SSC (event) in the NICU if the parent falls asleep. The likelihood of serious safety events during SSC is not increased by the biological action of falling asleep but by the removal of safety mechanisms provided by the parent. Thus, additional strategies must be used to keep infants safe

Nehal A. Parikh, DO, MS, is professor, Perinatal Institute, Cincinnati Children's Hospital Medical Center and affiliate of Department of Pediatrics, College of Medicine, University of Cincinnati, Cincinnati, OH.

Jennifer J. Hofherr, MS, OTR/L, C/NDT, CNT, is a neonatal therapy program manager, Department of Neonatology, Nationwide Children's Hospital, Columbus, OH.

Kristin C. Voos, MD, FAAP, is an associate professor, Department of Pediatrics, School of Medicine, Case Western Reserve University, Cleveland, OH.

Heather C. Kaplan, MD, MSCE, is an associate professor, Perinatal Institute, Cincinnati Children's Hospital Medical Center and affiliate of Department of Pediatrics, College of Medicine, University of Cincinnati, Cincinnati, OH.

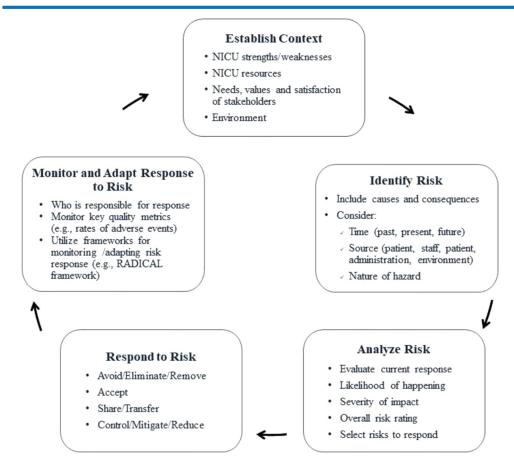


Figure 1. Risk management life cycle.

when parents are not able to use their hands or maintain attention during SSC. We explore the use of the Risk Management Life Cycle to address the safety of parent sleep during SSC, but this approach could also be used to mitigate other types of risks related to SSC.

The Risk Management Life Cycle

Establish Context

To manage risks, NICU teams need to first establish the context or identify the environment in which the risk occurs. There must be an understanding of the internal and external aspects of their NICU environment that could or should affect the team's response to risks associated with SSC. Elements of the NICU environment that should be explored can include benefits and challenges related to parent sleep during SSC; available resources, such as equipment, furniture, and personnel; and the needs, values and satisfaction of key stakeholders, including patients, families, neonatal staff, and organizational

leaders (see Figure 1). Resources to support the risk response can differ widely based on the practice context in which SSC is implemented.

Benefits of parent sleep during SSC in the

NICU. Safe SSC is best practice and an important element of evidence-based and family-centered neurodevelopmental care. Skin-to-skin care is increasingly being recognized as a basic right of parents (Phillips et al., 2020) and a requirement for certain certifications and Baby-Friendly Hospital designation (Spatz, 2018). Allowing parents to sleep during SSC with safety measures in place meets one of the core Standards on Infant and Family Centered Developmental Care in the Intensive Care Unit (Browne, Jaeger, Arvedson, et al., 2020; Browne, Jaeger, Kenner, and Gravens Consensus Committee, 2020):

Parents should be allowed to fall asleep during Kangaroo Care when safety measures are in place that include a) parent and baby are in a non-rocking, reclining

Avoiding parent sleep during skin-to-skin care misses the chance to promote better outcomes for preterm infants and their parents

chair or bed; b) baby is well secured by an appropriate wrap to parent's chest; c) baby is electronically monitored, if indicated; and d) an appropriate health care provider is immediately available. (Phillips et al., 2020, Standard 1, Skin-to-Skin Contact: Competency 1.10, para. 10)

Based on objective (e.g., actigraphy) and subjective (e.g., self-report) measures of fatigue, Krawczak et al. (2016) reported that the average parent of an infant in the NICU is extremely sleep deprived. In parents, SSC promotes relaxation; lowers blood pressure, heart rate, cortisol levels, and feelings of depression and anxiety; and increases oxytocin levels (Pados, 2019). It is often difficult for sleep-deprived parents to stay awake for hours during long SSC sessions (Weber et al., 2020). These factors culminate to produce a situation in which SSC is a natural time for the parent and infant to share restorative sleep. To provide the best care in NICUs, strategic plans should be in place to ensure that every infant that can participate in SSC is able to do so, as early as possible, for as long and as safely as possible. When done systematically and intentionally, an SSC program increases satisfaction of the parents, patients, and health care team; improves health care outcomes; elevates quality of care; and decreases the cost of health care for the life of the child (Boundy et al., 2016).

Challenges related to parent sleep during SSC in the NICU. A common yet significant challenge to SSC is the sole reliance on the parent to adequately contain and attend to the infant (Weber et al., 2020). Inappropriate containment during transfers, interventions, or sleeping in SSC can cause the infant to slide, lose proper posture, fall, or dislodge equipment. Likewise, inattention during SSC (e.g., when the parent is asleep) makes the parent unable to respond to the infant's cues, position, needs, and cardiorespiratory events. These risks also occur when parents no longer contain the infant using their hands (e.g., grabbing a drink of water) and when they are distracted while awake (e.g., responding to a phone call). Instead of sole reliance on the parent to ensure infant safety, risk mitigation strategies can be used to support the parent while awake or asleep during SSC. One such strategy is the use of an appropriate SSC device (Weber et al., 2020; Weber & Jackson, 2021). For the purposes of this article, we define an SSC device as a wrap, fabric, or garment whose main purpose is to aid the caregiver with holding the infant in a proper SSC position for prolonged sessions, without the need of the parent's hands, to ensure the safety, comfort, proper posture, and containment of the infant.

Resources for parent sleep during SSC. In the NICU, infants are continuously monitored through pulse oximetry and/or electrocardiogram, including during SSC, and they commonly experience apnea, bradycardia, and oxygen desaturations related to positioning and/or developmental immaturity (Eichenwald Committee on Fetus and Newborn, American Academy of Pediatrics, 2016). Staff in the NICU have significant resources with which to address cardiorespiratory events during SSC, such as lower patient ratios, easy access to advanced equipment (e.g., patient-ready suction, ambu bags, oxygen/flowmeters, etc.), highly trained intensive care staff, and multidisciplinary personnel. The need for other key resources, such as a nonrocking, reclining chair or bed and an appropriate SSC device or wrap to secure the infant to the parent's chest, should be evaluated (Phillips et al., 2020, Standard 1, Skin-to-Skin Contact: Competency 1.10, para. 10.)

Needs, values, and satisfaction of key stakeholders during SSC in the NICU. Clinicians need quiet, easy, immediate, and effective access to the infant during SSC for scheduled health care interventions and in cases of emergency. They need to ensure that the infant is properly contained so that medical equipment remains in place and visible. Ideally, clinicians should be able to perform a variety of interventions during SSC so that infants receive related pain and stressreducing benefits (Pados, 2019). Parents should be confident and trained to collaborate with the team to ensure the safety of the infant (Browne, Jaeger, Arvedson, et al., 2020; Browne, Jaeger, Kenner, and Gravens Consensus Committee, 2020; Phillips et al., 2020). Clinicians should be properly trained to safely implement SSC with critically ill infants, and peers with appropriate experience and expertise can serve as resources and mentors for the neonatal team (Smith et al., 2017).

Infants should be comfortably and safely contained in the proper SSC position by the parent's



Figure 2. Parent ready for sleep in skin-to-skin contact with an intubated infant hospitalized in the NICU. Parent is wearing a skin-to-skin contact device to properly secure the infant and is sitting in a recliner with arm rests. NICU equipment and wiring are visible, secure, and attached to an electronic monitor. Copyright 2022 from Nurtured by Design. Reprinted with permission.

hands or an SSC device to support self-regulation, protect the infant's airway, and minimize risk of equipment dislodgement (see Figure 2).

Appropriate infant containment also prevents accidental falls and sliding during SSC. Infants need to be protected from cold air drafts and be minimally disrupted during SSC transfers and sessions (Browne, Jaeger, Arvedson, et al., 2020; Browne, Jaeger, Kenner, and Gravens Consensus Committee, 2020; Phillips et al., 2020).

Parents need anticipatory guidance for what to expect before, during, and after SSC sessions. They should be trained on how to safely transfer their infants to/from the bassinette/incubator, how to assess their infants during SSC for proper position, and when to notify the team if they have a concern or question. Ample parent education, preparation, and monitoring are essential to minimize stress and anxiety about safely holding a medically fragile infant and to maximize the ability to safely perform SSC in collaboration with

the health care team (Smith et al., 2017). Skin-to-skin care is a time for intimate connection between parent and infant and when managed properly, it can be calming for the dyad (see Figure 3).

It should be easy and relaxing for parents to hold their infants for several hours, even if they need to use their hands for other activities or if they fall asleep (Browne, Jaeger, Arvedson, et al., 2020; Browne, Jaeger, Kenner, and Gravens Consensus Committee, 2020; Phillips et al., 2020). If applicable, parents need easy access to their infants for breastfeeding and milk extraction/pumping during SSC.

Identify Risk

Once the context is fully explored, the team can identify all the safety issues that could prevent the successful achievement of the goals and objectives of the SSC program (see Figure 1). Risks associated with parent sleep during SSC include infant airway compromise because of airway obstruction (Shipstone et al., 2017), unplanned extubation and equipment dislodgement (Al-Shehri & Binmanee, 2021; Kenaley et al., 2020), and accidental infant falls (Feldman-Winter et al., 2016). Risks are best identified by a multidisciplinary team who can analyze a problem from diverse perspectives to create an optimal solution.

It is imperative to create a comprehensive list of risks, causes, and potential consequences (Becker, 2004; Häring, 2015; Lavanya & Malarvizhi, 2008; Project Management Institute, 2019). Importantly, teams should identify risks associated with implementing an activity and risks associated with not implementing an activity that could have direct benefits to the organization. For example, the risks associated with not allowing parents to sleep during risk-controlled SSC include physical, mental, and emotional exhaustion for the parent and secondary negative consequences for the infant (Maghaireh et al., 2017; Phillips et al., 2020). Not allowing parents to sleep cuts SSC sessions short and deprives infants of the many documented benefits of SSC. Parent sleep can have positive outcomes (i.e., opportunities) if risks are managed appropriately and safety mechanisms are in place to provide attention and secure containment for the infant.

Risk management worksheets (see Supplementary Figure S1) can be used to enumerate all possible risks and their potential causes and consequences. A risk can have one or multiple causes, and each

cause can, in turn, contribute to one or multiple risks (Becker, 2004; Häring, 2015; Lavanya & Malarvizhi, 2008; Project Management Institute, 2019). For example, the likelihood of unplanned extubation is increased when a parent falls asleep and the parent's hands no longer contain the infant (potential cause) or if the endotracheal tube is not properly secured (potential cause; see Supplementary Figure S1). It is important that a multidisciplinary team identify all possible risks when completing the risk management worksheet because failing to do so affects subsequent life cycle stages.

Analyze Risk

After identifying all possible risks, causes, and potential consequences, the team can begin to analyze each risk and its potential effect (i.e., severity) and probability (i.e., likelihood), the effectiveness of current risk mitigation strategies (i.e., existing response), and areas needed for improvement (see Supplementary Figure S2). Neonatal intensive care unit teams should list all processes, policies, practices, and/or actions that are currently in place to address risks (i.e., risk controls) and the overall strengths, limitations, and effectiveness of those controls (Becker, 2004; Häring, 2015; Lavanya & Malarvizhi, 2008; Project Management Institute, 2019). A systematic analysis of each risk helps the team objectively evaluate risks in relation to each other, prioritize risks most pertinent to the team and to the NICU's context, and determine the best response (if any) to each risk (see Supplementary Figure S1). For example, a NICU staff member who struggles to have parents practice SSC might focus on the risk of staff not properly educating families about the many benefits of SSC, expectations during patient transfer, and strategies for effective collaboration with the team to ensure everyone's safety and lower levels of anxiety. NICU staff who work in a unit that experiences high numbers of unplanned extubations related to SSC might prioritize evaluation of the causes of the unplanned extubations and the development of a risk response that increases safety during SSC. Whatever the risk priorities are, it is critical that key stakeholders with diverse professional backgrounds, perspectives, and roles, including parents, participate in the analyses to maximize objectivity and to develop a shared understanding of the risk analyses, response recommendations, and subsequent implementation of action plans.

Finally, the development of the team's shared understanding of risk is not the result of simply



Figure 3. Parent asleep in skin-to-skin contact with an infant hospitalized in the NICU. Parent is wearing a skin-to-skin contact device to properly secure the infant during sleep without hands to support the infant. Copyright 2022 from Nurtured by Design. Reprinted with permission.

filling out the risk management worksheet. Rather, a comprehensive analysis ensures that the team addressed the range of possible questions and considerations that arise only when diverse stakeholders are invested in the risk management process. Questions to ask and answer when completing risk management worksheet with the neonatal team could include the following: Who is affected and in what proportion if the event happens? What is the distribution of costs and benefits among different stakeholders? Note that cost is not only monetary. The risk management worksheet also supports the calculation of an overall risk rating that captures the seriousness of the risk related to the likelihood that it occurs and the consequences should it occur. Generally, risks that receive the highest scores should be prioritized first. Analyzing each risk with this inclusive and methodic process allows clinicians to take all information into account when deciding how to manage it (Chartered Accountants Australia and New Zealand, 2019).

Respond to Risk

After each risk is analyzed, evaluated, and compared, the team can begin to design a response to address each identified risk (see

Table 1: Controls for SSC Risks Informed by the Simons Risk Management Control System

Control Examples

Diagnostic control

Performance measures are used to track progress (Kruis et al., 2016).

Data are used to communicate strategy execution and successful completion.

Boundary control

Behavioral hazards are recognized and dealt with in codes of conduct. Employees/patients are informed which actions are unacceptable.

Belief control

The organization's core values and mission statement are used to outline what the organization uses to motivate employees to make a difference.

Interactive control

Personal conversations, meetings, and organizational events are used to focus on updating and redirecting.

Internal control

Procedural measures are used to mitigate risk. This helps enhance compliance to laws and regulations.

- Staff simulation SSC transfers/accidental extubation with feedback provided
- Information from electronic medical record, including frequency/length of time of SSC, accidental extubations, accidental falls, and how early SSC is initiated
- Adherence to an SSC safety checklist for each SSC session to ensure secure positioning of the infant and parent
- Clear inclusion and exclusion criteria for SSC determined by an interprofessional collaborative team (e.g., the Safe Sleep Bedside Card; Hofherr, 2017)
- · Patient safety contracts
- Experienced ICU staff who are comfortable with SSC transfers assist/mentor less experienced staff to support the care standard and to help the trainee understand the beliefs and mission of the unit (Phillips et al., 2020)
- Creation of policy and guidelines that align with mission statement
- Training and support to help clinicians understand why the mission statement (e.g., patient safety) is important to the organization (Kukla & Ludington-Hoe, 2017)
- Verbal feedback with nursing staff to explain what is successful/unsuccessful regarding a NICU's SSC protocol and its implementation
- Make SSC, developmental care, and family-centered care recurring themes in the minds and on the agendas of each stakeholder from every level
- Frequent monitoring/documentation of vital signs and frequent visual assessment by highly trained health care providers
- · Falls-prevention interventions such as
 - parent/staff education (e.g., e-mail alerts, posters, staff meeting announcements)
 - o targeted risk assessment
 - o signage in patient rooms
 - policies, procedures, guidelines, and improved equipment safety (Ainsworth et al., 2016)
- Secure positioning with comfortable seating, support pillows, and SSC device^a (Phillips et al., 2020)
- Allow parents to practice transfer with a mannequin before transfer with infant (Phillips et al., 2020)

(Continued)

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Table	1.	Continue	d

Control Examples

- Use major developmental milestones (e.g., graduating from the incubator) as markers for teaching parents about American Academy of Pediatrics Recommendations for Safe Sleep (Voos et al., 2015)
- Develop, revise, and review hospital policy and unit quidelines

Note. The Simons levers of control is a framework for designing risk control response that includes the five different controls listed to mitigate risk (Simons, 1994). Each of these can be used in different capacities to mitigate/control risk in parent sleep during SSC. Authors A.M.W. and Y.C.J. created this table and categorized each control under the Simons control categories. SSC = skin-to-skin care.

^aA wrap, fabric, or garment whose main purpose is to aid the caregiver with holding the infant in the proper SSC position for prolonged sessions without the need of the parent's hands to ensure the safety, comfort, proper posture, and containment of the infant.

Figure 1). Each risk response is categorized based on four mutually exclusive mitigation plans: avoid, accept, share, or control (High Level Group for the Modernisation of Official Statistics & Modernisation, 2017). Each risk must be accompanied by a corresponding, documented action in the response plan, even if the team decides to do nothing at present (i.e., accept the risk) or to just monitor the situation (Becker, 2004; Häring, 2015; Lavanya & Malarvizhi, 2008; Project Management Institute, 2019). Importantly, just because a given risk has a high overall risk rating on the risk management worksheet does not mean that the risk management solution must be complex or that the cost of mitigation will be high.

Risk response: Avoid. The default response to the risks associated with parents falling asleep during SSC is often risk avoidance (Fluharty et al... 2020), which means that clinicians respond by halting SSC at the first sign of the parent falling asleep or avoiding SSC altogether. Hospitals are often instructed to add "parents sleeping during SSC care is not allowed" to SSC policies and print posters and to verbally instruct parents to not fall asleep (Feldman-Winter et al., 2016). One of the significant drawbacks to using a risk avoidance response in this context is that this approach also avoids opportunities to provide developmentally appropriate and evidence-based care. Avoidance of parent sleep during SSC misses the chance to promote better outcomes in terms of parent stress, depression, anxiety, bonding, lactation, and sleep, as well as for infant stress, sleep, thermoregulation, oxygenation, cardiorespiratory stability, immune function, growth, brain maturation, and optimal development (Boundy et al., 2016).

Moreover, many times, parents do not intend to or realize that they are falling asleep. In a worst case scenario, even when using a risk response of avoidance, the exhausted parent falls asleep during SSC with no controls in place, despite instructions that parent sleep is not allowed (Ainsworth et al., 2016). In this scenario, a risk avoidance response (verbalizing hospital policy) inadvertently transitions into risk acceptance because the parent falls asleep without proper controls in place to mitigate risk. Thus, a risk avoidance response to parent sleep may jeopardize what the response was initially intending to achieve. Therefore, more effective risk mitigation strategies beyond avoidance and verbal instructions should be used (Feldman-Winter et al., 2016).

Risk response: Accept. Risk acceptance is when the team decides to acknowledge the risk and not take any action unless the risk event occurs. This is generally a reactive approach. For example, in the case of unplanned extubation during SSC, risk acceptance would be to allow parents to engage in SSC without any control and acknowledge that the infant may slide or move during SSC and experience unplanned extubation. The team accepts the risk and prepares to stop SSC and re-intubate any infant who extubates. When it comes to patient safety, acceptance is rarely an appropriate risk response because there is too much as stake. The high likelihood that parents will fall asleep during SSC, regardless of hospital policy, makes risk acceptance a less desirable response. Hospital or unit policies should always promote the safety of the infant, including the common scenario of parents falling asleep during SSC. Without a specific

Table 2: Risk Management for Skin-to-Skin Care Based on the RADICAL Framework

Raise awareness and understanding

- Simulation/scenario training for infant SSC transfers at orientation and once per year
- Patient safety information/risk management for SSC is discussed at orientation, staff meetings, quality improvement huddles, and just-in-time training at daily staff huddles
- Information about safe and developmentally appropriate positioning is disseminated verbally at staff meetings and via e-mail for those not present

Design for safety

- Multidisciplinary teams assess infants for SSC readiness during rounds according to inclusion/exclusion criteria
- Clinicians are aware of SSC champions on the unit who are available to help with difficult transfers and to answer questions
- Appropriate number and type of personnel are at bedside to help with patient transfer
- NICU SSC safety checklists are readily available and used

Involva usars

- Staff are encouraged at orientation and at staff meetings to report SSC safety incidents
- Families are educated at admission and throughout the hospital stay about safe SSC and are encouraged to report safety incidents
- Families are assessed for their comfort level regarding SSC
- Staff are debriefed after difficult transfers to discuss what went well and what could be improved

Collect and analyze safety data

- Staff and patient safety reports related to SSC
- Information about accidental extubation, accidental falls, and equipment dislodgement
- Root cause analyses of accidental extubation; analyses are stored in a database

Learn from patient safety incidents

- NICUs set target numbers for yearly accidental extubations related to SSC
- Results from accidental extubation root cause analyses are disseminated to all staff at staff meetings with outlined action
 plans for improvement (i.e., the use of a safety checklist if one was not used)

Note. Adapted from Edozien, L. C. (2013). The RADICAL framework for implementing and monitoring health care risk management. Clinical Governance: An International Journal, 18(2), 165–175. https://doi.org/10.1108/14777271311317945. Copyright 2013 Emerald Publishing. Used with permission. The RADICAL framework is a risk management framework whose domains are interconnected. For example, collecting information about rates of accidental extubation (collect and analyze) can inform new action plans for risk prevention (learn from incidents) and is connected to how clinicians will be trained/educated about positioning in the future (raise awareness). RADICAL = raise awareness, design for safety, involve users, collect and analyze data, learn from incident; SSC = skin-to-skin care.

safety plan in place, the decision of when and how to implement SSC will likely be determined by the comfort level and the amount of risk the nurse is willing to accept. This leads to practice variability regarding which infants can be held, for how long, and if parents are allowed to fall asleep (Fluharty et al., 2020).

Risk response: Share. This response distributes risks among different parties. A common example is acquiring insurance to mitigate a highly costly and not very likely consequence at the administration level, such as a medicolegal consequence. A risk may also be shared among

different departments, so staff take ownership and responsibility and work together to ensure patient safety during SSC. In the example of parent sleep during SSC, administrators may decide to transfer/share the risk by purchasing extra insurance that explicitly covers the costs of re-intubation and potential legal consequences. An SSC program will only be successfully implemented if all stakeholders do their own part to reduce the risks.

Risk response: Control. Along with shared accountability for risks, we advocate for a controlled approach to parent sleep. Tools and

To implement a successful skin-to-skin care program that ensures infant safety, NICU staff need to use effective risk management strategies.

resources are available (see Tables 1 and 2 and Supplementary Figure S3) that clinicians can use to inform themselves and to champion change by adopting a more effective risk response approach. Rather than avoiding the evidencebased practice of SSC, cutting SSC sessions short, or merely accepting the consequences of a hazard that has the potential to cause patient harm, the team can adopt a control response to intentionally reduce or eliminate safety risks. Through a control response, clinicians acknowledge the physiologic, developmental, and public health importance of parent and infant sleep (Weber et al., 2020) and evaluate the risks that need to be addressed. A control response was used in quality improvement projects that successfully reduced unplanned infant extubation through comprehensive risk management plans (Crezeé et al., 2017; Hu et al., 2017; Powell et al., 2016).

We encourage neonatal teams to design a risk management control system that deploys effective, practical strategies for risk control during parent sleep. Many frameworks for designing risk-controlled responses exist in the health care and business sciences (Edozien, 2013; Eiser et al., 2012; Simsekler et al., 2018; Ward et al., 2010). For example, more than 25 years of research evidence supports the application of the Simons levers of control framework (see Table 1; Kruis et al., 2016; Martyn et al., 2016; Simons, 1994). Based on the Simons framework, five different types of controls are essential to effectively addressing risks: diagnostic controls, boundary controls, belief controls, interactive controls, and internal controls, and many examples of these controls currently exist in the literature on SSC (Chan et al., 2017; Goodstein et al., 2021; Kukla & Ludington-Hoe, 2017; Weber & Harrison, 2019). Several examples of each type of control are included Table 1. For example, a boundary control would be the use of a safety checklist (see Supplementary Figure S3) that neonatal staff and parents can use to maximize safe positioning during SSC.

Hofherr (2017) recently implemented an innovative boundary control via a developmental approach to safe sleep transitions and parent

sleep in the NICU. A rubric and safe sleep bedside card practice guideline addressed the intersecting practices of parent sleep during SSC, developmental positioning support, infant transition to a safe sleep environment, and parent education surrounding safe sleep and sudden infant death syndrome. Based on an admissionto-discharge continuum, infants received red, orange, or green cards to signal readiness for a safe sleep environment (Hofherr, 2017), which the team evaluated by three criteria. These criteria included medical stability, maturity or developmental capacity, and parent engagement in safe sleep before discharge. The safeguards inherent in the safe sleep bedside card ensured that parents could spend many hours safely holding their infants and meet their own needs for sleep. The cards readily identified to staff and parents what sleep support, practices, and positions were appropriate for each infant. Parents could partner with clinicians to adjust to changing needs of the infant, including the transition to SSC without parent sleep when indicated. A uniform definition for medical stability and an objective measure for developmental readiness were essential to ensure that implementation was standardized, easy for NICU staff to follow, and effective to address the seemingly conflicting medical and developmental needs of NICU infants. This quality improvement project demonstrated improved compliance in safe sleep practices at 1 week before discharge from 60% to 83% in 2017 and sustained at 93% until 2020. This program is an excellent example of a boundary control that establishes inclusion and exclusion criteria and mitigates risk.

Monitor and Adapt Response to Risk

SSC should be treated as a quality improvement metric (Joshi et al., 2018) that is continuously monitored, reviewed, and reported, similar to rates of infection and medication errors. Once a response plan is in place, the team should continue to monitor, review, revise, and report on the effectiveness and outcomes related to the plan because risks evolve and change (High Level Group for the Modernisation of Official Statistics & Modernisation, 2017). Examples of quality metrics related to SSC include the number of SSC sessions per parent per day; duration (minutes) of SSC sessions; time to first SSC session after birth; breastfeeding initiation/maintenance rates; and self-reported symptoms of fatigue, stress, anxiety, and depression in parents (Hall et al., 2016). Rates of adverse events (e.g., unplanned extubation, central line dislodgement) that occur during SSC should also be tracked to allow for risk mitigation plans to be altered as needed. Stakeholders should select SSC outcomes that are measurable and specifically related to the NICU staff's focus on SSC. For example, a NICU staff that experiences dislodged umbilical lines during parent sleep may focus on reviewing the length (centimeters) of the umbilical venous catheter and umbilical arterial catheter at the umbilicus and how the infant is being contained before, during, and after SSC to monitor for dislodgement.

Finally, stakeholders must be willing to learn, adapt, and improve the plan over time. In most situations, multiple interventions to address each link in a causal chain of risks will be needed for effective implementation. Multiple frameworks for monitoring and adapting risk response can be used to connect individual aspects of a risk response. One such framework that is specific for the clinical environment is the raise awareness, design for safety, involve users, collect and analyze data, learn from incident (RADICAL) framework (Edozien, 2013). In this framework, multiple domains of risk management are used and interconnected. Using this framework, clinicians can see how their risk response for SSC can be adapted at the level of multiple domains and how adaptations will affect other domains (see Table 2). With patience and the right approach, teams gain better understanding of the risk factors that are specific to the NICU's context; how, when, and where these factors operate; and the appropriate risk response to each.

Conclusion

Despite the known benefits of longer durations of SSC for premature infants and their parents, a common barrier to SSC is the risk to the infant if the parent falls asleep during SSC. Organizations should develop hospital or unit policies that provide detailed strategies to mitigate the risks associated with SSC, especially if a parent falls asleep. A risk management framework can help neonatal clinicians enact change and increase safe implementation of SSC within their organizations. Clinicians should critically evaluate the risk context of their own practice settings; identify and analyze the risks of SSC with diverse stakeholders; design a comprehensive risk control response; and effectively implement a risk management control system that is regularly monitored, reported, and revised according to the evolving nature of our NICU environments. It is

also important to tailor the risk response to the infant's unique developmental and medical needs. Finally, the information provided herein can provide a foundation, framework, and tools to help champion a risk-controlled response to parent sleep during SSC.

SUPPLEMENTARY MATERIAL

Note: To access the supplementary material that accompanies this article, visit the online version of the *Journal of Obstetric, Gynecologic, & Neonatal Nursing* at http://jognn.org and at https://doi.org/10.1016/j.jogn.2022.02.004.

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CONFLICT OF INTEREST

Yamile C. Jackson, PhD, PE, PMP, is an ergonomics, safety, and risk engineer and the chief executive officer, Nurtured by Design, Sugar Land, TX. Nurtured by Design is a company that sells a range of developmental care products, including devices to facilitate skin-to-skin care. Dr. Jackson holds a patent for such a device (the Zaky Zak) and receives royalties for her company's products. Nurtured by Design did not provide any funds or compensation for this work. All other authors report no conflicts of interest or relevant financial relationships.

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JOGNN 2022; Vol. ■, Issue ■ 13