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# Analyzing Methods to Improve Infant Sleep Safety

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# WPI

## Analyzing Methods to Improve Infant Sleep Safety

An Analysis of Infant Deaths Related to Sleep Environments and  
Recommendations for Reducing Infant Sleep Related Deaths

An Interactive Qualifying Project submitted to the faculty of Worcester Polytechnic  
Institute in partial fulfillment of the requirements for the Degree of Bachelor of Science

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# Abstract

Annually, in the United States, nearly 3,500 infants die before their first birthday due to Sudden Unexpected Infant Death (SUID). For many years, researchers have tried to determine how to lower the incidence of and lower the incidence of these deaths. Despite the numerous efforts by many organizations, sleep related infant deaths in the United States remain disproportionately higher than other nations. Working with the United States Consumer Product Safety Commission (CPSC), research of previous efforts to help lower the rate of SUID in the United States was conducted, and where these methods were successful and where they could be improved were analyzed. Through stakeholder interviews, a literature review, and focus groups, the obstacles caregivers face to adopting the American Academy of Pediatrics' recommendations to reduce the risk of SUID were identified. A set of recommendations were made to the CPSC and safe sleep network to help address the barriers caregivers and parents face, and created a map of many of the organizations working in this field.

# Executive Summary

Sudden Unexpected Infant Death (SUID) is defined as the death of a seemingly healthy infant less than 1 year old that has no immediately, obvious cause (CDC, 2017). The United States has a disproportionately high rate of SUID compared to other wealthy countries. In 2015, there were 3,700 cases of SUID in the United States (CDC, 2017). There are three categories of SUID: Sudden Infant Death Syndrome (SIDS), accidental suffocation and strangulation in bed, and unknown cause. SIDS has the highest incidence of the three, and is defined as the death of an infant where the cause cannot be determined, even after an autopsy, a review of clinical history, and a death scene investigation (CDC, 2017). The current theory is that SIDS is caused when an infant with underlying abnormalities, going through a critical developmental period is exposed to an environmental stressor that a normal baby would be able to overcome. Although there is no way to prevent SIDS, parents and caregivers can reduce the risk of SIDS by following recommendations set by the American Academy of Pediatrics (AAP) (NICHD, 2013). Accidental suffocation and strangulation in bed is the most preventable of the three categories, and has been on the rise in recent years. Along with the introduction of the Back to Sleep campaign in 1994, many organizations and agencies launched campaigns to spread the message of safe infant sleep. These campaigns have generally been successful; parents for the most part are aware of the recommendations and since 1994, SIDS rates dropped nearly 50% (NICHD, 2017). The main issue is that parents struggle to follow the recommendations due to outside stressors, such as desperation for sleep and stress. This report will analyze methods in which the barriers can be overcome, and provide recommendations to the CPSC and safe sleep network on how to increase caregiver adherence to safe sleep behaviors.

Common infant sleep environments include standard cribs, bassinets and play yards; infants also fall asleep in products such as car seats and bouncers. The CPSC attempts to reduce hazards in environments intended for infant sleep through various methods such as ASTM standards and recalls of unsafe products. ASTM standards require a variety of warning labels stating the dangers of product misuse. However, warning labels are often not effective on their own because they are often ignored by consumers. Therefore, public safety messages are necessary to reinforce safe sleep behaviors. The most widespread campaign is the National Institute of Child Health and Human Development's (NICHD) "Back to Sleep" campaign, which has since been superseded by the "Safe to Sleep" campaign, that was launched in 1994. In addition, organizations across the country, such as non-profits public health organizations and health departments, have safety campaigns of their own to spread awareness of SUID and provide suggestions for prevention. Although the current safety campaigns have made progress in educating the public and reducing sleep related infant deaths, there is a need to address the barriers parents face in adopting the safe sleep behaviors. Many of this project's recommended methods for overcoming these barriers do not involve public safety campaigns but rather target the information parents receive subliminally, and change policies to address these issues.

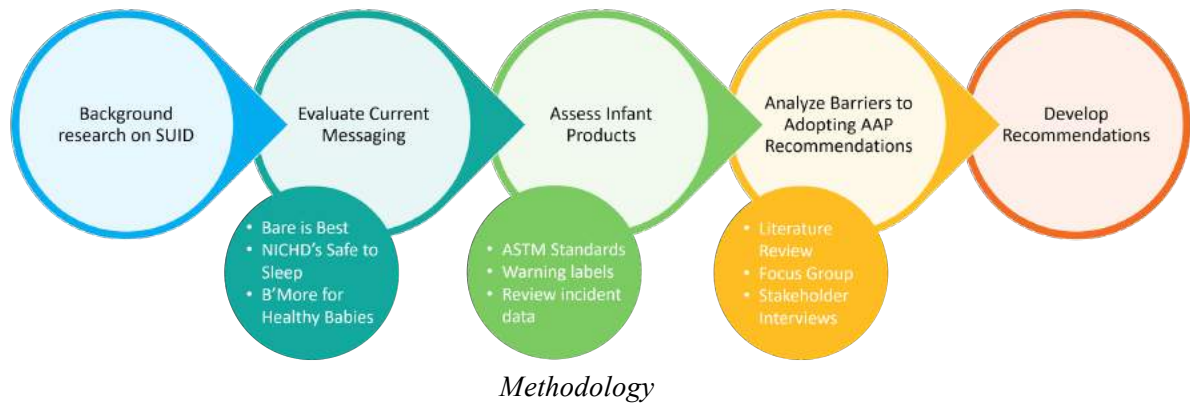
## Project Mission, Objectives, and Methodology

The goal of this project was to help reduce sleep related infant deaths in the United States by analyzing barriers caregivers face in adopting safe sleep behaviors, and recommending methods to help overcome these barriers. The first half of the semester was spent at WPI conducting research on SUID, current educational campaigns, and messaging about safe sleep. For example, the CPSC's "Bare is Best" campaign, the NICHD's "Safe to Sleep" campaign and Baltimore's "B'More for Healthy Babies" campaign were examined for their messaging strategies and metrics for success.

During the seven weeks at the CPSC, the first step was to assess infant sleep products. A list of products that parents and caregivers use to place their infants to sleep was created. Then voluntary standards and warning labels were examined to determine how parents might interpret the messaging. After products were assessed, many stakeholders involved in safe sleep were identified, and more than a dozen interviews were conducted throughout the duration of the project.



A main goal of the project was to look at the barriers that parents and caretakers face to when adopting the AAP recommendations to reduce SUID. A literature review, stakeholder interviews, and a parent focus group were conducted to explore these barriers. Finally from all of this information a list of recommendations for the CPSC and the safe sleep network to reduce SUID rates was developed. The figure below, shows a summary of the methodology for the project.

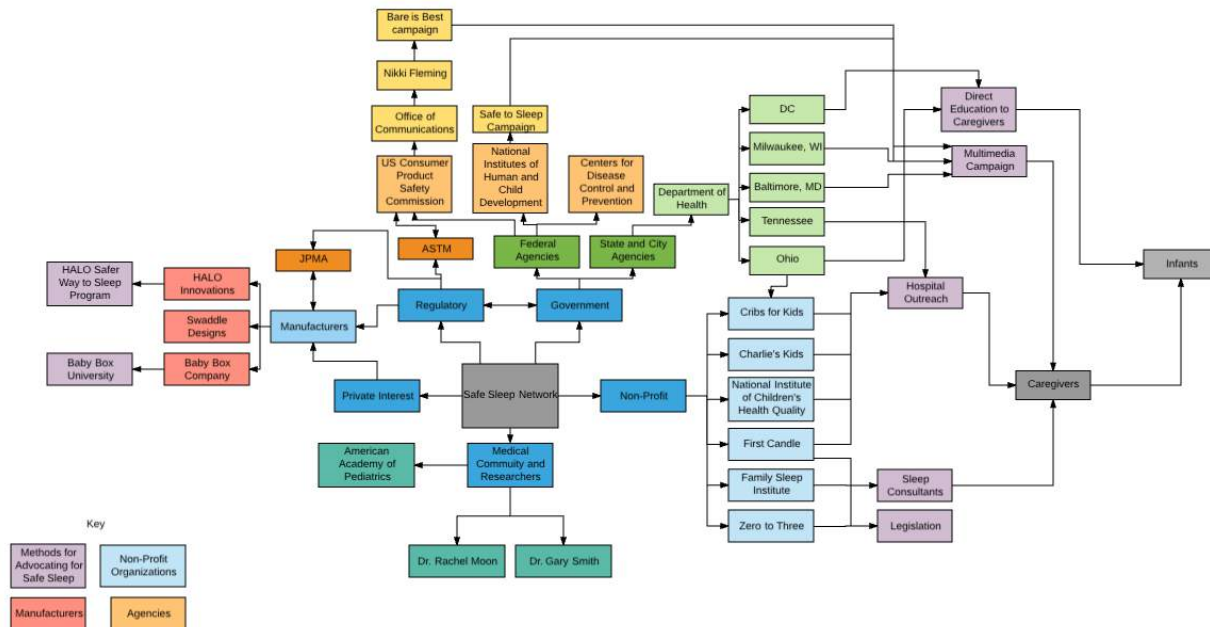


## Findings and Results

Through stakeholder interviews and a literature review, several recurring themes arose, which were grouped into three categories. The first category concerns the extensive network of groups and organizations whose missions’ surround safe sleep. The second category of findings relates to perceptions and behaviors of caregivers and parents. The third group of findings focuses on the social issues affecting safe infant sleep.

### **There is an extensive network of safe sleep interested groups and organizations but opportunities exist for greater synergy among them**

The map below is our current understanding of the network. While mapping the network, each organization and their respective strategies for safe sleep advocacy were noted. During interviews with those within the network, thoughts about what is working and what needs improvement were explored. While there are many organizations, agencies and companies working on safe sleep, there is still opportunity for improved synergistic relationships so that organizations can learn from one another and plan their initiatives in ways that complement each other.



*Safe Sleep Network*

### Desperation for sleep often leads to unsafe behaviors

A common theme in interviews and focus groups was that parents and caregivers become desperate for sleep after many restless nights. Parents have noted that how they place their baby to bed is often based on their own need for sleep rather than medical advice (Moon, 2017). In the parental focus group, one mother explained that her desperation for sleep led her to bedshare, which she said, “changed her life” because of how much more sleep she was getting. Mothers also noted that having multiple children made getting sleep difficult, and they had to go against the AAP recommendations because they did not “have the capacity to follow every rule to a T.”

### Parents want less risky alternatives to bedsharing because some bedshare regardless of risk awareness

Bedsharing increases the risk for SUID. Adult beds are not designed for infant sleep, and they present hazards to infants such as extra pillows and blankets. With that said, many parents end up bedsharing regardless of this risk. Campaigns want to drive home a message of safety, but at the end of the day parents make their own decisions based on their own needs. While there is no safe way to bedshare, but there are ways to reduce the risk of the SUID while bedsharing. This includes removing pillows and blankets, and placing the mattress close to or even on the floor.

### Parents can be overwhelmed with abundant, often conflicting information

Another common theme from interviews was that, throughout the process of preparing for a child, parents receive so many pamphlets, books and recommendations that they are overloaded with information. Brochures tend to be thrown away and forgotten. But one organization we interviewed addressed this issue by creating a board book (Desmond, K., telephone interview, November 3, 2017). It is given to every parent in hospitals in Georgia and Tennessee and contains safe sleep information. A representative from the organization says the goal is to not be a throw away book like a pamphlet or brochure but rather a book that is repeatedly read as a bedtime story.

Warning labels on children’s products may be another contributor to the problem of parents being overloaded with information. Some interviewees claimed that often warning labels have far too much text, causing consumers to largely ignore them. This applies to having safe sleep recommendations on a

product, label, or a set of instructions. Another organization we spoke with, discussed a QR code they place on their products that leads parents to a comprehensive list of recommendations on their smartphone instead of an overwhelming list of recommendations on the product (Damir, L. & Damir, J., telephone interview, November 6, 2017).

Much of the information parents receive about safe sleep conflicts with other providers' recommendations on safe sleep. This can lead parents to take the AAP safe sleep recommendations "with a grain of salt," meaning they are less likely to follow them. During a focus group session, one mother of three discussed how each of her children was delivered in different hospitals and all of the hospitals gave different information about safe sleep. Another mother explained how her neonatologist said bedsharing was not safe and should never be practiced. But her lactation consultant contradicted that by telling her that she needs to learn to sleep in the same bed as her newborn if she wants to breastfeed successfully. As expected, many health care providers are concerned mainly with their area of specialty. For example, a main concern of a GI doctor is the long-term effects of acid reflux on a baby's esophagus, whereas a lactation consultant is focused on making breastfeeding easier for mothers. Differences among providers result in confusion and conflicting messages to parents who hear different messages and must then balance among several risks to make the safest decision in the moment. Therefore, it is recommended to standardize sleep education so parents receive consistent information regardless of the specialist whom they see.

### **Parents generally know the AAP recommendations, but they often do not understand the reasoning behind them**

Through interviews and focus groups, we found caregivers are generally aware of the AAP recommendations, but often do not fully understand what the message is trying to address. During a focus group conversation, mothers expressed confusion over what "bare is best" campaign really means. This message refers to keeping a crib free of soft bedding and extraneous objects, but parents in the focus group thought it may refer to having the infant sleep without clothing, or even placing a stuffed bear in the crib. The tension is that successful campaigns and outreach programs often favor simple messages, so by their nature they often lack specific reasoning for the recommendations, and do not do enough to address questions parents may have (Moon et al., 2016a).

### **Many older caregivers are not up to date on current recommendations**

As more research is conducted and knowledge is developed, safety recommendations are changed.. Many older people, including grandparents, who have not been parents of an infant for a long time, are not up to date on current recommendations. Some mothers indicated that safe sleep is a difficult conversation to have with their parents. One mother said her parents think she is insane when telling them about the recommendations and asking that they all be followed.

### **Sleep environments are often depicted unsafely in media and advertising**

Advertisements and other media often show unsafe sleep environments with cribs, for example stuffed with extraneous objects for the purpose of making the scene more "adorable" or "inviting" (K. Kovaleski, phone interview, November 19, 2017). These depictions of soft cribs lead many parents to believe that is what a safe crib should look like, and cribs that follow AAP recommendations look more "like a jail cell" to many parents (E. Bonzon & S. Brandon, phone interview, December 1, 2017). It is important to open the discussion on the common depiction of unsafe sleep environments in the media and advertisements, and to work with manufacturers and retailers to promote safe sleep through advertisements so that caregivers do not receive subliminal messaging of unsafe sleep environments.

### **As consumers, parents are highly influenced by their peers and consumer reviews**

When asked during the focus group, mothers unanimously agreed that when they want advice about products to purchase they turn to other mothers. In a separate interaction, a father explained that he takes advice from experienced parents because "they have been through it before and they know what

works.” One mother explained how she purchased an inclined sleeper, which have been advised against because of a suffocation risk, for her baby after a couple nights of no sleep and she explained that the reviews of how amazing other babies slept in it, was what sold her. We also analyzed the reviews of several products that are not intended for sleep. A review of 128 customer reviews for an infant pillow showed over 60% of the reviews promoted unsafe uses of the product (Amazon Customer, 2017). If a caregiver is sleep deprived they may purchase products and use them incorrectly in a desperate effort for sleep.

Mothers also expressed how they are more likely to trust their peers than medical professionals. One mother explained that because of the way the recommendations are presented as black and white and unsafe and safe, it can be difficult for parents to follow the recommendations. Some parents view it as unrealistic to follow all the recommendations and balance the reality of parenthood.

### **Many caregivers do not think they can prevent SIDS but believe suffocation is preventable**

After research into the categories of SUID, including SIDS and suffocation and strangulation, it is important to recognize important differences. The most crucial is that the exact cause of SIDS is not known and some parents describe it as “God’s will” (Moon, 2017). Because of this, campaigns concerned with reducing SUID do not use the phrase “prevent SIDS”, but rather “reduce the risk of SIDS” (NICHD, 2017). Some AAP recommendations are designed to reduce the risk of SIDS. Strangulation and suffocation is the most preventable of the categories of SUID. The Back to Sleep campaign has reduced the rate of SIDS by 50% since 1994, but rates of strangulation and suffocation continue to slowly rise. Therefore, any further campaign should be one focused on reducing strangulation or suffocation related deaths.

### **Parents in the US lack national parental leave policy available in other countries**

SUID is not as common in other industrialized countries as in the United States, with experts pointing to the social services and benefits available in these countries as possible reasons for this phenomenon (R. Moon, phone interview, October 31, 2017). While there have been no conclusive studies that prove infant mortality and paid family leave are directly linked, they have been shown to be correlated (Rapaport, 2016). Parental leave allows parents to take time off work and focus on their child, to help prevent desperation for sleep without having to sacrifice a large portion of their income. The US is the only industrialized nation in the world to not have paid maternity leave, and currently only guarantees employees 12 unpaid weeks of leave (Family and Medical Leave Act of 1993). While many individuals in the US do receive paid family leave through employers and individual states, there is no national mandate, so leave opportunities are variable. To this effect, the discussion of expanding paid parental leave in the United States should be continued.

### **Messages on warning labels are unclear**

Warning labels on juvenile products, such as the one on the left in the figure below, commonly advise to “never leave child unattended,” which should ideally be read as “do not allow a child to sleep unsupervised for prolonged periods.” This ambiguity may cause confusion when warning labels should be blunt and straightforward. A recommended change would be to explicitly state “do not allow infant to sleep in product” such as in the label on the right. This would mean that there are no questions and a parent is told outright that placing their infant to sleep in a certain product could be dangerous.



*Warning Labels*

## Recommendations

After considering the responses from interviewees, the next step was to develop recommendations to address the safe sleep challenges parents face. Multiple stakeholders suggested or approved of these recommendations, and hopefully, these will help reduce sleep related infant mortality in the United States:

1. Increase synergy among safe sleep interested groups
2. Educate parents on strategies to reduce the risk of SUID when bedsharing
3. Work with manufacturers and retailers to promote safe sleep through advertisements
4. Add safe sleep practices to the high school health curriculum
5. Standardize sleep education across child care specialties so parents receive consistent information
6. Develop a suffocation based public health campaign
7. Update and improve warning labels on infant products so parents understand risks associated with certain products and behaviors
8. Incentivize manufacturers to refute reviews from consumers promoting unsafe product use
9. Continue discussion about expanding paid parental leave in the United States

## Conclusion

Considering the research into the current state of safe sleep awareness and practices in the United States, it can be concluded that there is still work to be done to guide parents to make safe decisions. Additionally, infant sleep needs to be portrayed correctly and safely in the media, so parents are not passively receiving mixed messages. The recommendations are provided with the goal to inspire organizations and agencies to take action and help parents to overcome the barriers they face in safe sleep.

# Chapter 1: Introduction

Every parent wants their children to be safe when they go to sleep, but dangers present in infant sleep environments may keep parents awake at night. Several infant products on the market are designed to be safe and help parents make their children comfortable, but many of these products may pose risks to sleeping infants. Sudden Unexpected Infant Death (SUID) claims the lives of approximately 3,500 seemingly healthy infants in the US every year (AAP, 2015). The products and practices parents use can impact their infant's chances of dying from SUID. Campaigns designed to promote awareness about sleep-related deaths have caused the number of SUIDs to drop over the last twenty years and have increased awareness of the recommendations to reduce the risk of sleep related deaths set by the American Academy of Pediatrics. However, parents continue to place infants in unsafe environments due to several barriers to adopting all the recommendations set by the AAP (Moon et al., 2016a).

Several factors can lead to SUID such as suffocation in soft bedding, strangulation in crib slats, and restricted airways in car seats (Williams, et al., 2016). The Consumer Product Safety Commission (CPSC) takes this issue seriously with many regulations on manufactured products for children. Adaptations to cribs, play yards, and bassinets have been required over the years due to regulatory changes. The goal is to have manufacturers conduct more rigorous testing on their products to determine potential hazards before they reach the public. In addition to regulation changes, public messaging systems like the National Institute of Children's Health and Human Development's (NICHD) "Back to Sleep" campaign aim to inform the public about infant safety. This campaign was successful when it was released in 1994, but SUID remains an issue. Non-profits and several manufacturers around the country are also concerned with safe sleep and craft their own ways to reach out to parents and caregivers. The CPSC, other federal agencies, and organizations cannot reduce the SUID rate without addressing caregiver's concerns, questions and struggles with following the safe sleep recommendations.

The campaign, "Back to Sleep," superseded by "Safe to Sleep," (the largest national campaign) was responsible for reducing sleep-associated unexpected infant deaths by 53% but these decreases have plateaued in the last decade (Moon et al., 2016b). Many caregivers continue to have difficulty following all the recommendations such as placing infants on their back, avoiding bedsharing, and not putting soft bedding in the crib (Moon et al., 2016a). Because of this, other efforts have been put forth to change infant sleep practices. Cities and states have developed local campaigns to change perceptions that prevent caregivers from adopting the necessary health interventions and build upon successes of "Safe to Sleep." Product standards and warnings produced by the CPSC alert parents to potentially dangerous products. Also, non-profit organizations do their part to spread awareness with public safety messages of their own. These combined efforts continue to decrease the rate of SUID.

Though the CPSC, other federal agencies and nationwide non-profit organizations have made significant progress in reducing infant mortality in sleep environments, obstacles remain. Safe sleep habits and infant mortality are a nationwide problem, therefore differing opinions and beliefs among caregivers about safe sleep practices exist. In addition, many public safety messages often leave more questions than answers among their audience. "Safe to Sleep," while currently adequate, has limited potential to grow without the addition of focused messaging for targeted communities. Research shows that, due to the wide range of personal beliefs and experiences, there are significant barriers that prevent the adoption of safe sleep behaviors. Therefore, analyzing methods to overcome these obstacles and propose them to the safe sleep network was the main objective of this project.

This project considered existing research on the reasons infants are dying in unsafe sleep environments, and why caretakers put infants in these unsafe environments despite knowing the risks. A focus group was conducted, stakeholders were interviewed, and current safety campaigns were reviewed to discover methods to help parents overcome critical barriers that may be putting their infants' lives in danger. Using the data gathered, a list of recommendations was created.

## Chapter 2: Background Information

Infant mortality is a worldwide problem, but the United States has a much higher rate than almost any other wealthy nation (CIA, 2017). Government agencies at the federal and state level and non-profit groups are devoting significant resources to investigate the reasons why this is the case. This section will look at Sudden Unexpected Infant Deaths, its risk factors, and recommendations to prevent such deaths. It will examine the CPSC’s role in protecting consumers and in reducing SUID. Finally, it will examine some of the current messages available to the public.

### 2.1 Sudden Unexpected Infant Death (SUID)

SUID claimed the lives of 3,700 seemingly healthy infants in the United States in 2015 (Center for Disease Control, 2017). SUID is broken down into three separate categories: Sudden Infant Death Syndrome (SIDS), unknown cause, and accidental suffocation and strangulation in bed (Center for Disease Control, 2017). The criteria for death by SIDS is a death of a child under the age of 12 months that remains unexplained even after an autopsy, an investigation of the death scene, and a review of the infant’s health. SIDS is the leading cause of death for infants 1-12 months old. Of the 3,700 SUIDs in 2015, 43% were attributed to SIDS (Center for Disease Control, 2017). SIDS usually occurs while a baby is sleeping and although the exact causes are still unknown, some scientists believe it may have to do with brain abnormalities associated with breathing and a baby’s ability to wake up (Naeye, 2016). If these assessments cannot be completed, then the infant death is ruled an unknown cause. The third category of SUID is suffocation and strangulation, and is considered the most preventable type of SUID. Common causes include overlay, when another person rolls on top of an infant, and asphyxiation, caused by objects in the sleeping environment (Center for Disease Control, 2017).

SIDS rates in the United States have dropped steadily since the introduction of the “Back to Sleep” campaign in 1994. However, the overall SUID rate shows little improvement since the late 1990s, as depicted in Figure 1, below, from the Centers for Disease Control and Prevention (CDC, 2017). According to a study published in the journal *Pediatrics* in 2009, the exact reason for the increase in suffocation deaths is unknown, but it coincides with an increase in bedsharing (Shapiro, et al., 2009). It is also possible that with the decreasing rate of SIDS that examiners are better at determining the cause of death in an infant, causing an increase in reported cases of suffocation. The lack of improvement in the combined SUID rate, however, was the motivation behind the project.

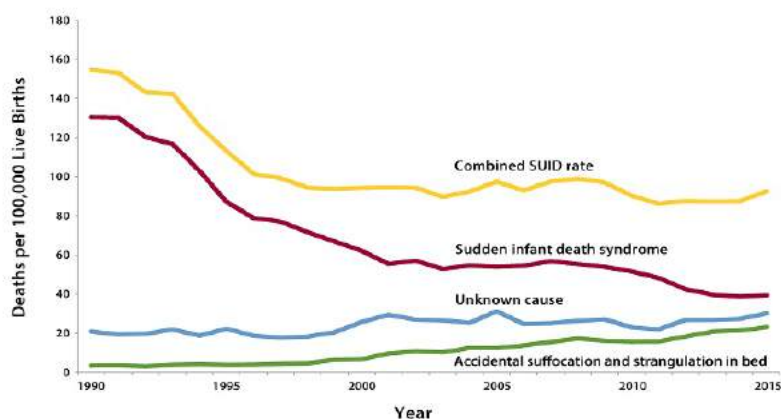


Figure 1: Trends in SUID (CDC, 2017)



### 2.1.1 SUID in the United States and the World

Christopher Ingraham, a reporter at the *Washington Post*, who previously worked in research at the Brookings Institution in Washington D.C, found that the United States has the highest health care spending in the world and the highest infant mortality rate compared to 27 wealthy countries (2014). Fifteen countries report SUIDs, and the United States currently ranks last along with New Zealand (Hitchcock, 2012). Despite high healthcare spending, a baby born in the United States is less likely to reach their first birthday than a baby born in Cuba (Ingraham, 2014). The infant mortality gap between the US and other developed nations is not a new trend. Figure 2 shows that, in the beginning of life infant mortality rate is similar in the US, Finland and Austria. However, as an infant grows closer to one-year old, the rate of death in the US is higher than both Finland and Austria.

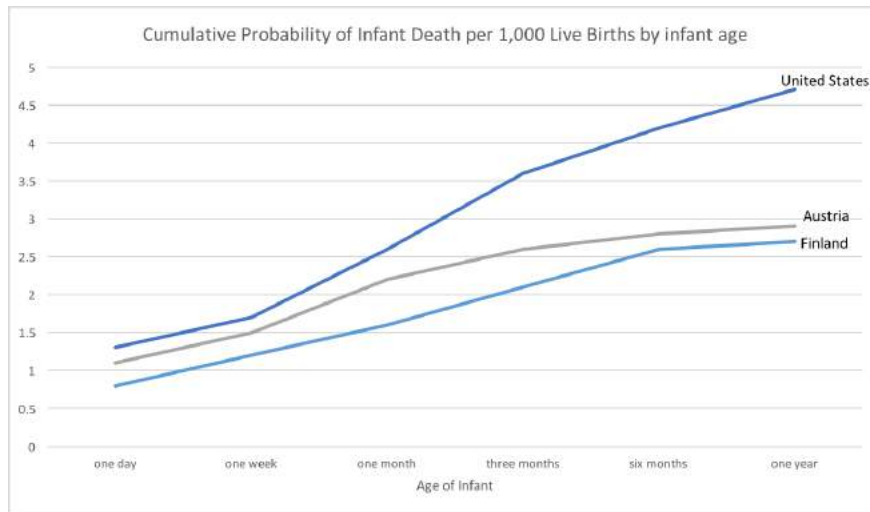


Figure 2: Infant Mortality Probability in US vs. Finland and Austria (Ingraham, 2014)

Research also indicates a significant racial and ethnic disparity for SUID incidence. African American and Native American infants are four times more likely to die from SUID than Hispanic infants, and Hispanic and Asian American/Pacific Islanders had the lowest incidence of SUID among all racial and ethnic groups as seen in Figure 3 below (CDC, 2017). This is likely due to cultural norms within different communities (Mathews et al., 2016). For example, bedsharing is a cultural norm in African American communities. In addition, Hispanic mothers are more likely to place infants in supine position because, for them, that is the norm and the position is viewed as comfortable for the infant. However, African American parents are more likely to place infants in the prone position for their own cultural reasons (Mathews et al., 2016). This indicates the need for targeted intervention that can sensitively address cultural norms surrounding infant sleep while promoting safe sleep practices.



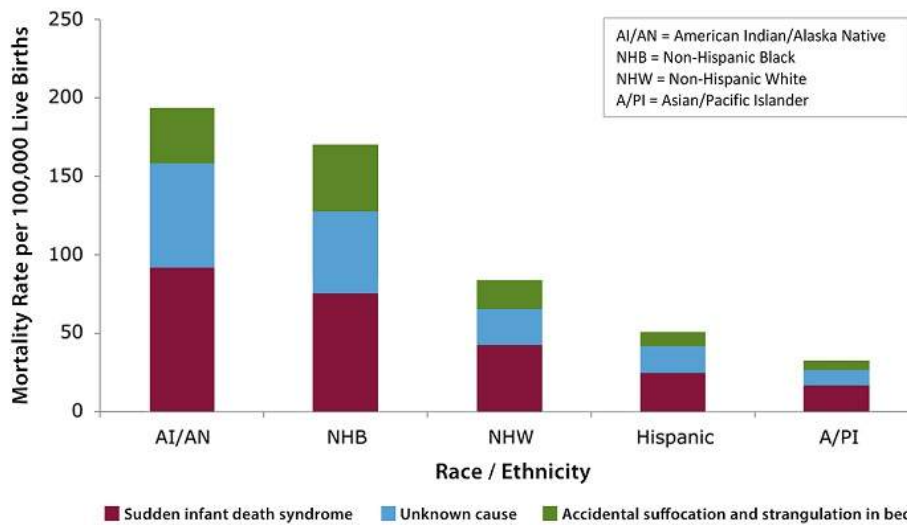


Figure 3: Sudden Unexpected Infant Death by Race/Ethnicity, 2011-2014 (CDC, 2017)

### 2.1.2 The Triple Risk Model

The triple risk model is the current hypothesis for the cause of SIDS (Moon, 2017), and is used as the “contextual construct for understanding SIDS deaths” (NICHD, 2013). There are three risk factors thought to contribute to SIDS, and, when an infant is at the intersection of these risks, they are at risk for SIDS as shown in Figure 4.

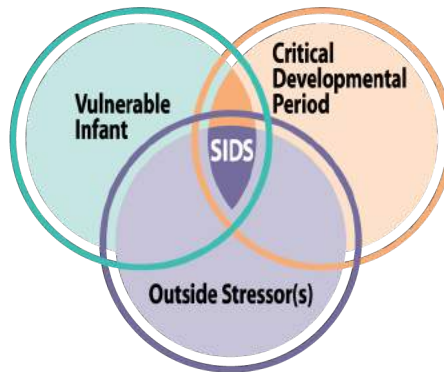


Figure 4: Triple Risk Model for SIDS Cause (Nebraska Department of Health, n.d.)

The first risk factor is a vulnerable infant, meaning that an infant has some underlying genetic defect or brain abnormality (NICHD, 2013). Many infants who die of SIDS had an upper respiratory infection in the prior four weeks. Premature babies are also at a higher risk of SIDS. Research has also shown that, at the time of death, SIDS infants had higher levels of serotonin in their brain (Nebraska Department of Health, n.d.).

The second risk factor is the infant being in a critical development period. During the first six months of life, there is rapid change and development in infants (NICHD, 2013). It is believed these changes can be seen through changing sleep and awake patterns, or small, unnoticeable changes in respiration and blood pressure that can “destabilize the infant’s internal systems temporarily or periodically” (NICHD, 2013).

The third risk factor is outside stressors. Outside stressors include supine sleep position, overheating, secondhand smoke, or an upper respiratory tract infection. Most babies encounter outside stressors and are able to survive these interactions. However, a vulnerable infant in a critical development period may not be able to overcome them (NICHD, 2013). Asphyxia has always been a factor when considering what causes SIDS, and it is believed that SIDS “results when a vulnerable infant cannot adequately defend against an asphyxiating environment” (Moon, 2017).

The first two risk factors, vulnerable infants and a critical development period, are not able to be controlled. However, there are certain practices that can reduce the number of outside stressors, and reduce the risk of SIDS.

### 2.1.3 Recommendations to Prevent SUID

Many organizations and federal agencies focus on reducing SUID nationwide, most prominently of which is the AAP. The Center for Disease Control (CDC), the National Institutes of Health (NIH) and the Consumer Product Safety Commission (CPSC) are other federal agencies concerned with SUID. These recommendations were published in a *Pediatrics* article “SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Infant Sleeping Environment in October of 2016” (Moon et. al., 2016). This article is the main source of recommendations for almost all of the groups currently working to distribute safe sleep materials. It contains 19 recommendations for parents, caregivers, and doctors, summarized in Table 1, below. The recommendations include 15 tips for caregivers to reduce the likelihood of SUID and 4 recommendations on topics for scientists to continue to research. The AAP also encourages the endorsement of safe sleep practices by health care professionals and the media (2016). There is extensive evidence and scientific reasoning behind each recommendation and each recommendation has a letter code (A, B, C) associated with the strength of evidence for it, with A being the strongest.

	<b>Strength</b>	<b>Recommendation</b>
1	A	Place infant on their back to sleep for every sleep
2	A	Use firm sleep surface
3	A	Breastfeeding is recommended
4	A	Do not share a bed with infant, but have infant in the same room
5	A	Keep soft objects and loose bedding away from sleep area
6	A	Offer a pacifier during sleep
7	A	Avoid smoke exposure during pregnancy and after birth
8	A	Avoid alcohol and illicit drug use during pregnancy and after birth
9	A	Avoid overheating with clothes or room temperature
10	A	Receive regular prenatal care
11	A	Immunize infants per CDC and AAP recommendations
12	A	Do not use cardiorespiratory monitors as a strategy to reduce SIDS
13	B	Avoid products marketed to reduce SIDS, including wedges and positioners
14	B	Place infants on their stomach while awake under supervision
15	C	Swaddling can be used but there is no evidence that it reduces SIDS
16	A	Health care providers should endorse and model recommendations
17	A	Media and manufacturers should follow safe sleep guidelines in their advertising
18	A	Pediatricians should actively participate in Safe to Sleep campaign
19	C	Continue research and surveillance on risk factors

Table 1: AAP Recommendations to Reduce Risk of SUID (Moon et al., 2016a)

The previous set of AAP recommendations published in 2005, contained 11 recommendations for reducing SUID (Moon, et al. 2016b). Between 2005 and 2016 the AAP changed its recommendation from cautioning about the use of bumpers to recommending that they never be used. They stated that minor injuries associated with not using bumper pads are far outweighed by the risk of death from suffocation from using them (Hitchcock, 2012). It is widely understood that parents practice what they observe health care providers do more often than what health care providers say. Therefore, Neonatal Intensive Care Unit (NICU) nurses and health care professionals should promote safe sleep behaviors immediately following birth (Moon, et al. 2016b). Health care professionals who display different behaviors and attitudes send mixed messages to parents, further complicating adherence to recommendations.

## 2.2 Common Infant Sleep Products

Many products are used for infant sleep including environments that are specifically designed for them to sleep, such as cribs, bassinets, and environments that can be dangerous for infant sleep such as swings and car seats. This section describes many infant sleep environments parents and caregivers use and their potential risks.

### 2.2.1 Cribs

A crib is a sleeping environment with latticed sides. Common in infant households, they provide a safe place for the child to sleep protected from hazards present in an adult bed, such as falling.

#### **Standard Cribs**

This style of crib is the most popular available today, and can be seen in Figure 5 below. The standard crib size is 28 inches wide by 52 inches tall. Most other infant products are designed with this size in mind (CPSC, 2011). Standard cribs are traditionally made from wood, are solid and not meant to fold or transform. Standard cribs used to commonly feature both single and double drop-sides, which would allow a caretaker to easily handle the child when they were in the crib. However, in July 2011, a CPSC regulation banned the use of drop-sides on standard cribs (CPSC, 2011).



*Figure 5: Standard Crib (NICHD, 2014)*

### Portable Cribs

A portable crib is like a regular crib, only smaller. Portable cribs are normally not as large as a full-sized crib, so they can be easily transported. Some portable cribs are certified by the Juvenile Products Manufacturers Association (JPMA), but many are not recommended by the CPSC (*Consumer Reports*, 2016). Portable cribs are most often used if the parents live in a small apartment, or for travel.

### Play Yards

A play yard is a compact alternative when traveling, since hotels may not provide a safe crib. As seen in Figure 6, below, they are frequently made of lightweight materials and are compact for storage while traveling (*Consumer Reports*, 2016). They are shaped similarly to cribs but have mesh sides instead of traditional wood slats.

Despite their benefit for traveling, there are safety concerns associated with play yards. Between 1988 and 2001, the CPSC received over 200 reports of infant deaths in play yards (CPSC, 2001). Sixty-eight of these reports involved soft bedding when the infants died of SIDS or suffocation, and 25 of these deaths involved extra mattresses or cushions. The CPSC advises consumers to only use mattresses or cushions included with the product, and to not place infants less than 12 months old in a sleep environment with soft bedding (CPSC, 2001). In 2013, the CPSC issued new regulations that ban units that make a sharp “V” shape when folded, and require stronger corner brackets to prevent collapse and stronger attachments to prevent mattress movement (Williams, 2013).



Figure 6: Infant Play Yard (NICHD, 2014)

### 2.2.2 Cradles and Bassinets

Cradles and bassinets are both small infant sleeping environments. They usually have a rounded frame and are lined with cloth. Bassinets are portable, while cradles are larger and more difficult to move around. Cradles are unique because they rock or move in the frame, as seen below in Figure 7. However, cradles and bassinets are not as popular as other sleeping environments. These products are also less regulated than standard cribs, so parents must rely on adherence to voluntary standards and JPMA certification to ensure that the product is safe (*Consumer Reports*, 2016).



*Figure 7: Bassinet (NICHD, 2014)*

### 2.2.3 Potentially Dangerous Environments and Products

Not every place that parents put their children to sleep is designed for sleep. Placing infants to sleep in these environments may pose a threat to their safety. This section will discuss dangerous and unintended sleep environments including adult beds, car seats, and sleep positioners.

#### **Adult beds**

Many parents may choose to sleep in the same bed as their infant, and many online sources highlight the benefits of bedsharing (Carpenter, et al., 2004). According to a 2013 study the number of parents who shared a bed with their infant increased from 6.5% in 1993 to 13.5% in 2010 (National Institutes of Health, 2013). Pediatrician Dr. William Sears is an avid spokesperson for bedsharing, and claims that it promotes breastfeeding and synchronizes the sleep-wake cycles of the mother and infant. This means that the mother is under much less stress and gets more sleep (Whiteman, 2014).

Despite these benefits, bedsharing is not a safe practice and is associated with an increased risk of SUID. Adult beds are much softer than infant beds, and may contain soft bedding. Bedsharing also increases the likelihood of suffocation caused by overlay. The AAP now recommends an infant and parent share a room, but not a bed, which has many of the benefits of bedsharing without the danger (Moon, et al., 2016).

#### **Inclined seating devices**

According to Selena Silva, a program coordinator of the Child Passenger Safety Program at Children’s Hospital in Denver, Colorado “new parents are desperate to find any comfortable place for an infant to sleep” (Mann, 2009). This may cause parents to use products not designed for sleep, such as car seats and swings, as make-shift cribs. The AAP, CPSC, Consumer Reports and other organizations strongly recommend that infants sleep on their back on a firm, flat surface.

Multiple deaths have been reported of infants suffering from asphyxiation based on their sleeping angle. A 2015 review by Penn State Medical Center, focused on 47 cases where infants died while sleeping in car seats, swings, bouncers and other seating devices while in the house and found that these deaths could have been prevented (Corley, 2017).

A study conducted in 2009 found that sitting in car seats can result in “mild respiratory compromise” in 20% of newborns (Mann, 2009). Car seats can compress chest walls and reduce airway size in infants, decreasing blood oxygen supply (Mann, 2009). Another study found that infants sitting at a 40-degree angle for 30 minutes experienced significantly higher breathing and heart rates and lower blood oxygen levels (Williams, et al., 2016). Some trials in this study found that infants seated in car seats showed signs of “cardiorespiratory compromise” (Williams et al., 2016). This study also found that sitting at a 30-degree angle had minimal effects on infants. When infants sit at an angle, they “tend to have their head turned down” which could lead to airway constriction (Haque, 2009).



Many pediatricians stated that these findings should not alarm parents, and they should continue using car seats for travel (Haque, 2009). The author of the 2009 study, T. Bernard Kinane, specifically stated that car seats are safe for travel, but should not be a replacement for a crib (Mann, 2009).

Despite these concerning findings, products are advertised claiming to make sleeping in car seats safe. One product is designed to wrap around the car seat and head of the infant to keep the infant upright in the seat. Another product is designed to support smaller infants in car seats, and many reviewers mention how easily their infants fall and stay asleep in the car seats while using this product. A typical car seat is shown in Figure 8, below.



*Figure 8: Infant Car Seat (Champion, 2009)*

### **Sleep Positioners**

In 2010, the CPSC and FDA issued a warning about infant sleep positioners. Manufacturers claim sleep positioners prevent infants from rolling onto their stomach (thereby lowering the risk of SIDS) and prevent acid reflux by elevating the head (CPSC, 2010). However, no current studies show that these products are effective in reducing the risk of SIDS (Wanna-Nakamura, 2009).

In fact, twelve infant deaths were linked to sleep positioners from 1999 to 2010 (CPSC, 2010). Despite being designed to keep infants in supine position, parents and caregivers still place infants in prone position or on their side, which resulted in five deaths from 1997 to 2009 (Wanna-Nakamura, 2009). Some sleep positioners are designed to keep infants on their sides, despite AAP and CPSC warnings against side sleeping. Sleep positioners come in two varieties: a flat mat or inclined mat (CPSC, 2010). Both varieties often have side bolsters to keep infants in place. However, babies can suffocate if they roll over and lie their face against the bolsters (Consumer Reports, 2012). The FDA has investigated the product's claims about acid reflux but concluded that the risks from suffocation outweigh any potential benefits (CPSC, 2010).

At popular retailers, such as Amazon, Walmart, and Target, sleep positioners are marketed to parents who wish to place infants on their side and in the supine position. On Amazon, twelve of the top 60 products listed under "infant sleep positioners" promote side sleep. Walmart sells multiple varieties of sleep positioners, including a few promoting side sleeping, and others designed to keep infants in supine position. Such devices are shown in Figure 9 below.



Figure 9: Infant Sleep Positioners (CPSC, 2011) (FDA, 2010)

### Soft Bedding

Soft bedding in cribs adds an additional risk to sleeping infants. If an infant rolls over onto blankets, pillows, crib bumpers, stuffed animals or other soft objects, they risk suffocating. Laying against soft objects may cause the infant to re-breathe their own carbon dioxide rather than fresh, oxygen-rich air (Consumer Reports, 2016). The AAP, CPSC, and Consumer Reports all recommend keeping cribs bare, and free from soft bedding of any kind (Consumer Reports, 2016).

Despite risks, soft bedding and crib adornments are prominently featured on many retailers' websites including those of Amazon, Target, Walmart, Babies“R”Us, and Pottery Barn Kids. This includes products specifically designed to be used in cribs such as crib bumpers, baby blankets, and comforters. Most descriptions for these products do not include warnings about risks associated with soft bedding.

## 2.3 Consumer Product Safety Commission (CPSC)

The CPSC is an independent government agency, located in Bethesda and Rockville, Maryland, tasked with protecting the public from unreasonable risks associated with the use of thousands of consumer products. In this section, there will be a discussion of regulations, and the recall process both generally and as related to infant safety. A background of the CPSC can be found in Appendix A.

### 2.3.1 CPSC Rulemaking Process

As a federal agency, the CPSC must adhere to the processes described by the Administrative Procedure Act (APA) (CPSC, 2012a). This statute governs the rulemaking process of all federal agencies. The APA defines a rule as “the whole or part of an agency statement...designed to implement, interpret, or prescribe law or policy” (CPSC, 2012a). Agencies must publish a notice of proposed rulemaking (NPRM) in the Federal Register, which must explain any proposed rules and provide an opportunity for public comment (CPSC, 2012a). The agency considers any public comments, then issues a final rule in the Federal Register containing the new rules or standards and responses to public comments (CPSC, 2012a). The process is purposely lengthy to allow time for public input and any necessary research that may need to be conducted.

Rules and regulations are administered by agencies under the authority of legislation passed by Congress. The CPSC has authority under several statutes including the Consumer Product Safety Act, Federal Hazardous Substance Act, the Flammable Fabrics Act, the Poison Prevention and Packaging Act, and the Consumer Product Safety Improvement Act (CPSC, 2012a).

### 2.3.2 Consumer Product Safety Improvement Act of 2008

The Consumer Product Safety Improvement Act of 2008 (CPSIA) includes new statutes and standards regarding many classes of products (Consumer Product Safety Improvement Act of 2008). The CPSC is responsible for making regulations to enforce the new law and Title I of the CPSIA is devoted entirely to children's products.

Section 102 of the CPSIA requires that certain children's products be tested by a third party which is intended to certify that a product complies with all "rules, bans, standards, or regulations applicable to this product under [the CPSIA] or any other Act enforced by" the CPSC (Consumer Product Safety Improvement Act of 2008). Manufacturers and importers are required to submit samples to a CPSC accredited lab to be tested for "compliance with such children's product safety rule." After testing, manufacturers are required to issue a Children's Product Certificate (CPC) to distributors of their product (CPSC, n.d. a).

Section 104, also known as the Danny Keysar Child Product Safety Notification Act, requires the CPSC, in agreement with consumer groups, juvenile product manufacturers, and independent experts, to use standards that are the same or more stringent than voluntary standards to "reduce the risk of injury associated with such products" (Consumer Product Safety Improvement Act of 2008).

### 2.3.3 CPSC Recalls

As incidents are reported, it is important for the CPSC to recall potentially dangerous products to inform and protect the public. In addition to keeping products deemed "unsafe" off the shelves, safety regulations are put into place to guide manufacturers on how to make safer products. Due to CPSC supervision, the manufacturing industry takes precautions to limit potential sources of danger before the products are available to the public. The CPSC has made several recalls of infant products to warn customers of potential dangers and reduce potential infant fatalities.

Many agencies in the federal government are responsible for recalls. Food, drug, and medical device recalls are dealt with by the Food and Drug Administration, meat recalls go through the US Department of Agriculture, and vehicle recalls go through the National Highway Traffic Safety Administration (Cox, 2015). Essentially recalls for everything else consumers buy goes through the CPSC (Cox, 2015).

Recalls through the CPSC can be initiated in one of two ways. The first is when the manufacturer or importer reports defects or dangers that creates an unreasonable risk of injury or death, fails to comply with CPSC rules, or causes an accident where a child chokes on a small part of a toy that causes serious injury, death, or medical treatment. A recall can also be initiated when consumers report defective products directly to the CPSC (CPSC, 2012b). The report of a potential hazard to the CPSC does not necessarily mean a recall will start (CPSC, n.d. c).

Companies and manufacturers are responsible for their own recalls and the CPSC must rely on their cooperation (Cox, 2015). The CPSC urges companies and manufacturers to start early. To start the recall process, manufacturers must go to the CPSC website to file a report. The report must include specific product details such as dates of manufacture, brand, defect, incident details, and details about how, when, and where the product was sold or distributed (CPSC, n.d. d). They must also include details of any corrective action they intend to take that removes a product from the distribution chain, and files supporting the report (e.g. incidents, engineering tests) (CPSC, n.d. d).

Manufacturers may also participate in the CPSC Fast Track Recall Program. This program allows products to be removed from the market quickly to lower the potential for injuries or incidents to consumers, which can reduce potential product liability for the manufacturer. To participate, businesses must provide a corrective action plan (CAP) that is ready to be implemented within 20 working days. The CAP must include a remedy (e.g. refund, replacement, or repair), news release, logistics plan for the recall, and announcements to consumers and distributors (CPSC, n.d. b).



Once a recall is initiated, the manufacturer must alert consumers. Some common methods include press releases, website posting, email to customers, social media posts, in-store posters, television ads, telephone calls, and hotlines with information about the recall (CPSC, 2015).

Almost every recall is a voluntary recall, but this does not mean recalls are optional. Recalls are the result of an agreement between the CPSC and the manufacturer to remove dangerous products from the market and supply a remedy to consumers (*Consumer Reports*, 2010). When a company refuses to issue a voluntary recall, the CPSC may have to get a court order to force a mandatory recall. This is a costly process that can last years, so the CPSC tries to avoid this. In 2012, the CPSC filed a complaint in court about a magnetic toy, that if swallowed by children, caused severe injury. The company fought back against these allegations, but eventually was forced to close and the CPSC reached a settlement with the former owner of the company to initiate a recall that would allow consumers to get a refund (Cox, 2015).

## 2.4 Voluntary Standards and Testing Organizations

Voluntary standards for consumer products are developed in conjunction with the CPSC and the multiple voluntary standards organizations. This collaborative process brings government agencies, manufacturers, and consumer groups together “to agree on the best consumer product safety practices” (CPSC, 2017). Technical experts work in voluntary standards organizations to develop product standards covering testing requirements, product specifications, hardware specifications and more. Federal agencies often rely on these organization’s expertise when developing regulations. This section covers organizations that develop standards and certify products.

### 2.4.1 ASTM International

ASTM International (ASTM, formerly the American Society for Testing and Materials) is a non-profit organization that develops voluntary technical standards for a wide range of consumer products (ASTM International, 2017). They boast 30,000 members, who ASTM describes as “top technical experts” that represent 140 countries. The members are responsible for creating testing methods, specifications, classifications, and guides that “support industries and governments worldwide.” ASTM currently has over 12,000 standards for products (ASTM International, 2017).

ASTM standards are voluntary for manufacturers but are often referenced by federal agencies including the CPSC, at which point they become mandatory. The National Technology Transfer and Advancement Act, passed in 1995, requires federal agencies to use privately developed standards in regulations when possible (EPA, 2017). CPSC regulations enacted in 2011 that banned drop-side cribs, referenced thirteen ASTM standards that are now required for all new cribs sold in the United States (CPSC, 2010).

### 2.4.2 Juvenile Product Manufacturers Association (JPMA)

The Juvenile Product Manufacturers Association is a trade organization that represents the manufacturers of products intended for infants and young children. They represent about 250 manufacturers that are collectively responsible for 95% of “prenatal to preschool products” (“Who is JPMA?” 2017). The JPMA is responsible for monitoring regulations, promoting industry, serving as a resource on safety standards for manufacturers, educating consumers on safe use and selection of infant products, and gathering and distributing industry statistics (“Who is JPMA?” 2017).

The JPMA offers a certification program to help “guide parents” to make safe choices about the products they buy (“Certification Program,” 2017). To become JPMA certified, a product must undergo testing to conform to ASTM standards and federal and state safety requirements. JPMA certification is highly regarded in the industry by both manufacturers and consumers; *Consumer Reports* recommends consumers buy cribs that have JPMA certification (“Crib Buying Guide,” 2016).

## 2.5 Public Safety Messages

Public safety messaging is a tool used to inform the public about a hazard or risk with the objective of raising awareness and changing attitudes and perceptions about the issue. This section describes effective messaging types, examines current messages available to the public and discerns barriers and reasons for lack of adherence to messaging.

### 2.5.1 Social Marketing

Social marketing is a messaging strategy that applies traditional marketing principles and techniques to deliver a message to influence the behaviors of the target audience (Lefebvre, 1988). The target audience is usually diverse and the influence is on a large scale (Smith, 2016). It is a strategy focused on behavior change and services whereas traditional marketing is focused on selling a product (Lefebvre, 1988). Social marketing conceptualizes safety practices as “attractive, accessible, affordable, and appropriate products” (Rice et al., 2012). Social marketing should be a community based approach in terms of defining the problem all the way through intervention with the product (Rice, et al., 2012). Incident data can be used to identify problem sources that need to be addressed and then the community can assist in applying the marketing strategies. This marketing strategy can be used to design and evaluate programs related to behavior change. Social marketing concepts have been applied to promote traffic safety, drug prevention, improved nutrition and childhood immunizations (Smith, 2006).

Message creators must be aware of two obstacles that can arise with the social marketing approach, and their product must address the barriers to be successful. The first obstacle is failure to identify the target audience (Lefebvre, 1988). The second barrier is the need to work with multiple intermediaries who then relay the message to the consumer (Lefebvre, 1988). The intermediaries may interject their own opinions which can modify the message before it reaches the consumer. Therefore, channels of distribution should be as direct to the consumer as possible. A specific facet of social marketing is health marketing, defined by the CDC as “creating, communicating, and delivering health information and interventions using consumer-centered and science-based strategies to promote the health of diverse populations” (Bernhardt, 2006). This relatively new strategy of combining marketing and public health has gained popularity such that the CDC established the National Center for Health Marketing (NCHM) in 2004 (Bernhardt, 2006). A social marketing approach could be utilized as a model for marketing safe infant sleep practices.

### 2.5.2 Current Infant Safety Messaging

Many organizations across the country promote safe sleep through public safety messaging. There are a wide range of messages that target specific audience groups. Some of the messages are developed by state health departments, whereas others are published by non-profit organizations and federal agencies. This section discusses several campaigns including the those developed by Baltimore Department of Health, Ohio Department of Public Health and the NICHD.

#### **“B’More for Healthy Babies” Campaign**

The Baltimore Department of Health ran a study which found that 85% of SUIDs in Baltimore happen outside of the crib and 78% of these deaths occurred during bedsharing (Moon et al., 2016a). In response, Baltimore Department of Health produced a video titled “SLEEP SAFE: Alone, Back, Crib, No Exceptions” which featured testimonials from three local mothers who lost babies while bedsharing (Johns Hopkins CCP, 2011). The video features local families and helps to convey a relatable message that no infant is immune to this tragedy (Moon et al., 2016a). In addition, it conveys an emotionally triggering, rather than logical, message, which tends to be more effective (Witte, 2001). The Department of Health expanded the video to WIC sites (i.e. sites that support the Special Supplemental Nutritional Program for Women, Infants, and Children), city detention centers, Department of Social Services offices, and jury duty locations to maximize the audience the video was reaching (Moon et al., 2016a). They also developed additional videos targeting fathers, grandparents, and Spanish speakers (Moon et al., 2016a).

Since the program started in 2010, the rate of infant sleep-related deaths in the city decreased by 46% (Moon et al., 2016a).

### Milwaukee's Scare Tactics

Public safety messaging often uses scary advertisements to increase the perception of personal susceptibility by implying horrible things will happen if one does not comply with the message (Moon et al., 2016). This strategy is common in anti-smoking campaigns which often feature graphic images of diseased lungs, mouth cancer, and corpses in a morgue to dissuade people from smoking (Moon et al., 2016). Between 2006 and 2009, there were 89 cases of SUID in Milwaukee, Wisconsin and forty-six of them were associated with bedsharing (Milwaukee, 2012). To curb this problem, the Milwaukee Department of Health launched the Safe Sleep campaign and used scare tactics. The first image, released in 2010 featured an adult bed with a tombstone for a headboard, shown as the center image in Figure 10 below. The tombstone reads “For too many babies last year, this was their final resting place” (Milwaukee, 2012). This was followed up in 2011, by another image featuring a baby in an adult bed lying next to a butcher’s knife with the message “your baby sleeping with you can be just as dangerous,” as seen on the left and right of Figure 10 below (Milwaukee, 2012). Other media included multiple TV and radio spots, and outdoor displays. These images were controversial but ultimately successful. The Milwaukee Department of Health saw requests for cribs increase from 671 requests in 2009 (the year before the campaign started) to 1604 requests in 2010 and 2043 requests in 2011 (Moon et al., 2016a).



Figure 10: Safety Campaigns (Milwaukee Department of Health, 2010)

### Ohio's ABCs of Safe Sleep

Ohio has one of the highest infant mortality rates in the United States, ranking 47th out of the 50 states in 2010 and 2012 (Sleep Review, 2014). On average, three infants died every week in an unsafe sleep environment, totaling 819 deaths from 2007 to 2011 in the state alone. In 2014, Ohio launched the ABC's of Safe Sleep in an effort to combat this problem.

The Ohio campaign uses the ABC's to help parents remember the most important tips for a safe sleep environment: Alone, on their Back, in a Crib, as seen in Figure 11, below (Sleep Review, 2014). The simple message of the campaign provides an easy way for parents and caregivers to remember how to create a safe sleep environment. In addition to providing educational materials, posters, and videos, the state also partnered with Cribs for Kids, a non-profit dedicated to providing free cribs, in high-risk areas of Ohio (Ohio Department of Public Health, 2017).

# Infant Safe Sleep



*Figure 11: The ABC's of Sleep (Ohio Department of Health, 2014)*

The full effects of this campaign are difficult to assess because the initiative is relatively new. However, early numbers are promising. In Hamilton County, Ohio, infant sleep deaths are down from 17 annually between 2007 and 2011 to 13 between 2012 to 2016 (Saker, 2017), and Ohio now ranks 44th of 50 states for infant mortality (Marcel, 2017). The racial disparity in Ohio remains high, with African American infant deaths triple the number of white infant deaths (Marcel, 2017).

## **Tennessee's Approach to Safe Sleep**

In 2015, 569 Tennessee babies died before the age of one. Infant mortality rates in Tennessee remain higher than the national average, and 25% of all infant deaths in the state are related to unsafe sleep environments (Tennessee DOH, 2015). To combat this problem, the Tennessee Department of Health developed a statewide initiative to combat SUIDs specifically related to sleep environments. Their work mainly focuses on hospitals, where 98.7% of Tennessee newborns are born (Tennessee DOH, 2013).

Hospital staff are now required to undergo safe sleep training and model these safe sleep behaviors with newborns. Parents often emulate what they see in hospitals, so it is important for nurses to always practice safe habits. According to Rachel Heitmann from the Department of Health, hospitals must randomly do crib audits and send summaries to the state (R. Heitmann, phone interview, November 13, 2017). Heitmann reported that when comparing the first crib audit to the most recent, hospitals have improved their safe sleep practices.

In addition to their hospital efforts, they have also distributed large amounts of literature to expecting and new parents. They have a home visitor program where social workers visit homes of new and expecting parents and bring parents a Welcome Baby kit containing information on a wide variety of newborn health topics, including safe sleep (R. Heitmann, phone interview, November 13, 2017). They also work with Charlie's Kids, a non-profit dedicated to reducing sleep related SUID, to distribute a board book to parents about safe sleep. They have found that parents respond favorably to "keepsake" items which parents are far less likely to just toss out than a paper brochure. They also focus education efforts on grandparents because they are likely to act as caretakers for a young infant, but may not be up to date about safe sleep recommendations (R. Heitmann, phone interview, November 13, 2017).

## **"Safe to Sleep" Campaign**

The "Safe to Sleep" campaign is an infant safety campaign organized by the NICHD a branch of the National Institutes of Health. The "Safe to Sleep" Campaign was formerly the "Back to Sleep" campaign which launched in 1994 and educated millions of caregivers about the risks associated with infant sleep deaths (National Institutes of Health, n.d.).

In 1994, the US Surgeon General issued a policy statement that "healthy infants should be placed on their back or side to reduce the risk of SIDS" (National Institutes of Health, n.d.). Very shortly thereafter the NICHD launched the Back to Sleep campaign in partnership with the AAP, the SIDS Alliance (now called First Candle), the Association of SIDS and Infant Mortality Programs (ASIP), the National Heart, Lung, and Blood Institute (NHLBI) and the Maternal and Child Health Bureau of the

Health Resources and Services Administration (HRSA) (National Institutes of Health, n.d.). The outreach associated with the program included flyers and campaign materials mailed to all US hospitals with newborn nurseries as well as public service announcements to 6,700 radio stations and 1,000 television stations to widely broadcast the safe sleep recommendations (National Institutes of Health, n.d.). In 1998 the outreach expanded to include more than 250,000 childcare centers and in 1999 Johnson & Johnson included Back to Sleep brochures in their First Aid Kits for New Parents (National Institutes of Health, n.d.). The NICHD updated the messaging to recommend solely placing infants on their back after more research by the AAP Task Force showed the side position is just as risky as the stomach (National Institutes of Health, n.d.).

The campaign targets specific groups and communities identified to be most at risk for SUID and communities that were most likely to engage in risky behaviors with specialized outreach including education programs and materials. For example, in 2004, the campaign partners developed a new initiative to spread safe sleep messages throughout Mississippi, which has one of the highest infant mortality rates in the country (National Institutes of Health, n.d.). The NICHD has also done similar programs in other states, particularly ones with high infant mortality rates, such as Arkansas and Alabama. They work with state Departments of Health, the AAP, and the American College of Obstetricians and Gynecologists (ACOG) to promote safe sleep practices. In Arkansas, the infant mortality rate dropped 65% in the three years after the program (NICHD, 2017) Another example of targeted outreach occurred in 2002 when the NICHD examined methods to effectively reach members of the American Indian/Alaskan Native communities (National Institutes of Health, n.d.).

Another important component of the “Back to Sleep” campaign is the nursing self-study course that teaches about risk factors of SUID and ways to effectively communicate safe sleep messages to caregivers (National Institutes of Health, n.d.). Nurses have a powerful influence because they are around parents before the infant is born, during labor and delivery, immediately following birth and after the infant goes home. It is important that nurses and doctors model safe sleep practices in the hospital as they are important role models for new parents learning how to care for an infant. The course teaches nurses that the simplest delivery technique is often the most effective such that straightforward verbal statements to always place the baby on his back during all sleep periods is more effective than using medical jargon well above the understanding of the parent (National Institutes of Health, n.d.).

In 2012, the campaign was officially renamed to “Safe to Sleep” because it included new recommendations on all safe sleep practices rather than just the child positioning as emphasized in the Back to Sleep campaign (National Institutes of Health, n.d.). The improved campaign updated its materials to include the AAP 2011 recommendations for a safe sleep environment as shown in Figure 12 below, and included an updated website with resources and campaign materials that the media and spokespersons can use to educate members of their community (National Institutes of Health, n.d.).



Figure 12: Safe Sleeping Environment (National Institutes of Health, n.d.)

### 2.5.3 Barriers to Adopting Recommendations

Over the past two decades, infant deaths due to sleep-related suffocation and undetermined causes have quadrupled in the United States (Hackett, 2013). Most death investigations show babies are in the prone position, or bedsharing which indicates lack of adherence to messaging. In data gathered by the CPSC there were over 800 deaths associated with bedsharing out of the roughly 2000 infant mortalities analyzed, dated between 2015 and 2017. Despite warnings to stop bedsharing behavior, many families continue the practice. Upon consulting with a pediatrician with over 10 years of experience, she expressed that despite knowing the recommendations and warning other parents for years about the dangers, her two children slept in her bed with her every night until they were 8 months old because it was the only way they would all get sleep. In a survey reported on the *Maternal and Child Health Journal*, 16.5% of white mothers, and 37.6% of black mothers always or often shared a bed with their infant (Ward, 2014). The National Infant Sleep Position study reported that rates of bedsharing increased from 6.5% of families in 1993 to 13.5% in 2010. Parental values and beliefs play an important role in parenting practices including sleep habits. Bedsharing is identified as one of the sleep behaviors most prominently affected by cultural beliefs (Ward, 2014). Reasons for bedsharing include ease of nighttime feeding, comforting crying babies, a belief that bedsharing allows for better and more sleep, following a parent's instinct to want to monitor their child around the clock, protecting the baby from possible crime, following family tradition, lacking knowledge of the danger, or a disagreement with the presence of danger (Ward, 2014).

Cultural barriers indicate that no matter how effective safety messaging is, there are unavoidable reasons for parents not heeding the warnings. Cultural associations with sleep and parenting practices are far too complex for a safety campaign to change. Therefore, an effective strategy to reduce this barrier could be to acknowledge the benefits associated with bedsharing but state that the potential benefits are outweighed by the risk of SUID.

One of the reasons that parents do not lay their infant on their back to sleep is they fear for their child will choke on spit up or acid reflux. However there is significant evidence disproving that an infant is more likely to choke while on his back (Hitchcock, 2012). The AAP warns parents that they must be



aware of how tired they are when feeding or holding the infant to avoid falling asleep in unsafe places (Moon, et al. 2016b). Pediatricians do not recommend that infants sleep in car seats or strollers, hence the parent should move the infant to a flat surface as soon as possible after the infant falls asleep in a seated device. If the caregiver is holding the infant and the infant falls asleep with his head against the adult's clothing or body, suffocation can result because the infant has not developed the reflexes to remove herself from a dangerous situation. The AAP recommendations provide a comprehensive list of behaviors that are essential for keeping an infant safe during sleep. The challenge that remains is how to best portray the recommendations to the public to elicit compliance.

Another reason for lack of adherence is that researchers do not understand the actual cause of SIDS (Hackett, 2013). Doctors know there is a connection between stomach sleeping and SIDS, but are still unsure of what the connection is. No matter how many times you tell someone to do something, if they do not understand the purpose, they are most likely not going to comply. In addition, the Back to Sleep campaign has been responsible for a 50% decline in SIDS since it launched in 1994, which means fewer parents have a personal connection to someone who suffered a loss; making the campaign a victim of its own success (National Institutes of Health, n.d.). This makes it even more likely that the parent is not going to heed the warnings to do something that they do not have any scientific proof that it will prevent SIDS, and that their baby is not comfortable doing while the perception is that death is not very common.

Due to technology, social media and the influence of traditional media, there is access to an overwhelming amount of information that may contradict recommendations from health care providers and educators. For example, Dr. Kelly Brogan, a women's health psychiatrist with a medical degree from Cornell University, wrote an article posted on her website about the connection between SIDS and infant vaccinations (2015). She states that although the CDC asserts there is no connection between SIDS and vaccines, there is indeed a connection between hexavalent vaccines and SIDS and provides graphs and evidence of such correlation (Brogan, 2015). This could cause a lot of confusion for parents and is just one example of contradictory articles from individuals with reputable backgrounds.

As expected, there are critics of safe sleep recommendations. The troubling factor though is that in recent years the critics have been more vocal than the supporters which is causing grave confusion for parents (Hitchcock, 2012).

### **The Health Belief Model**

A common issue with public health messaging is that people often believe they are immune to certain phenomena (Moon et al., 2016a). They reassure themselves that this only happens to other people, not them or their family. The Health Belief Model, explained in Figure 13 below, was developed to understand why people fail to adopt health interventions, states that the likelihood of adherence to a recommendation is tied to perceptions about the phenomenon the intervention is intended to address (BU SPH, 2016). The Health Belief Model has become the most used model for the study of the effects of new messaging (Jones et al., 2014). If parents do not realize SUID can happen to their child, they may fail to take precautions to prevent it.

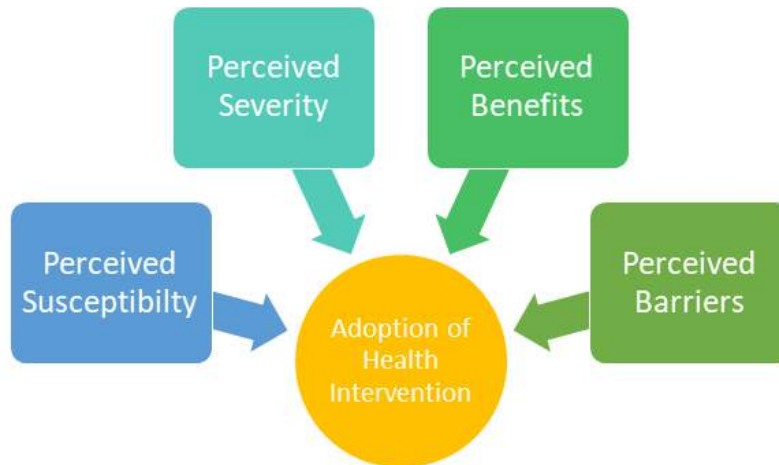


Figure 13: Health Belief Model (adapted from BU SPH, 2016)

**Perceived susceptibility** refers to an individual’s perception of the risk a health phenomenon presents (BU SPH, 2016). In terms of SUID, this refers to a caregiver’s assessment of the risk that their child will die from SIDS or suffocation. Because SIDS only happens to seemingly healthy babies and its exact cause is unknown, caregivers may not realize their infant’s susceptibility (Moon et al. 2016a).

**Perceived severity** is a person’s feelings on the seriousness of experiencing the health phenomenon. This includes both the seriousness of the “medical consequences” (death, injury) and “social causes” (family life, social life) (BU SPH, 2016). SUID has grave consequences, and any public messages should address this in the strongest terms (Moon et al., 2016a).

**Perceived benefits** are a person’s perceptions on the effectiveness of the health intervention. If caregivers do not believe that placing infants in the supine position is beneficial, or that bedsharing presents serious dangers they may fail to adopt new behaviors recommended to them (Moon et al., 2016a).

**Perceived barriers** refer to a person’s view of the obstacles to adopting a health intervention (BU SPH, 2016). This can include financial worries about purchasing safe sleep products, and fears that back sleeping or sleeping without blankets or pillows is harmful to infants (Moon et al., 2016a). According to an older analysis conducted between 1974 and 1984, the ability of a campaign to address perceived barriers is the most powerful predictor of the adoption of a health intervention (Jones et al., 2014).

The final step toward the adoption of a health intervention is a cue to action (BU SPH, 2016). This is the stimulus needed to trigger the decision to adopt the new behavior (BU SPH, 2016). This cue to action can be public messaging. If public messaging can address and change the perceptions listed in the graphic above, then the public messaging can be the impetus for caregivers to adopt new behaviors.

### Sound Bites in Health Messaging

A common type of marketing is the use of “sound bites.” These are short phrases that attempt to convey an entire message in just a few seconds using few words (Moon et al., 2016a). This works well for brand advertising, but is often inadequate for health messaging (Moon et al., 2016a). NICHD’s original campaign “Back to Sleep” conveys, in a quick, catchy phrase, that infants should sleep on their backs (Moon et al., 2016a). The message is clear, but it can often leave concerned parents with pressing questions. Will a baby choke if placed on their back? Why is back sleeping so important? Why does back sleeping prevent SIDS? These are important questions that the sound bite fails to answer and may affect whether a parent adopts the health intervention the campaign is advertising (Moon et al., 2016a).



## Chapter 3: Methodology

This project focused on examining barriers parents and caregivers face in adopting the AAP recommendations and is intended to aid the CPSC and safe sleep network in addressing these barriers. The project included these main objectives:

1. Background research on Sudden Unexpected Infant Death
  - a. Evaluate current safety messaging
  - b. Stakeholder interviews
2. Assess products used for infant sleep and associated regulations
  - a. Voluntary standards
  - b. Incident data
3. Analyze barriers for adopting AAP prevention recommendations
  - a. Literature review
  - b. Parent focus groups
  - c. Stakeholder interviews
4. Develop recommendations of methods to assist parents in overcoming obstacles in safe sleep behavior adoption

### 3.1 Background research on Sudden Unexpected Infant Death

A significant amount of research was done on SUID and the risks associated with it. In addition, it was important to research the medical community's perspective on SUID and current advancements in research. The AAP's recommendations were discussed in depth in the background chapter. The key insights drawn from this objective, like the risk factors and vulnerable demographics, informed the findings for the project. After SUID was generally understood, examination of current products, including those that caregivers use that are not made for sleep, began.

#### 3.1.1 Evaluate current messaging

To gain a better understanding of public safety messaging and risk communication strategies, activities of other organizations with infant safety initiatives were examined. Research was conducted into various campaigns and their effects to find out what had been successful for other organizations. This is outlined in the background section 2.5 above and section 4.1 below.

#### 3.1.2 Stakeholder interviews

Numerous interviews were held with researchers, manufacturers, retailers, and representatives from parent groups. These groups were identified as the main stakeholders for the project. From initial interviews it was discovered that safe sleep campaigns are successful in reaching a large audience, and most parents generally know the safe sleep recommendations.

Interviews with stakeholders also involved discussion on how to effectively reach parents in different manners. Public safety campaigns are not the only steps taken by stakeholders on the issue of infant sleep safety. Other examples of methods include children's books, user friendly warning labels and various hospital programs.

### 3.2 Assess products used for infant sleep and associated regulations

The mission of the CPSC is to protect consumers from unreasonable risks and injuries related to products. Therefore, the CPSC is interested in SUID as it relates to infant products. Through background research, literature reviews, and interviews with stakeholders, experts and parents, a list of products that parents may use for infant sleep was created. Interviews with experts in the field provided insight into perspectives on safe products which are intended for sleep such as play yards, cribs and bassinets and the

unsafe products are not intended for sleep and include bouncers, swings, and car seats. However, because research indicates parents are misusing these unsafe products and putting their children to sleep in them, they were included for further review. After the list was created, there was an evaluation of the required ASTM standards for each product. All of the clauses related to warning labels in the standards were compiled into a list, shown in Appendix E.

### 3.3 Analyze barriers to adopting AAP recommendations

Before developing recommendations to help parents overcome obstacles to adopting AAP recommendations, a general idea of parents’ current infant sleep practices was established. This was done through literature review, a parent focus group and stakeholder interviews to determine the barriers that face.

#### 3.3.1 Literature review

Safe sleep is a topic that has been researched for decades. There are many experts whose papers are accessible for review. For example, pediatrician and safe sleep expert Dr. Rachel Moon of the University of Virginia conducted multiple studies and reviews pertaining to infant sleep environments and SUID. Her work was a valuable source of information about SUID and barriers that parents face in adopting the recommendations.

#### 3.3.2 Stakeholder interviews

To gain more information on the current messages available to the public and parents’ struggles with following the AAP recommendations, several stakeholders and experts in the field were interviewed. After conducting background research, a list of contacts that were affected by or who work on safe sleep was created.

After the stakeholders were identified, several were contacted to see if they were interested in speaking and sharing their insights and expertise in their field as it pertains to safe sleep. Table 2 below identifies the stakeholders who responded, all of whom were interviewed. Speaking to members of the medical community was crucial to understand the AAP recommendations to reduce the risk of SUID and the struggles they hear from parents about following the recommendations.

<b>Company / Organization</b>	<b>Contact Person / Title</b>	<b>Category of Stakeholder</b>
<b>Charlie’s Kids</b>	Kate Desmond, Communications	Non-Profit, Education
<b>National Institute for Children’s Health Quality</b>	Zhandra Levesque, Safe Sleep Project Director	Non-Profit, Education
<b>First Candle</b>	Barbara Himes, Director of Education	Non-Profit, Education
<b>P.A.C.E. Mothers</b>	Beth Morgenstern	Non-Profit, Support Group
<b>Zero to Three</b>	Rebecca Parlakian	Non-Profit, Interest Group
<b>Family Sleep Institute</b>	Katie Kovalski, Safe Sleep Coach	Non-Profit, Expert
<b>HALO Innovations</b>	Bill Schmid, Founder	Manufacturer, Education
<b>Swaddle Designs</b>	Jeff Damir, COO & Lynette Damir, CEO	Manufacturer
<b>Baby Box Company</b>	Caleb Hudgins, Research Director	Manufacturer
<b>CPSC Office of Communications</b>	Nikki Fleming, Karla Crosswhite	Federal Agency, Campaign
<b>Tennessee Department of Health</b>	Rachel Heitmann, Injury Prevention Chief	Agency, Campaign
<b>DC Department of Health</b>	Erin Bonzon, Infant Health Division Chief & Sharon Brandon, Safe Sleep Program Coordinator	Agency, Campaign
<b>Paula Quinn</b>	WPI Associate Director of Project Based Learning	Focus Group Expert
<b>The Ad Council</b>	Tony Foleno, SVP Strategy and Evaluation	Campaign Expert
<b>Dr. Rachel Moon</b>	Dr. Moon, Safe Sleep Spokesperson AAP	Medical Community

*Table 2: Interview Contacts*

## **Interview Plan**

Interviews with stakeholders were performed to gather important insights from those in the field. An interview was chosen as opposed to a survey because interviews allowed personal connections to be made and the questions were tailored to each informant instead of utilizing a uniform general set of questions. Prior to each interview a list of questions were drafted to serve as general guidance for the flow of conversation. In some of the interviews, questions were answered during a discussion before actually posing the question and in others, the informant made a statement that resulted in the rest of the questions becoming irrelevant. The interview questions are attached in Appendix B.

### **3.3.3 Parent focus group**

The parent focus group provided insight into parents' struggles with always following the safe sleep guidelines. The main benefit of the focus group was learning from the participants' perspectives (Gibbs, 1997). A focus group was the most appropriate method in this case because it allowed for an inquiry about participants' attitudes, feelings and reactions in a way that is not possible with a survey or questionnaire (Gibbs, 1997).

Prior to conducting the focus group, experts and experienced focus group moderators were contacted for input and suggestions. Advertising for the focus group was done through local non-profit parent support groups that serve the DC metro area. These groups posted the flyer on their social media platforms to encourage parents to sign up. Through funding from WPI, participants were incentivized with \$50 cash. Additionally a colleague at the CPSC connected with a friend who volunteered to host the focus group at her house with other members of a moms group. A specific demographic was not required for participation, however, the focus group consisted of 7 mothers between the ages of 31 and 37. The education level ranged from a Bachelor's of Science to a PhD. All mothers had at least 2 kids and breastfed their children.

Paula Quinn, a professor at WPI and an expert at running focus groups, helped develop a plan and protocol for the focus groups. To make the best use of time and gather essential perspectives, it was decided to inform all participants about the AAP safe sleep recommendations immediately after quickly soliciting their ideas on what the recommendations are. This was decided to ensure time was spent discussing the obstacles to following all the recommendations rather than spending time refuting parents' potentially incorrect impressions of what SIDS and SUID are. The focus group protocol is provided in Appendix C. Four main questions were asked and then follow-up questions were posed to probe further into parents' thoughts. All participants were given informed consent and confidentiality statement forms that required review and signature before proceeding.

Multiple factors were considered in analyzing the information received from the focus group. Frequency and extensiveness in participants' comments were an important factor in figuring out what was most important (Krueger, 2002). If a topic was discussed more by participants or the same comment made often that indicated a topic was of special interest to the group. This was especially true if those comments were made with special intensity or "depth of feeling" (Krueger, 2002).

## **3.4 Develop recommendations to assist parents in overcoming obstacles in safe sleep behavior adoption**

Examining existing research and conducting interviews with experts in the field led to the conclusion that developing a new public safety campaign would not be an effective strategy in helping to reduce SUID. There have been many safe sleep campaigns in the past, and many parents are overwhelmed with all the information. Therefore, the team will provide recommendations for the CPSC, other government agencies, and to the network of safe sleep organizations and experts for future work in the safe sleep field.

The recommendations are intended to be distributed to the extensive safe sleep network, so that marketing experts, lawyers, policymakers, educators, curriculum developers and other experts can use this knowledge as a way to help reduce risks from unsafe sleep nationwide through their own work.

## Chapter 4: Results and Analysis

This chapter presents the results and findings essential to the core of the project’s objectives. Through stakeholder interviews and a focus group, several different perspectives were gained on infant safe sleep, including the reasons parents do not always follow the recommendations and methods that can be implemented to help increase the likelihood of safe sleep practices.

### 4.1 Evaluation of Current Messaging

A literature review indicated that in general parents were unaware of the safe sleep recommendations, however interviews with stakeholders and conversations with parents, proved otherwise. Therefore it became important to understand where parents were learning the recommendations. A review was conducted of some of the more well-known safe sleep campaigns. The results are summarized in Table 3 below.

Campaign	Media	Message Type	Year Campaign Began	Metrics for Success
<b>Safe to Sleep (National)</b>	Educational materials, Education for nurses	Statistics and fact based	1994	Decreased SUID rate by almost 50% (National Institutes of Health, n.d.)
<b>Safe Sleep (DC Department of Health)</b>	Free Pack ‘n Play, Video, Personal education	Seven steps to reduce SIDS video, one-on-one education sessions with parents	2000	Home visits 3 and 6 months after birth of child indicate 72% of parents are compliant with AAP recommendations
<b>B’More for Healthy Babies (Baltimore, MD)</b>	Video	Testimonials from local mothers who lost infant co-sleeping	2010	Sleep-related deaths decreased by 46% (Moon, et al., 2016a)
<b>Safe Sleep (Milwaukee, WI)</b>	Billboards, Posters	Scare tactics to curb co-sleeping deaths	2010	Requests for free cribs increase from 641 cribs to 2043 cribs; a 204.5% increase in 2 years (Milwaukee, 2012)
<b>ABC’s of Safe Sleep (Ohio)</b>	Website with educational materials	Simple conceit of A- Alone, B-Back, C- Crib, sound bite	2014	Still early in campaign but down to 13 deaths annually in 2016 from 17 deaths annually in 2011 (Saker, 2017)
<b>Safe Sleep Initiative (Tennessee Department of Health)</b>	Education for healthcare professionals	Statistics and fact based, partner with Charlie’s Kids	2015	Still early in program but crib audits in hospitals from first year to most recent indicates hospitals are more compliant with AAP recommendations and have improved safe sleep practices (R. Heitmann, phone interview, November 3, 2017)

Table 3: Current Public Safety Campaigns

### 4.2 Interview and Focus Group Findings and Analysis

Interviews spanned a range of stakeholders that all have an important role in helping to reduce SUID in the United States. Each provided important information that led to the development of recommendations that target barriers that prevent parents from always complying with safe sleep recommendations. A focus groups was also conducted with parents to understand their opinions on following the recommendations and how to make safe infant sleep easier for parents. A list of interviewed stakeholders can be found in section 3.3.2. Below is a list of findings gathered from interviews and focus groups that will be discussed in further detail in the sections that follow.

1. There is an extensive network of safe sleep interested groups and organizations but opportunities exist for greater synergy among them
2. Desperation for sleep often leads to unsafe behaviors
3. Parents want less risky alternatives to bedsharing because some bedshare regardless of risk awareness
4. Parents can be overwhelmed by abundant, often conflicting information
  - a. Parents generally know the recommendations, but they often do not understand the reasoning behind them
  - b. Some parents find the recommendations to be unnecessarily frightening
5. Many older caregivers are not up to date on current recommendations
6. Sleep environments are often depicted unsafely in media and advertising
7. As consumers, parents are highly influenced by their peers and consumer reviews
8. Many caregivers do not think they can prevent SIDS but believe suffocation is preventable
9. Parents in the US lack national parental leave policy available in other countries

#### 4.2.1 There is an extensive network of safe sleep interested groups and organizations but opportunities exist for greater synergy among them

In the initial stages of research, it became obvious that there is an extensive network of groups and organizations interested in safe sleep, and a lot of the organizations' work seems to overlap. This network was utilized for planning stakeholders interviews. A network map of those working on safe sleep was created to identify who could combine forces to reach a greater number of people as shown in Figure 14 below. In mapping the network, each organization and their respective strategies for safe sleep advocacy were noted. During conversations with those within the network, thoughts about what is working and what needs improvement were expressed. The expectation of providing the map to stakeholders is to promote synergy in the network so that organizations learn from one another and plan their initiatives in ways that complement each other and build off previous work.

Five main categories of the network were identified: private interest, regulatory, government, non-profit, and medical community and researchers. These are further divided into specific subgroups identified as stakeholders of infant sleep safety. The subgroups are organizations, businesses or individual people. The arrows off the subgroups point towards their method of informing parents and caregivers. All the light purple boxes are strategies and methods the organizations utilize to advocate safe sleep. For example, the Ohio Department of Health's Safe Sleep program utilizes Cribs for Kids and hospital outreach to reach caregivers as shown on the right side of the map. Although the AAP has no avenues of messaging branched from it, they are the primary researchers and wrote the latest 19 recommendations to reduce the risk of SUID. They do not do any messaging themselves, rather, organizations involved in safe sleep endorse the AAP's recommendations. Below the map, is a summarized list of the missions and goals of each group. It shall be noted that although this is the current understanding of the state of the safe sleep field, there are other states and organizations that have safe sleep initiatives not included in this report. This contains only the groups who have been contacted and others who are well known for safe sleep advocacy.

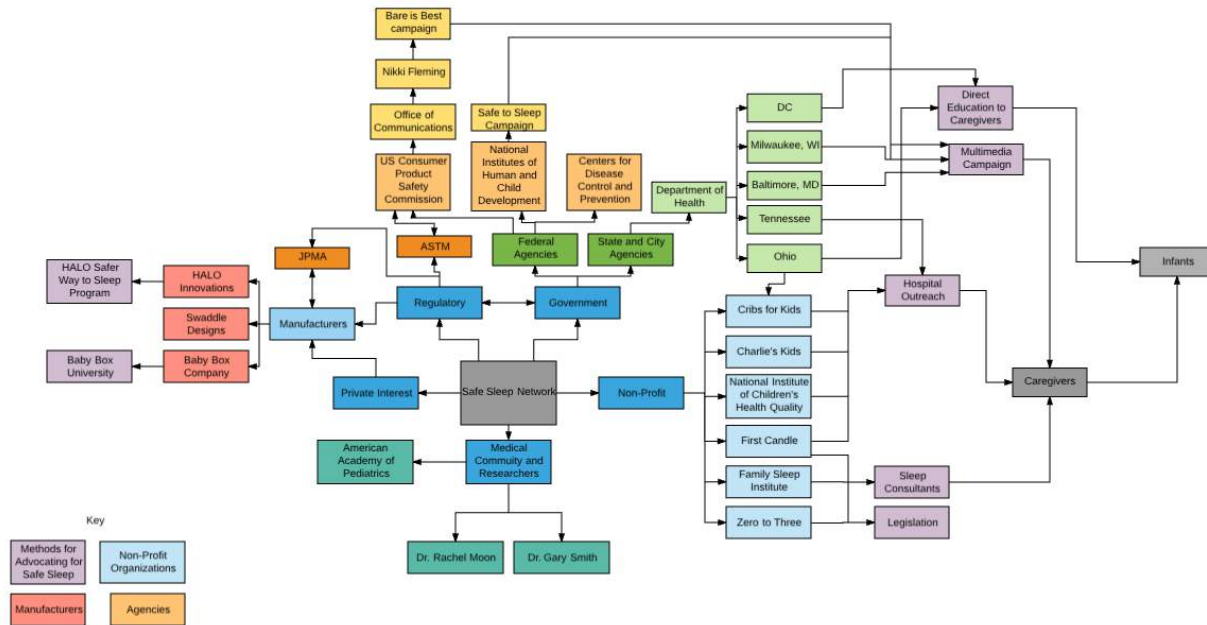


Figure 14: Safe Sleep Network Map

**Zero To Three** is an international non-profit organization with the mission of ensuring that all babies and toddlers have a strong start in life. Zero To Three envisions a society that has the knowledge and will to support all infants and toddlers in reaching their full potential, and works to build this society through partnerships with parents, professionals and policy-makers. By supporting the caring adults who touch the lives of infants and toddlers, they hope to maximize their long-term impact in ensuring all infants and toddlers have a bright future (Zero to Three, n.d.).

**Cribs for Kids** National Safe Sleep Initiative is dedicated to reducing sleep-related SUID. Their work, based on AAP guidelines, helps prevent SUID deaths by educating parents and caregivers about safe sleep practices, and provide Graco Pack ‘n Play portable cribs to families who could otherwise not afford a safe sleep environment for their babies. In addition, they partner with organizations across the country to promote safe sleep (Cribs for Kids, n.d.).

**Charlie’s Kids** was established in 2011 by two parents, Sam and Maura Hanke, who lost their son, Charlie, to SIDS. It was founded “with the purpose of increasing safe sleep awareness and education.” The main vehicle for their message is a board book, *Sleep Baby Safe and Snug*, which are distributed to parents by hospitals during prenatal doctor’s visits, or through a Cribs for Kids safe sleep survival pack (Charlie’s Kids, n.d.).

**First Candle**, previously called the SIDS Alliance, is committed to “the elimination of SIDS, SUID, and preventable stillbirths through education and research.” The SIDS Alliance was a key partner in the Back to Sleep campaign. They expanded their mission in 2002, becoming First Candle, and continue to focus on “saving babies and supporting families” by working with local organizations to educate parents about unexpected infant death (First Candle, n.d.).

**National Institute of Children’s Health Quality (NICHQ)** is a non-profit organization dedicated to helping “every child achieve optimal health.” Their mission is to “drive dramatic and sustainable changes in the complex health issues facing children and their families.” They have created many programs that focus on safe infant sleep. These include, Collaborative Improvement and Innovation Network to Reduce Infant Mortality (IM CoIIN) which was a multiyear national movement engaging federal, state and local leaders, public and private agencies, professionals, and communities to employ quality improvement, innovation and collaborative learning to reduce infant mortality and improve birth outcomes. National Action Partnership to Promote Safe Sleep Improvement and Innovation Network



(NAPSS-IIN) is an initiative to make infant safe sleep and breastfeeding the national norm by aligning stakeholders to test safety bundles in multiple care settings to improve the likelihood that infant caregivers and families receive consistent, evidence-based instruction about safe sleep and breastfeeding. National Network of Perinatal Quality Collaboratives (NNPQC) provides resources and expertise to nationwide state-based perinatal quality collaboratives (PQCs) with the goal of deepening and accelerating improvement efforts for maternal and infant health outcomes (NICHQ, 2017).

**Family Sleep Institute** provides education through the Child Sleep Consultant Certification program with the core value of supporting “sleep safety by requiring all consultants to complete a SIDS risk reduction course” as a way to promote safe sleep habits when consultants work with families. It is required that all graduates of Family Sleep Institute include safe sleep guidelines in all paperwork given to the families they work with (Family Sleep Institute, n.d.).

**American Academy of Pediatrics** is a professional organization dedicated to helping attain “optimal physical, mental, and social health and wellbeing for all infants, children, adolescents, and young adults.” They were key in developing the “Back to Sleep” campaign, which reduced SIDS incidence in the US by more than 50%, and continue to provide recommendations to help parents and caregivers reduce their infant’s risk of SUID (AAP, n.d.).

**Dr. Rachel Moon** is a pediatrician and internationally recognized expert who has extensively studied factors affecting SIDS and sleep-related deaths. She is the safe sleep spokesperson for the American Academy of Pediatrics.

**Dr. Gary Smith** is a professor and researcher of pediatrics, emergency medicine, and epidemiology. His research in the area of safe sleep focuses on the epidemiology of consumer-product related injuries.

**Nikki Fleming** is an employee at the CPSC Office of Communications and is a national expert on safe sleep. She was part of the 1994 AAP Task Force to look into safe infant sleep. She is also responsible for the “Bare is Best” slogan and many other safe sleep materials that have been distributed for many years.

**Baby Box Company** is a company and program inspired by Finnish tradition of using a box as a safe sleep space for an infant. These boxes meet all of the bassinet standards from the CPSC and ASTM. Their educational program, Baby Box University, is one that grants parents with a free Baby Box upon completing the course. They partner with hospitals, government agencies, and non-profits across the globe to distribute these Baby Boxes. They also partner with regional doctors and educators to craft community-centric syllabi. One of their main goals is educating parents on safe sleep practices in an effort to help reduce SUID (The Baby Box Co., n.d.).

**Swaddle Designs** is a swaddle blanket designer and manufacturer founded by registered nurse Lynette Damir in 2002. All swaddle blankets have swaddling instructions sewn to the side of the blanket and a QR code that brings the consumer to swaddleclub.com that has safe sleep instructions. Swaddle Designs strives to inform parents of the most up to date safe sleep messages (Swaddle Designs, n.d.).

**HALO Innovations** was founded by Bill Schmid and his wife Cathy after they lost their first born daughter to SIDS over 25 years ago. From this tragedy HALO and its mission were born. For over 20 years the company has been dedicated to putting the health, safety and well-being of babies first by creating products that make safe sleep easier. In addition, Bill developed the "Safer Way to Sleep" program which provides hospitals with the tools to model safe sleep on newborns. This unique way to teach safe sleep, which includes demonstrating safe sleep techniques on your own newborn by eliminating blankets and utilizing a HALO SleepSack swaddle, is a highly effective method for parents to continue that behavior at home. Currently, the program reaches more than 50% of all babies born in the U.S. (HALO Innovations, n.d.)

**US Consumer Product Safety Commission** is an independent federal agency “charged with protecting the public from unreasonable risks of injury or death” associated with consumer products. The CPSC’s involvement with SUID is to regulate infant sleep products and work with manufacturers to recall those products that are unsafe. The “Bare is Best” campaign slogan was launched by the CPSC to warn

parents of the risk of placing soft bedding in an infant’s sleep space (Consumer Product Safety Commission, 2017).

**DC Department of Health** has a program to promote safe sleep to DC residents that provides a free Graco Pack ‘n Play for parents who complete their education program. This program has been successful in guiding parents to practice safe sleep habits with their infant. The learning tools that are used include a video published by the AAP on safe sleep and a pre and post survey gauging how much information was retained through the program (DC Department of Health. n.d.).

**National Institutes of Child Health and Human Development**, a division of the National Institutes of Health, is the lead organizer of the “Safe to Sleep” campaign that aims to teach parents and caregivers the importance of following safe sleep practices to reduce the risk of SUID (NICHD, n.d.).

**Centers for Disease Control and Prevention** works to protect Americans from health, safety, and security threats and strives to increase the health security of the United States. The CDC’s Division of Reproductive Health has SUID monitoring programs in states and jurisdictions that account for 30% of all SUIDs nationwide (Center for Disease Control, 2017).

**Juvenile Products Manufacturers Association** is a trade organization representing approximately 250 manufacturers who make 95 percent of the prenatal to preschool products in the U.S. market. They serve as a top resource for public safety standards. A JPMA certification on a product ensures adherence to ASTM standards, federal and state laws and some retail requirements (JPMA, 2017b.).

#### 4.2.2 Desperation for sleep often leads to unsafe behaviors

A common theme in many interviews and among focus group participants was that due to the lack of sleep of an infant, parents often become desperate for sleep, which affects their decision on where and how their infant sleeps. According to the founder and CEO of SwaddleDesigns, Lynette Damir, parents frequently become sleep deprived when their child is 2 to 3 months old (Telephone interview, November 6, 2017). She also stated and it was confirmed in a Center for Injury Research and Policy study (Gaw et al., 2017) that this coincides with the time that children are most likely to die from SUID.

In a focus group conducted by Dr. Rachel Moon, parents stated that they choose where they put their baby to bed based on their own need for sleep more than safe sleep recommendations (Moon, 2017). Many times, an infant is not able to sleep through the night alone, on their back, and in a crib or bassinet. These repeated wakings can exhaust parents, especially those who have work in the morning. This causes parents, despite being generally aware of safe sleep recommendations, to compromise on the recommendations just to get the infant to sleep. Dr. Moon found that the desperation for sleep is when parents are likely to turn to bedsharing.

In a focus group, one mother explained how her desperation for sleep led her to bedshare with her newborn, which “changed her life.” Another mother explained how she had to place her child on his side to sleep because, even though she knew it was not recommended, she needed to sleep and the baby only slept with her. The mothers in the focus group also explained how the desperation for sleep increases after the first child. All the mothers were told to “sleep when your baby sleeps.” However, they noted how difficult this was to follow when there were other children to care for. Parents of multiple children have to sleep at night so they can care for their other children during the day. One mother noted that following the AAP recommendations with the first child is easier. However, she had to let her guard down with her other kids because she did not “have the capacity to follow every single rule to a T.”

Despite the desperation for sleep, the fear of acting against a doctor's recommendations still concerned parents. Mothers in the focus group expressed that there were terrified when they were unable to follow the recommendations for their first child. But as they had more children, they “let their guard down” and were able to do things such as bedsharing with less fear and anxiety because it worked with their previous children and they survived.



A representative of Charlie's Kids, the non-profit previously mentioned that works with the Tennessee Department of Health, uses the slogan "safe sleep is hard, your baby is worth it" to convince parents that their infant's safety should always come before their own needs (Desmond, K. telephone interview, November 3, 2017). This is an important, but difficult, message to send out to parents.

#### 4.2.3 Parents want less risky alternatives to bedsharing because some bedshare regardless of risk awareness

The AAP recommends that a baby sleeps by themselves, in the same room, but in a separate sleep environment than parents or other people. However, not all parents are willing to sleep away from their baby. Bedsharing is normal practice in many cultures, and, in the United States, parents from these cultures often do not get information that they need to bedshare with their infant in the safest way possible. Some babies also sleep better when they are in the same bed as the parents, meaning that the parents are woken up less than if the baby is in a crib. The parents that will not separate from their baby need to be informed of the safest way to bedshare with their infant.

The wahakura is an invention from the Māori people in New Zealand that has been identified as a potentially safe alternative to bedsharing. It is an infant bed made from woven flax with six inch tall sides with the intent of providing a safe sleep surface for the infant in the parent's bed (Moon, et al. 2016b). It enables a separate sleep surface while bedsharing, allowing for close proximity of infant and mother as displayed in

Figure 15. It has been reintroduced and studied in the Māori communities in New Zealand where SUID rates are extremely high because of the prevalence of bedsharing.

A study in New Zealand concluded that there are no significant additional risks of an infant sleeping in a wahakura compared to a bassinet and there are increased benefits including ease of feeding, further supporting that the wahakura may be a safe alternative to bedsharing (Baddock, et al., 2017). The study also showed the quality of infant and maternal sleep increases as well as breastfeeding rates, most likely because of the infant being in close proximity to the mother (Moon, et al., 2016b).



Figure 15: Wahakura (HealthEd.gov, 2015)

This is an important finding because through stakeholder interviews and focus group discussion it became apparent that despite its risks, due to the desperation for sleep, parents take their children to bed with them. Bedsharing was responsible for over 800 infant deaths between 2015 and 2017, so providing recommendations to parents to make bedsharing less risky could prove very useful (CPSC Incident Data, 2017). Parents who use a wahakura or other bedsharing device must still follow other safe sleep recommendations including placing the baby to sleep on their back, and not using pillows or blankets. A

wahakura could even be woven by parents who are interested as there are detailed instructions and videos online of how to do so. The safety of the wahakura is still being studied, so while early results are promising, it may be irresponsible to fully recommend this product at the moment. Similar products currently on the market can be used as a compromise to bedsharing such as bassinets beside the bed or any other product that allows a baby to be near the parents but in a separate sleep surface.

#### 4.2.4 Parents can be overwhelmed by abundant, often conflicting information

Another common theme from interviews was that, throughout the process of preparing for a child, parents receive so many pamphlets, books, and recommendations that they are overloaded with information. Parents may become confused and overwhelmed, which may lead them to not making the best decisions.

It is important to present information to parents in a way they can revisit when necessary. Brochures tend to be thrown away and forgotten, but Charlie's Kids developed a board book entitled "Sleep Baby Safe and Snug" that is issued to every parent in hospitals in Georgia and Tennessee. The goal, according to a representative, is to not be a "throw away book" like a pamphlet but rather a book parents repeatedly read as a bedtime story (Desmond, K., telephone interview, November 3, 2017). Repetition is an effective method in educating parents on safe sleep.

Another major issue with receiving all this information is that much of it is conflicting. This leads parents to take the recommendations with "a grain of salt" meaning they are less likely to follow them. One mother stated that each of her three children were born in a different hospital within a 5 year time span, and she received different information about what was safe for each baby. Another mother concurred with this statement sharing she had the same experience.

Mothers also agreed that care providers need to communicate and collaborate to give parents consistent information. One mother explained how when her child was born, the NICU nurses warned about the dangers of an infant sleeping on an inclined surface but when she visited a gastroenterologist weeks later, the doctor endorsed the incline sleep position. Another mother explained how her neonatologist warned about the dangers of bedsharing and strongly advised against the practice. But on the contrary, her lactation consultant told her she needs to learn to sleep in the same bed as her newborn if she wants to breastfeed successfully. Parents expressed their desire to have health care professionals provide consistent information instead of just being focused on their own specialty.

Warning labels on children's products may be another contributor to the problem of parents being overloaded with information. Some interviewees claimed that often warning labels have far too much text, causing consumers to largely ignore them. This applies to having safe sleep recommendations on a product, label, or in a set of instructions. SwaddleDesigns discussed a QR code they place on products that leads parents to a comprehensive list of recommendations on their smartphone (Damir, L. & Damir, J., telephone interview, November 6, 2017).

#### **Parents generally know the recommendations, but they do not understand the reasoning behind them**

Representatives from non-profits and the medical community, reported that most parents know, or are at least are generally aware of the AAP's recommendations to reduce the likelihood of SUID. This was also confirmed in discussions with parents during focus group sessions. This differs from prior assumptions going into this project, which was that the messaging had failed in some way and most parents were unaware of the recommendations. However, through social media, medical providers, public events, and word of mouth, most parents generally know their infant is safest alone, on their back, and in an empty crib.

During a focus group conversation, one mother mentioned the Bare is Best slogan which prompted questions and comments such as "bare meaning no clothes on the baby?" or "bare meaning a stuffed bear in the crib?" An interview with the NICHD "Safe to Sleep" representative reported that the A in the ABC's of Safe Sleep confuses parents as they are unsure if alone is referring to being alone in a

sleep environment or alone in the room (Kaplan, L., personal interview, November 29, 2017). Another mother of 3 children stated in a focus group that she is well educated and would like to see the research behind the recommendations to understand how her behaviors could potentially harm her children.

One mother explained that she does not fully understand what overheating means. Another mother said she heard the infant should have one more layer of clothing than the mother has on, but expressed how difficult this is to determine in the weeks immediately following the birth. She suggested that the recommendations be redeveloped to have realistic expectations.

Interviews suggested the issue may be that no campaigns or outreach education programs inform parents of specific reasoning for the recommendations, nor do they do enough to address questions parents may have. Dr. Moon suggested this is a significant barrier to adopting recommendations (Moon et al., 2016a). Parents have questions and concerns but they are not answered with the campaigns. Among the most popular campaigns are short videos and sound bites, but they fail to convey all the information parents want. Nikki Fleming suggests that a campaign that focused more on the why of infant sleep recommendations will be more successful in getting parents to actually follow the recommendations.

### **Some parents find the recommendations to be unnecessarily frightening**

During a focus group session there was consensus among seven mothers that the number of recommendations and the way they are presented causes unnecessary stress and anxiety for parents. One mother stated that the recommendations are very dramatic and that “everything you do can kill your baby.” One mother of a 3 week old stated her NICU nurses warned her not to let her child sleep in a car seat due to the lack of head control an infant has and the subsequent increased risk of suffocation. She described how fearful this recommendation made her because her baby falls asleep in the car and she is unable to see if she is breathing in her rear facing seat which results in paranoia and fear. Several other mothers sympathized with this fear, agreeing that if they heard that recommendation for their first child, they would have been terrified. One mother added “I wouldn’t leave my house for the first year of his life if it was my first child.” During the discussion of obstacles to following the recommendations, one mother wondered if the AAP recommendations were largely based on fear and if the risks associated with the recommendations were actually as high as educators portray them as.

## **4.2.5 Many older caregivers are not up to date on current recommendations**

Zero to Three, recently ran a grandparent focus group where they asked grandparents about experiences and challenges associated with being a grandparent (R. Parlakian, phone interview, October 30, 2017). One major finding was that many grandparents are not up to date on current health and safety recommendations. Many grandparents and older caregivers tend to follow recommendations and practices that were acceptable during their time as new parents, and may not be aware of current recommendations.

This was further echoed by the Tennessee Department of Health which has developed messaging specifically targeting grandparents and other older caregivers (R. Heitmann, phone interview, November 13, 2017). The hope with this messaging is that grandparents will become up to date with new information and encourage new parents to talk to their parents about what is best for their baby.

Mothers in the focus group also noted that safe sleep is a difficult conversation to have with their parents. One mother noted her parents think she is “insane” when she tells her parents some of the recommendations and asks that the recommendations be followed. Other mothers commented that their parents are not likely to follow the recommendations, and will do what worked when their parents were new parents themselves.

## **4.2.6 Sleep environments are often depicted unsafely in media and advertising**

Manufacturers and experts state that parents and caregivers are influenced by pictures they see in movies, advertising, or on television. Safe sleep recommendations call for an empty crib, but according to focus groups and research studies, parents often add soft bedding to their baby’s cribs because that is how the crib was advertised (Moon, R., 2017). Catalogues often depict cribs full of soft bumpers and warm

bedding, making parents think these are essential items for their child's crib. Movies and television shows often further perpetuate the image of a cozy crib. Advertisements and retail crib displays regularly promote sleep environments that are not aligned with the AAP recommendations.

A study by Dr. Michael Goodstein, a neonatologist and member of the AAP task force on SUID found less than 5% of all images on the top three stock photo websites comply with safe sleep guidelines (Goldstein, et al., 2017). This causes concern that parents are immersed in potentially incorrect information that could lead to unsafe sleep behaviors. For example Figure 16 depicts a baby sleeping with her father in an adult bed, a practice which leads to hundreds of infant deaths per year (CDC Reproductive Health, 2017).



*Figure 16: Infant and Father Bedsharing (Bustle, 2015)*

Pediatric pulmonologist Dr. Bradley Troxler and colleagues examined the number of retail crib displays that conform with AAP guidelines (Kreth, et al., 2016). Of the 1758 displays analyzed, less than half adhered to all guidelines, with most of the non-adhering cribs containing bumper pads and loose bedding such as shown in Figure 17 (Kreth, et al., 2016). The concern with advertisements promoting unsafe sleep habits is heightened when considering the amount of time parents and caregivers are exposed to advertisements compared to the amount of time spent face to face with a physician or immersed in safe sleep campaigns.



*Figure 17: Crib Retail Display (Krevetac, 2008)*

A representative of Swaddle Designs, stated they attempted to reach out to other companies to persuade them to show infants alone in a crib with no loose bedding, but have had very little success with this cooperative approach (Damir, L., & Damir, J., telephone interview, November 6, 2017). They felt that if parents were always exposed to the image of an infant alone, on their back, and in a crib they would be more likely to follow those practices on a regular basis.

#### 4.2.7 As consumers, parents are highly influenced by peers and consumer reviews

When asked about how parents decide if a product should be purchased for their infant, the majority stated consumer reviews are highly influential. One father of an infant stated that he “takes advice from experienced parents because they have been through it a couple times and they know the things that work and do not work.” One new mother explained how she purchased an inclined sleeper for her baby after a couple nights of no sleep and that the reviews at how amazing other babies slept in it, was what sold her.

This is an important finding because many products on the market that may help a baby sleep better are in direct conflict with the AAP’s recommendations. Some of these products include co-sleeping pillows and incline sleep positioners. The soft inclined surface shown in Figure 18 creates an increased risk for suffocation. Although the manufacturer warns that the product should not be used for prolonged periods of sleep, first hand reviews from hundreds of parents state otherwise. One Amazon customer stated “this is the best thing I purchased for my son! He went from sleeping okay in a bassinet and waking up 2-3 times a night to sleeping all night and sleeping soundly” (Amazon Customer, 2015).



*Figure 18: Inclined Sleeper*

The co-sleeper is a pillow designed for lounging and is supposed to simulate the womb to comfort the baby as seen in

Figure 19. However, the raised soft sides around the perimeter are a suffocation hazard if the infant were to place their face against the edge. Consumer reviews indicate other unsafe uses of the product. One mother states “from the moment my infant started sleeping in it, her sleeping patterns started lasting 10-11 hour stretches. Without it she does not sleep...It is her safe place and it’s peace of mind for me knowing she’s safe there too” (Amazon Customer, 2017). An Amazon customer explains her success with bedsharing: “I never worry about co-sleeping anymore. My husband and I keep him in the middle and he has his own little space” (Amazon Customer, 2017).



*Figure 19: Bedsharing Pillow*

The reviews promote unsafe uses of products and have the potential to result in more parents buying products and using them incorrectly, putting additional children at risk. This finding indicates a call for action to manufacturers and shopping website such as Amazon to monitor consumer reviews and refute the ones promoting unsafe uses.

#### 4.2.8 Many caregivers do not think they can prevent SIDS but believe suffocation is preventable

Another issue to consider is that parents have described SIDS as “God’s will” and therefore no matter what they do, there is no way to prevent it (Moon, 2017). When campaigns are targeted towards SIDS prevention, parents may become confused because they believe SIDS is unpreventable therefore they are less likely to follow the recommendations, even if they could save the child from suffocation.

Dr. Moon highlighted this issue particularly. She stated that although the recommendations for SIDS and suffocation are the same, a campaign primarily surrounding suffocation would likely be more successful (Telephone interview, October 31, 2017). Parents and the public perceive suffocation and strangulation as preventable, and a campaign focused on suffocation may create a sense of self-efficacy that their actions could actually save their baby’s life. Not only would the campaign help prevent accidental suffocation, but could also reduce instances of SIDS.

She noted however the importance of differentiating between public messaging and bereavement. She cautioned about the emotional trauma messaging focused on suffocation could cause for parents who have already lost a child in this way. A parent who learns their child’s death was suffocation rather than SIDS may believe they played a role in their child’s death may blame themselves for the loss of their



infant. Therefore a public messaging campaign on suffocation needs to be different than a campaign would be for SIDS.

#### 4.2.9 Parents in the US lack national parental leave policy available in other countries

Dr. Moon stated that infant mortality is not a major problem in other industrialized like it is in the United States (Moon, R., telephone interview, October 31, 2017), this was not new information however, as described in section 2.1.1 above. Dr. Moon pointed to a couple of reasons as to why this may be the case. The United States is the only industrialized country that does not mandate paid maternity leave, so many new mothers cannot take sufficient time off work to care for their newborn infant. Many interviewees suggested that the pressure to wake up for work in the morning is one of the main causes for parental exhaustion. In other countries, in addition to parental leave, more services are provided to parents, including home visitors and social support for families.

Although there is no current research on the link between SUID rate and parental leave, a preliminary comparison indicates a lower SUID rate in countries with paid parental leave laws. For example, according to the National Center for Education in Maternal and Child Health at Georgetown University, Japan and the Netherlands have the lowest infant mortality rates (Hauck, et al., 2010) while the World Policy Center indicates Japan and the Netherlands have 52 and 18 weeks paid maternity leave, respectively (World Policy Center, 2014). It is also noted that the United States is the only developed nation in the world that does not require paid maternity leave for all its citizens as seen in Figure 20 below.

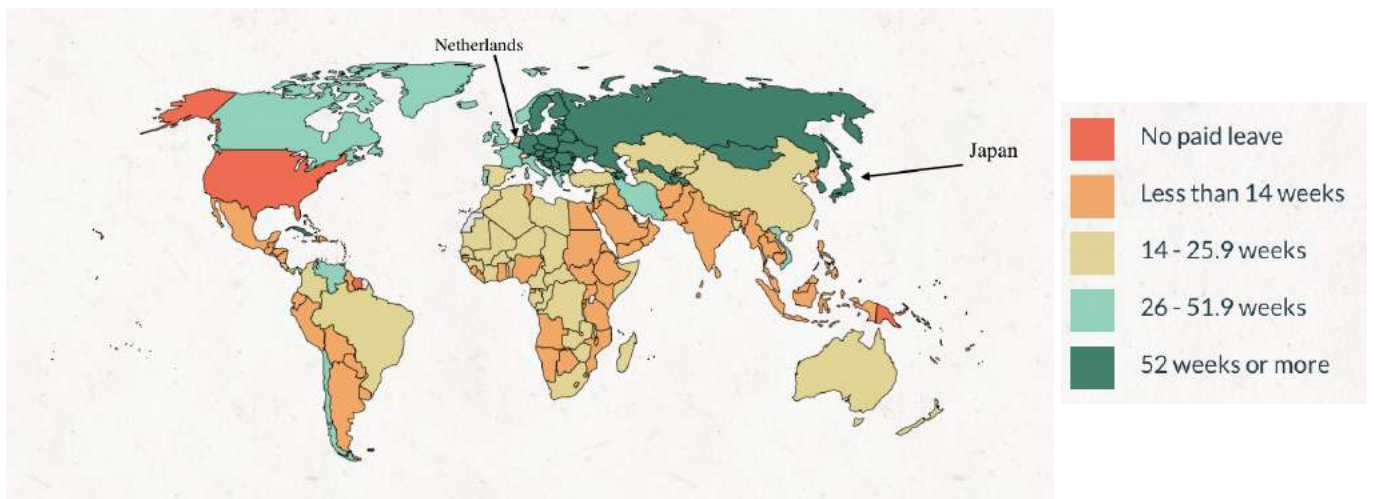


Figure 20: Paid Parental Leave Map (World Policy Center, 2014)

### 4.3 Warning Label Analysis

To understand what information parents are given about the safety of infant products as it pertains to sleep, ASTM and AS/NZS voluntary standards were analyzed. Standards for these products are very specific about what must be included, and require a minimum font size that manufacturers must put their warnings in. A table containing the warnings and specific standards can be found in Appendix E.

Generally, the warning labels appear to be very lengthy. It is important to warn consumers of potential hazards associated with a product, however consumers may be overwhelmed or unlikely to read the warnings simply due to their length. Warning labels are considered to be the least successful way to



protect consumers from product hazards (Lenorovitz, Karnes, & Leonard, 2012) . If the manufacturer is unable to design out or protect against a hazard, only then will they add a warning as shown in the hierarchy below (Figure 21) adapted from the CDC Hierarchy of Controls.



Figure 21: Safety Hierarchy

The placement and size of warning labels on products was also examined and they varied on different products and different brands. Manufacturers who follow voluntary standards and regulations place warnings where the consumer is likely to see it. Warning labels seem to be placed in multiple areas on the product, and manufacturers often include relevant warnings on inserts inside a product’s packaging. Some products warning labels were small, but still compliant with ASTM standards. Others made certain parts of the warning larger, likely in an attempt to catch the eye of the consumer. Figure 22 below depicts warning labels on two different products.



Figure 22: (Left) Play Yard warning label on the side of the product; (Right) Bassinet warning label featuring significantly larger font than play yard

### 4.3.1 Sleeping environments

This section will discuss common themes on warning labels on products intended to be used as a sleep environment by infants. This includes cribs, play yards (folding cots), cradles, bassinets, and bedside sleepers. The warnings associated with these products most often reference entanglement and suffocation hazards. Warnings for full-size cribs, play yards, cradles, and bassinets all include a message about suffocation or strangulation. In addition, warnings for full-size cribs, play yards, and bassinets warn against placing an incorrectly fitting mattress, citing entrapment hazards. The warnings for these products

also warn parents about SIDS and suffocation, by advising parents to place infants on their back to sleep, unless advised otherwise by a pediatrician

Bedside sleepers must include a warning about dangerous gaps between an adult bed and the sleeper. Consumers are further warned to not place soft objects to cover any gaps between the sleeper and adult bed because those would present a suffocation hazard.

#### 4.3.2 Bedding and accessories

This section will discuss common themes on warning labels for products that consumers may place in the sleeping environment. This includes portable bed rails, infant bedding and related accessories, crib mattresses, and infant inclined sleep products.

This is a more varied category, but the warnings are fairly consistent. The warnings required for bedding and related accessories advise consumers to not place soft or loose bedding within a child's reach, and to make sure the mattress and fitted sheets fit securely to prevent entrapment and strangulation. For pillows, consumers are specifically warned that they are decoration only, and should not be used by an infant. The warnings for crib mattresses must include a statement to place infants on their back to sleep.

Inclined sleep products must contain a warning stating that infants have suffocated on extra bedding. When sold as an accessory, inclined sleep products must also contain a warning advising consumers to never place extra padding under or beside an infant. The warning also includes a statement to place infants on their back to sleep.

#### 4.3.3 Products not intended for infant sleep

This section will discuss common themes on warning labels for products that are not intended for infant sleep, but have warnings relevant to sleep risks. This includes air mattresses, toddler beds, infant swings, and infant rockers.

Air mattresses and toddler beds, while intended for sleep, they are not safe for infants to sleep in. Air mattress warnings advise consumers to not put an infant younger than 15 months to sleep in that product. They also contain a warning that infants have suffocated on an inflatable mattress. Toddler beds contain a similar warning that infants have died from entrapment, and likewise warn against placing an infant younger than 15 months in one.

Infant swings and infant rockers both have warnings that advise consumers to not place an infant upright in those products because of a suffocation risk. Warnings for swings tell parents to keep the seat reclined until the infant is able to hold their head up on their own. Warnings for rockers specifically state that this product is not intended for prolonged or unsupervised periods of sleep.

## Chapter 5: Recommendations

In many of the interviews, the person or organization interviewed had strong feelings about safe infant sleep. When asked if they had recommendations for ways to reduce the rate of SUID many of the same solutions were recommended by multiple interviewees. The following list of recommendations contains both those proposed by interviewees and those developed from the findings.

1. Educate parents on strategies to reduce the risk of SUID when bedsharing
2. Work with manufacturers and retailers to promote safe sleep through advertisements
  - a. Update voluntary standards to promote safe sleep on product packaging
  - b. Draft regulations to require safe sleep depictions in advertising
3. Educate parents about infant sleep patterns
4. Add safe sleep education to high school health curriculum
5. Standardize sleep education across all child care specialties so parents receive consistent information
6. Develop a suffocation based public health campaign
7. Update and improve warning labels on infant products so parents understand risks associated with certain products and behaviors
8. Incentivize manufacturers to refute reviews from consumers promoting unsafe product use
9. Continue discussion about expanding paid parental leave in the United States

### 5.1 Educate parents on strategies to reduce the risk of SUID when bedsharing

The AAP recommends that parents sleep in the same room as their baby, but not in the same bed or sleep environment. However, as explained above, many parents become desperate and resort to bedsharing, despite knowing the associated risks. In one focus group all seven mothers admitted to bedsharing, especially when they had multiple children and were exhausted. These mothers were aware of the recommendations, yet succumbed to fatigue. The education level of this group points out that even highly educated parents do not always follow recommendations. If a mother bedshares with her baby in an adult bed that is full of pillows and blankets the risk of SUID is higher than if the mother and infant sleep in a bed with no soft bedding. Therefore, parents should be educated on ways to reduce SIDS while bedsharing since some are going to do it anyway.

One way this can be achieved is by making sleep consultants more accessible to parents. During an interview with a representative of the Family Sleep Institute she noted that although they do not endorse bedsharing as a means to help parents sleep, if she encounters a family who is adamant about it, she will teach them the safest and least risky ways to do it. Access to sleep consultants or other professionals should be expanded to parents to reduce the incidence of death from bedsharing.

Another way to educate parents is by taking a personalized approach to their health care by having parents openly discuss with health care professionals, the barriers that prevent the adoption of the AAP recommendations. This strategy would allow for more nuance when discussing safe sleep recommendations, and allow parents to have a more family-centered and culturally sensitive discussion of sleep practices (Moon, 2017). Health care professionals would be able to discuss with the parents how to prepare proactively when a health care professional has concerns that parents may bedshare such as when a mother often falls asleep while breastfeeding or an infant has difficulty falling asleep on their own sleep surface. Professionals would be able to discuss the risks associated with this practice, and recommend ways to reduce the risk of SUID while bedsharing (Moon, 2017).

## 5.2 Work with retailers and manufacturers to promote safe sleep through advertisements

Consumers will often emulate what they see in media and television. If manufacturers and retailers show a crib full of soft blankets and stuffed animals, they may believe that this sleep environment is safe, or that an infant is more comfortable with extra items in the crib. The Tennessee Department of Health requires all hospitals model safe sleep behaviors so parents will be more likely to pick up on safe behaviors when they bring their child home. Advertisements for infant sleep products should not include depictions of an unsafe sleep environment.

Ideally, this could be achieved by working with retailers and manufacturers to update their media to promote safe sleep behaviors. A cooperative agreement between them and organizations working to promote safe sleep would be beneficial, and is likely the most time-effective option. Infant products are only used for a short and vulnerable period of an infant's life, so it is necessary that that misleading advertising be dealt with quickly. The National Action Partnership to Promote Safe Sleep Improvement and Innovation Network (NAPPSS-IIN) has reached out to manufacturers in the past, and have had some luck in persuading them to change their images (L. Kaplan, personal interview, November 29, 2017). JPMA issued a press release regarding their position on crib displays. Their official position is that "crib displays should not include items that present a suffocation hazard to the baby" but the cribs "do not need to be completely bare is the accessories included in the display follow ASTM guidelines" (JPMA, 2016). However, there must be a larger effort to contact manufacturers and retailers in order to enact real change.

### 5.2.1 Update voluntary standards to promote safe sleep on product packaging

The CPSC does not have the authority to regulate advertising. However, ASTM International voluntary standards may include requirements about how a product is marketed. For example, the standard for infant bathtubs states that any "pictorials on the product shall not indicate or imply that the infant may be left in the product without an adult caregiver in attendance" (ASTM Standard F2670-17, 2017). The goal of this standard is to prevent caregivers from leaving children alone in a tub by displaying proper behavior on packaging. This standard applies to images on packaging produced by the manufacturers but does not apply to retailers, who are free to develop their own advertising for a product. Manufacturers, however, often supply retailers with promotional materials, so getting to the manufacturers could be critically important.

### 5.2.2 Draft regulations to require safe sleep depictions in advertising

Under the Federal Trade Commission (FTC) Act, the FTC was given the authority to "prevent...unfair or deceptive acts or practices in or affecting commerce." (FTC Act, 1914) This means the FTC was given a broad mandate to find "deception if there is a representation, omission, or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment" (FTC, 1984). In other words, an advertisement is considered deceptive when it contains a claim that would mislead a reasonable consumer (Ohio Bar Association, 2016). The FTC has often challenged advertisements as unfair or deceptive when they "induce" the audience to adopt an unsafe behavior. For example, the FTC successfully challenged an ad for Uncle Ben's Rice that depicted a child cooking over a stove without proper adult supervision (FTC, 2016).

The right of the FTC to challenge unfair depictions in advertising has been upheld by the Supreme Court. In *Valentine v. Chrestensen* (1942) the court held that commercial speech is not constitutionally protected to the same extent as regular speech under the First Amendment. Further, in *Central Hudson Gas & Electric v. Public Service Commission of New York* (1980) the court defined a test for restrictions on commercial speech. The justices held that for commercial speech to be restricted, the "asserted governmental interest" must be substantially and directly served by the restriction, and the restriction may not be more extensive than absolutely necessary. In this case, the asserted governmental interest would be to promote safe sleep practices to reduce incidences of SUID. If the FTC or another

independent regulatory agency were to draft regulations on the depiction of safe sleep in advertising, it would be a lengthy and costly process requiring time for proper research and public input. This would not be the ideal route, and any new regulations would likely be extremely controversial and strongly opposed by manufacturers and retailers, but may result in a new regulation that would help to normalize safe sleep in the media.

### 5.3 Educate parents about infant sleep patterns

Babies have drastically different sleep patterns from those of adults, and it is often hard for parents to adjust to their infant's sleep schedule, especially if they have other obligations outside of parenting, such as a job. The average newborn infant sleeps for most of the day and night, but there is no set schedule that every infant follows (Stanford Children's Health, n.d.). In general, newborn infants sleep 8-9 hours during the day and 8 hours at night waking occasionally for feeding. Most infants do not sleep through the night without waking until 3-6 months but it may take up to a year for some infants to sleep through the night. Young infants have a small stomach and need to wake up every few hours for feeding (Stanford Children's Health, n.d.).

This can be difficult for parents, but educating them on the details of infant sleep schedules may allow them time to prepare for this. Providing information on what to expect 2-3 months after the birth could benefit parents. For the first month of their baby's life, parents run on adrenaline, but become desperate for sleep around 2-3 months, the time when an infant is at the highest risk of SIDS (L. Damir & J. Damir, telephone interview, November 6, 2017). Giving parents the knowledge and resources to adapt to a more fragmented sleep schedule ahead of time may prevent the exhaustion and desperation that pushes parents to practice unsafe sleep behaviors.

### 5.4 Add safe sleep education to high school health curriculum

The process of becoming a parent is one that can be emotionally as well as physically overwhelming. It can be a rush of emotions for parents the day a baby is born. Overflow of information in pamphlets and booklets parents receive at the hospital can also be additionally stressful. Programs already exist in hospitals that teach parents how to safely put their babies to sleep. Nurses are required to follow AAP recommendations so that parents can remember and emulate that behavior when they bring the baby home. As helpful as this is, this education may or may not resonate with the parent, which can lead to problems.

When asked, many representatives of agencies, companies, and non-profits agreed that it is a good idea to instill safe sleep knowledge before people become parents. A way to do this is to provide exposure to AAP recommendations in high school health class. This curriculum would teach students at a young age the safest methods for infant sleep. It would also prepare students with safe ways to deal with a restless baby. The system would ideally reflect any future changes to the recommendations.

It would take a considerable amount of time to add this education into each state's public education system, but it could save many future lives. The earlier parents are exposed to safe sleep habits, the more equipped they will be in the future to reduce the likelihood of SIDS.

### 5.5 Standardize sleep education across all child care specialties so parents receive consistent information

Mothers in a focus group discussed how information between different medical professionals was often inconsistent and confusing. As expected many health care providers are concerned mostly with their area of focus rather than considering the overall welfare of "the entire child." For example, the main concern of a gastroenterologist is the long term effects of reflux on a baby's digestive tract. Whereas a lactation consultant is focused on making breastfeeding easier for mothers. The divide among providers results in confusion among parents who hear different recommendations based on which provider they go to.

One way to address this is to create an interdisciplinary group of providers that develops a hospital policy that requires all providers affiliated with that hospital to provide the same recommendations to parents, regardless of the provider’s specialty. This could be similar to the safe sleep modeling program that has been implemented in hundreds of hospitals across the country. The program should include standard information that is given to parents and it should coincide with the AAP recommendations.

## 5.6 Develop a suffocation based public health campaign

As identified previously in the findings section, a suffocation campaign might be more effective than one based on SIDS. Using the Jacob and Powell four step model discussed below, a suffocation based campaign could provide a way to instill self-efficacy in parents and teach that behaviors could potentially save their child’s life.

Researchers suggest that message designers should follow a sequence of four steps to design a public safety message. In 2010, Casey Jacob, a food science professor at Kansas State University along with Douglas Powell, summarized the four basic principles to consider when designing a message (Figure 23) for food safety hazards, but the strategies are applicable to any campaign (Jacob, et al., 2010).



Figure 23: Effective Message Creation (Jacob, et al., 2010)

Understanding the target audience is a critical aspect of developing an effective campaign. If an organization presents a public health message in a way that is not applicable to the target audience, then the message is useless. The designers must study the target audience and tailor the campaign to address the audience’s specific needs, concerns, and interests. It is also important to understand the motivations, opinions, concerns and feelings of the individuals and groups that make up the audience in relation to the hazard. An aspect of understanding the audience is to determine their perception of the hazard, determine their knowledge and behavior regarding risks involved, and understand their motivation to act on the hazard (Jacob, et al., 2010).

Through incident data analysis a demographic of the highest incidence should be chosen. However it should be noted that reaching minority populations is a difficult task and most effectively done through one-on-one meetings in the community to answer questions and facilitate a discussion with members of the population (N. Fleming & K. Crosswhite, personal interview, November 2, 2017). Social media and traditional advertising has not been quite as effective in these populations (N. Fleming & K. Crosswhite, personal interview, November 2, 2017).

When it comes to creating a reliable message, those based on logic and reason are not as effective as those based on emotion because much of our decisions are based on emotions rather than logic (Witte, 2001). Naturally, people fear illness, disease, injuries and death. Therefore, most health risk messages target this vulnerability and are “fear appeals” that utilize scare tactics to persuade the public to act a certain way (Witte, 2001). An aspect of creating a reliable message is to remember that the audience’s level of trust in the source of the information presented is a factor in their acceptance of the message (Jacob, et al., 2010). The campaign by the Milwaukee Department of Health utilized scare tactics to frighten parents into not bedsharing which resulted in the tripling of requests for free cribs (Moon, et al., 2016a). Speaking with experts highlighted that many of the most successful campaigns are social media campaigns because in the digital age, parents are often on the Internet and social media and are immersed in extreme amounts of information.

The most successful method for spreading awareness and reaching target communities is through face to face meetings (L. Kaplan, personal interview, November 29, 2017). An important aspect of the NICHD's "Safe to Sleep" campaign is going into states with the highest SUID rates and training community health workers in tactics to have a successful personal conversation with community members on safe sleep. The "Safe to Sleep" campaign director highlighted this as a crucial facet of the campaign because it allows the education to be specifically tailored to the needs of the individual (L. Kaplan, personal interview, November 29, 2017). Care providers can also address the questions and concerns of the individual in a way that a mass media approach cannot (L. Kaplan, personal interview, November 30, 2017). Therefore in the creation of a suffocation based campaign, effort should be made to have personal communication and outreach as an integral part of the program.

Repetition is the third step in creating an effective message. The more times a message is presented, the more likely recipients are to receive and abide by the message. Organizations should distribute their messages repeatedly and update them promptly following the release of new scientific evidence to maintain consistency with current research and opinions (Jacob, et al., 2010). For example, the successful "B'More for Healthy Babies" displayed videos in multiple locations so parents were continually exposed to it (Moon, et al., 2016a).

Ten years after the launch of Back to Sleep, the NICHD and CDC re-evaluated statistics related to infant mortality and found that the SIDS rate dropped significantly. This was their way of testing and evaluating messages; the fourth component in campaign design. After distribution, there must be evidence-based evaluations to determine the message's effectiveness on knowledge and behavior (Jacob, et al, 2010). If, after 10 years, the NIH and CDC reported no change in infant mortality, then the campaign mostly likely would have had no impact, and the agencies would have potentially stopped the campaign due to ineffectiveness.

## 5.7 Update and improve warning labels on infant products

A problem with current warning labels is that they fail "at distinguishing between large and small risks (Robinson et al., 2016)." The issue is that current warning labels warn consumers of dangers of both large and small risk, so consumers may, after encountering multiple small risks, fail to heed the large risks. Placing excessive warnings about small risks on a product creates skepticism about all warnings, but it is irresponsible not to warn consumers about hazards, even small ones (Robinson et al., 2016). A meta-analysis of data found that while some consumers did read labels, it was at a low rate (Argo & Main, 2004). This study also found that when warning labels contained colors and symbols, the likelihood they were noticed increased.

Designing an effective warning label would include accounting for significant risks and placing them most prominently on a label, such as the risk of SIDS when placing soft bedding in a crib. A warning label that places large risks ahead of smaller risks, while still providing consumers with information about hazards associated with small risks, would likely be the most effective. The addition of multiple colors and symbols would also help to make sure the labels are more likely to be noticed.

Some warning labels also state to "never leave child unattended," which may be read as "do not allow a child to sleep in this product since they will be unattended." This ambiguity may cause confusion and warning labels should be blunt and straightforward. Therefore a recommended change would be to explicitly state "do not allow infant to sleep in product. Suffocation or death may result." This would mean that there are little likelihood of misinterpretation questions and a parent is outright told that placing their infant to sleep in a certain product could result in death.

It is also important to note that "product warnings do not exist in a vacuum" (Robinson et al., 2016). The decline in cigarette smoking has been largely attributed to the addition of warnings on the packaging, but this was combined with outreach and education campaigns that warn consumers of the dangers associated with smoking. An effective warning label on infant products would be an important factor in changing the behavior of parents, but it must be combined with a large outreach effort to significantly affect change.



## 5.8 Incentivize manufacturers to refute reviews from consumers promoting unsafe product use

A review of 128 customer reviews for a co-sleeper on Amazon showed over 60% of them were promoting the success of unsafe uses of the product such as co-sleeping and stating that it was a “safe space for a newborn.” However these claims are in direct conflict with the AAP recommendations to reduce the risk of SUID. Parents can be highly influenced by customer reviews, so the reviews endorsing unsafe usage, is potentially dangerous. If a caregiver is sleep deprived and desperate for sleep, they may purchase products and use them incorrectly in an effort to get sleep.

Therefore a potential solution to this problem is to encourage manufacturers and online shopping websites like Amazon to remove or refute consumer reviews that endorse the unsafe use of a product. If there was a review that stated an incline sleeper provided a safe place for the baby to sleep and the manufacturer had to comment back and state it is not recommended for long periods of sleep, it may affect the amount of parents who use the product in an unsafe manner.

## 5.9 Continue discussion about expanding paid parental leave in the United States

In about half of US households, both parents work full-time and only a quarter of two-parent households see the mother not working outside of the home (Livingston, 2016). This is a significant social shift from the 1970s where almost half of mothers were stay-at-home moms (Pew Research Center, 2015). The laws regarding maternity and parental leave, however, have not kept up with these changes. Out of 41 of the highest income industrialized nations, the US is the only country to not offer any paid parental leave (Livingston, 2016). In fact, the only countries in the world without any paid parental leave law on the books are Papua New Guinea, Suriname, a few Pacific Island nations, and the United States of America (Deahl, 2016). The US guarantees twelve, unpaid, job-protected workweeks of leave in a 12-month period for the birth of a child or to care for the child in the first year of life for employees of companies that employ more than 50 people through the Family and Medical Leave Act of 1993.

In most countries, families rely on the income of both parents and many cannot afford to have a lengthy period of time without income (Deahl, 2016). However, newborns require intense parental care in the first year of life, which leaves parents in a difficult situation. Several US states have policies to provide workers with more family leave benefits. Only three states currently offer paid parental leave (California, New Jersey, and Rhode Island with New York joining this group in 2018) (NSCL, 2016). The programs for these states is paid for through employee-paid payroll taxes and administered through disability-programs (NSCL, 2016).

Giving parents time from for work may prevent desperation for sleep. Taking care of a newborn is a full-time job for parents, and it can make following safe sleep recommendations difficult, especially when an infant has difficulty sleeping alone, on their back, or on a separate sleep surface. Allowing new parents to stay home with their infant, without having to sacrifice income can help them care for their infant on a more flexible schedule and in a safer way.

# Bibliography

- AAP. (n.d.). About the AAP. Retrieved from <https://www.aap.org/en-us/about-the-aap/Pages/About-the-AAP.aspx>
- The Baby Box Co. (n.d.). About Us - The Baby Box Co. Retrieved from <https://www.babyboxco.com/pages/about-us>
- Amazon Customer. (2015, December 2). Customer Review. Retrieved December 01, 2017, from [https://www.amazon.com/gp/customer-reviews/R3BJ7SRFQGVIF7/ref=cm\\_cr\\_dp\\_d\\_rvw\\_ttl?ie=UTF8&ASIN=B00BUO4664](https://www.amazon.com/gp/customer-reviews/R3BJ7SRFQGVIF7/ref=cm_cr_dp_d_rvw_ttl?ie=UTF8&ASIN=B00BUO4664)
- American National Standards Institute. (n.d.). Introduction to ANSI. Retrieved from [https://www.ansi.org/about\\_ansi/introduction/introduction?menuid=1](https://www.ansi.org/about_ansi/introduction/introduction?menuid=1)
- Argo, Jennifer J. and Kelley J. Main (2004), "Meta-Analyses of the Effectiveness of Warning Labels," *Journal of Public Policy & Marketing*, 23(2), 193-208.
- Arya R, Williams G, Kilonback A, et al. Is the infant car seat challenge useful? A pilot study in a simulated moving vehicle Archives of Disease in Childhood - Fetal and Neonatal Edition Published Online First: 30 September 2016. doi: 10.1136/archdischild-2016-310730
- ASTM International. (2017). *Detailed Overview*. Retrieved from [https://www.astm.org/ABOUT/full\\_overview.html](https://www.astm.org/ABOUT/full_overview.html)
- ASTM Standard F2670-17 (2017), "Standard Consumer Safety Specification for Infant Bath Tubs," ASTM International, West Conshohocken, PA, DOI: 10.1520/F2670-17, [www.astm.org](http://www.astm.org).
- Atkins, K. (2011, April 28). New Cribs Safety Standards Go into Effect. *Lawyers Weekly USA*. Retrieved September 3, 2017.
- Baddock, S. A., Tipene-Leach, D., Williams, S. M., Tangiora, A., Jones, R., Iosua, E., . . . Taylor, B. J. (2017). Wahakura Versus Bassinet for Safe Infant Sleep: A Randomized Trial. *Pediatrics*,139(2). doi:10.1542/peds.2016-0162
- Benaroch, R., MD. (2016). Is the Fisher Price Rock 'n Play Safe? Retrieved December 01, 2017, from <http://www.cribsforkids.org/is-the-fisher-price-rock-n-play-safe/>
- Bernhardt, J. M., PhD, MPH. (2006). Improving Health Through Health Marketing. *Preventing Chronic Disease*,3(3), a73. Retrieved September 23, 2017.
- Bonzon, E. & Brandon, S. (December 1, 2017) Telephone interview.
- Brogan, K., MD, & Ji, S. (2015, August 05). Could this be driving the epidemic of Sudden Infant Death (SIDS). Retrieved September 10, 2017, from <http://kellybroganmd.com/driving-epidemic-sudden-infant-death-sids/>
- BU SPH. (2016, April 28). The Health Belief Model. Retrieved from <http://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChangeTheories/BehavioralChangeTheories2.html>
- Carrier, C. T., MSN, RN, CNS. (2009). Back to Sleep: A Culture Change to Improve Practice. *Newborn and Infant Nursing Reviews*,9(3), 163-168. doi:https://doi.org/10.1053/j.nainr.2009.07.006
- CDC Reproductive Health. (2017, April 17). Sudden Unexpected Infant Death and Sudden Infant Death Syndrome Data and Statistics. Retrieved September 15, 2017, from <https://www.cdc.gov/sids/data.htm>
- Center for Disease Control. (2017). Sudden Unexpected Infant Death and Sudden Infant Death Syndrome. Retrieved August 31, 2017, from <https://www.cdc.gov/sids/aboutsuidandsids.htm>
- Center for Disease Control. (n.d.). National Center for Health Marketing. Retrieved from <https://www.cdc.gov/maso/pdf/nchmfs.pdf>
- Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*, 447 U.S. 557 (1980)
- Central Intelligence Agency (2017) CIA – The World Factbook: Infant Mortality Rate. Retrieved from <https://www.cia.gov/library/publications/the-world-factbook/fields/2091.html>.
- Charlie's Kids. (n.d.). About Us. Retrieved from <http://www.charlieskids.org/about-us>.

- Consumer Product Safety Commission. (2017, June 05). About CPSC. Retrieved from <https://www.cpsc.gov/es/about-cpsc>
- Consumer Product Safety Commission. (2001, July). Deaths Associated with Playpens. Retrieved from <https://www.cpsc.gov/s3fs-public/pdfs/playpen.pdf> [PDF]
- Consumer Product Safety Commission. (2009, July 8). Kolcraft recalls 1 Million Play Yards Due to Fall Hazard. Retrieved from <https://www.cpsc.gov/Recalls/2009/kolcraft-recalls-1-million-play-yards-due-to-fall-hazard>
- Consumer Product Safety Commission. (2010, September 10). Deaths Prompt CPSC, FDA warning on infant sleep positioners. Retrieved from <https://www.cpsc.gov/newsroom/news-releases/2010/deaths-prompt-cpsc-fda-warning-on-infant-sleep-positioners/>
- Consumer Product Safety Commission. (2011, June) Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs; Final Rule. Retrieved from <https://www.cpsc.gov/PageFiles/101628/cribfinal.pdf>
- Consumer Product Safety Commission. (2012a, April 25). Rulemaking. Retrieved from <https://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking>
- Consumer Product Safety Commission. (2012b, May 15). Be Prepared: Recall Planning. Retrieved from <https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/Be-Prepared-Recall-Planning>
- Consumer Product Safety Commission. (2015, January). Types of CPSC Recall Notifications. Retrieved from <https://www.cpsc.gov/s3fs-public/Recall-Notifications-External-2015.pdf> [pdf]
- Consumer Product Safety Commission. (2017a). Voluntary Standards. Retrieved from <https://www.cpsc.gov/Regulations-Laws--Standards/Voluntary-Standards>
- Consumer Product Safety Commission. (2017b) U.S. Consumer Product Safety Commission Fiscal Year 2018 Performance Budget Request to Congress. Retrieved from <https://www.cpsc.gov/s3fs-public/FY2018PBR.pdf?BIZZV4RI85b6qG7.GPDfnT2ZdDDBsQ.f>
- Consumer Product Safety Commission. (n.d. a). Children's Product Certificate. Retrieved from <https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Childrens-Product-Certificate/>
- Consumer Product Safety Commission. (n.d. b) *CPSC Fast Track Recall Program*. Retrieved from <https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/CPSC-Fast-Track-Recall-Program>
- Consumer Product Safety Commission. (n.d. c) *Duty to Report to CPSC: Rights and Responsibilities of Businesses*. Retrieved from <https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/Duty-to-Report-to-the-CPSC-Your-Rights-and-Responsibilities>
- Consumer Product Safety Commission. (n.d. d). Filing an Online Initial Section 15b Report. Retrieved from [https://www.cpsc.gov/s3fs-public/Online\\_Report\\_Guide\\_final.pdf?60\\_mCupzy7hmQcZ5ZZJ3KATDuQ1MSBg](https://www.cpsc.gov/s3fs-public/Online_Report_Guide_final.pdf?60_mCupzy7hmQcZ5ZZJ3KATDuQ1MSBg) [PDF]
- Consumer Reports. (2017) About Us. Retrieved from <https://www.consumerreports.org/cro/about-us/index.htm>
- Consumer Reports. (2010, February 15). Unsafe by definition: Voluntary recall. *Consumer Reports*. Retrieved from <https://www.consumerreports.org/cro/news/2010/02/unsafe-by-definition-voluntary-recall/index.htm>
- Corley, H. (2017, April 4). Napping in the Car Seat Could Be Deadly for Baby. Retrieved September 24, 2017, from <https://www.thespruce.com/napping-in-car-seat-maybe-deadly-293483>
- Cox, K. (2015, June 8). How Recalls Work (And Don't) And Why They're All So Different. Retrieved from <https://consumerist.com/2015/06/08/how-recalls-work-and-dont-and-why-theyre-all-so-different/>
- "Crib Buying Guide." (2016, May). *Consumer Reports*. Retrieved from <https://www.consumerreports.org/cro/cribs/buying-guide>
- Cribs for Kids. (n.d.). About Us. Retrieved from <http://www.cribsforkids.org/about-us/>.
- Crosswhite, K. & Fleming, N. (November 2, 2017). Personal interview.
- Damir, L. & Damir, J. (November 6, 2017). Telephone interview.

- DC Department of Health. (n.d.). About DOH. Retrieved from <https://doh.dc.gov/page/about-doh>
- Deahl, J. (October 6, 2016). Countries around the world beat the U.S. On Paid Parental Leave. *NPR*. Retrieved from <https://www.npr.org/2016/10/06/495839588/countries-around-the-world-beat-the-u-s-on-paid-parental-leave>
- Desmond, K. (November 3, 2017). Telephone interview.
- EPA. (2017). Summary of the National Technology Transfer and Advancement Act. Retrieved from <https://www.epa.gov/laws-regulations/summary-national-technology-transfer-and-advancement-act>
- Expert Help for New Parents, 24/7. (n.d.). Retrieved November 16, 2017, from <https://pacify.com/>
- Family and Medical Leave Act of 1993, 29 U.S.C. §§ 2601–2654
- Family Sleep Institute. (n.d.). Family Sleep Institute, Child Sleep Consultant Certification Program. Retrieved from <http://www.familysleepinstitute.com/>.
- Federal Trade Commission Act of 1914, 15 U.S.C. §§ 41-58, as amended.
- First Candle. (n.d.). About Us. Retrieved from <https://firstcandle.org/about-us/>.
- Fleming, N. (n.d.). Baby sleep safety. Retrieved from <http://healthylivingmadesimple.com/baby-sleep-safety/>
- FTC. (2016). Advertising to Kids and the FTC: A Regulatory Retrospective That Advises the Present.” Retrieved from [https://www.ftc.gov/sites/default/files/documents/public\\_statements/advertising-kids-and-ftc-regulatory-retrospective-advises-present/040802adstokids.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/advertising-kids-and-ftc-regulatory-retrospective-advises-present/040802adstokids.pdf)
- FTC. (1984). FTC Policy Statement on Deception. Retrieved from [https://www.ftc.gov/system/files/documents/public\\_statements/410531/831014deceptionstmt.pdf](https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf)
- Gary A. Smith, MD, DrPH. (n.d.). Retrieved from <http://www.nationwidechildrens.org/gary-a-smith>
- Gavin, M. L. (Ed.). (2016, December). Bed-Sharing. Retrieved September 10, 2017, from <http://kidshealth.org/en/parents/cosleeping.html>
- Gaw, C. E., Chounthirath, T., Midgett, J., Quinlan, K., & Smith, G. A. (2017, 11). Types of Objects in the Sleep Environment Associated With Infant Suffocation and Strangulation. *Academic Pediatrics*, 17(8), 893-901. doi:10.1016/j.acap.2017.07.002
- Gibbs, A. (1997, January). Focus Groups. Retrieved September 22, 2017, from <http://sru.soc.surrey.ac.uk/SRU19.html>
- Goodstein, M. H., Lagon, E., Bell, T., Joyner, B. L., & Moon, R. Y. (2017). Stock Photographs Do Not Comply With Infant Safe Sleep Guidelines. *Clinical Pediatrics*. doi:10.1177/0009922817728698
- Grainger. (n.d.). Understanding ANSI, ASTM International, FM Global, NFPA, SEI, UL, and CSA Group. Retrieved from <https://www.grainger.com/content/qt-safety-ansi-astm-international-100>
- HALO Innovations. (n.d.). The HALO Story - Safe Sleep for Babies - Infant Sleep Safety. Retrieved from <http://www.halosleep.com/our-story/>
- Hauck, F. R., Herman, S. M., Donovan, M., Iyasu, S., Moore, C. M., Donoghue, E., . . . Willinger, M. (2003). Sleep Environment and the Risk of Sudden Infant Death Syndrome in an Urban Population: The Chicago Infant Mortality Study. *Pediatrics*, 111(1), 1207-1214.
- Hauck, F. R., & Tanabe, K. O. (2010). International Trends in Sudden Infant Death Syndrome and Other Sudden Unexpected Deaths in Infancy: Need for Better Diagnostic Standardization. *Current Pediatric Reviews*, 6(1), 95-101. doi:10.2174/157339610791317241
- Hackett, M. (2013). Parental Adherence to Infant Sleep Safety Recommendations. *Journal of Community Medicine & Health Education*, 3(4). doi:10.4172/2165-7904.1000219
- Haque, Atif. (2009, August 24). Car seat safety concerns pop up for newborns. *ABC News*. Retrieved from <http://abcnews.go.com/Health/Parenting/story?id=8386027>
- Heinrich, P. (November 8, 2017). Telephone interview.
- Heitmann, R. (November 3, 2017). Telephone interview.
- Himes, B. (November 9, 2017). Telephone interview.
- Hitchcock, S. (2012). Endorsing Safe Infant Sleep. *Nursing for Women's Health*, 16(5), 386-396. doi:10.1111/j.1751-486x.2012.01762.x
- Hudgins, C. (November 8, 2017). Telephone interview.

- Huffington Post, (2013, February 21). Paid Parental Leave: U.S. vs. The World (INFOGRAPHIC). Retrieved from: [https://www.huffingtonpost.com/2013/02/04/maternity-leave-paid-parental-leave-n\\_2617284.html](https://www.huffingtonpost.com/2013/02/04/maternity-leave-paid-parental-leave-n_2617284.html)
- Ingraham, C. (2014, September 29). Our infant mortality rate is a national embarrassment. Retrieved September 03, 2017, from [https://www.washingtonpost.com/news/wonk/wp/2014/09/29/our-infant-mortality-rate-is-a-national-embarrassment/?utm\\_term=.6364b7b293b5](https://www.washingtonpost.com/news/wonk/wp/2014/09/29/our-infant-mortality-rate-is-a-national-embarrassment/?utm_term=.6364b7b293b5)
- Jacob, C., Mathiasen, L., & Powell, D. (2010). Designing effective messages for microbial food safety hazards. *Food Control*, 21(1), 1-6. doi:10.1016/j.foodcont.2009.04.011
- Johns Hopkins CCP. (2011). U.S.A Maternal/Child Health: B'More Babies Safe Sleep Campaign Video [Video File]. Retrieved from <https://www.youtube.com/watch?v=yBBiG6e4xRw>
- Jones, C. L., Jensen, J. D., Scherr, C. L., Brown, N. R., Christy, K., & Weaver, J. (2015). The Health Belief Model as an Explanatory Framework in Communication Research: Exploring Parallel, Serial, and Moderated Mediation. *Health Communication*, 30(6), 566–576. <http://doi.org/10.1080/10410236.2013.873363>
- JPMA. (2016). *JPMA Crib Display Position Statement*. [Press release]. Retrieved from <http://c.yimcdn.com/sites/www.jpma.org/resource/collection/123b143f-dacf-4bbd-b683-5f8817714440/JPMA%20-%20Crib%20Display%20Position%20Statement.pdf>.
- JPMA. (2017a). *Certification Program*. Retrieved from <http://www.jpma.org/?page=certification>
- JPMA. (2017b). *Who is JPMA?* Retrieved from <http://www.jpma.org/?page=about>
- Kaplan, L. (November 29, 2017). Personal interview.
- Kovaleski, K. (November 9, 2017). Telephone interview.
- Kreth, M., Shikany, T., Lenker, C., & Troxler, R. B. (2016). Safe Sleep Guideline Adherence in Nationwide Marketing of Infant Cribs and Products. *Pediatrics*, 139(1). doi:10.1542/peds.2016-1729
- Krueger, Richard A. (2002, October). Designing and Conducting Focus Group Interviews. Retrieved from <http://www.eiu.edu/ihec/Krueger-FocusGroupInterviews.pdf>
- Livingston, G. (September 26, 2016). Among 41 nations, U.S. is the outlier when it comes to paid parental leave. *Pew Research Center*. Retrieved from <http://www.pewresearch.org/fact-tank/2016/09/26/u-s-lacks-mandated-paid-parental-leave/>.
- Lefebvre, R. C., PhD, & Flora, J. A., PhD. (1988). Social Marketing and Public Health Intervention. *Health Education Quarterly*, 15(3), 299-315. doi:10.1177/109019818801500305
- Lenorovitz, D. R., Karnes, E. W. and Leonard, S. D. (2014). Mitigating Product Hazards via User Warnings Alone: When/Why “Warnings-Only” Approaches Are Likely to Fail. *Hum. Factors Man.*, 24: 275–297. doi:10.1002/hfm.20379
- Mann, Denise. (2009, August 24). Infant Car Seats Lower Oxygen Levels in Blood During Sleep. *Health*. Retrieved from <http://www.health.com/pregnancy/infant-car-seats>
- Marcel, Dan. (2017, September 8). Doctor: ABC’s of infant sleeping key to their safety. *WKBN*. Retrieved from <http://wkbn.com/2017/09/08/doctor-abcs-of-infant-sleeping-key-to-their-safety/>
- Martin, A. (2011, July 16). After a Long Battle, Safer Cribs. *The New York Times*. Retrieved September 23, 2017.
- Mathews, A. A., Joyner, B. L., Oden, R. P., Alamo, I., & Moon, R. Y. (2015). Comparison of Infant Sleep practices in African-American and U.S Hispanic Families: Implications for Sleep-Related Infant Death. *Journal of Immigrant and Minority Health / Center for Minority Public Health*, 17(3), 834–842. <http://doi.org/10.1007/s10903-014-0016-9>
- McDonnell, E., & Moon, R. (2014, February 7). Infant Deaths and Injuries Associated with Wearable Blankets, Swaddle Wraps, and Swaddling. *HHS Public Access*, 10.1016/j.jpeds.2013.12.045
- Meyer, A. (2015, October 29). <https://www.thespruce.com/napping-in-car-seat-maybe-deadly-293483>. Retrieved September 24, 2017, from <http://kfor.com/2015/10/29/putting-your-baby-to-sleep-in-a-car-seat-can-be-a-deadly-mistake/>
- Miller, A. (2012, February 28). Consumer Product Safety Commission strengthens crib safety standards. *McClatchy-Tribune Business News*. Retrieved September 23, 2017.

- Milwaukee Department of Health. (2012). Safe Sleep Campaign. Retrieved from <http://city.milwaukee.gov/health/Safe-Sleep-Campaign>
- Moon, R. (October 31, 2017). Telephone interview.
- Moon, R. Y., Hauck, F. R., & Colson, E. R. (2016a). Safe Infant Sleep Interventions: What is the Evidence for Successful Behavior Change? *Current Pediatric Reviews*, 12(1), 67–75. <http://doi.org/10.2174/1573396311666151026110148>
- Moon, R. Y., Darnall, R. A., Feldman-Winter, L., Goodstein, M. H., & Hauck, F. R. (2016b). SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment. *Pediatrics*, 138(5). doi:10.1542/peds.2016-2938
- Moon, R. Y., Hauck, F. R., Colson E. R., Kellams, A. L., Geller, N. L., Heeren, T., Kerr, S. M., Drake, E. E., Tanabe, K., McClain, M., Corwin, M. J. (2017). The Effect of Nursing Quality Improvement and Mobile Health Interventions on Infant Sleep Practices: A Randomized Clinical Trial. *JAMA*, 318(4):351–359. doi:10.1001/jama.2017.8982
- Moon, R. Y., (2017). Engaging Families in Safe Sleep: Lesson Learned from High Risk Family Focus Groups. Chicago, IL: American Academy of Pediatrics.
- Morgenstern, B. (November 1, 2017). Telephone interview.
- Naeye, R. L., M.D. (2016). Brain Stem and Adrenal Abnormalities in the Sudden-infant-death Syndrome. *American Journal of Clinical Pathology*, 66(3), 526-530. doi:<https://doi.org/10.1093/ajcp/66.3.526>
- National Institutes of Health. (n.d.). Explore the Campaign. Retrieved September 10, 2017, from <https://www.nichd.nih.gov/sts/campaign/Pages/default.aspx>
- NCSL. (July 19, 2017). State Family and Medical Leave Laws. Retrieved from <http://www.ncsl.org/research/labor-and-employment/state-family-and-medical-leave-laws.aspx>
- Nebraska Department of Health & Human Services. Risk Factors: Triple Risk Model. Retrieved from <http://dhhs.ne.gov/publichealth/SIDS/Pages/TripleRiskFactor.aspx>.
- Neighborhood Safety Network. (2015) The New Federal Crib Standards for Home and Childcare. Retrieved from [http://keepingbabiesafe.org/wp-content/uploads/2015/01/NewFederalCribRequirements\\_2011.pdf](http://keepingbabiesafe.org/wp-content/uploads/2015/01/NewFederalCribRequirements_2011.pdf).
- NICHD. (2013). Research on Possible Causes of SIDS. Retrieved from <https://www.nichd.nih.gov/sts/campaign/science/Pages/causes.aspx>.
- NICHD. (n.d.). Safe to Sleep® Public Education Campaign. Retrieved December 07, 2017, from <https://www.nichd.nih.gov/sts/Pages/default.aspx>
- Ohio Bar Association. (2016) Federal Law Regulates Advertising. Retrieved from <https://www.ohiobar.org/ForPublic/Resources/LawYouCanUse/Pages/LawYouCanUse-672.aspx>
- Parlakian, R. (October 30, 2017). Telephone interview.
- Pediatrics* Jan 2015, 135 (1) 10-17; DOI: 10.1542/peds.2014-1793. Carrie K. Shapiro-Mendoza, Eve R. Colson, Marian Willinger, Denis V. Rybin, Lena Camperlengo, Michael J. Corwin (January 2015) VOLUME 135 / ISSUE 1 Trends in Infant Bedding Use: National Infant Sleep Position Study, 1993–2010.
- Pew Research Center. (November 4, 2015). Raising Kids and Running a Household: How Working Parents Share the Load. Retrieved from <http://www.pewsocialtrends.org/2015/11/04/raising-kids-and-running-a-household-how-working-parents-share-the-load/>.
- Principe, G. F. (1997, May). Racial Differences in Risk Factors for Sudden Infant Death Syndrome: A Case-Control Study in North Carolina. Retrieved September 16, 2017, from <http://www.schs.state.nc.us/schs/pdf/schs105.pdf>
- Quinn, P. (November 3, 2017). Telephone interview.
- Quinn, P. (November 13, 2017). Telephone interview.
- Rapaport, L. (April 8, 2016). Paid maternity leave linked to lower infant mortality rates. *Reuters*. Retrieved from <https://www.reuters.com/article/us-health-infantmortality-maternity-leav/paid-maternity-leave-linked-to-lower-infant-mortality-rates-idUSKCN0X51S0>.
- Rice, R. E., & Atkin, C. K. (2012). *Public Communication Campaigns* (4th ed.). Sage Publications.

- Robinson, L., Viscusi W. K., Zeckhauser, R. (November 30, 2016). Consumer Warning Labels Aren't Working. *Harvard Business Review*. Retrieved from <https://hbr.org/2016/11/consumer-warning-labels-arent-working>.
- Safe Sleep Tips for Infants. (2009, September 9). *Consumer Reports*. Retrieved from <https://www.consumerreports.org/cro/news/2009/09/safe-sleep-tips-for-babies/index.htm>
- Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs, 75 Fed. Reg. 81765 (December 28, 2010) (to be codified at 16 C.F.R. pts. 1219, 1220, & 1500).
- Saker, Anne. (2017, April 11). Infant deaths hit historic low for Hamilton County. *Cincinnati Enquirer*. Retrieved from <http://www.cincinnati.com/story/news/2017/04/11/infant-deaths-hit-historic-low-hamilton-county-2016/100283058/>
- Schmid, B. (November 1, 2017) Telephone interview.
- Shapiro-Mendoza, C. K., Kimball, M., Tomashek, K. M., Anderson, R. N., & Blanding, S. (2009). US Infant Mortality Trends Attributable to Accidental Suffocation and Strangulation in Bed From 1984 Through 2004: Are Rates Increasing? *Pediatrics*,123(2), 533-539. doi:10.1542/peds.2007-3746
- SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment. (2011, 10). *Pediatrics*, 128(5). doi:10.1542/peds.2011-2285
- Sinclair, M. (1984, April 5). Crib Parts Blamed for Deaths. *The Washington Post*. Retrieved September 3, 2017.
- Sleep Review. (2014, April 2014). Ohio Launches ABCs of Safe Sleep Campaign. *Sleep Review*. Retrieved from <http://www.sleepreviewmag.com/2014/04/ohio-abcs-of-safe-sleep-campaign/>
- Staff. (2009, June 12). Deaths bring crib safety into question. *Atlanta Journal-Constitution*. Retrieved September 3, 2017.
- Stanford Children's Health. (n.d.). Newborn-Sleep Patterns. Retrieved from [http://www.stanfordchildrens.org/en/topic/default%3Fid%3Dnewborn-sleep-patterns-90-P02632&sa=U&ei=58e3VM6CIr5yATNnIGwAg&ved=0CG8QFjAT&usq=AFQjCNFvyKhlh5\\_8yFZvCBirEv-fTY56pQ](http://www.stanfordchildrens.org/en/topic/default%3Fid%3Dnewborn-sleep-patterns-90-P02632&sa=U&ei=58e3VM6CIr5yATNnIGwAg&ved=0CG8QFjAT&usq=AFQjCNFvyKhlh5_8yFZvCBirEv-fTY56pQ).
- Smith, W. A. (2006). Social marketing: an overview of approach and effects. *Injury Prevention*,12(Suppl\_1), I38-I43. doi:10.1136/ip.2006.012864
- Swaddle Designs. (n.d.). About Us. Retrieved from <http://www.swaddledesigns.com/about/about-us.html>
- Tennessee Department of Health. (2013). Safe Sleep Hospital Project. Retrieved from <https://www.tn.gov/health/article/safe-sleep-hospital-project>.
- Tennessee Department of Health. (2015). Tennessee Statistics. Retrieved from <https://www.tn.gov/health/article/safe-sleep-statistics>.
- The Atlanta Journal-Constitution, Metro Atlanta / State news. (July 12, 2009). Crib safety called into question. Retrieved from <http://www.ajc.com/news/local/crib-safety-called-into-question/HKNA6kEyFy87s1xrsy7DIP/>
- Universal Accreditation Board. (n.d.) The Four Step Process. Retrieved September 21st, 2017, from <http://www.praccreditation.org/resources/documents/APRSG-Planning.pdf>
- University of Virginia School of Medicine. (n.d.). Retrieved from <https://research.med.virginia.edu/chrc/current-projects/rachel-y-moon-md/>
- Valentine v. Chrestensen*, 316 U.S. 52 (1942)
- Wanna-Nakamura, Suad. (2009). Infant Sleep Positioning Products and Wedges. Retrieved from <https://www.cpsc.gov/s3fs-public/pdfs/positioners09.pdf>
- Ward, T. C. (2014). Reasons for Mother–Infant Bed-Sharing: A Systematic Narrative Synthesis of the Literature and Implications for Future Research. *Maternal and Child Health Journal*,19(3), 675-690. doi:10.1007/s10995-014-1557-1
- Whiteman, H. (2014, October 22). Bed-sharing with baby: The risks and benefits. Retrieved September 18, 2017, from <https://www.medicalnewstoday.com/articles/284275.php>



- Williams, Mari-Jane. (2013, June 2013). How to buy a play yard. *Washington Post*. Retrieved from [https://www.washingtonpost.com/lifestyle/on-parenting/how-to-buy-a-play-yard/2013/06/25/11e4bf68-d21c-11e2-9f1a-1a7cdee20287\\_story.html?utm\\_term=.d7a79e784a46](https://www.washingtonpost.com/lifestyle/on-parenting/how-to-buy-a-play-yard/2013/06/25/11e4bf68-d21c-11e2-9f1a-1a7cdee20287_story.html?utm_term=.d7a79e784a46)
- Witte, K., Meyer, G., & Martell, D. P. (2001). *Effective health risk messages: a step-by-step guide*. Thousand Oaks, CA: Sage Publications.
- Zero to Three. (n.d.). Our Mission and Vision. Retrieved from <https://www.zerotothree.org/about/our-mission-and-vision>.
- Zorn, P. (2011, October 11). Cribs: A changing landscape. *McClatchy-Tribune Business News*. Retrieved September 3, 2017.
- “13 Dangerous Baby Products to Avoid.” (2012, May). *Consumer Reports*. Retrieved from <https://www.consumerreports.org/cro/2012/05/13-dangerous-baby-products-to-avoid/index.htm>

## Appendix A: CPSC Background

In 1972, Congress passed the Consumer Product Safety Act establishing the Consumer Product Safety Commission. The act also established the CPSC's basic authority and authorized the agency to develop standards, bans, and recalls (CPSC, 2017a). According to their website (CPSC, 2017a), deaths, injuries, and property damage from consumer product incidents cost the nation more than \$1 trillion annually (CPSC). Their website states that incidents and deaths have declined in the 40 years since their founding.

Since its founding, the CPSC ensures products are safe for consumer use. When multiple accident reports come in for a product, action must be taken by initiating recalls and regulation change. From 1980 to 1983, 167 incidents were reported, including 34 infant deaths (Sinclair, 1984). In 1984, the CPSC commissioners passed a vote to improve the timeliness of recalls. It was important to improve the recall process of potentially faulty cribs because as former CPSC commissioner Stuart Statler explained, crib hardware firms had a history of delaying voluntary recalls (Sinclair, 1984). Another concern was that it could take as long as four years to get a product off the market under the Hazardous Substances Act. Under the Product Safety Law, authorities can act with greater force (Sinclair, 1984). The process has improved significantly over the past twenty years; per the CPSC website, with new safety regulations being passed every year for different household items.

The CPSC has a hierarchical structure and is typically led by four presidentially nominated commissioners and a Chairman. The current Acting Chairman is Anne Marie Buerkle who received a promotion to the position on February 9, 2017. Her term will expire in October of 2018 (CPSC, 2017b). The other current commissioners are Robert S. Adler, Marietta Robinson, and Elliot F. Kaye,.

For the 2018 fiscal year, the CPSC requested a \$123 million budget from Congress (CPSC, 2017b). The budget is broken down into four categories:

1. Workforce—Cultivate the most effective consumer product safety workforce.
2. Prevention—Prevent hazardous products from reaching consumers.
3. Response—Respond quickly to address hazardous consumer products both in the marketplace and with consumers.
4. Communication—Communicate useful information quickly and effectively to better inform decisions (CPSC, 2017b).

The objectives of this project fall under the communication section of the budget, which consists of approximately 8% of the CPSC's total budget (CPSC, 2017b).

The CPSC official website provides general information about the mission of the CPSC as well as incident data associated with consumer products in the marketplace. Past rulings and regulations are easily accessible and there are many pages on crib recommendations and associated regulations which are particularly applicable to this project. Based on the layout of the website, infant and youth safety seems to be a significant current concern. Roughly a quarter of rulings in the last decade regarded infants or toddlers and their safety, from nursing pillows to bassinets and cribs. This is probably because it is important to protect infants due to their vulnerability.

# Appendix B: Interview Questions

## **Zero to Three**

1. Can you tell us more about what you have done to advocate for infant sleep safety?
2. What does your group do to educate parents about infant safety?
3. What other methods of advocating for infant sleep safety have you used?
4. How do you reach out to parents with messaging?
  - a. What do you believe is the most effective method for getting your message to parents?
  - b. What are the main challenges that you face in distributing your message?
5. Is there anything you think the public is not aware of about aspects of infant sleep safety?

## **Dr. Rachel Moon**

1. Do you think the National Institutes of Health's "Safe to Sleep" campaign is still effective?
  - a. What suggestions do you have to improve the campaign?
  - b. Do you think it has been effective in reaching enough of the public in recent years?
2. Is there anything you think parents and caregivers are not aware of about aspects of infant safety?
  - a. What would you say to parents who have concerns about recommendations (e.g. believe supine sleep may cause an infant to choke)?
3. In some focus group reports you parents express that they often make decisions for their child based on their own sleep needs. Often causing them to ignore rules set by doctors and experts:
  - a. Are there any safe alternatives to sleeping alone in a crib, such as a bedside sleeper or other device to allow the baby to be closer to the parents?
  - b. If there aren't any other safe locations, what suggestions do you have so both the parent and baby can sleep?
  - c. Would it be appropriate to include alternate suggestions in a potential safety campaign?
4. From your research, what is the area of messaging that needs the most improvement so that more parents follow the recommendations?
5. Do you think there has been any improvement in parent awareness of SUID over the past ten years?
6. We are aware of SUID disparities among different demographics. Is there one group in particular that you think should be targeted in terms of receiving education on safe sleep?
7. We know you organized a focus group to better understand why the recommendations aren't always followed. How did you recruit participants for your focus group? What suggestions do you have for another focus group on infant sleep safety?
8. You noted in your paper from a high risk focus group that parents tend to see SIDS as "an act of God" but suffocation as preventable. Do you think the recent trend of decreasing rates of SIDS and increasing rates of suffocation could cause any behavioral changes?
  - a. Would a campaign focused on reducing suffocation rates adequately cover all of SUID, or is there something more specific that needs to be said about SIDS?
9. If you could only chose one recommendation for parents, what would be the most important?

## **HALO Innovations**

1. What are specific things the program teaches parents? How do parents typically respond to the training? Does the program mention warning labels on products?
2. What does the program teach health professionals? Do you find that they are generally willing to adopt behavior changes? What challenges have you faced with educating healthcare professionals?
3. How widespread is your hospital program for new parents and health care providers?
4. Do you have any specific recommendations that you think could be adopted by the industry as a whole?

5. What is the best advertising platform to sell your products for those concerned with sleep safety?
6. Do more of your sales come from retail or online? What products are the most sold?
7. How important do you think warning labels are for informing parents? Do you make extra effort to make sure parents read them?
8. Have you faced any criticism about your products or are most parents generally open to the idea of wearable blankets and empty cribs?

#### **P.A.C.E Mothers**

1. What is your perception of what parents understand as safe sleep environments and behaviors? Is there one recommendation in particular that you feel most parents are unaware of or chose not to follow if they are aware?
2. Do the mothers ever discuss proper ways of putting an infant to sleep? Are there any problems that you find parents have following safe sleep recommendations? What questions and concerns do you hear from parents about sleep safety and sleep related issues?
3. Where do you find most parents get their information about safe infant sleep practices or other practices in general?
4. Do you think parents are willing to adapt to suggestions made by other parents through discussion at these group meetings?
5. One thing we have found in our research is that parents who work will often bring a baby into bed with them so that they can get some sleep themselves. Is this something that has come up in one of your discussions?

#### **CPSC Office of Communications**

1. To what extent do you think “Safe to Sleep” is an effective campaign?
2. Did you interact with the local community or target audiences about campaigns?
  - a. What do these interactions involve?
3. Are there particularly important aspects about infant sleep safety about which the general public is less than fully aware?
4. When the CPSC develops public safety campaigns or messages, how are specific target communities selected? SUID has disparities among different demographics, however, in general is a nationwide issue. How do you suggest we tackle this?
5. How does the CPSC typically send out public safety messages (e.g. social media, CPSC website, press releases, TV and radio advertisements)?
6. Can you tell us more about the general strategies for developing a public safety campaign?
7. One of the main concerns that we saw is that infants do not sleep as soundly on their backs, and parents are desperate to get their child to go to sleep and will do whatever it takes. Is there any other safe environment for an infant to sleep besides alone and in a crib, away from the parents?

#### **Charlie’s Kids**

1. Besides your children’s book and truck, do you have any other outreach campaigns that educate parents on safe sleep habits?
2. Are parents generally receptive to safe sleep recommendations during the educational program you provide? Do you find that send a representative to talk and answer questions allows parents to fully understand recommendations?
3. What has the response been towards the book? Are a lot of copies being sold? Do you get questions from parents or are most of them receptive of the idea of safe sleep?
4. Do you find a struggle for parents to adapt to these do’s and don’ts when they have problems putting infants to sleep?
5. With parents getting overwhelmed with information once becoming parents, how do you aim to reach out to these parents and separate yourselves from other sources of information

6. Can you talk about your opinions on the Baby Box? There is information on your website saying how there are neither added benefits or dangers to using it but there has been success in Finland, where the idea seemed to have been practiced for years.
  - a. Are there any other products that Charlie's Kids has issued statements/warnings about, or had concerns about?
7. How many hospitals and how widespread is your partnership with organizations like that as of now?
8. Any general advice on how to reach parents effectively?

### **SwaddleDesigns**

1. There is information on your website about safe sleep. Do you distribute this information in ways other than just displaying on the website?
2. Do you have any specific recommendations that you think could be adopted by the industry as a whole?
3. Your website contains a lot of swaddles, is it important that a baby is swaddled, or can something else be done to help them transition to a crib?
4. Have you faced any criticism about your products or are most parents generally open to the idea of wearable blankets?
5. What is the best advertising platform to sell your products for those concerned with sleep safety?
6. Do more of your sales come from retail or online? What products are the most sold?
7. How important do you think warning labels are for informing parents? Do you make extra effort to make sure parents read them?
8. One of the main concerns that we have heard is that infants do not sleep as soundly on their backs, and parents are desperate to get their child to go to sleep and will do whatever it takes. Is there any other safe environment for an infant to sleep besides alone and in a crib, away from the parents?

### **National Institute of Children's Health Quality**

1. How do you distribute safe sleep information to the public? What are the most successful methods?
2. Do you think that parents generally listen to safe sleep recommendations
  - a. What are some of the challenges that they face in practicing safe sleep?
3. Could you tell us more about the Safety Bundle?
  - a. How far into development are you?
  - b. Are there any findings you can share with us?
4. A big focal point in our project is the dilemma where parents need their sleep and an infant is not falling asleep. This situation can cause parents to be desperate and not follow recommendations. As someone concerned with education for parents, do you think there can be a compromise or solution to this?
5. What do you think about the creation of an app (like pacify) where parents could get in touch with safe sleep experts at any time?
6. What do you think about teaching safe infant sleep practices in high school health classes to help normalize safe sleep? Do you think this would be feasible/effective?
7. What do you think about a possible law preventing the positive depiction of unsafe sleep environments in television and advertising?
  - a. Your safe sleep depiction checklist
  - b. Similar to how smoking is treated in advertising

### **Baby Box Company**

1. Could you talk about the Baby Box University? How old is it? How widespread is it?
2. What does Baby Box University use to inform parents about safe habits? Do you find some more effective? Does it depend on demographic?
3. Do you have any recommendations you think could be adopted by other manufacturers?
4. Could you talk more about the “Free Box” program?
5. Have you faced any criticism about your products or are most parents generally open to the idea of a box used as a sleeping environment? How do you convince parents that may be skeptical?
6. A big focal point in our project is the dilemma where parents need their sleep and an infant is not falling asleep. This situation can cause parents to be desperate and not follow recommendations. As someone concerned in the education for parents, do you think there can be a compromise or solution to this?

### **First Candle**

1. We know you were a partner in developing the “Safe to Sleep” campaign. What was your role in doing this?
2. Do you think most parents are generally aware of safe sleep behaviors?
3. Are there any safe sleep practices parents struggle with the most?
4. How do you educate parents on the importance of safe sleep practices?
5. Your website has a section on advocacy and reaching out to members of Congress. Have you been involved in passing any laws related to safe sleep in the past? Are there any laws you think could be helpful at this point for reducing infant mortality?
6. A big focal point in our project is the dilemma where parents need their sleep and an infant is not falling asleep. This situation can cause parents to be desperate and not follow recommendations. As someone concerned with education for parents, do you think there can be a compromise or solution to this?
7. What do you think about the creation of an app (like pacify) where parents could get in touch with safe sleep experts at any time?
8. What do you think about teaching safe infant sleep practices in high school health classes to help normalize safe sleep? Do you think this would be feasible/effective?
9. What do you think about a possible law preventing the positive depiction of unsafe sleep environments in television and advertising?
  - a. Similar to how smoking is treated in advertising

### **Family Sleep Institute**

1. When do parents decide they need a sleep consultant? Before the baby is born? After some restless nights?
2. What are some things typically taught in the SIDS risk reduction course in your certification program?
3. What concerns and problems do parents have with adhering to the safe sleep guidelines?
4. What tips do you give to parents who are having trouble putting their child to sleep in a safe sleep environment?
5. What legislative actions do you think are necessary at this time to reduce infant mortality rates?
6. A big focal point in our project is the dilemma where parents need their sleep and an infant is not falling asleep. This situation can cause parents to be desperate and not follow recommendations. What do sleep consultants typically recommend parents do when faced with this problem?
7. What do you think about the creation of an app (like pacify) where parents could get in touch with safe sleep experts at any time?
8. What do you think about teaching safe infant sleep practices in high school health classes to help normalize safe sleep? Do you think this would be feasible/effective?

9. What do you think about a possible law preventing the positive depiction of unsafe sleep environments in television and advertising?
  - a. Your safe sleep depiction checklist
  - b. Similar to how smoking is treated in advertising

#### **Tennessee Department of Health**

1. Do you believe most parents are informed about safe sleep practices or do you think there is still a gap and parents are not receiving that information?
2. How do you distribute safe sleep information to parents? What is the most effective method?
3. The website says you educate community agencies, clergy, law personnel and emergency responders about SIDS. What methods do you use to educate those groups?
4. What is the biggest barrier you find to parents always following safe sleep guidelines?
5. How have you measured the success of your campaigns?
6. In general what are the basic steps you used to develop the campaign? How do you select an appropriate target audience and make sure the messaging platform is satisfactory for their needs?
7. Can you talk more about the safe sleep hospital program?
8. Have you found the distribution of the “Sleep Baby, Safe and Snug” book to be effective? Do parents respond positively to message?
  - a. Do you believe the board book is an effective vehicle for the message?
9. What do you think about the creation of an app (like pacify) where parents could get in touch with safe sleep experts at any time?
10. What do you think about teaching safe infant sleep practices in high school health classes to help normalize safe sleep? Do you think this would be effective?
11. From many of our other interviews, we heard that parents are confused by the mixed messaging in the media. What do you think about a possible law or standard preventing the depiction of unsafe sleep environments in television and advertising?

#### **Juvenile Product Manufacturers Association (JPMA)**

1. What legislative actions do you think are necessary at this time to reduce infant sleep mortality?
2. In order for a product to be JPMA certified are there any requirements pertaining to safe sleep?
3. What do you think about a law or standard preventing the depiction of unsafe sleep environments in advertising and the media?
  - a. What about adding that manufacturers aren’t allowed to display unsafe sleep environments in their packaging in order to be JPMA certified?
  - b. On your website there are recommendations for retailer crib display, do you think this should become mandated or a law? Or do most retailers comply even though it's not required?
4. Do you have any education programs to educate manufacturers and retailers about safe sleep so they can inform consumers accordingly? Do you distribute any materials to manufacturers or retailers?
5. Do you think there should be changes to warning labels on products? For example, stating a product is not intended for sleep instead of “do not leave child unattended in this product?”



### **National Institutes of Child Health and Human Development**

1. What methods made the Back to Sleep campaign successful in 1994? How does that differ from messaging techniques used today?
2. What does NICHD currently use to spread the “Safe to Sleep” message? Social media, hospitals, etc.?
  - a. What are some of the challenges you think parents face in adopting the safe sleep strategies?
  - b. Aside from the 50% reduction in SIDS, how have you measured the success of the “Safe to Sleep” campaign?
3. Where do you think the “Safe to Sleep” campaign could be improved?
4. Do you think it’s important to depict safe crib/infant sleep environments in the media?
  - a. How do you think this could be addressed?
5. How do you reach out to specific demographics of the population?
6. Is there any recommended strategy for a safe way to put a baby to sleep when they just won't sleep by themselves in a crib?

### **DC Department of Health**

1. What kind of information is included in your educational program for parents?
2. What is your impression on parents responses to having infants sleep in an empty crib on their back? What are questions or concerns you hear from parents?
3. Do you find that parents tend to stick with the practices taught to them at the workshops?
4. How do you measure the success of the Safe Sleep program? Has there been a reduction in sleep related deaths in DC since the beginning of the program?
5. How many families participate in your programs? How do you market your programs?
6. Aside from the educational program for parents, do you have any general advertising for safe sleep available to the general public?
7. What demographic attends the workshops? Is a specific group targeted? Has this group changed over time?

# Appendix C: Focus Group Protocol

*Italicized are “speaking parts”*

## Roles

Moderator: Erin

Timekeeper: Ryan

Note taker: Alison

Note taker / Audio Recorder: Kyle

## **15 MINUTES MAX – END BY 6:15**

1. Begin by welcoming participants and thanking them profusely.
  - a. Each participant needs a name tag (first name only) and moderator needs one too. The name tag can be folded piece of paper on a desk or sticky name tags.
  - b. *“Hi my name is Erin and I will be the moderator for today’s infant sleep safety focus group. My project partners Alison, Kyle and Ryan will be observing and taking notes. A focus group is a gathering of people to explore views on a certain topic in a conversational manner. Today we will be discussing infant sleep safety and your opinions on the current recommendations and thoughts and concerns about how to help your own baby go to sleep safely. It is our expectation that your opinions and experiences will help us learn more about the obstacles parents face in following the recommendations. The information we discussed will be organized into themes and used to help develop recommendations for organizations working on safe sleep for ways to reduce infant sleep related deaths. Your personal information will not be connected to the results of this focus group.”*
2. Housekeeping and Forms
  - a. On recording, ask all participants if they consent to an audio recording and pictures taken throughout.
  - b. All participants need to sign informed consent, and we need to keep that.
  - c. All participants need to sign a confidentiality agreement.
  - d. *We would like to audio record today’s event for review purposes later on. If everyone is okay with that, can you all please say yes.....okay perfect. That’s \_\_\_yeses so we will continue recording.*
  - e. *I am passing around a consent form and a confidentiality agreement. By signing these forms, you are agreeing to participate in today’s focus group and to keep our discussion confidential. If you feel uncomfortable for any reason signing these forms, or at any point during today’s meeting, you are free to leave at any time. Please take a moment to read over the forms. If you do not feel comfortable being photographed, simply indicate and we will not take your picture.*
3. Logistics
  - a. *“The way this will work is that I am going to ask some questions. Feel free to jump in and comment or ask a question as this is supposed to be a conversation. However please make sure not to interrupt anyone and make sure everyone gets a chance to speak. It’s important to hear all of your opinions. This is a time for everyone to feel free to express their opinions and viewpoints. You will not be asked to reach an agreement and there are no right or wrong answers.”*
  - b. *“There are a lot of things we would like to talk about today, so if I get a sense that we are getting away from the topics we have planned, please don’t take it personally if I cut you off in order to move on to the next part. Does anyone have any questions?”*

4. Introductions

- a. *“Ok, we are ready to start. Let’s begin by going around the room and saying your name and telling us how many children you have and their ages.”*

**10 MINUTES MAX – END BY 6:25**

1. Review of SUID and recommendations

- a. Have a slide with the AAP recommendations and quick definitions of what SUID is
- b. *Sudden unexpected infant death is the unexplained death of a seemingly healthy infant under 1 year. For our purposes, we will focus on sleep related incidents. The American Academy of Pediatrics published recommendations to reduce the risk of sudden unexpected infant death. How many do you think this group can list? Ryan will write them down and then we will look at the AAP’s list to see how well we did.*
  - i. Ask for recommendations
- c. *Can you tell us where you learned these.*
  - i. *Did you understand the recommendations when they were presented to you?*
- d. Go through recommendations on handout.

**15 MINUTES MAX – END BY 6:40**

1. *So there are 19 recommendations. What do you think about the someone’s ability to follow them? (Probe for what parents do)*
  - a. *Ok we have these recommendations and there’s a lot of them. To what extent do you think parents follow them? Why do you think that?*
  - b. *Could you tell us about your own experience following these?*
  - c. *When your child hasn’t slept night after night, or had a hard time going to sleep night after night, or woken up repeatedly so that everyone becomes really tired what do you do then?*
  - d. *What are other times when it is really hard to follow these?*

**20 MINUTES MAX – END BY 7:00**

2. *The AAP has these guidelines but manufacturers offer products that seem to provide alternatives. Where is it that you get the message about what products are safe and what you should buy for your infant?*
3. *How do you decide if you are going to purchase a product? Does anyone ever read consumer reviews? Do these reviews influence how you will use the product?*

**20 MINUTES MAX – END BY 7:20**

4. *If a doctor wanted to get this important information about safe sleeping for your baby to you, what way would be most likely to catch your attention?*
5. *How can people spread the word on infant safe sleep? What type of communication means do you pay attention to?*
  - a. *If no one talks about social media then probe further: Would you pay attention to Facebook, twitter, TV, news broadcasts?*

**CONCLUSION**

1. *Thank you very much for your participation in today’s safe sleep focus group. As a reminder, the information shared today will be used to generate recommendations for methods to reduce infant sleep related incidents but your identity will not be linked to the comments. If you have any questions or comments you’d like to share after we leave today, feel free to contact us. Your informed consent form that you kept has our contact information on the bottom of it. Thanks again!*

## Informed Consent and Confidentiality Form

WPI Interactive Qualifying Project in Partnership with the US Consumer Product Safety Commission – Analyzing Methods to Reduce Infant Sleep Related Incidents - Focus Group	
Date	November 30, 2017
Location	Petworth Neighborhood Library, Washington DC

We are students from Worcester Polytechnic Institute (WPI) located in Worcester, Massachusetts working on our Interactive Qualifying Project (IQP) with the Consumer Product Safety Commission (CPSC) on Infant Product Safety Analysis. A primary goal of this project is to provide recommendations to the Consumer Product Safety Commission and safe sleep groups nationwide about methods to reduce sleep related incidents.

We would like to understand your opinions on current recommendations to lower the risk of sudden unexpected infant death and obstacles that parents face in following the recommendations. If we have your permission, we might include information you provide in our report that will be published online. However, your identity will be kept confidential and anything from this meeting used in our report will not state your name or any identifying characteristics. We expect no harm to come from your participation in today's focus group. We also expect that you won't receive any great benefit, but that you will receive \$50 in appreciation for your participation.

All audio recordings will be held as private property and will not be released. A copy of the final report will be made available to you, should you choose, when completed and approved by WPI and the CPSC, if you provide your email below.

This focus group is completely voluntary. You may decide not to participate at any time and any information you provided will not be used in our report. You have the right not to answer any question you are not comfortable with, and you may withdraw any responses at any time.

Because of the nature of focus groups, we cannot fully ensure confidentiality of the information. However, we ask that participants respect the confidentiality of each other, and not share information outside of the group.

You are entitled to retain a copy of this agreement.

By initialing here, you agree to allow us to audio record you during this focus group. \_\_\_\_\_

By initialing here, you agree to allow us to include pictures of you in our final report. \_\_\_\_\_

If you would like a copy of our final report, please provide your email below. The report will be ready by late December.

\_\_\_\_\_

By signing below, you acknowledge that you have been informed about and consent to be a participant. By signing below, you also agree to keep confidential all proceedings of today's event and to not discuss anything from today's focus group once the session ends to respect the privacy of all participants.

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Contact Information

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# Appendix D: Focus Group Summary

Focus Group held on December 5, 2017 in North Bethesda, Maryland

## Participants:

- A 37 year old mother with a master's degree and 3 children - 5 years, 2 years, and 9 months
- A 31 year old mother with a master's degree and 3 children - 4 years, 2 years, and 7 months
- A 33 year old mother with a master's degree and 3 children - 7 years, 2 years, and 1 year
- A 35 year old mother pursuing a master's degree with 2 children - 6 years, and 3 years
- A 37 year old mother with a bachelor's degree and 2 children - 3 years, and 4 years
- A 36 year old mother with a master's degree and 2 children - 3 years and 2 years
- A 33 year old mother with a PhD and 3 children - 4 years, 2 years, and 3 weeks

All breastfeeding moms

All Maryland mothers (although some came from different places), so it is important to note bumpers are banned in MD and Chicago

## Summary/Report

### 1. Review of SUID and recommendations.

The moms seemed generally aware of the most well-known recommendations. Back to sleep was the first recommendation brought up, and everyone else seemed to be aware of that recommendation through the conversation. Other recommendations the moms listed included a tight-fitting sheet, pacifier use, placing a fan in the room, not inclining the infant while sleeping, and bare is best. While the mothers seemed to know to keep extra pillows and blankets out of the crib, some showed confusion when the term "Bare is Best" was brought up. Some mothers were unsure if this meant limiting the amount of clothing the infant was wearing.

### 2. Parent's ability to follow the recommendations.

They all expressed doubt that any parent would be able to follow all 19 recommendations, and spoke of their own personal experiences. One mother commented the recommendations are very "dramatic" and read as very black and white. Another commented that these recommendations are so specific and that there are so many of them it is impossible to follow them all. One mother said that when they were presented to her, the doctors/nurses did not do so with much sympathy and would have liked to be presented with "safe" ways to bedshare.

All the mothers said they had bedshared in the past. Some said they do not do it every night, while some said it was a nightly occurrence for them. One mother said she had trouble operating on such little sleep, and bedsharing "changed her life." Another mother spoke to the difficulty of breastfeeding at night. She said it was hard to stay awake, and would often fall asleep sitting up, which she knew was dangerous. She said bedsharing has made it easier to breastfeed at night, and many of the mothers agreed with this.

There was also confusion from the parents about conflicting advice that was given to them. They said because of the conflicts, they have to take advice with a grain of salt. One said that her lactation consultant specifically told her to avoid using pacifiers for the first month because it could cause nipple confusion. This is in direct conflict with the AAP safe sleep recommendations which encourage pacifier use. Another said her lactation consultant specifically instructed her to learn how to sleep with her baby. Conflicting messages became a big topic in the discussion.

The mothers said they received a lot of conflicting recommendations depending on who gave it. Information regarding SIDS advised against placing an infant on an incline to sleep, but parents who visited GI-experts were told inclined sleep helped reduce acid reflux. Multiple mothers expressed a desire for medical professionals from different specialties to collaborate to reduce conflicting information.

The mothers also talked about being experienced parents, and how that affects their ability to follow recommendations. When they had their first kid, they were careful to follow safety advice, and were terrified when they could not follow it. As they had more children, they let their guard down, and were able to do things such as bedsharing with less anxiety because it worked with their previous children. Another mother acknowledged it was scary to not follow recommendations, but she needed sleep. She placed her son on his side to sleep because it was the only way he would fall and stay asleep. Another mother noted that at nine months old she placed her infant on their side to sleep for the first time and that was the best night of sleep she got since they were born.

The mothers also expressed concern about their own parents' ability to follow safe sleep recommendations. One said her parents believe she is insane when she tells them recommendations because there are so many, and they differ from when her parents were new parents themselves. Another mother wondered where you draw the line when she sends her kids to her parent's house.

### **3. Obstacles that prevent the adoption of recommendations**

All the mothers in this focus group were experienced mothers with at least two children of varying ages. They spoke at length about the difficulty of following recommendations when there is more than one child to worry about. A common piece of advice they received to prevent sleep deprivation was "sleep when your baby sleeps." This was difficult to impossible for some of these mothers to follow because they had other children to worry about. They have to get sleep at night, so they are able to take care of their other young children during the day. One mother noted that while following these recommendations with the first child is easier, you have to let your guard down as you have more kids because "you don't have the capacity to follow every single rule to a T."

One mother brought up the issue of postpartum depression. Prior to birth, and the weeks immediately following it she had difficulty sleeping because of her depression. She said reading all the recommendations given to her at the hospital made her depressed, causing difficulty sleeping. She wondered if the recommendations were asking too much of parents.

Another topic that was brought up was finances. The mothers in this group were all highly educated and relatively financially secure; one participant described them as a middle-class group. They could imagine that it is difficult for mothers without their privileges to buy the baby equipment necessary to follow recommendations. One mother stated that she could not afford to buy every single product she wanted, and was had to choose what she wanted to buy new and then bought some infant products used, and accepted hand-me-downs for others.

Another point brought up was confusion about what some of the recommendations meant. One mother brought up that she does not fully understand what overheating meant. Another chimed in saying she heard infant should have one more layer than the mother has on, but this can be difficult to determine. Another mother stated she really does not understand the recommendations and wondered if they were largely based on fear and if the risks associated with each recommendation were really that big.

### **4. Where parents go for advice about products**

When this question was posed, the mothers unanimously agreed that their top source for product recommendations was other mothers. One mother pointed out she would not go to her own mother, but would instead seek the advice of mothers her own age such as friends and sisters. Another mother said she often looked to BabyCenter where mothers post product recommendations.

Another said, that as a first-time mom, she would research every little thing to make sure she was getting a safe product. But, as another mom pointed out, when you become an experienced mother, you are not as likely to do such in-depth research.

Hospitals and medical professionals were not a common source for product recommendations. One mother pointed out she gave birth at three different hospitals for her three children and they each gave her different information. Another said the information she received at one hospital was conflicting depending on who gave her the information or recommendation.

#### **5. Recommendations for recommendations**

The mothers all expressed a desire for the recommendations to change so they were easier to follow. A big problem that a lot of them saw was that the recommendations were very black and white, and they wanted to operate in the gray area. They believed there should be a “safe” way to bedshare, and that doctors/medical professionals should teach parents about ways to reduce risk of SIDS while bedsharing. One mother likened this to needle exchange programs. She said that while not bedsharing would be the safest thing to do, parents should be presented with safer ways of doing it.

Another mother expressed a desire to know which recommendations were the most important, so she could somehow prioritize them. All the mothers agreed it is impossible to follow every recommendation, but agreed having a top three or four to follow would be easier to do.

Another mother felt that the way the recommendations are communicated can affect a mother’s perception of them. She believed that the doctors and nurses were not very sympathetic that following the recommendations is difficult, and if they acknowledged their difficulty while stressing their importance she would be keener to follow them.

#### **6. Advice about campaigns**

The mothers generally agreed that they do not have time for social media. When they can log on to the internet, they are only able to do so for a few minutes. They also generally agreed that short messages would be the most effective because they would have time to read and understand them. One mother pointed to “Back to Sleep” as a good example of a quick message.

Another mother expressed desire for a sort-of one-stop-shop for parenting information regarding safe sleep run by professionals. She said she would like a place where she could find professional recommendations about how to bedshare safely, as well as read medical advice from professionals. Other mothers stated that finding good professional advice was difficult and time-consuming.

# Appendix E: Warning Label Standards

Note: Additional warning labels may be required. This list only includes warnings pertaining to sleep, suffocation and strangulation.

## F2012 – 16 Stationary Activity Centers

- No warnings pertaining to sleep

## F2085 – 12 Portable Bed Rails

- Gaps in and around bed rails have entrapped young children and killed infants

## AS/NZS 2088:2009 Prams and strollers

- Not recommended for a child under 6 months old

## AS/NZS 2195:1999 Folding cots

- The mattress for this cot should be XX mm wide, YY mm long and no more than ZZ mm thick. Using the wrong size or thickness of mattress may create hazardous gaps that could result in suffocation or reduce the height of the cot which may result in your child falling from the cot.

## F406 – 15 Non-Full-Size Baby Cribs/Play Yards

- Strangulation hazard: Strangulation Hazard: Always attach {describe attachment} securely. If {describe attachment} is not secured, child in play yard/non-full-size crib can lift or shift {describe attachment} and get neck trapped between {describe attachment} and non-full-size crib/play yard frame.
- [*Statement describing the hazard*] Never leave {describe attachment} in place when child is in non-full-size crib/play yard.
- WARNING—Never leave infant in product with sides down. Infant may roll into space between pad and loose mesh side causing suffocation.
- WARNING - Infants can suffocate in gaps between a mattress too small or too thick and product sides and on soft bedding. NEVER add a mattress, pillow, comforter, or padding.
- Child can become entrapped and die when improvised netting or covers are placed on top of product. Never add such items to confine child in product.
- Check proper fit of mattress. Should be not more than in XX thick. The maximum gap between mattress and inside of crib border (or edge) should be no more than 1 in.
- To reduce the risk of SIDS, pediatricians recommend healthy infants be placed on their back to sleep, unless otherwise advised by your physician.

## F833 – 15 Carriages and Strollers

- No warnings pertaining to sleep, suffocation or strangulation.

## F977-12 Infant Walkers

- No warnings pertaining to sleep, suffocation or strangulation.

## F1169-13 Full-Size Baby Cribs

- WARNING – Infants can suffocate on soft bedding. Never add a pillow or comforter. Never place additional padding under an infant.

## F1821-16 Toddler Beds

- WARNING – Infants have died in toddler beds from entrapment. Openings in and between bed parts can entrap head and neck of a small child. Never use bed with children younger than 15 months.



#### F1917-12 Infant Bedding and Related Accessories

- Crib Bumper: WARNING To reduce the risk of suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected. To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure.
- Flat Mattress Covers: WARNING Prevent suffocation or entanglement hazard. This cover shall only be used in a crib or sleep environment when properly secured underneath a tight-fitting sheet that fits securely on mattress and wraps around the mattress corners.
- Fitted Mattress Covers: WARNING Possible strangulation or entanglement hazard. Never use crib mattress cover unless it fits securely on crib mattress and wraps around the mattress corners.
- Pillows: WARNING To prevent suffocation, do not put any pillow in a crib or near an area where an infant may sleep. Pillows are a decorator item only and are not intended for an infant's use.
- Fitted Sheet: WARNING Prevent possible strangulation or entanglement. Never use crib sheet unless it fits securely on crib mattress.

#### F2755-15 Inflatable Air Mattresses

- Infants have suffocated on inflatable mattresses.
- Never place an infant aged birth to 15 months on an inflatable mattress
- When used by children over 15 months old, provide at least a shoulder width space between inflatable mattress and vertical surfaces to avoid entrapment.

#### F2906-13 Bedside Sleepers

- Entrapment Hazard – To prevent death from entrapment, beside sleeper must be properly secured to adult bed using attachment system.

#### F2088-15 Infant Swings

- Products having adjustable seat recline with a maximum seat back angle greater than 50 from horizontal: Keep swing fully reclined until child is at least 4 months old and can hold head up without help. If seat is too upright, infant's head can drop forward, compress the airway and result in death.

#### F2167-17 Infant Bouncer Seat

- Babies have suffocated when bouncers tipped over on soft surfaces. Never use on a bed, sofa, cushion, or other soft surface. Never leave baby unattended.

#### F2194-16e1 Bassinets and Cradles

- Infants have suffocated in gaps between extra padding and side of the bassinet/cradle on soft bedding. Use only the pad provided by the manufacturer. Never add a pillow, comforter or any other mattress for padding. To reduce the risk of SIDS, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

#### F2236-16a Soft Infant and Toddler Carriers

- Infants under 4 months can suffocate in this product if face is pressed tight against your body. Do not strap baby too tight against your body. Allow room for head movement. Keep infant's face free from obstruction at all times.

#### F2449-14a Frame and Child Carriers

- No warnings pertaining to sleep, suffocation or strangulation.

F2907-15 Sling Carriers

- Suffocation Hazard: Babies younger than 4 months can suffocate in this product if face is pressed tightly against your body. Babies at greatest risk of suffocation include those born prematurely and those with respiratory problems.

F2933-13 Crib Mattresses

- To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.
- Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute.
- Do not cover the heads of babies with a blanket or over bundle them in clothing and blankets. Overheating can lead to SIDS.
- Only use sheets and mattress pads designed specifically for crib mattresses.

F-3084-16 Infant and Infant/Toddler Rockers

- This product is not intended for unsupervised or prolonged periods of sleep.
- The upright position is only for children who have developed enough upper body control to sit up without tipping forward.

F3118-17a Infant Inclined Sleep Products

- Suffocation hazard – infants have suffocated: on added pillows, blankets and extra padding. Only use the pad provided by the manufacturer. Never place extra padding under or beside an infant.
- Always place child on back to sleep.

F2060-16 Infant Carriers

- Never leave child unattended.
- Suffocation hazard: Infant carrier can roll over on soft surfaces and suffocate child. Never place carrier on beds, sofas, or other soft surfaces.