Assessing Risk Factors For Sudden Infant Death Syndrome And Caregivers’ Perceptions Of The Cardboard Box For Infant Sleep

Nisha Dalvie

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Assessing Risk Factors for Sudden Infant Death Syndrome and Caregivers’ Perceptions of the Cardboard Box for Infant Sleep

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

by
Nisha Dalvie
2020
ASSESSING RISK FACTORS FOR SUDDEN INFANT DEATH SYNDROME AND CAREGIVERS’ PERCEPTIONS OF THE CARDBOARD BOX FOR INFANT SLEEP. Nisha S. Dalvie, Victoria Nguyen, Eve Colson, and Jaspreet Loyal. Department of Pediatrics, Yale University, School of Medicine, New Haven, CT.

Some US hospitals are giving out cardboard boxes as a way to address behaviors associated with Sudden Infant Death Syndrome (SIDS). Our goal was to evaluate the cardboard box for this purpose by quantifying current practices and qualitatively assessing caregivers’ perceptions of the cardboard box. Study participants were English or Spanish-speaking caregivers of 2-16 week old infants presenting to primary care clinics in New Haven, CT. Caregivers completed a survey asking about demographic data and SIDS risk factors, such as non-supine positioning and bed-sharing. Some caregivers also participated in a semi-structured interview about the cardboard box, created used a grounded theory approach. Of 120 survey respondents, 38% of all participants and 63% of Spanish-speaking participants reported bed-sharing at least some of the time. Factors associated with bed-sharing included Spanish as the primary language (OR: 4.3 [95% CI: 1.9-9.9]). Factors associated with non-supine positioning included Hispanic ethnicity (OR: 2.6 [95% CI 1.2-5.8]), caregiver born outside the US (OR: 4.2 [95% CI: 1.8-9.6]), Spanish as the primary language (OR: 6.3 [95% CI: 2.7-14.7]), and less than high school education (OR: 3.4 [95% CI: 1.3-8.9]). Of 50 interview participants, 52% said they would use the cardboard box for their infant to sleep in compared with 48% who said they would not. The following 3 themes emerged from the data: (1) safety of the cardboard box; (2) appearance and (3) variation in planned use. In conclusion, bed-sharing rates were higher in our study population compared to the national average, highlighting the need for better resources; however, participants were divided about whether they would actually use the cardboard box, indicating it may not be a successful intervention in our community.
Acknowledgements

Thank you to Dr. Eve Colson for her introduction to this field and her crucial expertise. Thank you to Dr. Maryellen Flaherty-Hewitt and Camisha Taylor for their flexibility in the primary care clinic workflow so that this project could succeed. Most importantly, thank you to Dr. Jaspreet Loyal for her incredible mentorship, unwavering support, and life-long lessons in pediatric clinical care that all clinician-educators should aspire to.

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Introduction

Sudden Infant Death Syndrome (SIDS): Background and Risk Factors

Sudden infant death syndrome (SIDS), a type of sudden unexpected infant death (SUID) often associated with sleep, is defined as the sudden unexpected death of a child less than 1 year of age and outside of the perinatal period that remains unexplained after thorough work-up, including a complete autopsy.\(^1\) It is the leading cause of post-neonatal mortality in the United States and the third leading cause of infant death overall, responsible for 3,600 deaths in 2017.\(^2\) Although SIDS remains a diagnosis of exclusion, risk factors related to intrinsic biological factors as well as the external sleep environment have been identified.\(^3\) The most well-established risk factors are non-supine sleep positioning, soft and loose bedding, presence of items such as pillows and blankets, sleeping on surfaces other than cribs (i.e. adult beds, sofas), and bed-sharing, where bed-sharing is defined as an infant sleeping on the same surface as another person.\(^4\) Other factors correlated with higher SIDS incidence include male sex, black race, families who identify as lower socio-economic status, mothers younger than 20, low birth weight / preterm infants, and cigarette smoking during pregnancy.\(^5\) It is important to note that none of these risk factors are sufficiently strong enough to identify a pathophysiologic cause, but have assisted in creating a descriptive profile that associates maternal, neonatal, and environmental factors with SIDS risk, as illustrated in Figure 1.

Based on this emerging profile, the American Academy of Pediatrics has published recommendations for pediatricians to counsel families on modifiable factors to prevent SIDS. The first guideline, published in 1992, recommended that infants be placed in a non-prone position for sleep; in 1994, this guideline became the basis for the “Back-to-Sleep”
**Figure 1:** Maternal, Neonatal, and Environmental Risk Factors for SIDS (Triple Risk Model adapted from Filiano and Kinney⁶)

---

campaign (later becoming the “Safe-to-Sleep” campaign), a collaboration between the AAP and the National Institute of Child Health and Development (NICHD).⁷ Over the next 8 years, the percent of infants placed on their backs to sleep increased from 17% to 70%, and the incidence of SIDS decreased by over 40%.⁸⁻⁹ Some papers note that part of the reason for the drop in SIDS incidence may simply be because of diagnostic shift, with more cases of SUID being ruled as accidental suffocation rather than SIDS as more thorough death scene investigations were performed later in the decade, but it is unlikely for changing classifications to account for all the decrease throughout the decade.¹⁰⁻¹² The safe sleep recommendations have been updated several times since the 1990s, with the most recent 2016 recommendations expanding to specify placing infants in the supine position for sleep, avoiding cigarette smoke during and after pregnancy, using a firm sleep
surface with tight fitting bedding and no other loose articles such as pillows, and to avoid bed-sharing.⁵

Despite the improved strength of these recommendations and their uptake by pediatricians and parents alike, SIDS incidence has not significantly decreased in the past two decades in the United States as a whole, although there are wide variations between states.¹³ Several large-scale studies have identified non-adherence to the AAP recommendations and associated factors as a potential explanation for this plateau. An analysis of results from the Web-based National Child Death Review Case Reporting System (NCDR-CDS) showed that, out of over 3000 cases of SIDS across 9 states, 70% of cases identified the infant on a surface not intended for infant sleep and 64% of infants were sharing a sleep surface with an adult or older child.¹⁴ The nationally representative Study of Attitudes and Factors Effecting Infant Care (SAFE), which surveyed over 3000 caregivers about infant sleep practices between 2011-2014, found that although 77.3% of mothers usually place their child supine, only 43.7% intentionally place their child exclusively supine.¹⁵ In addition, this study found that black mothers and mothers with less than a high school education were more likely to place their child in a non-supine position compared to white mothers and mothers with at least a high school education, aligning with results from a prior national survey from 1993-2007 and older studies on SIDS risk factors.⁵,¹⁶

**Barriers to Safe Sleep and Successful Interventions**

These findings lead to the all-important question: why are caregivers still practicing sleep positions that are non-adherent to current safety recommendations? It seems unlikely to be primarily caused by lack of adequate education, as caregivers who practice non-
supine positioning indicate they are aware of their doctors’ recommendations, although studies have found caregivers that use prone positioning are less likely to be aware of the associated SIDS risk.\textsuperscript{16} Studies on the “ABC” messaging of safe sleep (Alone, on the Back, and in a Crib) have found no statistically significant changes in sleep positioning before and after caregivers receive this information via crib card, as more than 80\% of them were already aware supine positioning is the safest. This study found significant changes in sleep environment before and after patients communicated with nursing about safe sleep practice, including a 40\% reduction in loose articles within the crib, but could not attribute this to “ABC” messaging due to low compliance of using the crib card.\textsuperscript{17} These findings indicate that such communication methods may not be the most effective target to reducing SIDS risk factors, possibly because lack of knowledge is no longer the biggest barrier to safe sleep practices as it was in the 1990s and early 2000s: in 2015, 99\% of caregivers at one hospital were aware of supine positioning and crib recommendations both at time of discharge and at 6 month follow-up, a significant increase compared to the National Infant Sleep Position (NISP) study results from 1993-2010.\textsuperscript{16,18}

Interventions based in health messaging have been more successful if they gave caregivers specific rationales rather than re-iterating the best practices. This has been demonstrated by randomized controlled trials in Washington, DC and Porto Alegre, Brazil that showed reduced bed-sharing rates and increased supine positioning after educational sessions designed to elicit reasons for choosing sleep positions.\textsuperscript{19-20} Other examples of successful education-based interventions include a nursing quality improvement (NQI) pilot to provide postpartum teaching about safe sleep practices prior to discharge, and a mobile health texting service to deliver tailored messages to caregivers about safe sleep for
2 months post-discharge. These were both evaluated through the Social Media and Risk-Reduction Training (SMART) clinical trial, which demonstrated that caregivers who received both the NQI and the mobile health interventions for safe sleep reported the highest percentages of adherence to safe sleep practices.\textsuperscript{21} The success of all these initiatives emphasizes the importance of understanding families’ attitudes about safe sleep practices in order to actually counteract barriers adherence: the one-on-one discussions, mobile health messages, and nursing education time were to address each caregiver’s unique concerns about safety recommendations, specifically about the comfort of supine positioning and reminders that their children are not immune to SIDS.

This was not the first study to identify caregivers’ attitudes around the AAP recommendations as a potential barrier to safe sleep practices. In 2005, qualitative findings from focus groups of mainly black mothers in urban areas, a population which has been identified as high-risk for non-adherent practices since the 1990s, demonstrated concerns about choking in supine position, lack of trust in health providers compared to mothers in their families, and the perception that infants would be more comfortable on their stomachs.\textsuperscript{22} The previously mentioned Study of Attitudes and Factors Effecting Infant Care (SAFE) from 2011-2014 also examined caregivers’ attitudes about sleep practices, and identified that mothers who believed they did not have control over their infants’ choice of sleeping position were much more likely to include prone sleep in their intended practices.\textsuperscript{15} These findings make it clear that simply stating AAP recommendations to caregivers is not enough to ensure their uptake- successful interventions must address the root causes of parents’ concerns, whether that means anticipatory explanations about choking risk in the supine position or being culturally respectful of mothers’ traditions.
while explaining the dangers of bed-sharing. This framework is particularly important for populations that are already at a higher risk for SIDS, particularly pre-term infants, black families, and younger or less formally educated mothers.

*Cardboard Box for Infant Sleep*

With the context of SIDS risk factors, AAP recommendations, and the best interventions to improve adherence, we can now focus on a proposed intervention that has captured the attention of pediatricians around the globe: a cardboard box for infant sleep. The government of Finland has utilized this resource since the 1930s, during which time infant mortality rate was recorded as high as 9\%.\textsuperscript{23-24} Initially, only low-income mothers who had attended all their prenatal care appointments were eligible, making the box both an incentive for mothers to attend all their appointments and a public health intervention for mothers who could potentially not afford another sleeping space; the box itself came with gauze diapers, muslin to stitch baby clothes, and a baby mattress.\textsuperscript{25} Although it is impossible to determine the effect of these kits on maternal health or infant outcomes such as SIDS, especially with other important interventions such as vaccinations and midwife delivery beginning during this time period, the infant mortality rate in Finland decreased to 3\% by 1950 and is now 0.17\%, one of the lowest in the world.\textsuperscript{26} The cardboard box kit is now offered to all new caregivers, including those who adopt, and includes indoor and outdoor baby clothes, diapers, toys, bibs, bathing products, and a picture book in addition to the fitted mattress.\textsuperscript{27} Over 95\% of caregivers choose the kit over an alternative cash voucher, indicating its popularity and long-standing place in Finnish culture.\textsuperscript{23}

Its popularity is expanding to other countries, both in the form of public health interventions and commercial products. In 2017, Scotland approved the distribution of
baby boxes with a mattress, fitted sheet, clothes, a thermometer, bath towels, and a changing mat to any mother who fills out a request form at her 24-week perinatal appointment, at a £6 million annual cost. The Finnish baby box has also been cited as an inspiration for products such as the Barakat Bundle, a kit which includes a foldable cradle and sterile delivery supplies for rural Indian mothers, and the Thula Baba Box, a plastic bin for South African mothers to use as an infant bath tub complete with bathing supplies.

In the United States and Canada, the baby box has become a phenomenon largely due to The Baby Box Company, a company that sells baby boxes directly to parents as well as to hospitals for large-scale distribution. All boxes come with a mattress and fitted sheet, but can also include various clothes, toys, and diapers for a higher cost; all boxes also come with an online educational course created by The Baby Box Company on SIDS risk factors and safe sleep practices.

Part of the cardboard boxes’ popularity can be attributed to Dr. Meghan Heere’s work at Temple University Hospital. In 2016, as director of the well-baby nursery, she set-up a large pilot study including over 2,500 women who delivered at Temple University Hospital. Mothers were surveyed over the phone about bed-sharing and breastfeeding practices within the first week of their hospital discharge. 1,264 of these women received no education safe sleep practices or other resources after delivery; 423 of them received face-to-face education on safe sleep practices prior to discharge; and 391 received a cardboard box for their infants to sleep in as well as face-to-face education on safe sleep practices. Analysis demonstrated that women who received both the cardboard box and the inpatient education reported 27% less bed-sharing with their infant in the first week of life compared to women in the control group, and exclusively breastfeeding mothers reported
nearly 50% less bed-sharing compared to women in the control group. Half of the mothers reported using the cardboard box for infant sleeping, with 12% using it as the primary sleeping space; many mothers also reported satisfaction with the box, especially as proximity to the infant facilitated breast-feeding.\textsuperscript{33}

The cardboard box was deemed a successful intervention based on these results, prompting the creation of the Sleep Awareness Family Education at Temple (SAFE-T) Program at Temple University Hospital. This program was created to continue funding the distribution of cardboard boxes and face-to-face safe sleep education from specially trained inpatient nursing staff. The boxes are purchased from The Baby Box Company, with funding from donations by Temple University Hospital and the Lewis Katz School of Medicine at Temple University; the SAFE-T program has given out over 10,000 boxes with safe sleep education since 2016.\textsuperscript{34} Dr. Heere’s research efforts are now focused on quality improvement cycles for the SAFE-T program as well as long-term effects on sleeping practices during the first year of life and Philadelphia’s SUID mortality rate.\textsuperscript{35}

The results of this program, combined with the reputation of baby boxes from Finland, prompted other hospitals in the US and Canada to partner with The Baby Box Company to give out cardboard boxes and a membership for their online safe sleep education program.\textsuperscript{36} After year-long pilots, New Jersey and Texas now have universal state-wide programs for every mother who wants to receive a box, which totaled to about 400,000 boxes given away from each state in 2017.\textsuperscript{37-38} Alabama’s public health department sponsored 60,000 boxes between 2017 and 2018 with the plan to examine their effect on bed-sharing rates before increasing distribution plans.\textsuperscript{39} Ohio state government launched a partnership with several Cincinnati hospitals to give out 160,000 boxes in 2017,
and similar pilot programs have launched in Alberta and Toronto, Canada to a few thousand expecting mothers in 2018.\textsuperscript{40-42}

Despite the growing popularity of baby boxes in the US, many pediatricians, government officials, and parents have reservations about the use of the cardboard box for infant sleep. The AAP has declined to state that cardboard boxes are safe, citing both the lack of evidence in preventing infant deaths as well as the lack of regulation around them.\textsuperscript{43} Since the boxes do not meet the federal definition of a crib, bassinet, play yard, or handheld carrier, they are not required to meet the same regulations set by the Consumer Product Safety Commission.\textsuperscript{44} Experts, including members of the AAP’s Task Force on SIDS, have expressed concern about how popular the cardboard boxes are, especially given their somewhat vague intended use: per the company’s instructions, the box is meant to be “placed on the floor or a sturdy wide surface, such as a coffee table” and not placed in the adult bed or used as a carrier, yet the way they are designed easy for parents to do both.\textsuperscript{45-46} Pediatricians have also raised specific concerns about the durability of cardboard, the lack of visibility in a cardboard box compared to a crib or bassinet, and the risk of injury if the box is placed on the floor or a high surface\textsuperscript{47}; these exact concerns were echoed by a focus group of mothers when asked interviewed about the cardboard boxes.\textsuperscript{48}

\textit{Our Project}

Amidst the abundance of controversy, the fact remains that there is limited evidence on cardboard boxes as an intervention to improve safe sleep practices and SIDS outcomes. Their safety and efficacy, especially in populations at higher risk for SIDS, are of particular research interest as their usage expands into larger academic hospital centers. Therefore, we sought to evaluate cardboard boxes as a resource for caregivers at Yale New
Haven Hospital’s Pediatric Primary Care Centers (PCC), a population that has been previously identified as at high risk for unsafe sleep practices. By collecting baseline data about current sleep practices and SIDS risk factors among these caregivers, our objective was to better understand our own community as well as analyze whether the cardboard box would address the same barriers that Dr. Heere identified at Temple University Hospital. Secondarily, we would collect data on attitudes towards safe sleep practices and perceptions of the cardboard box itself to understand what caregivers’ response would be if the boxes were to be distributed by the hospital, especially in the context of The Baby Box Company considering a partnership with Yale New Haven Hospital. To this end, we designed a mixed-methods study combining a quantitative survey with a qualitative interview in order to capture both of these key steps in designing a successful intervention against unsafe sleep and SIDS.
Statement of Purpose

To evaluate the cardboard box for infant sleep as an intervention to improve safe sleep outcomes among urban caregivers, by identifying their current barriers to safe sleep practices and understanding their perceptions of the cardboard box as a resource.

Specific Aims

1. Quantify baseline prevalence of SIDS risk factors among caregivers in our community, including formula feeding, smoking, bed-sharing, and infant sleep positioning.

2. Elicit caregivers’ attitudes towards safe sleep in the context of the cardboard box and determine what factors influence positive or negative qualitative perceptions.
Methods

Setting and Sample

The study was conducted at two pediatric primary care clinics in New Haven, Connecticut. Our sample included English and Spanish-speaking mothers of infants ages 2 to 16 weeks who presented for well-child visits at our pediatric primary care clinics from June to August 2017. We attempted to approach every family with an infant aged 2 to 16 weeks on any given day in clinic. Our inclusion criteria were designed to identify participants who have experienced a key concept being explored in the study and/or have membership in a subgroup with distinct characteristics; in this case, the subgroup in this study were mothers of young infants, thus the use of the cardboard box would be relevant to them and would allow them to make salient comments about its usage for the qualitative portion. Patients were screened for inclusion / exclusion criteria by Jaspreet Loyal, the primary investigator (JL) on a weekly basis, with the list being passed down to the student Nisha Dalvie (ND) once reviewed and approved by Maryellen Flaherty-Hewitt, the clinic director (MFH). We chose the pediatric primary care clinics to access families at higher risk of not following AAP recommendations for safe sleep, as identified in the background, and were also likely to use our hospital maternity services.49

Data collection

Our mixed-methods approach included in-person surveys and audio-recorded interviews, both of which were performed by the student (ND) with caregivers at their child’s well visits between 2-16 weeks after birth. The quantitative survey was adapted from the Infant Care Practices survey, a validated tool administered nationally by the Slone Epidemiology Center.51 Survey data included questions about where the infants sleeps,
infant sleep positioning practices and intentions, bed-sharing practices and intentions, and other risk factors such as cigarette smoking and breast feeding; demographic data collected included age, race/ethnicity, years of education, and health insurance (see Appendix A for full survey). The semi-structured interviews were conducted using a grounded theory approach, where each new interview was discussed by the research team in order to inform the structure of the next interview. An initial interview guide was created based on current literature and expert opinion. The interview guide (Table 1) was revised in an iterative process as new information emerged from the data.

**Table 1:** Semi-structured Interview Guide

<table>
<thead>
<tr>
<th>Interview question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you heard of the cardboard box for babies to sleep in?</td>
</tr>
<tr>
<td>If no, research associate shows picture or actual box.</td>
</tr>
<tr>
<td>2. What do you think of the cardboard box?</td>
</tr>
<tr>
<td>3. What are some things you like about the cardboard box? What are some things you dislike about the cardboard box?</td>
</tr>
<tr>
<td>4. What do you think you would use it for? (Probing question: Would you use it for your baby to sleep in?)</td>
</tr>
<tr>
<td>5. (If participant stated he/she would not use it for their infant to sleep in). The hospital is planning to give the cardboard box to parents at no cost, what do you think about that? How would this affect your decision to use the cardboard box?</td>
</tr>
<tr>
<td>6. Where would you put the cardboard box in your home?</td>
</tr>
<tr>
<td>7. Do you have anything else to share?</td>
</tr>
</tbody>
</table>
Verbal was obtained from each participant in English or Spanish by the student (ND) at the time of their appointment. The survey was conducted via secure Yale Qualtrics link on an encrypted electronic tablet held by the student (ND), while verbally asking each question to the caregiver in either English or Spanish. Surveys were conducted during caregivers’ waiting time in the exam room and took approximately 10 minutes each. Semi-structured interviews were conducted by the student (ND) in a private room in the clinic space after the conclusion of the medical visit, each lasting for 15 to 20 minutes. During the interview, participants were shown a picture of the cardboard box (Figure 2) or the physical box itself – at the time of this study, the cardboard boxes were being distributed with a lid. Interviews were audiotaped and transcribed verbatim by the student (ND). Interviews conducted in Spanish were translated into English during the transcription process by the student (ND), who is a certified Spanish language translator in the Yale New Haven Hospital system. Approval from the Yale University Human Investigation Committee as well as the primary care clinic directors was obtained prior to beginning the project.

**Figure 2:** Image of the cardboard box shown to qualitative interview participants
**Data Analysis**

Quantitative survey data was exported from Qualtrics to Microsoft Excel 2016 by the student (ND) and organized by anonymous, randomized response ID. Variable names were calibrated for further analysis and relationships of interest were identified by the student (ND) before being sent to the primary investigator (JL) who had access to the necessary software. Data analysis, including calculated chi-square values, odds ratios, and associated 95% confidence intervals, was completed in SPSS (Armonk, NY). Reported behaviors were compared demographic data to quantify outcomes such as safe infant positioning, bed-sharing frequency, and other practices of interest. Unadjusted odds ratios for which the confidence interval did not include 1.0 were considered statistically significant.

Data from the qualitative transcripts were analyzed using coding techniques common to qualitative research using grounded theory methodology.\textsuperscript{53-54} Data analysis was conducted in an iterative process, with data collection and analysis continuing concurrently until no new themes emerged (‘thematic saturation’). In the first part of the analysis, an initial code list was created based on the first read-through of transcripts. Codes, defined as participant’s words, phrases, or authors’ concept words, served as labels for important participant data. Transcripts were coded by 4 independent investigators: the student (ND), the primary investigator (JL), an expert in the field of safe sleep practices (EC), and a nursing trainee (VN). Transcripts were then compared and discussed as a group to share reflections and abstract commonalities in the codes each author had assigned. From these codes, the initial code list was created. This list was iteratively revised using the constant comparative method as new interviews were conducted and coded. In the second part of the
analysis, codes were clustered into cohesive categories. To reduce redundancy among the categories and to ensure the category linkages were firmly established, all researchers came to agreement in the coding schema, which was then reviewed for data that expressed the main ideas or themes. In the third part of the analysis, data were reviewed for evidence of relationships among themes.

Trustworthiness in the data was established through 1) ongoing debriefing sessions by the authors to discuss reflections, insights and incoming data; 2) coding development over 3 months, enabling prolonged engagement with the data to recognize biases or distortions and 3) member checking during interviews to ensure correct interpretation of what was being shared, and by discussing tentative themes and interpretations with a subset of research participants. Data was organized in Microsoft Excel 2016.
Results

Overall

Of 129 caregivers approached, 120 caregivers (93%) consented to fill out the survey. Out of the participants who consented to the survey, 50 caregivers (42%) also consented to participate in the semi-structured interview. Most of the mothers who did not consent to either the survey or the interview portion cited time as their principal reason for not participating. Characteristics of survey and interview participants are shown in Table 2.

Sex of infants was almost equally split between male and female in both the total surveyed group and subset who also participated in the interview. There was representation of several infant ages, with 42.5% presenting at their 2 week or 4 week well-child visits, 25.8% presenting at their 4 month well-child visit, and 31.7% presenting in between those visits; distribution was comparable in the interview-participant subset. 59.2% of respondents identified as mothers and the primary caregiver of their infant, compared to 35% of respondents identifying equal caregiving between mother and father and a small group (5.8%) identifying as non-parent caregivers, consisting of grandparents, an aunt, and a non-relative. In the interview-participating group, 90% of participants were mothers who identified as the primary caregiver; only 2 mother-father pairs were interviewed, as well as one grandmother. Caregiver age was nearly equally distributed between younger than 30 years and older than 30 years, with no caregivers younger than 20 years. For 26.7% of caregivers, the infant at the appointment was their first child compared to 73.3% with at least one other child at home. In the interview-participating subset, this distribution was similar with 36% respondents having only one child and 67% having more than one.
### Table 2: Demographics of Participants (Total N = 120, Interview N = 50)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Number (Percent)</th>
<th>Interview Number (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infant Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>59 (49.2%)</td>
<td>26 (52%)</td>
</tr>
<tr>
<td>Male</td>
<td>61 (50.8%)</td>
<td>24 (48%)</td>
</tr>
<tr>
<td><strong>Infant’s age (weeks)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 1 month</td>
<td>51 (42.5%)</td>
<td>24 (48%)</td>
</tr>
<tr>
<td>1-3 months</td>
<td>38 (31.7%)</td>
<td>15 (30%)</td>
</tr>
<tr>
<td>4 months</td>
<td>31 (25.8%)</td>
<td>11 (22%)</td>
</tr>
<tr>
<td><strong>Primary Caregiver</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>71 (59.2%)</td>
<td>45 (90%)</td>
</tr>
<tr>
<td>Mother and Father</td>
<td>42 (35.0%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Other&lt;sup&gt;A&lt;/sup&gt;</td>
<td>7 (5.8%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td><strong>Age of Primary Caregiver (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 30</td>
<td>57 (47.5%)</td>
<td>27 (54%)</td>
</tr>
<tr>
<td>30+</td>
<td>63 (52.5%)</td>
<td>23 (44%)</td>
</tr>
<tr>
<td><strong>Number of Children in household</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One</td>
<td>32 (26.7%)</td>
<td>18 (36%)</td>
</tr>
<tr>
<td>Two or more</td>
<td>88 (73.3%)</td>
<td>32 (64%)</td>
</tr>
<tr>
<td><strong>Caregiver’s country of birth</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States incl. Puerto Rico</td>
<td>86 (71.7%)</td>
<td>37 (74%)</td>
</tr>
<tr>
<td>Other&lt;sup&gt;B&lt;/sup&gt;</td>
<td>34 (28.3%)</td>
<td>13 (26%)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity of Caregiver</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>60 (50%)</td>
<td>24 (48%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>50 (41.7%)</td>
<td>14 (28%)</td>
</tr>
<tr>
<td>White</td>
<td>5 (4.2%)</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2.5%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Other&lt;sup&gt;C&lt;/sup&gt;</td>
<td>2 (1.7%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td><strong>Preferred Language of Caregiver</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>85 (70.8%)</td>
<td>38 (76%)</td>
</tr>
<tr>
<td>Spanish</td>
<td>35 (29.2%)</td>
<td>12 (24%)</td>
</tr>
<tr>
<td><strong>Highest Education Level of Caregiver</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>20 (16.7%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>High school/GED</td>
<td>55 (45.8%)</td>
<td>25 (50%)</td>
</tr>
<tr>
<td>Some college or college graduate</td>
<td>45 (37.5%)</td>
<td>21 (42%)</td>
</tr>
<tr>
<td><strong>Smoking Status of Caregiver</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Smoker</td>
<td>5 (4.2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Before Pregnancy</td>
<td>15 (12.5%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Never smoked</td>
<td>100 (83.3%)</td>
<td>46 (92%)</td>
</tr>
<tr>
<td><strong>Breastfeeding Status of Caregiver</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mostly or only breastmilk</td>
<td>51 (42.5%)</td>
<td>25 (50%)</td>
</tr>
<tr>
<td>Equal breastmilk and formula</td>
<td>28 (23.3%)</td>
<td>15 (30%)</td>
</tr>
<tr>
<td>Mostly or only formula</td>
<td>41 (34.2%)</td>
<td>10 (20%)</td>
</tr>
</tbody>
</table>

<sup>A</sup>Other includes grandparents (5), an aunt (1), and a non-relative such as babysitter or friend (1)

<sup>B</sup>Includes Ecuador (9), Mexico (9), the Dominican Republic (1), El Salvador (1), Guatemala (2), Honduras (2), Trinidad (1), Spain (2), Albania (1), Greece (1), Barbados (1), Jamaica (1), Grenada (1), China (1), and Togo (1)

<sup>C</sup>Includes Pacific Islander (1) and Native American (1)
Of 120 total participants, 50% identified as black and 41.7% identified as Hispanic, compared to 4% of participants who identified as white. In the interview-participating subset, 47% of respondents identified as black and 28% identified as Hispanic and compared to 16% of participants who identified as white. The majority of participants (71.7%) were either from the continental United States or Puerto Rico compared to 28.3% from various other countries in Central America, South America, Europe, and Asia; distribution was similar in the interview-participating subset. The majority of participants identified English as their primary language (70.8%) compared to 29.2% of primarily Spanish speakers. For the interview portion, 76% of interviews were conducted in English and 24% were conducted in Spanish.

Of 120 participants, 45.8% reported their highest level of education was high school or equivalent compared to 16.7% with less than high school education and 37.5% with at least some college education; distribution was similar in the interview subset. Most participants reported they had never smoked (83.3%) compared to 12.5% who quit before pregnancy and 4.2% who smoked during pregnancy or currently; distribution was similar in the interview subset. Of 120 participants, 42.5% reported mostly or exclusively breastfeeding compared to 34.2% who used mostly or exclusively formula and 23.3% who did an equal mix of breastfeeding and formula feeding. In the interview subset, 50% of participants reported mostly or exclusively breastfeeding compared to 20% who mostly or exclusively formula fed and 30% who reported an equal mix of formula and breastfeeding.
Sleep practices

Survey participants were asked about how they position their infant to sleep (on the back, on the side, or on the stomach), where their infant sleeps (free text response that was grouped into categories), and the environment their infant sleeps in (i.e. with a firm mattress, with a swaddle blanket, or with other items such as thick blankets, pillows, or toys.) In the context of each of these behaviors, they were also asked to identify their initial plans for sleep practices before bringing their infant home, the most commonly occurring practice since bringing their infant home, and any other practices that sometimes occur; these are signified by “Intended Practice”, “Most Common Practice” and “Practice occurs Sometimes” respectively in Table 3.

Table 3: Intended and Most Commonly Practiced Sleep Behaviors (Total N = 120)

<table>
<thead>
<tr>
<th></th>
<th>Intended PracticeA (% of Total)</th>
<th>Most Common Practice (% of Total)</th>
<th>Practice occurs Sometimes (% of Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine</td>
<td>103 (85.8%)</td>
<td>105 (87.5%)</td>
<td>120 (100%)</td>
</tr>
<tr>
<td>Side</td>
<td>25 (20.8%)</td>
<td>10 (8.7%)</td>
<td>24 (20%)</td>
</tr>
<tr>
<td>Prone</td>
<td>18 (15%)</td>
<td>5 (4.3%)</td>
<td>13 (10.8%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crib / Bassinet</td>
<td>120 (100%)</td>
<td>115 (95.8%)</td>
<td>117 (97.5%)</td>
</tr>
<tr>
<td>Pack and Play</td>
<td>0</td>
<td>1 (.8%)</td>
<td>35 (29.2%)</td>
</tr>
<tr>
<td>Car seat</td>
<td>0</td>
<td>0</td>
<td>6 (5%)</td>
</tr>
<tr>
<td>Moses basketB</td>
<td>2 (1.7%)</td>
<td>2 (1.7%)</td>
<td>2 (1.7%)</td>
</tr>
<tr>
<td>Bed-sharingC</td>
<td>25 (20.7%)</td>
<td>2 (1.7%)</td>
<td>46 (38.3%)</td>
</tr>
<tr>
<td><strong>Environment</strong>D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Firm mattress</td>
<td>-</td>
<td>113 (94.1%)</td>
<td>120 (100%)</td>
</tr>
<tr>
<td>Swaddle blanket</td>
<td>-</td>
<td>17 (14.2%)</td>
<td>29 (24.2%)</td>
</tr>
<tr>
<td>Thick blankets, pillows, or toys</td>
<td>-</td>
<td>2 (1.7%)</td>
<td>6 (5%)</td>
</tr>
</tbody>
</table>

ARespondents were able to select more than one option for Intended Practice and Practices occurring Sometimes, so the sum of all responses is greater than total N of 120
BIncludes any product designed to be placed on adult mattress
CIncludes any surface where an infant sleeps on the same surface as another person, such as adult mattresses and sofas
DCaregivers were not asked about intended sleeping environment and these are not mutually exclusive choices, so the sum of all responses is greater than total N of 120
Participants that intended a specific practice and practiced it exclusively versus participants that intended a specific practice but ended up also practicing other behaviors were categorized in Table 4; participants whose current practices were not included in their initially intended practices are also listed in Table 4. Any participant whose current practice differed from their intended practices were asked to explain the reason for the change in a free text option. Participants were only asked about intended behaviors in the context of sleep position and location, so no data on intentions for sleep environment could be organized. Participants were also asked about intentions for sleeping in the same room, but not the bed, as their infant, but the majority of these responses had complicated explanations based on number of caregivers in the home, presence of other children, and infants’ ages, so these results were not further organized or analyzed.

Table 4: Changes in Intentions: Exclusive Practices, Non-Exclusive Practices, and Divergent Practices (Total N = 120)

<table>
<thead>
<tr>
<th></th>
<th>Practice was Intended and Occurs Exclusively (% of Intended Practitioners)</th>
<th>Practice was Intended but Does Not Occur Exclusively (% of Intended Practitioners)</th>
<th>Practice was Not Intended but is Now Practiced (% of Non-Intended Practitioners)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine</td>
<td>78 (75.7%)</td>
<td>25 (24.3%)</td>
<td>4 (23.5%)</td>
</tr>
<tr>
<td>Side</td>
<td>0</td>
<td>25 (100%)</td>
<td>5 (6.5%)</td>
</tr>
<tr>
<td>Prone</td>
<td>0</td>
<td>18 (100%)</td>
<td>14 (18.2%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crib / Bassinet</td>
<td>45 (37.5%)</td>
<td>85 (62.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Pack and Play</td>
<td>0</td>
<td>0</td>
<td>35 (29.2%)</td>
</tr>
<tr>
<td>Car seat</td>
<td>0</td>
<td>0</td>
<td>6 (5%)</td>
</tr>
<tr>
<td>Moses basket</td>
<td>1 (50%)</td>
<td>1 (50%)</td>
<td>0</td>
</tr>
<tr>
<td>Bed-sharing&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1 (4%)</td>
<td>24 (96%)</td>
<td>9 (9.5%)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Respondents were able to select more than one option for Intended Practice and Practices occurring Sometimes, so the sum of all responses is greater than total N of 120

<sup>b</sup>Includes any surface where an infant sleeps on the same surface as another person, such as adult mattresses and sofas
Sleep positioning

Out of 120 participants, 105 caregivers (87.5%) reported supine positioning as their most common practice compared to 15 caregivers (12.5%) who most commonly practiced prone or side positioning, but a total 37 caregivers (30.8%) reported non-supine positioning at least sometimes. Only 78 caregivers (65% of total participants and 75.5% of those who intended to practice supine positioning) practiced supine positioning exclusively, leaving 25 caregivers who intended to practice supine positioning but also practiced side and prone positioning. Of 77 caregivers whose plans only included supine positioning, 5 caregivers ended up switching to side positioning (6.5%) and 14 caregivers ended up switching prone (18.2%). Some reasons these caregivers cited for their switch included “feeling that [their baby] had a preference for [their] stomach”, “getting advice that [their baby] might choke [in supine position]”.

Of 120 participants, 43 caregivers (35.8%) reported that non-supine positioning was part of their intended practice (20.8% planned on side positioning compared to 15% who planned on prone positioning). Of these 43 caregivers, only 4 ended up switching to supine positioning (23.5%); these 4 caregivers all cited education about safe sleep from their pediatrician as their main reason for switching. Unadjusted odds-ratio analysis for association between demographic data and supine versus non-supine positioning is outlined in Table 5. Association was considered statistically significant if the 95% confidence interval (CI) did not include 1.0; based on this criteria, caregivers born outside of the US (including Puerto Rico), caregivers of Hispanic ethnicity, and caregivers with less than high school education, and primarily Spanish-speaking caregivers were associated with greater odds of non-supine positioning.
Table 5: Factors Associated with Non-Supine Positioning (Total N = 120)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Any Non-Supine Positioning (N=42)</th>
<th>Only Supine Positioning (N=78)</th>
<th>Unadjusted OR (95% CI)A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infant</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Sex</td>
<td>18 (42.9%)</td>
<td>41 (52.5%)</td>
<td>0.7 (0.3-1.4)</td>
</tr>
<tr>
<td>Infant &lt; 2 months old</td>
<td>14 (33.3%)</td>
<td>46 (59.0%)</td>
<td>0.5 (0.2-1.0)</td>
</tr>
<tr>
<td>Mostly or exclusively breastfed</td>
<td>16 (38.1%)</td>
<td>35 (44.9%)</td>
<td>0.8 (0.4-1.6)</td>
</tr>
<tr>
<td><strong>Caregiver</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother ± FatherB</td>
<td>39 (92.8%)</td>
<td>74 (94.9%)</td>
<td>0.7 (0.1-3.2)</td>
</tr>
<tr>
<td>Age &lt;30 yrs old</td>
<td>17 (40.5%)</td>
<td>40 (51.3%)</td>
<td>0.6 (0.3-1.4)</td>
</tr>
<tr>
<td>One child in the home</td>
<td>11 (26.2%)</td>
<td>21 (26.9%)</td>
<td>0.7 (0.3-1.8)</td>
</tr>
<tr>
<td>Non-US / Puerto Rico born</td>
<td>20 (47.6%)</td>
<td>14 (17.9%)</td>
<td>4.2 (1.8-9.6)</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>24 (57.1%)</td>
<td>26 (33.3%)</td>
<td>2.6 (1.2-5.8)</td>
</tr>
<tr>
<td>Black race</td>
<td>18 (42.9%)</td>
<td>42 (53.8%)</td>
<td>0.5 (0.2-1.0)</td>
</tr>
<tr>
<td>Spanish as Primary Language</td>
<td>22 (52.4%)</td>
<td>13 (16.7%)</td>
<td>6.3 (2.7-14.7)</td>
</tr>
<tr>
<td>Less than high school education</td>
<td>13 (30.1%)</td>
<td>7 (9%)</td>
<td>4.5 (1.6-12.6)</td>
</tr>
<tr>
<td>Any tobacco smokingC</td>
<td>7 (16.7%)</td>
<td>13 (16.7%)</td>
<td>1.0 (0.5-2.1)</td>
</tr>
</tbody>
</table>

AOR indicates Odds Ratio; CI indicates Confidence Interval
BIncludes mothers who co-identified as primary caregivers with fathers
CDefined as past or current tobacco smoking
Sleep location

Out of 120 survey responses, 115 caregivers (95.8%) indicated the crib or bassinet as their infant’s most common sleeping space, leaving 1 caregiver (0.8%) who identified their infant’s usual sleeping space as a Pack and Play, 2 caregivers (1.7%) who identified a Moses basket or similar product designed to go in the adult bed as their infant’s usual sleeping space, and 2 caregivers (1.7%) who identified bed-sharing in an adult mattress or sofa as their infant’s usual sleeping space. 45 of these caregivers (37.5%) exclusively placed their infant in a crib or bassinet to sleep, leaving 85 caregivers (62.5%) who planned to place their infant in a crib or bassinet but at least some times placed their infant elsewhere. No caregivers identified Pack and Plays or car seats as part of their child’s intended sleep area, but 41 caregivers (34.2%) reported using them occasionally.

Out of 120 respondents, 25 caregivers (20.7%) included bed-sharing in their intended practices. However, a total of 46 caregivers (38.3%) reported actually bed-sharing at least some of the time. Out of 95 caregivers that did not plan to bed-share, 9 respondents (7.5% of total and 9.5% of caregivers that did not plan to bed-share) ultimately practiced bed-sharing at least some of the time, citing convenience with breast-feeding or wanting to spend more quality time with their child as their main reasons for switching.

Odds-ratio analysis for association between demographic data and bed-sharing is outlined in Table 6. Association was considered statistically significant if the 95% confidence interval (CI) did not include 1.0; based on this criteria, only caregivers who identified Spanish-as their primary language were associated with greater odds for bed-sharing.
Table 6: Factors Associated with Bed-Sharing (Total N = 120)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Any Bed-sharing N=46</th>
<th>No Bed-sharing N=74</th>
<th>Unadjusted OR (95% CI)A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infant</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Sex</td>
<td>27 (58.7%)</td>
<td>32 (43.2%)</td>
<td>1.9 (0.9-3.9)</td>
</tr>
<tr>
<td>Infant &lt; 2 months old</td>
<td>21 (45.7%)</td>
<td>31 (41.9%)</td>
<td>1.2 (0.5-2.4)</td>
</tr>
<tr>
<td>Mostly or exclusively breastfed</td>
<td>9 (19.6%)</td>
<td>8 (10.8%)</td>
<td>2.0 (0.7-5.6)</td>
</tr>
<tr>
<td><strong>Caregiver</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother ± FatherB</td>
<td>44 (95.7%)</td>
<td>69 (93.2%)</td>
<td>1.5 (0.3-8.5)</td>
</tr>
<tr>
<td>Age &lt;30 yrs old</td>
<td>23 (50%)</td>
<td>34 (45.9%)</td>
<td>1.2 (0.6-2.4)</td>
</tr>
<tr>
<td>One child in the home</td>
<td>17 (37%)</td>
<td>15 (20.3%)</td>
<td>2.3 (0.9-5.3)</td>
</tr>
<tr>
<td>Non-US born</td>
<td>17 (37%)</td>
<td>17 (23%)</td>
<td>1.9 (0.8-3.9)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>23 (50%)</td>
<td>27 (36.5%)</td>
<td>1.7 (0.8-3.6)</td>
</tr>
<tr>
<td>Black</td>
<td>23 (50%)</td>
<td>37 (50%)</td>
<td>1.0 (0.5-2.0)</td>
</tr>
<tr>
<td><strong>Spanish as Primary Language</strong></td>
<td>22 (47.8%)</td>
<td>13 (17.6%)</td>
<td><strong>4.3 (1.9-9.9)</strong></td>
</tr>
<tr>
<td>Less than high school education</td>
<td>12 (26.1%)</td>
<td>8 (10.8%)</td>
<td>2.4 (0.8-3.9)</td>
</tr>
<tr>
<td>Any tobacco smokingC</td>
<td>8 (17.4%)</td>
<td>12 (16.2%)</td>
<td>1.1 (0.4-2.9)</td>
</tr>
</tbody>
</table>

A OR indicates Odds Ratio; CI indicates Confidence Interval
B Includes mothers who co-identified as primary caregivers with fathers
C Defined as past or current tobacco smoking
**Qualitative Themes**

We identified 3 major themes: (1) safety, (2) appearance and (3) planned use. Themes, subthemes, and exemplar quotes are compiled in Table 5 with additional quotes in the text below. These results are also reported in a published study.55

1. **Safety**

Participants expressed concern with the safety of the cardboard box material as not being sturdy enough and that the lid had the potential for suffocation if the cardboard box was left covered while the baby was inside. Another concern was the possibility of the infant rolling out of the cardboard box in their sleep. In contrast, others felt that the cardboard box would be safe for the baby. For example, one participant discussed her friends’ usage of a similar product which influenced her perspective. She stated, “In my group there are moms who have baskets for the baby in their beds. So, this is like that...so I will use it.” Another participant valued a physician’s recommendation, “Well if the doctors give it to you, you’re supposed to use it right? Like if this is safer than a crib or whatever then I would prefer to use that.”

2. **Appearance**

For some participants, the simplicity of the design was appealing. One participant stated, “It’s cute, I like it.” For another participant, the cardboard was unattractive. She stated, “It’s not appealing at all, it literally looks like a box that you would...use to mail something.” When the physical box was brought to clinic, many participants commented on its apparent bulkiness. Some participants compared the cardboard box to existing products like cribs or bassinets, which were perceived as being more socially acceptable than the cardboard box. Some participants associated use of the cardboard box with a
negative social status: “You look like you’re giving away your baby…it looks like a dog box.”

3. Variation in Planned Use

When participants were asked how they would use the box, some planned to use it in their bed. One participant stated, “We could have it in the bed, it could go in the middle.” Another participant said she would only use the box for storage, and one participant thought of using it during the day, stating “I think it is also nice to use during the day when he’s playing, and I’m trying to keep watch on him.” Participants commented on the ease of travel with the cardboard box and the convenience of having the cardboard box close by when breastfeeding. Some participants were excited at the prospect of receiving the cardboard box and contents at no cost. For some participants who initially stated they wouldn’t use the cardboard box, the no cost provision changed their attitude and many stated they would use the product if given at no cost. Other participants stated that they had already purchased cribs and therefore had no use for the cardboard box.

*Perceptions of the Cardboard Box, Demographics, and Sleep Practices*

Out of 50 interview participants, 26 (52%) ultimately said they would use the cardboard box for their infant to sleep in, 21 (42%) said they would not use it for their infant to sleep in, and 3 (6%) were unsure. For the interview-participating subset, analysis was performed to determine if parents who stated they would or would not use the cardboard box for their infant to sleep in had similar demographic factors or reported similar sleep behaviors – results are shown in Table 9. No association based on unadjusted ORs was found between indicated interest in using the cardboard box for infant sleep and any demographics, including those known to be SIDS risk factors, nor with unsafe sleep practices.
Table 8: Caregivers’ Perspectives on Cardboard Boxes: Themes and Subthemes

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Example Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAFETY</td>
<td>Lid</td>
<td>“It has a cover over it and it should never have a cover over it.”</td>
</tr>
<tr>
<td></td>
<td>Size</td>
<td>“[I wouldn’t use that...] Because you’re going to kill the baby, he might suffocate in there.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“And it looks like it’s roomy for the baby, it doesn’t look like it’s too small, like a little coffin.”</td>
</tr>
<tr>
<td></td>
<td>Material</td>
<td>“He rolls around his crib all the time so I feel like he would just fall out of that.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“...I don’t know if it’s made out of cardboard, that’s not safe either, it could always split.”</td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>Design</td>
<td>“I would not buy that product out of a store, it looks just like a cardboard box.”</td>
</tr>
<tr>
<td></td>
<td>Status</td>
<td>It would be like the baby is, I don’t want to say, homeless or something? Like something out of the shelter?</td>
</tr>
<tr>
<td></td>
<td>Comparison to Existing Product</td>
<td>“It’s cute, it looks like the bassinet without the legs.”</td>
</tr>
<tr>
<td></td>
<td>Size</td>
<td>“That’s a big box. It looks uncomfortable to carry.”</td>
</tr>
<tr>
<td></td>
<td>Simplicity</td>
<td>“So yeah it’s a good idea, it’s convenient.”</td>
</tr>
<tr>
<td></td>
<td>Mattress</td>
<td>“The mattress is so thin too.”</td>
</tr>
<tr>
<td>PLANNED USE</td>
<td>When traveling</td>
<td>“You can move it wherever you want.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Say if we’re at someone’s house and I don’t want to put her in someone else’s bed, I would use that.”</td>
</tr>
<tr>
<td></td>
<td>Breastfeeding</td>
<td>“It’s much better for breastfeeding at night when the baby is sleeping next to you.”</td>
</tr>
<tr>
<td></td>
<td>In bed</td>
<td>“It’s perfectly sized for the bed, which is great, because sometimes we want to lay on the bed with him, but we’re scared we’re going to turn over or something.”</td>
</tr>
<tr>
<td></td>
<td>Storage</td>
<td>“I guess it might be good for storage but I would never let my baby sleep in that.”</td>
</tr>
<tr>
<td></td>
<td>During playtime</td>
<td>“I think it is also nice to use during the day when he’s playing.”</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td>“I think it’s helpful for the people that can’t afford he cribs and stuff like that.”</td>
</tr>
<tr>
<td></td>
<td>Necessity</td>
<td>“Well we had already bought her a crib so if it was given to me now I wouldn’t use it.”</td>
</tr>
</tbody>
</table>
Table 9: Factors Associated with Perception of Cardboard Box for Infant Sleep  
(Total N = 50)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Would Use Box</th>
<th>Would Not Use or Unsure of Box</th>
<th>Unadjusted OR (95% CI)^A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infant</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Sex</td>
<td>13 (50%)</td>
<td>13 (54.1%)</td>
<td>0.8 (0.3-2.6)</td>
</tr>
<tr>
<td>Infant &lt; 2 months old</td>
<td>17 (65.4%)</td>
<td>13 (54.1%)</td>
<td>1.6 (0.5-5.0)</td>
</tr>
<tr>
<td>Mostly or exclusively breastfed</td>
<td>15 (57.7%)</td>
<td>10 (41.2%)</td>
<td>1.9 (0.5-5.9)</td>
</tr>
<tr>
<td><strong>Caregiver</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother ± Father^B</td>
<td>25 (96.1%)</td>
<td>22 (91.7%)</td>
<td>2.3 (0.2-26.9)</td>
</tr>
<tr>
<td>Age &lt;30 yrs old</td>
<td>15 (57.7%)</td>
<td>12 (50%)</td>
<td>1.4 (0.4-4.2)</td>
</tr>
<tr>
<td>One child in the home</td>
<td>7 (26.9%)</td>
<td>11 (45.8%)</td>
<td>0.4 (0.1-1.4)</td>
</tr>
<tr>
<td>Non-US born</td>
<td>8 (30.8%)</td>
<td>5 (20.8%)</td>
<td>1.7 (0.5-6.1)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>14 (53.8%)</td>
<td>10 (41.7%)</td>
<td>2.5 (0.7-8.0)</td>
</tr>
<tr>
<td>Black</td>
<td>8 (30.8%)</td>
<td>6 (25%)</td>
<td>1.3 (0.4-4.6)</td>
</tr>
<tr>
<td>Spanish as Primary Language</td>
<td>6 (23.1%)</td>
<td>6 (25%)</td>
<td>0.9 (0.2-3.3)</td>
</tr>
<tr>
<td>Less than high school education</td>
<td>3 (11.5%)</td>
<td>1 (4.2%)</td>
<td>3.3 (0.3-34)</td>
</tr>
<tr>
<td>Any tobacco smoking^C</td>
<td>2 (7.7%)</td>
<td>2 (8.3%)</td>
<td>0.9 (0.1-7.1)</td>
</tr>
<tr>
<td>Any bed-sharing</td>
<td>11 (42.3%)</td>
<td>6 (25%)</td>
<td>2.2 (0.7-7.4)</td>
</tr>
<tr>
<td>Any non-supine positioning</td>
<td>10 (38.4%)</td>
<td>8 (33.3%)</td>
<td>1.3 (0.4-4.0)</td>
</tr>
</tbody>
</table>

^AOR indicates Odds Ratio; CI indicates Confidence Interval  
^BIncludes mothers who co-identified as primary caregivers with fathers  
^CDefined as past or current tobacco smoking
Discussion

*Our Caregiver Population*

To fully assess the cardboard box as an intervention to reduce SIDS risk factors, we must first discuss our caregiver population. We can compare our populations’ demographics and prevalence of certain sleep behaviors to prior studies on safe sleep in New Haven, as well as national data and the pre-intervention data of the Temple University Hospital study on cardboard boxes. Our results demonstrate key characteristics related to unsafe sleep practices in our community and identify potential barriers to correcting these practices, with or without the use of the cardboard box.

To start, we will focus on racial demographics. In national studies gathering data on sleep practices via phone call, between 6-7% of participants have identified as black and Hispanic compared to over 80% identifying as white.\textsuperscript{15} This is very different from caregiver demographics in urban centers such as Boston (44% identifying as black, 30% identifying as Hispanic, and 21% identifying as white), Philadelphia (67% identifying as black, 22% identifying as Hispanic, and 9% identifying as white), and even New Haven (54% identifying as black, 23% identifying as Hispanic, and 10% identifying as white).\textsuperscript{56,49} These breakdowns are an important finding because caregivers who identify as black were previously shown to be at higher risk of not following safe sleep recommendations; it therefore followed that populations with a majority of black caregivers should have an even greater focus on safe sleep interventions to reduce overall SIDS mortality in the United States.\textsuperscript{5,16,57} However, all of the studies cited above excluded non-English speaking caregivers. In our study, where we included Spanish-speaking caregivers, 41.7% of participants identified as Hispanic- this is a significantly higher percentage than in the studies listed above where only English-speaking Hispanic patients were surveyed.
Including these participants allowed us to identify primarily Spanish-speaking as a demographic association with unsafe sleep behaviors; if these participants had not been included, 100% of caregivers who at least sometimes practice bed-sharing and non-supine positioning would have been black, leading to potentially incorrect analysis on the relationship between race and SIDS risk factors. This emphasizes the importance of including representative samples of an entire patient population when analyzing the relationship between demographics and practices that occur throughout a community.

Other important demographics previously associated with increased SIDS risk include breast feeding prevalence and smoking prevalence. National data from the CDC demonstrates exclusive breastfeeding rates for the first 3 months of life at around 47% in 2016, compared to 36% in 2009.\textsuperscript{58} In our population, caregivers reported mostly or exclusively breastfeeding within the first 4 months of life was 42.5%, a similar rate to the last reported national number. Some studies from the 1990s demonstrated an association between breastfeeding and bed-sharing, leading to concern for SIDS / SUID in this population; however, new data has shown that breastfeeding, even non-exclusively, has a protective effect against SIDS, although the reasons why are still being postulated.\textsuperscript{59-60} Since we have no prior data in our population to compare breastfeeding rates, non-supine positioning, and bed-sharing, we are unable to discuss how these variables have changed over time, but our analysis shows no association between breastfeeding and unsafe sleep practices in this population. Conversely, exposure to smoke during pregnancy has long been identified as an independent risk factor for SIDS.\textsuperscript{61} National data from the CDC reports 7.2% of women who delivered in 2016 smoked during pregnancy; our population data is lower at only 4.2%.\textsuperscript{62} Our data shows no association between smoking during
pregnancy and unsafe sleep practices, but it is important to note that smoke exposure is a risk factor for SIDS unrelated to sleep practices and should continue to be apart of studies on SIDS risk factors.

Comparing National Prevalence of Sleep Practices with Our Data

Findings from our study on supine positioning in our community are more in-line with national trends. 87.5% of our participants cited supine positioning as their infant’s most common sleep position, compared to a national prevalence of 71.7% in 2007. Although this high percentage is encouraging, only 65% of our participants intended to and exclusively practiced supine positioning, compared to 43.7% nationally in 2017. We can further consider demographic risks, considering that national data that has consistently identified a lag between number of black infants sleeping supine and the number of white infants sleeping supine. The National Infant Sleep Position (NISP) study reported only 41.6% of black infants usually slept supine between 2003-2007, which was theoretically associated with an excess of 719 black infants dying of SIDS during this time period. These results are similar to a large multi-centered national study which reported 32.4% of black caregivers practice supine position exclusively, compared to 51.2% of white caregivers. In our study, exclusively supine positioning among caregivers who identified as black was much higher at 53.8%; we did not have enough white participants to compare this percentage meaningfully, but even without comparison, this number raises important points for discussion. Based on national data, we would have expected numbers for supine positioning to be much lower among our clinics’ black caregivers; however, with a significantly higher of black participants, our overall data showed more adherence to supine positioning and no association with non-supine positioning among caregivers.
identifying as black. The overall trend towards supine positioning has been increasing since 1994, so it is hard to figure out how much of the difference in these numbers can be attributed to improvements in safe sleep education over time versus the demographics of our community; however, the potential bias from non-optimal sampling in the NISP and similar national studies, which have had a much smaller percentage of black participants as discussed above.

For less safe sleep positions, 35% of our caregivers reported using non-supine positioning at least some of the time, with 8.7% of caregivers citing side as their most common position and 4.3% citing prone as their most common practice. Data from a multi-center study in 2017, which asked caregivers on what sleep practices they had used within the last 2 weeks, showed 50.8% of participants using non-supine positioning at least once, with 14.1% of caregivers citing side as their most common position and 7.8% citing prone as their most common practice. Only 15% of our caregivers included side or prone positioning in their intended practice, compared to 41% of caregivers in the multi-center study. One explanation for these differences is the fact that our participants had infants aged 16 weeks and under, compared to the national study whose participants had infants between 60 to 227 days old- this could suggest that caregivers of older infants are more likely to include non-supine positioning. Since the peak incidence of SIDS is in infants less than 6 months of age, non-supine in older infants may not be as concerning, especially older infants are strong enough to turn from supine to prone and vice versa, making non-supine positioning an unavoidable factor. Although this trend in older infants has not specifically been studied, caregivers who perceive they “do not have control” over their infants sleeping positioning have a higher prevalence of non-supine positioning.
possible association, it seems likely that pediatricians do not emphasize safe sleep practices as much as infants grow older due to the need to prioritize different aspects of anticipatory guidance at each well-child visit, and that parents are less likely to prioritize exclusively supine positioning as their infants grow enough to roll on their own.

The reasons why caregivers choose non-supine positioning have been studied using qualitative methods: findings have identified the most common reasons among black caregivers being parent perception of safety, comfort, and considering family advice as more trustworthy than system recommendations from representatives of the healthcare system. Although we did not conduct qualitative interviews to understand sleeping position, a subset of our caregivers (24.7%) only intended to practice supine positioning but ended up practicing either side or prone positioning and cited the same reasons: perceived safety and comfort of non-supine positioning over supine positioning. Conversely, 23.5% of parents who did not plan on supine positioning ended up practicing supine positioning, citing education from their pediatricians or hospital staff as the reason for their switch, contradicting one of the themes brought up in prior studies. We did not have enough data points to reach thematic saturation and thus analyze this as a qualitative study, but it is encouraging to see the effect of primary care clinic pediatricians on safe sleep and important to identify what specific topics should be covered more comprehensively to address caregiver concerns.

In our community, demographic factors associated with caregivers who practiced any non-supine positioning included being born outside of the US / Puerto Rico, identifying as Hispanic, having Spanish as the primary language, and having less than high school education. National findings have shown the most significant demographic factor
associated with non-supine positioning, especially prone positioning, is a caregiver identifying as black.\textsuperscript{63} It is important to analysis from national surveys, with sample sizes larger than 5,000, included adjusted odds ratios using logistic multivariable analysis.\textsuperscript{15} Due to the smaller numbers in our study, we did not perform an adjusted analysis which limits our ability to draw conclusions about factors associated with lack of adherence to safe sleep practices. Despite this difference, it remains clear that in our majority black population, non-supine positioning was significantly lower compared to national data. Reasons why Hispanic ethnicity, international origin, and Spanish-speaking may be associated with non-supine positioning have not been specifically studied, but it has been established that Spanish-speaking patients often have worse primary care-related outcomes due to communication barriers.\textsuperscript{64} In our primary care clinic, interpretation is almost always done over the phone, which takes a longer time and is often less effective than in-person interpretation, and is an added pressure on an already rushed appointment. It seems likely that tailored explanations addressing the perceived discomfort, choking hazards, and lack of control over supine positioning are not addressed with the same amount of time as with English-speaking caregivers. Prepared handouts on safe sleep do not address the specific concerns of this population identified above, even when they are translated into other languages, and may not be assessed for patients with lower literacy. Prior studies have also shown that Hispanic caregivers, especially first-generation immigrants, are much less likely than other populations to be familiar with SIDS and the Back-to-Sleep campaign, making the education from primary pediatricians even more crucial in this population.\textsuperscript{65} Identifying these results and barriers emphasize the need to improve communication between physicians and high-risk caregiver populations.
For sleep location results, our most important finding is that 100% of participants included a crib or bassinet in their sleeping plans, meaning that 100% of participants already had or were planning to have access to a crib or bassinet by the time of their discharge. Of 120 participants, 95.8% also cited the crib or bassinet as their infant’s most common sleep location. Other common alternative locations for our population included pack and plays, car seats, and products designed to sit in the adult bed such as Moses baskets, all of which AAP has stated are not associated with an increased risk of SIDS. Despite these encouraging numbers, it is important to note that 20.7% of participants included bed-sharing as part of their intended practices; although only 2 participants (1.7%) cited it as their infant’s most common sleep location, 38.3% of our population reported bed-sharing at least occasionally. This is similar to national numbers: in 2008, 32% of mothers from Women, Infants and Children (WIC) centers reported bed-sharing occasionally. Additionally, 9.5% of our participants who did not include bed-sharing in their intended practices ended up practicing it, and when asked why, explained that it was often an accident to fall asleep with their infant after breastfeeding or comforting them in the middle of the night. Prior studies with black caregivers have identified similar reasons for bed-sharing, especially concerning convenience; other reasons not found in our community include perceived safety of bed-sharing with environmental dangers. The one study that included Hispanic caregivers identified breastfeeding as an additional reason cited by Hispanic caregivers more than black caregivers, and also reported that Hispanic caregivers were much more likely to exclusively breastfeed. In our population, 60% of Hispanic caregivers and 82.4% of primarily Spanish-speaking caregivers reported mostly or exclusively breastfeeding compared to 31.7% of black caregivers. In addition, our study
identified Spanish-speaking as a risk factor for bed-sharing; this cannot be fully attributed to breastfeeding, since breastfeeding was not independently associated with bed-sharing in our analysis, it could partially explain why this population seems to be at a higher risk.

Additional reasons for Spanish-speakers to be at a higher risk of bed-sharing include the barriers to effective communication discussed above, but more importantly, the effect of cultural and family networks. Social network analysis has become an increasingly important part of understanding why caregivers may not adhere to pediatricians’ recommendations regarding safe sleep: strong networks (family, frequent contact) and dense networks (where many members know each other) have demonstrated increased influence over patient decision making.68 A study on how social networks influence bed-sharing found that mothers in exclusive networks were more likely to practice non-recommended behaviors compared with mothers in expansive networks, where exclusive networks are defined as more homogenous and containing a greater number of connections between contacts. This study also found that black mothers were more likely to have exclusive networks.69 Although this study did not include Spanish-speaking patients, immigrant patient populations have demonstrated more exclusive social networks, possibly as a way to reduce stress related to acculturation.70 It therefore follows that exclusive networks in our Spanish-speaking caregivers could contribute to higher bed-sharing rates among this population in our community. Our results highlight the need to better understand the relationship between acculturation and social networks in Spanish-speaking patients in order to create a successful intervention for this population.
Evaluation of the Cardboard Box for Infant Sleep

We will approach the evaluation of the cardboard box for infant sleep as an intervention for safe sleep based on a framework identifying barriers and incentives for behavior change, as adapted by members of the AAP Task Force on SIDS for a review on successful interventions (Figure 3).71

**Figure 3:** Barriers and Incentives for Behavior Change in the Context of Safe Infant Sleep Practices (Taken from Moon, Hauk, and Colson)

<table>
<thead>
<tr>
<th>Level</th>
<th>Barriers/Incentives</th>
<th>Examples of barriers specific to infant sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>Advantages in practice, feasibility, credibility, accessibility, attractiveness, personal relevance</td>
<td>• Parents do not understand rational for supine position for sleep &lt;br&gt; • Parents feel that infant is “immune” to SIDS &lt;br&gt; • Parents believe that recommended sleep practices will place baby at risk (e.g. choking)</td>
</tr>
<tr>
<td>Individual professional (Healthcare provider)</td>
<td>Awareness, knowledge, attitude, motivation to change, behavioral routines</td>
<td>• Healthcare provider does not believe that babies should sleep supine &lt;br&gt; • No standard of care for infant sleep in hospital or daycare</td>
</tr>
<tr>
<td>Breaking down barriers (for infant caregiver)</td>
<td>Knowledge, skills, attitude, compliance</td>
<td>• No money to buy crib &lt;br&gt; • Concern that infant will be uncomfortable without blankets &lt;br&gt; • Maternal smoking during and after pregnancy</td>
</tr>
<tr>
<td>Culture and tradition (social context)</td>
<td>Opinion of colleagues, cultural norms, collaboration, leadership</td>
<td>• Bed-sharing is family or cultural norm &lt;br&gt; • Elder family members are trusted sources of information and may encourage prone positioning &lt;br&gt; • Parents often receive unsafe bedding as gifts for baby</td>
</tr>
<tr>
<td>Legislation / regulation (organizational, economic, and political context)</td>
<td>Organization of care processes, structures; financial arrangements, regulations, and policies</td>
<td>• No safe sleep regulations in child care centers &lt;br&gt; • No safe sleep education given at birth in hospitals</td>
</tr>
</tbody>
</table>
This framework consists of 5 levels: innovation (usually in the category of health messaging), individual profession (education of health professionals in this context), breaking down barriers (for infant caregivers), culture and tradition (understanding caregiver social context), and legislation / regulation (organizational, economic, and political contexts that affect caregivers). Of note, this framework emphasizes that the best way to assess interventions for behavioral change is through randomized control trials; the cardboard boxes have not been studied in this way in America nor Finland, so all analysis below is based on the attitudes identified by our community’s caregivers and comparisons to better studied interventions.

At face value, the cardboard box falls into the category of breaking down barriers, where the barrier is not having the resources to afford another sleeping space, thus forcing caregivers to share their bed with their infant. This barrier does not apply for our population since, as discussed above, all of our caregivers already had access to a crib at the time of discharge- this was also explored in the qualitative interviews, as illustrated by one mother who said she “already had bought...a crib” and therefore did not need the box for their infant to sleep in. Even for populations who cannot afford a safer sleeping space, the box itself does not have a purely innovative advantage over programs such as Cribs for Kids, which provide free cribs and safe sleep education to caregivers who cannot afford them. The potential advantage of the cardboard box lies in breaking down the barrier of education: from the healthcare provider’s side, as it offers a tangible reminder to discuss safe sleep practices with parents and address their unique concerns; from the caregiver’s side, the Baby Box Company offers additional classes online that are more accessible than a pediatrician’s office. The presence of a physical stimulus for discussion on safe sleep,
provided by the hospital itself, may improve outcomes more than the cardboard box itself.

The box could also fall under the innovation category based on advantages identified by caregivers. They mainly noted its improved convenience for breastfeeding and travel; if these advantages were attractive enough to mothers who do bed-share despite having access to a crib or other safe sleep option, it could be worth implementing. However, the box also presents significant safety concerns that must be weighed against its potential advantages. As discussed above, it has not been put through the same safety testing as other products for infant sleep as it cannot be regulated by federal safety agencies. Even caregivers who identified positive aspects of the cardboard box raised concerns about the durability of cardboard, the potential for suffocation with the lid, the danger posed by carrying the box around with the infant still in it, and accidents that could occur if the box was placed on an elevated surface or the floor as recommended by the company. These concerns have been identified by prior studies on the cardboard box, but our results illuminated a new concept: the idea that, if hospitals were to give these out, parents would consider the box a safer option than other sleeping surfaces. The implications of this health messaging must be seriously considered for any hospitals that are weighing the risks and benefits of the cardboard box as an intervention, as they will have to combat this objectively incorrect perception.

Some articles have compared the cardboard box for infant sleep to products designed to be in the adult bed, such as the wahakura. For context, the wahakura falls in the category of culturally tailored interventions because they were specifically designed for Maori women, an indigenous population in New Zealand with a strong tradition of bed-sharing – an image of the wahakura is shown in Figure 4.
This product allowed Maori mothers to maintain their traditions while reducing risk for SIDS and suffocation-related death at the same rate as bassinets, which were used as a comparison in multiple studies; since its introduction, infant mortality among the Maori has dropped by 29%.\textsuperscript{75,76} However, comparisons of this product to the cardboard box are flawed as the cardboard box is not designed to go into the adult bed, contrary many of our caregivers’ perceptions when they clearly stated they would like to use the cardboard box in their bed. It is therefore inappropriate to consider this a tailored intervention for populations that emphasize bed-sharing as part of traditional infant sleep; in fact, its similarity in appearance to these products despite not having same level of evidence supporting their safety could be another reason why hospitals should be careful about promoting this product. It is also important to highlight our findings that the cardboard box does not specifically appeal to caregivers in our community who bed-share or practice non-supine positioning even without the context of cultural background: parents who practiced
unsafe sleep behaviors did not have greater odds of stating they would use the box. Although our sample size was too small to conduct more detailed analysis on the relationship between positive perception of the box and sleep behaviors, the unadjusted odds-ratios indicate that positive aspects of the box (i.e. convenience in breastfeeding, maneuverability, appearance) did not specifically appeal to its target audience.

In summary, the cardboard box does not seem like the most effective intervention to improve safe sleep practices in our community. All of our participants reported they planned to use a crib, meaning that caregivers who practiced unsafe behaviors such as bed-sharing did not do so due to lack of resources. Only 52% of participants stated they would use the box for their infant to sleep in, many of them specifying it would be for daytime naps only. Despite previous studies on its utility for caregivers who bed-share, the box did not hold specific appeal among parents who bed-share or practice non-supine positioning in our community. Although the box has aspects that are exciting to our caregivers, mostly in the domain of convenience, these do not seem to outweigh the multiple safety concerns and the larger-scale problems around health messaging that would be received by our community if this product was promoted by a hospital, especially since it does not meet the safety standards of traditional cribs or products designed to be placed in the adult bed. As a potential alternative, the utility of the Baby Box Company educational resources could be adapted as part of a modern Back-to-Sleep campaign, in the style of mobile messaging or other communication-based interventions that have been successful in hospital settings. The cardboard box’s success in other urban clinics is exciting, but there is no evidence that it will be a more effective intervention than any of the extensively studied alternatives discussed above based on our caregivers’ practices and perceptions.
Study Limitations and Opportunities for Future Work

Although we did our best to minimize problems with study design and analysis, our project had several limitations. The easiest limitation to identify is our sample size: although we were focused on drawing conclusions about our community, rather than the thousands of participants required to draw conclusions about national trends, having only 120 participants total limits our ability to draw conclusions from smaller demographic subsets. Although we successfully recruited a majority of black caregivers, as is representative of our urban clinic, we were unable to recruit a significant subset of Native American or Asian American caregivers and therefore were unable to draw any conclusions about these populations. While this might not be crucial to understand our community, it is important to recognize nationally as these subgroups are not well studied, and Native American infants have been noted in prior studies to be at a higher risk of SIDS compared to white infants. The demographics of participants who completed the interview did not match those of the total surveyed population, especially concerning primarily Spanish-speaking caregivers: many of these caregivers did not consent to participate in the qualitative portion after completing the survey, citing not having enough time to remain in clinic for the interview. Given how important this population is based on our results, it is important for future studies on safe sleep interventions in our community to over-sample for Spanish-speaking caregivers in order to address their unique barriers to adherence. In addition, although the student (ND) is a certified Spanish language translator, it is important to note that Spanish is not her native language and her Spanish ability was solely relied on for interviewing and transcription. In a qualitative study where understanding subtle perceptions is crucial, it is worth noting this a limitation and encourage future
studies to hire additional, and ideally native-speaking, Spanish translators.

Another significant limitation of our study was the method of our survey data collection. All of our data relies on self-reporting by caregivers, while in a clinic environment and speaking with a medical student. Although participants were assured their data would be anonymous and that researchers were not providers in the clinic, it is difficult to imagine that our participants felt 100% comfortable discussing the truth about their safe sleep practices, especially among those who are aware of their doctors’ recommendations and are concerned about repercussions for not following their instructions. A more reliable method of data collection would have been via anonymous URL, where caregivers could complete the survey in the privacy and comfort of their own environments, or even better, a study designed to directly observe caregiver practices. Neither of these methods were employed due to concern over collecting sufficient data and difficulties in conducting observational studies respectively. Future studies should consider these alternative methods to data collection to be more confident that their participants are telling the truth, and not just repeating what they think representatives of the healthcare system want to hear.

For the qualitative data, we successfully reached thematic saturation concerning the baby box as per our original goal. However, as the interviews continued, it became clear there was a missed opportunity to explore attitudes around sleep location in general, reasons for adhering to pediatrician recommendations or not, and family network influence. Although we gained a few insights from small questions, we did not gain enough data to fully understand these concepts in our community. Future qualitative studies would benefit from exploring these themes more thoroughly, especially in
populations of interest such as primarily Spanish-speaking caregivers, caregivers who bed-share, and caregivers who cite their families or pediatricians as their reason for changing practices.

Future studies should also consider trending sleep practices over time - both to understand the relationship between infant age and adherence to safe sleep practices, as well as explore the changes in attitudes that at-risk populations develop over time. A cohort study like this would also offer the opportunity to map social networks and determine if the national trends regarding exclusive versus expansive networks also apply in our community, especially among primarily Spanish-speaking caregivers and other populations of interest. Building up a cohort would also potentially mitigate concerns about false self-reporting as there are opportunities to build trusting rapport and incentivize ongoing participation for smaller groups. Based on our findings, another potential high-impact study would be to introduce an intervention against safe sleep that matches the unique barriers of our community, such as a multilingual health-messaging based intervention that would offer short, easy-to-digest reminders on safe sleep practices that could penetrate populations less likely to understand instructions from primary care pediatricians. Setting educational goals at group-based well-child visits for Spanish-speakers, which already exist within the infrastructure of our primary care clinics, also has a strong potential for success and offers a unique opportunity to take advantage of our caregivers’ existing social networks. Regardless of what follow-up study may occur next, it is clear that unsafe sleep practices are still an ongoing problem in our community and nation-wide: any interventions to address this problem must be carefully considered based on the attitudes and behaviors outline in this paper in order to maximize future success.
References


74.


Thank you for participating in this study. The beginning of the survey is in sections according to positioning your baby for sleep and where the baby sleeps. Each section begins with what you originally planned to do when the baby came home from the hospital. Then we will ask if your plans changed; what you do now and why. Remember, this survey is about your baby.

Many of the questions use a scale from 1 to 7. Choose the scale number according to how strongly you agree or disagree with the statement. Also, there is a number you may call or an email address you may use if you wish to ask a question of the study staff.

At the end of the survey we have a few questions about a new product that we are planning to use in our hospital and would like your opinion. For this part of the survey we will be audiotaping your responses.

**Sleep**

Response ID:

1. When I first brought my baby home from the hospital, I planned to place him/her....

2. Now, I plan to place my baby...
3. Since you brought your baby home, what position have you USUALLY placed your baby to sleep?

- [ ] On the side to sleep
- [ ] On the stomach to sleep
- [ ] On the back to sleep
- [ ] Other (please specify): 

4. Do you SOMETIMES place your baby to sleep in a different position?

- [ ] No, it's always the same
- [ ] Yes, on the side
- [ ] Yes, on the stomach
- [ ] Yes, on the back

5. LAST NIGHT, what position did you place your baby to sleep?

- [ ] On the side to sleep
- [ ] On the stomach to sleep
- [ ] On the back to sleep
- [ ] Other (please specify): 

6. Where do you USUALLY placed your baby to sleep?

- [ ] Crib
- [ ] Bassinet
7. Have you SOMETIMES placed your baby to sleep somewhere else? (Check all that apply.)

☐ No, it's always the same
☐ Yes, crib
☐ Yes, bassinet
☐ Yes, cradle
☐ Yes, carry cot
☐ Yes, pack and play
☐ Yes, adult bed or mattress
☐ Yes, sofa
☐ Yes, car or infant seat
☐ Other (please specify): 

8. LAST NIGHT, where did you place your baby to sleep?

☐ Crib
☐ Bassinet
☐ Cradle
☐ Carry cot
☐ Pack and play
☐ Adult bed or mattress
☐ Sofa
My baby's sleeping area has a firm mattress.

10 What items do you USUALLY place in your baby's sleeping area? (Check all that apply.)

☐ None
☐ Swaddle Blanket only
☐ Other Blankets
☐ Pillow(s)
☐ Other (please specify):

11. Have you SOMETIMES placed other items in your baby's sleeping area? (Check all that apply.)

☐ No, none
☐ Swaddle Blanket only
☐ Yes, blankets
☐ Yes, pillow(s)
☐ Yes, other (please specify):

12. LAST NIGHT, what items did your baby have in his/her sleeping area?

☐ Nothing
13. When I first brought my baby home from the hospital, I planned to sleep in the same bed with him/her...

14. Now, I plan to sleep in the same bed with him/her...

15. If your plan changed, please tell us why.

I planned to sleep in the same room (but not the same bad) as my baby...
18. Where does your baby USUALLY sleep?

- Alone in his/her own room
- In a parent’s room (or another adult’s room) in his/her own crib
- In a parent’s bed (or another adult’s bed) for part of the night
- In a parent’s bed for the whole night
- In a child’s room in his/her own crib
- In a child’s bed for part of the night
- In a child’s bed for the whole night
- Other (please specify): 

19. Has your baby ever SOMETIMES slept somewhere else? (Check all that apply.)

- No, nowhere else
- Alone in his/her own room
- In a parent’s room (or another adult’s room) in his/her own crib
- In a parent’s bed (or another adult’s bed) for part of the night
- In a parent’s bed for the whole night
- In a child’s room in his/her own crib
- In a child’s bed for the part of the night
- In a child’s bed for the whole night
- Other (please specify): 

20. LAST NIGHT, where did your baby sleep?

- Alone in his/her own room
21. If last night was different from where your baby usually sleeps, is there a reason why?

22. When I first brought my baby home from the hospital, I planned to breastfeed.

23. Since you brought your baby home, what has he/she been drinking?
Smoking

24. Did you smoke within a month of becoming pregnant?
   - Yes  
   - No

25. Did you quit smoking just before getting pregnant or during pregnancy?
   - Yes  
   - No

26. Are you a smoker now?
   - Yes  
   - No

27. Is anyone else around the baby a smoker?
   - Yes  
   - No  
   - Don’t know

The Baby Box

36. Have you ever heard of the Baby Box?
   - Yes  
   - No
37. If yes, where did you hear about it?

38. The Baby Box is a cardboard box with a fitted mattress that some hospitals are going to give to mothers at their time of discharge from the post-partum unit. Yale New Haven Hospital will begin distributing them soon. What do you think about this?

Demographics

We would now like to ask some questions about your background. These questions are purely to provide cultural context for our study to help us understand how demographics affect the way newborns are cared for. As a reminder, all of your responses are completely anonymous and confidential.

28. Over the next few months, who will be the person taking care of the baby the most while in the home?

○ You (baby’s mother)
What brand of diapers do you use at home?

29. How many babies have you given birth to (including the baby that was just born)?

- 1
- 2
- 3
- 4
- 5+

30. What is the sex of your baby?

- Male
- Female

31. How old are you?
32. In what country were you born?

33. Do you consider yourself Hispanic or Latino?

☐ Yes
☐ No

34. In addition, do you consider yourself to be...

☐ American-Indian or Alaskan Native
☐ Asian
☐ Black or African-American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Other
☐ Do not wish to answer

35. What is the highest level of education you have completed?

☐ Less than high school completion
☐ High school / GED
☐ Some college or associate’s degree
☐ College Graduate
☐ Graduate School
☐ Do not wish to answer