Supplement 1: RESEARCH STRATEGY

A. Significance

A1. SIDS and sleep-related infant deaths: the current challenge.

This grant application is designed to address the purpose of FOA PAR-11-242 “to improve the design and implementation, and effectiveness of preventive interventions for Sudden Infant Death Syndrome (SIDS) and unintentional injury infant deaths associated with the sleep environment.” We believe that this large randomized controlled trial (RCT) will provide evidence of effectiveness of innovative, practical to disseminate interventions that address many of the barriers to adherence to safe sleep recommendations in populations that are high risk for both non-adherence and infant mortality. The existence of the currently active SAFE Infant Care Practices study provides a timely and unique environment for testing interventions, and the proposed SMART project fully takes advantage of the opportunities that this infrastructure provides.

While the national Back to Sleep public health campaign was very successful, there are still many barriers to changing parent behavior and to creating safe sleep environments for infants, thus decreasing infant mortality. Adherence to supine sleep recommendations has plateaued since 2001, at a level well below targets, especially among Blacks. Further, US public health efforts have been less successful in changing behaviors with regard to soft bedding and bedsharing in high-risk groups. SIDS and other sleep-related infant deaths most commonly occur in the presence of multiple unsafe sleep practices (such as prone/side positioning, use of soft bedding, bedsharing, and pacifier nonuse). In addition, there are racial disparities in all of these sleep-related deaths. Black infants are twice as likely to die from SIDS, accidental suffocation and strangulation in bed, and undetermined deaths, compared to White and Hispanic infants. While the increased mortality rate in Blacks is disturbing, it is also concerning that the rate of unsafe sleep practices may be increasing in other racial/ethnic groups as well. Rates of prone positioning, parent-infant bedsharing, and use of soft bedding are higher among Blacks infants with younger parents, and those of lower educational and socioeconomic status.

As a team of investigators that has done much of the work nationally to understand and to change parent behavior related to safe sleep practices in the US, we are aware of the barriers to change and of the significant racial disparity that exists both in adherence and infant mortality. Collectively we have studied infant care practices related to SIDS since 1992 through an annual national telephone survey interviewing >15,000 caregivers, focus groups and face-to-face interviews with at-risk mothers, and >15,000 interviews with follow-up surveys at hospitals in Ohio and Massachusetts. Additionally, we have conducted the largest case-control study of SIDS in the US (Chicago Infant Mortality Study). Our research shows that recommendations for supine positioning, avoidance of soft bedding, pacifier use, and room sharing without bedsharing may not resonate with many people, often because of misconceptions or perceived barriers. Specifically, we have learned the following:

- Mothers want their sleeping infants to be comfortable (i.e., sleep longer with fewer awakenings) and are concerned that infants will be less comfortable on the back or on a hard surface. This concern for infant comfort often results in prone positioning and use of soft bedding.
- Mothers want their infants to be safe when they sleep. Those who worry about the danger of choking when the infant is supine are less likely to place their infant supine. Those who worry about falls and injury are more likely to use soft bedding. Those who bedshare with their infants often do so because they believe that bedsharing is the best way to keep their infant safe from any danger.
- Mothers often have conflicting feelings about pacifiers. Those who do not want to give their baby pacifiers worry about nipple confusion, attachment to the pacifier, dental problems, and
germs. Mothers are also skeptical about the data that demonstrate that pacifier use is protective against SIDS. 

Advice about sleep position is important, especially advice from healthcare providers and advice from respected family members such as grandmothers. Yet advice is often not given and if it is given, the advice is not always to place the infant on the back to sleep. In fact, we have shown that some of these barriers explain, at least in part, the racial disparity in adherence to safe sleep practices. Therefore, addressing these barriers would be expected to improve adherence and reduce the racial disparity in adherence. For that reason, we propose innovative interventions that both build upon our prior research and address these misperceptions and barriers bringing what we have learned about barriers and behaviors into practice through education.

A2. Social marketing techniques and culturally competent approaches in health promotion.

Social marketing is the use of commercial marketing concepts to design and implement programs to effect social change and is guided by the following principles: 1) the ultimate objective is to influence action; 2) action occurs when the target population perceives the benefits to outweigh the costs of the action; 3) programs are more effective when based on an understanding of the target population’s perceptions; 4) target populations are rarely uniform in perceptions and/or responses to social marketing efforts; 5) there are always behaviors that compete with recommended behaviors, and these must be understood and addressed; and 6) because of constant changes in the “marketplace,” there must be frequent monitoring in order to rapidly alter strategies as needed. Many health campaigns, however, have a one-size-fits-all approach, and thus are not necessarily effective in reaching all targeted audiences. Our goal is to develop educational messages for nursery staff and mothers that maximize social marketing techniques.

Furthermore, culturally and linguistically competent health promotion approaches respect cultural values, beliefs and practices of the target population; therefore, health promotion messages should ideally reflect these health beliefs and practices. This is often a challenge, as some of those beliefs and practices may be inconsistent with emerging knowledge of behaviors that support healthy outcomes. Culturally competent health promotion supports and honors those practices and beliefs that are protective or benign, and respectfully helps to identify and change those beliefs and practices that have a negative health impact. Our interventions will incorporate techniques to favorably influence infant care practices, while respecting parental beliefs.

A3. Rationale for interventions during the postpartum hospital stay.

Studies, including our own, have shown that the postpartum hospital stay provides a unique venue for intervention for several reasons. First, the birth of a child results in a change in the family dynamic that makes parents and family members more receptive to new information. Second, the postpartum hospital stay is a time when information can be delivered over several days and through multiple sources. Third, role modeling is a powerful tool and mothers often model what they learn in the nurseries. Fourth, since mothers often receive visitors, education can be directed to family and friends. Our research shows that family and friends can play a key role in influencing infant care practices at home. Finally, since virtually all newborns are born in the hospital, the newborn nursery provides access to mothers who might otherwise be inaccessible for intervention.

Surprisingly, although the Back to Sleep Campaign targeted newborn nurseries for dissemination of its messages, actual practice varies tremendously. One study found that only 30% of infants are placed supine by nursery staff, and 66% of nursery staff do not advise
parents to place their infants supine, largely because nursery staff share parental concerns that newborns will choke in the supine position.\textsuperscript{35,39} Our data among low-income mothers show that only 42% reported receiving advice from nurses to place infants supine.\textsuperscript{27} In our survey of low-income mothers in 2008, 29% reported that their infant was \textbf{not} placed to sleep on the back by nursery staff (Colson, unpublished data). We have shown that an intervention, focused on nursery staff, that addresses concerns and emphasizes the importance of role modeling on parental behavior is effective; parents report a significant increase in infants being placed on their back by nursery staff, healthcare provider advice to place infants supine, and most importantly, parents using the supine position at home.\textsuperscript{35} Thus, a well-designed, nursery-based intervention utilizing what we have learned, which would be practical to implement in hospitals nationwide, could have broad implications for infant health and has the potential to help decrease the racial disparity in post-neonatal deaths.

A4. Rationale for mHealth (mobile health) interventions in high-risk groups.

Most Americans now have internet access. In 2010, 59% of all Americans used the internet to search for health information.\textsuperscript{40,41} Internet access has become more affordable recently, largely through cellular telephones and smartphones,\textsuperscript{42} and these devices have become the primary means of internet access for lower SES groups.\textsuperscript{43} The highest usage rates for cell phones are among Blacks, adolescents, younger adults, and adults with lower SES and educational levels.\textsuperscript{44-46} Black cell phone owners utilize their phones more frequently and for more applications than White owners; they are more likely to use their cell phones for Internet access, emails and viewing videos.\textsuperscript{47} Younger persons, persons with lower educational status, Blacks and Hispanics are more receptive to receiving messages related to appointment or medication reminders and health-related education.\textsuperscript{48} In particular, parents and pregnant women, regardless of race or SES, have been receptive to receiving health-related messages about their children.\textsuperscript{49-52} Of note, of the first 523 SAFE study participants, 390 (75%) provided an email address; among women who have completed the follow-up survey to date, 85% did so online. Email is thus very promising as a conduit for health information. Furthermore, use of mobile health (mHealth) technologies, [those that use mobile communication devices (e.g., cell phones) to provide health services and information], results in increased behavior change,\textsuperscript{44,53-55} including positive impacts on immunization rates\textsuperscript{56} and diabetes self-management.\textsuperscript{45} Thus, mHealth strategies are likely to be well-accepted and effective, particularly among minority and low-income populations.

Most interventions using mHealth technologies have focused on automated message systems using voice messaging and SMS technology, and most of these have used "push" technology, in which target patients receive automated SMS or voice mail messages tailored to their specific health care needs and/or personal preferences without a user-initiated request.\textsuperscript{56,57} We have chosen to use email rather than SMS or voice mail technology for our interventions. Email can be accessed by many devices, including cell phones. Parents often prefer email for receiving health-related messages and videos, because some phone services charge extra for SMS or video\textsuperscript{58} via SMS, while email video access is free. One study found that some potential participants declined study participation because of the associated cost of receiving SMS messages.\textsuperscript{58} Streaming video that is embedded in an email message is technically easier than embedding video in SMS, as video in the latter must be mobile-enhanced, and different phone companies may use different mobile-enabling platforms. In addition, email messages can be accessed asynchronously (at any time convenient for that individual) and can be easily stored for future reference. Patients may perceive emails as less invasive than a phone call. Parents, particularly young and minority parents, may be more responsive to health messages when delivered by email than in person or by phone. It is more cost-effective for both the patient and provider than face-to-face interventions, as it takes less time (including travel time) than an in-person appointment and may be more practical for busy clinical settings. Customized email
messages can be tailored; personally tailored messages are more effective in changing health behaviors than untailored messages.\(^45,59\) Email messaging may also allow for a more interactive, participatory process, which in turn may be more effective in promoting health behavior changes.\(^60\) Finally, the messages can be mass distributed to target audiences at little additional cost.

A few studies investigating the effectiveness of using videos in patient education have shown that patients receiving video education have improved understanding, knowledge, and self-efficacy,\(^61,62\) and are more likely to change behavior.\(^63,64\) In addition, videos are considered significantly more appealing to patients than written pamphlets.\(^61,62\) Video may also be a more effective means of providing health information to low-literate families. Thus, video technology shows promise as an effective and appealing means of delivering health education.

In summary, our mHealth strategy is likely to be highly effective, because of its accessibility and appeal to our target population (young adults). Our innovative strategy will use mHealth to build upon the success of video education by 1) providing short, targeted videos via a personalized email that can be accessed at the mother’s convenience, and 2) using social marketing techniques to create interactive, tailored messages (e.g., if a mother expresses concerns about choking, she will be sent a video addressing these concerns). If shown to be effective in improving adherence to safe sleep recommendations, this technology could also be readily applied to multiple other health care messages.


With the successful completion of the SMART study, we will have shown the effectiveness of our interventions to improve adherence to safe sleep practices that would be practical to disseminate nationally in multiple diverse settings. These interventions include the use of: 1) social marketing techniques in developing educational interventions, 2) nursery staff education to improve education of mothers, and 3) mHealth technologies to disseminate health information. We anticipate that this study will have the following implications:

- Hospitals and health care providers nationally will adopt these strategies for safe sleep education. This will lead to increased adherence to safe sleep practices, which in turn will result in fewer sleep-related deaths.
- The value of these strategies will inform interventions for other health conditions, particularly those with racial/ethnic, educational, and socioeconomic disparities.

B. Innovation.

The SMART study is innovative for the following reasons:

- Unique collaboration of leaders in the field: Collectively, the investigators have contributed the majority of the research that support the rationale for this FOA and have assembled a multidisciplinary team with expertise in social marketing, cultural competence, educational theory, curriculum development, and media communication.
- Leverage of an existing infrastructure: The availability of the infrastructure developed for the NICHD-funded SAFE project will make it feasible to efficiently collect the data needed to both define the prevalence of the relevant infant care practices and to assess the factors that influence these practices. The timing of this proposal is unique because it coincides perfectly with the completion of the final year of the planned SAFE survey. Such an opportunity is unlikely to be available in the future.
- Two complementary interventions: The 2 interventions selected have the advantage of not being mutually exclusive. Because they use different approaches, they have the potential for having additive or synergistic impact.
- Use of social marketing strategies and expertise in all interventions: We will engage social marketing and advertising expertise that will inform and strengthen the content and strategies used in our messaging. This type of expertise is seldom brought to bear in health
interventions. We plan to develop positive messages and use techniques, such as humor, that appeal to our target audience and lead to a recognizable “branding” so that they look forward to each new message and share them with family and friends.

- **Use of mobile technology to deliver messages.** The mHealth intervention is a novel approach to delivering health messages to high-risk target audiences. This technique has enormous potential to have an impact in changing unsafe infant sleep practices that have been stubbornly stagnant. Use of personalized and interactive video messaging is a particularly unique approach in this setting.

- **Use of community resources and expertise.** The videos will be developed through an innovative collaboration with Duke Ellington School of the Arts (DESAP) in Washington DC, a magnet public high school. There are ~500 students at DESAP, 85% of whom are Black. We will be working with the Literary Media & Communications (LMC) Department, whose faculty is comprised of playwrights, authors, poets, digital media artists, and social media/internet marketing experts. LMC trains students in the different strands of communication, including written (dramatic writing, journalism), oral (public speaking, speech), and new media (online, film, documentary journalism, social media), and works collaboratively with other DESAP departments, including Theater, Visual Arts, and TDP (recording studio). Working with DESAP students, many of whom have similar demographics as families at highest risk for experiencing a sudden infant death, will provide a community context and increase credibility of the video content.

**C. Approach**

**C1. Overall strategy.**

We propose to utilize an already existing and operational infrastructure of 32 hospitals nationwide that are currently part of the SAFE infant care practices study. We will select 16 of the 32 hospitals to serve as sites in a 4-arm randomized clinical trial to assess 2 different safe sleep education strategies (Nursery Education and mHealth) compared to 2 control breastfeeding education strategies (Nursery Education and mHealth) (See Figure 1). The 16 hospitals will be divided into sets of 4 similar hospitals, which will then be randomly assigned to one of 4 study groups: Group 1 will receive Safe Sleep Nursery Education and Breastfeeding mHealth messaging; Group 2 will receive Breastfeeding Nursery Education and Safe Sleep mHealth messaging; Group 3 will receive Safe Sleep Nursery Education and Safe Sleep mHealth messaging; and Group 4 will receive Breastfeeding Nursery Education and Breastfeeding mHealth messaging. A total of 1600 mothers will be recruited (100/hospital), with 400 in each study group and an estimated response rate for the follow-up survey of 80%, resulting in mothers 320 per group.

*Figure 1: Four-armed Randomization by Hospital (I = Intervention; C= Control)*

There are 3 theoretical principles that inform our study design. First, the Theory of Planned Behavior is our framework for understanding the factors that are important in influencing the
health-related behaviors of interest. (This theory informed the development of the SAFE
survey). Second, to develop the educational curricula designed to impact these factors, we will
use Kern’s Six-Step approach. Finally, to inform the details of effective communication, we will
employ the principles of social marketing.

According to the Theory of Planned Behavior,65 intention to perform a certain behavior is
influenced by 3 main factors: 1) attitudes and beliefs (e.g., baby might choke if he’s on his
back); 2) perceived social norms (e.g., my friends don’t put their babies on the back to sleep, so
I won’t, either); and 3) perceived control (e.g., I would put my baby on the back, but my mother
takes care of her and likes the stomach).

In all of the education (Nursery Education and mHealth) components, we will be using
Kern’s Six-Step approach to curriculum development.66 These are:

1) Problem identification: Our previous studies have identified problems with accepting the safe
sleep recommendations, including but not limited to concerns about choking, safety, and
comfort.21, 22, 25, 27

2) Needs assessment of targeted learners: Our previous qualitative studies21-23, 25-27 and the
data currently being collected in the SAFE study lay the groundwork for the needs assessment.

We will be conducting additional needs assessments of nursery staff through focus groups.

3) Goals/objectives: Our overall goal is to improve infant sleep safety. Specifically, we will
address misconceptions and barriers to adherence with safe sleep recommendations.

4) Educational strategies: We will accomplish this through education of nursery staff (which will, in
turn, improve education of mothers) and direct education of mothers using mHealth
technologies. We will utilize social marketing techniques. Before finalizing the educational
strategies, we will conduct focus groups of nurses and mothers, and adjust the strategies and
content accordingly.

5) Implementation: The educational strategies will be put into place.

6) Evaluation and feedback: We will evaluate the Nursery Education and mHealth components
through initial and follow-up surveys assessing knowledge, attitudes, and practice regarding
sleep and feeding practices.

Based on our findings about attitudes and perceptions, we will then use social marketing
strategies to change behavior and assess their effectiveness. To accomplish this, we will utilize our social marketing
experts to review the relevant information, based on the Theory of Planned Behavior, from the
SAFE surveys and the focus groups conducted in year 1, to understand what the important
messages need to be. We will then work with our experts to develop optimal messaging
strategies to formulate and deliver the messages. Our cultural competency expert will review all
of the messages to assure that they are sensitive and appropriate for each target audience.


Using the principles above, we will develop 2 nursery-based education curricula: Safe Sleep
and Breastfeeding. The Safe Sleep Nursery Education curriculum will be developed by Dr.
Colson and Mary McClain, RN, MS (nursing education consultant), modeled after Dr. Colson’s
successful nursery intervention in New Haven, CT,35 using the NIH nursing curriculum67 as a
guide, and incorporating findings from our collective research about barriers to adherence to
safe sleep practices.21-23, 25-27 Development of the New Haven intervention included qualitative
assessment of nursery staff’s concerns about back sleeping, followed by curriculum
development and implementation targeting staff behavior change. Following implementation of
the curriculum, we found that nursery staff practices changed as desired and that maternal
adherence to back sleep recommendations improved from 42% to 75%.35 We will follow a
similar process in the current study, including qualitative assessment of nursery staff concerns
and feedback on the curriculum.
The Breastfeeding Nursery Education curriculum will be developed by Dr. Kellams in collaboration with Kathryn Heck, RN, IBCLC (breastfeeding education consultant) and modeled after the online Breastfeeding Training course for which Dr. Kellams is a scientific advisor. It will also be based on Dr. Kellams’ successful efforts in the UVA Newborn Nursery (UVA was designated as a 2010 University Hospital Consortium Top Ten Performer for exclusive breastfeeding rates in the hospital). Additionally, the curriculum will draw from the evidence-based WHO/UNICEF Ten Steps and the AAP and the Academy of Breastfeeding Medicine protocols to support breastfeeding in the hospital.

Key components of both Nursery Education curricula will include:

1) Enlisting a nurse educator to coordinate the intervention. For each site, Mary McClain and Dr. Kellams or Dr. Colson will contact the physician nursery director and the unit nurse manager. With their help, we will identify an appropriate nurse educator to oversee educational activities.

2) Ensuring uniform actions in the nursery (putting the intervention in place). The nurse educator will ensure that nursery staff receives educational material about either recommended infant sleep techniques or breastfeeding that they will be required to read and to watch. The materials will be based on established and tested curricula and will emphasize understanding of parental misconceptions and barriers that interfere with sleep safety behaviors and breastfeeding, so that these can proactively be addressed.

3) Emphasizing the importance of role modeling. Nurses will learn about the powerful influence their actions have on parental behavior at home. The importance of role modeling best practices will be emphasized.

4) Emphasizing the importance of providing up-to-date guidance to parents and family members. The nurses will deliver appropriate anticipatory guidance to mothers before discharge. In addition, nurses will provide information to family and friends who visit the infant in the hospital whenever possible. They will also provide, to mothers when available, language-appropriate written materials that have been developed by NICHD, AAP, and HHS.

5) Ensuring that the intervention itself is effectively in place (process evaluation). We will track whether the appropriate advice is being uniformly offered to mothers by: a) observation of the placement of infants; b) observation of the delivery of anticipatory guidance about safe sleep or breastfeeding; c) pre and post-test scores; and d) information about nursery practice, provided by mothers in the 2-5 month follow-up surveys.

C3. Development of mHealth education components.

C3a. Development of videos. Through pilot funding from the Clinical and Translational Science Institute at Children’s National Medical Center, DESAP students have begun developing concepts for safe sleep videos [led by Sundance award-winning director Adetoro Makinde (backdoorfilms.com)]. Each video will be ~2 minutes long and will discuss one aspect of infant safe sleep. Drs. Hauck, Kellams, and Moon will work with the students and with our social marketing consultants to develop the messages that will be in the videos. Letters of support from DESAP and Watermark Design are attached. Our goal is to create a clearly identified “brand” so that subsequent videos will be anticipated, recognized and viewed. Potential topics include but are not restricted to 1) rationale for supine sleep positioning, 2) how to encourage supine sleeping when the infant is fussy, 3) discussion of choking/aspiration and sleep position, 4) rationale for roomsharing without bedsharing, and 5) rationale for eliminating bedding from the infant crib area. We anticipate that 5-7 videos will be developed. In weekly team conference calls, ideas for videos will be discussed, scripts will be reviewed, and edited videos will be viewed. A variety of videos will be created, some that are multicultural (>1 racial/ethnic group) and others that are culturally specific (1 racial/ethnic group). Two sample video clips (not educational videos) created by DESAP students can be viewed at http://www.youtube.com/watch?v=NM4rQXi9uLA and http://gallery.me.com/sojournals#100077.

Videos about breastfeeding will be developed in a similar fashion under the direction of Dr.
Kellams, Kathryn Heck, RN, IBCLC and the social marketing consultants. Focus groups will be used to test and refine the video messaging (see section C4 for focus group methods).

**C3b. mHealth Intervention.** Recruited mothers will receive routine postpartum care, including safe sleep education from the nursery staff (who have received either the Safe Sleep or Breastfeeding Nursery Education). Within 72 hours of enrollment, participants will begin to receive email messages on safe sleep or breastfeeding, determined by the group assignment, which will continue on a twice-weekly basis until the infant is 2 months of age. We will be using an email platform developed by our mHealth consultant David Mathison, MD, MBA (letter of support attached), pediatric emergency physician and CEO of healthEworks, who has received NIH funding to create and evaluate mobile Video Prescriptions™ sent via email to pediatric emergency department patients. A sample algorithm for sleep position messages for the Safe Sleep mHealth groups is in Table 1. The messages will be interactive and tailored to participant responses. Similar algorithms have been developed for roomsharing, soft bedding, pacifier use, and for the Breastfeeding mHealth education.

### Table 1: Sample Algorithm for Sleep Position Messages

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<tr>
<th>Intervention Component</th>
<th>Sample Message/Content</th>
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| **Introduction to program**                  | • Welcome to SMART  
• As part of this study, we will send you messages twice a week for 2 months.  
What time of day would you like your message? (interactive) |
| **Encouragement of supine sleep position**   | • Check out this video [here](#)! It will help you keep (Baby’s Name) safe while s/he sleeps! (Personalized)  
• Video: rationale for supine sleep position |
| **Addressing barriers to supine sleep position** (choking/aspiration) | • Do you worry that (Baby’s Name) might choke if s/he is sleeping on the back?  
If YES: Look at this video [here](#). It talks about why you don’t have to worry about (Baby’s name) choking while on the back  
• Did you have a chance to see the video about choking that we recommended?  
If NO – provide link for video again  
If YES: Did you like the video? |
| **Addressing barriers to supine sleep position** (infant comfort) | • Does (Baby’s Name) ever have trouble falling or staying asleep on the back?  
If YES: This video [here](#) talks about ways to help your baby sleep on the back.  
• Did you have a chance to see the video about helping your baby sleep?  
If NO – provide link for video again  
If YES: Did you like the video? |

**C4. Focus group methodology.**

Focus groups will be conducted with nursery staff to obtain qualitative data to inform the Safe Sleep and Breastfeeding Nursery Education curricula. In addition, in focus groups, we will test all videos with members of the target audience for content validity, effectiveness, and cultural sensitivity. Drs. Colson, Hauck, and Kellams will coordinate the focus groups, and our social marketing and cultural competence consultants will advise us in this process. Mothers eligible for focus groups will be English-speaking, have infants <6 months of age (as young infants are at highest risk for sleep-related death), and have regular (at least weekly) email access. Participants for each maternal focus group will be fairly homogeneous with regard to SES and race/ethnicity, as homogeneity increases the comfort level of the participants, resulting in increased willingness to share thoughts and opinions. 77 Nursery focus groups will be comprised of newborn nursery nursing staff. Based on past experience, we believe that 3-5 focus groups per subgroup will be sufficient for analysis of themes and patterns. If new themes are still emerging at the end of these focus groups, more will be conducted until thematic saturation is reached. Each focus group will have 6-8 participants. To aid in recruitment, $50
and $25 store gift cards, respectively, will be provided to each mother and nursery staff member.

A trained facilitator will lead the focus groups, using a general interview guide, with topics to be discussed. However, the flow of the conversation will be largely framed and structured by the respondents. Nursing focus groups will discuss common concerns about and barriers to providing safe sleep recommendations to mothers, sample messaging for mothers, and the nursing curriculum as a whole. Maternal focus groups will be shown videos of varying length (including those made by DESAP and those available publicly that have been prescreened by research staff for appropriateness) and asked questions about the videos.

All focus groups will be recorded and transcribed. Qualitative analysis software (NVivo8) will be used to organize, sort, and code the data. Using grounded theory methodology, we will analyze the interviews for thematic content. Themes will be developed and revised in an iterative manner as patterns within the data become more apparent, and until no new themes are emerging (themantic saturation).

C5. Identification of sites and training of hospital-based study staff.

C5a. Site Recruitment. As stated above, the 16 SMART sites will be selected from sites currently participating in the SAFE study. Using probability sampling of all US hospitals that deliver ≥100 newborns per year, SAFE has recruited a nationally representative sample of 32 hospitals. Table 2 provides a list of these 32 hospitals, along with the number of births per year, and the calendar quarter during each year that the hospital is targeted to perform maternal recruitment.

<table>
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<th>Table 2: SAFE hospitals</th>
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<td>Quarter 1</td>
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<td>Riverside Reg Med Ctr VA</td>
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<td>Baylor U Med Ctr TX</td>
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<td>Mount Carmel OH</td>
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<td>Rush-Copley Med Ctr IL</td>
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In the current SAFE study, each hospital recruits ~40 mothers per year in their assigned calendar quarter to achieve a total of ~1250 mothers in each survey year (2011, 2012 and 2013). Therefore, prior to the start of the SMART study, each site will have 2 years of recruitment experience and data that can be used as a basis to select 16 SMART sites. Sites will be selected based on 1) their successful performance in the SAFE study, and 2) our ability to match sites into similar groups of 4, with regard to racial/ethnic mix, size of hospital, and baseline adherence to infant care practice recommendations (prioritizing sites with lower adherence). Within each hospital, we will use the same mother sampling strategy as has been used for the SAFE study, which was designed to ensure that 25% of the enrolled mothers were Black. To date, all of the hospitals currently in the SAFE study have been able to successfully meet their recruitment goals. To verify that current SAFE hospitals will be willing to participate in the SMART trial, we have received letters of support for this new project from all 8 of the Quarter 1 hospitals who have completed their work for the 2011 survey. Therefore, we are confident that almost all of the 32 current SAFE sites will be available as a pool from which we will be able to identify the proposed 16 SMART sites.

C5b. Identification and Training of Site Interviewers. Following the same approach as in the SAFE study, once a site agrees to participate in the SMART study, the site primary contact, with the assistance of central study staff, will identify one or more site interviewers to enroll and
C6. Recruitment procedures.

C6a. Rationale and Eligibility/Exclusion Criteria. Since randomization is at the hospital level, all mothers who deliver at a given hospital will be exposed to the educational practices resulting from the assigned Nursery Education (Safe Sleep or Breastfeeding). At each hospital, 100 mothers will be recruited who agree to receive the mHealth curriculum (randomization to Safe Sleep or Breastfeeding at the hospital level) and to provide survey information at baseline and at 2-5 months after delivery.

To be eligible for the study, the mother must live in the US, deliver a healthy infant in one of the study hospitals, plan to take her baby home with her, and be able to receive email messages. The infant must be admitted to the well newborn nursery. Excluded are mothers who are not English-speaking, whose infant is deceased, those who do not have custody of the infant, and those whose infants require hospitalization for more than 1 week, or have ongoing medical problems requiring subspecialty care. For multiple births, one infant will be randomly selected. (Please refer to section C11 for the rationale for exclusion criteria.)

C6b. Recruitment and Informed Consent. Recruitment will begin within one month following the completion of the Nursery Education training at each hospital and will use the same recruitment strategy as has been used in the SAFE study. We estimate that 85% of mothers will be eligible, and 75% of the eligible mothers will agree to participate. We thus project that each hospital will need to approach ~160 mothers about the study, resulting in 100 mothers recruited per hospital who complete the initial interview. Each hospital will be provided with written guidelines for sampling new mothers and the employee(s) designated for this task will be trained in their use. The hospital will be asked to enumerate all births happening within their specified data collection period and then to select a systematic sample of mothers using pre-assigned “start with” and “take every” numbers.

During the period of a given site’s subject recruitment, the interviewer will review each day’s hospital birth log and apply the subject-sampling scheme as described above. For each potentially eligible mother selected, the interviewer will approach a member of the mother’s care team to verify that a live birth occurred, that the infant and mother will receive care in that postpartum unit and that the mother’s medical condition does not prohibit approaching her. If these conditions are met, the interviewer will approach the potentially eligible mother and obtain verbal consent to verify the mother’s eligibility for the study. If the subject is deemed eligible, the interviewer will obtain written informed consent as required by their IRB. The interviewer will keep a log listing all potentially eligible subjects and the outcome for each (i.e., not approached;
approached but refused screening interview; screened but determined to be ineligible, screened as eligible but refused further participation; enrolled). The interviewer will, in a secure fashion, electronically send each day's log, including email addresses, to the mHealth center so that mHealth messages can begin in a timely fashion. If a given site's performance does not meet these expectations, we will provide further training to the interviewer(s) and help them identify and correct any impediments to successful subject recruitment.

C7. Performance of surveys.
The procedures established for the SAFE study will be used to perform an initial interview of mothers during the postpartum hospital stay to obtain demographic and tracking information and then to perform a follow-up survey when the infant is 2-5 months of age about infant care practices including sleep position, bed sharing, soft bedding, pacifier use, and feeding practices.

C7a. Initial Interview. Once consent is obtained, the interviewer will conduct the initial interview and record the subject's responses on an optically-scannable duplicate Teleform (Cardiff; Vista, CA). This interview will collect contact information (including home address, any alternate addresses, home and cell phone numbers, phone number of at least one close relative/friend, and email address), maternal demographic information, brief obstetrical history, data about the infant’s birth, and home environment. Each mother will also be asked if she would prefer to respond to the follow-up survey online or by telephone. The interviewer will fax a copy of each completed initial interview to the study coordinator at the Slone Epidemiology Center at Boston University (SEC) within 24 hours of completion, mail the original with a weekly batch of enrollments for verification, and keep a duplicate copy in their site study files as an additional backup. Each subject who completes the initial interview will receive a $10 gift card and a refrigerator magnet with the study logo and contact information.

C7b. Follow-up Surveys. The follow-up surveys will be the responsibility of SEC staff (supervised by Dr. Corwin), who have decades of experience in survey design and computer-assisted telephone interviews. Follow-up will consist of a single survey performed 2-5 months after enrollment. The timing of the survey coincides with the period when the infant is at highest risk for SIDS and sleep-related deaths and when the mother is most likely to change infant sleep position or location, so the survey will also ask about any potential changes in practice during this period. The survey may be performed online or by telephone, depending on subject preference and responsiveness. For online surveys, the SEC has developed proprietary techniques to design and implement customized surveys (e.g., ASP.Net [C# and VB.Net, Framework 2.0], PHP 4.x/5.x, Microsoft SQL server 2000/2005 database, Access 2000/2003 Database, IIS 6, Apache 1.3x and 2.x). Our online survey technology allows subjects to log into a secure internet study portal at their convenience 24 hours/day, 7 days/week. Surveys can be

Figure 2: Individual Subject Timeline

Birth Hospital Stay
Mothers Exposed to Intervention or Control Nursery Education as Assigned to Birth Hospital and Initial Survey Performed

Hospital Discharge - 2 Months Post-Delivery
Intervention or Control mHealth Communication as Assigned to Birth Hospital

2 - 5 Months Post-Delivery
Email and/or Phone Contact of All Mothers for Followup Survey
completed at one or multiple sittings. Data flow directly into the study’s main Microsoft Access database, eliminating the costs and errors inherent in secondary data entry.

For telephone surveys, we will employ a computer-assisted telephone interview (CATI) technique. The CATI technique is the primary means of data collection in numerous SEC studies as it facilitates accurate and efficient data collection. With CATI, interviewers can conduct interviews from any location via the study’s secure internet portal, facilitating the completion of evening and weekend interviews.

Mail surveys (used as a backup to online and telephone surveys as described below) will be formatted as Teleform documents. Teleform’s customized optically-scannable surveys can capture multiple-choice or free text responses. These surveys can be returned to the SEC by mail or fax and scanned into the study’s main Microsoft Access database.

**C7c. Follow-up Procedures.** Approximately 2 months after enrollment, each subject will be contacted either by email or telephone, according to subject’s preference, to complete the follow-up survey. For those subjects who stated a preference to complete the survey online, an email containing a link to the study internet portal and instructions will be sent. If the online survey is not completed within one week, a second email will be sent. If the online survey is not completed by one week after the second email, the subject will be contacted by telephone, as described below. Subjects who express a preference for telephone interview will be contacted by telephone. If a subject does not respond to the initial telephone interview attempt, a minimum of 10 call attempts will be made on different days of the week and at different times of day, utilizing all alternative telephone numbers collected at the time of enrollment. Subjects who do not respond to a minimum of 10 call attempts will be sent an abbreviated survey by mail covering the core infant sleep practice questions (see **Survey Content** below), along with a cover letter and pre-addressed postage-paid envelope. If the mailed survey is not returned within 2 weeks, a second identical survey will be mailed to the subject. Mothers who complete the follow-up survey will receive a $10 store gift card. We are successfully using this step-wise follow-up strategy in the SAFE study (80% response rate).

**C7d. Survey Content.** We will be using the 2 survey instruments being currently used for the SAFE study, with modifications to include questions about soft bedding and feeding practices.

The initial interview (current SAFE initial interview is provided in Appendix 1) is performed during the newborn hospital stay and includes general demographics (maternal age, race, ethnicity, marital status, education, income, employment), obstetrical history (gravidity, parity, smoking), infant history (gestational age at birth, birthweight), home environment (rent vs. own home, size of home, number of occupants, expected primary and secondary infant caretakers), and follow-up tracking information (addresses, phone numbers, email). The follow-up survey (current SAFE follow-up survey is provided in Appendix 2) is performed at 2-5 months of age and asks about past, current, and anticipated future behavior in relation to infant care practices (including feeding and sleep practices).

**C8. Data management.**

All study data will be managed at the SEC. Each subject will be assigned a unique study identifier code. Data from completed online surveys and CATIs will flow directly into the main study Microsoft Access database. Data from initial interviews and follow-up surveys received by mail will be optically scanned into the study database. Standard quality control and cleaning procedures will be applied to ensure that accurate data entry has occurred with each completed survey. All study data will be stored on secure password-protected computer servers, which are backed up automatically on a daily basis and maintained by the SEC’s full-time Information Systems staff. The database will be programmed to produce weekly reports tracking enrollment and follow-up completion and other periodic reports as required by study staff.

**C9. Data analysis.**
Our study follows a 2x2 factorial design testing the effectiveness of the Safe Sleep Nursery Education and Safe Sleep mHealth interventions. Randomization will occur at the hospital level, and so analyses will account for within-hospital clustering through generalized estimating equation (GEE) logistic regression models, which also allow for both individual-level and hospital-level covariates.

Preliminary analyses will examine loss to follow-up from in-hospital enrollment to follow-up, both examining demographic characteristics related to drop out and comparing rates of follow-up across the 4 study groups. Based on our experience with the SAFE study, we do not anticipate problems related to follow-up; however, if there are problems, multiple imputation procedures will be used to account for potential drop out-related bias. Preliminary analyses will also compare demographic characteristics of mothers and infants across the 4 study groups, to identify demographic characteristics to be examined as potential confounders in our primary analyses. Since randomization occurs at the hospital level rather than the individual level, randomization will provide less protection against patient-level differences between study groups.

For our primary analyses, separate analyses will examine intervention effects on each of the safe sleep outcomes (supine sleep position, not bed sharing, pacifier use, and avoiding soft bedding). For each outcome, we will first fit a multiplicative interaction model through GEE multiple logistic regression, with indicator variables representing the Nursery Education intervention, the mHealth intervention, and their interaction. We will also include as a hospital-level variable the pre-intervention prevalence for the outcome based on SAFE data, to control for pre-intervention hospital differences, and an individual-level variable for child age to account for differences in age at follow-up (from 2 to 5 months). The effectiveness of the combined interventions vs. each individual intervention (Hypothesis 1c) will be tested through two contrasts based on the model parameters for the intervention and interaction terms in this model. If the interaction term is significant, this model will be used to describe the effects of each intervention alone (Hypotheses 1a and 1b) and in combination (Hypothesis 1c). If the interaction term is not significant, we will fit a main effect model to test and describe the separate effects of the Nursery Education (Hypothesis 1a) and the mHealth (Hypothesis 1b) interventions. The GEE logistic regression modeling approach allows us to control for potential confounding due either to individual-level demographic factors found in preliminary analyses to differ between the 4 study groups, as well as hospital-level factors such as the pre-intervention rates of safe sleep practices. To acknowledge the multiple comparisons issue in evaluating the effectiveness of intervention on 4 safe sleep outcomes, we will use a Bonferroni adjustment for an overall 2-tailed alpha level of 0.05 (using a comparison-wise alpha level of 0.0125) when testing for intervention effects.

Analyses for our secondary aim will follow the approach of Baron and Kenny to evaluate the 3 domains of the Theory of Planned Behavior (attitudes/beliefs, social norms, perceived control) as mediators of any intervention effects. To establish that social norms is a mediator of the Nursery Education intervention effect of sleep position, for example, we would 1) show that the Nursery Education has a significant effect on social norms (through a GEE linear regression model); 2) show that social norms have a significant effect on sleep position (through GEE logistic regression); and 3) show that the effect of the Nursery Education intervention on sleep position is attenuated after controlling for social norms.

While our focus is on safe sleep outcomes, we will also be able to test the effect of the breastfeeding interventions on breastfeeding behavior (treating the safe sleep interventions as controls). Breastfeeding behavior will be captured through 4 outcome measures: exclusively breastfeeding (yes or no) and any breastfeeding (yes or no), both over the 2 weeks prior to the follow-up survey and at the time of discharge from the hospital. The effect of the 2 breastfeeding interventions on these outcomes will be evaluated through GEE logistic regression models, as described above.
Sample size and power considerations. We will enroll 100 mothers from each of 16 study hospitals, yielding enrollment samples of 400 mothers in each study group. Based on our SAFE experience, we anticipate 80% follow-up at 2-5 months, giving an analysis sample of 320 per study group or 1280 overall.

Given that this is a group-randomized design focusing on categorical outcome measures, intervention effects will be evaluated through generalized estimating equation (GEE) multiple logistic regression models to account for the within-hospital correlation structure of the sample, and sample size and power considerations depend on this within-hospital correlation as well as the intervention effects. We evaluated statistical power through simulation for the following scenario: the baseline prevalence of the outcome measure ranged from 0.50 to 0.60 across the study hospitals; hospitals were stratified by baseline prevalence and baseline prevalence was balanced across the 4 study groups; both the Nursery Education and mHealth interventions increased prevalence of the outcome by 10 percentage points and so those receiving both interventions would experience a 20 percentage point improvement in outcome. To acknowledge the multiple testing issue in examining intervention effects on four outcomes we used a Bonferroni adjustment for an overall two-tailed alpha level of 0.05 (comparison-wise alpha level of 0.0125). Under this scenario the average intra cluster correlation was 0.002 and the proposed study has 96% power of detecting a main effect of either the Nursery Education or mHealth intervention, and 80% power of showing that receiving both interventions is more effective than receiving one intervention alone.


Study implementation: Completion of study manual, site recruitment and IRB approvals by end of year 1.

Development of the interventions: Piloting and finalizing of intervention, including focus group testing of videos, by end of year 1.

Enrollment: Subject enrollment rate will be monitored on a weekly basis. If a given site is not meeting enrollment goals, a telephone conference between study investigators and the site staff will be convened to discuss enrollment procedures and difficulties encountered and a site visit may be arranged if the need for further site training is identified.

Retention: Strategies for retention are described in section C7c. In the SAFE study, these strategies have resulted in an 80% response rate in the follow-up survey. Response rates will be monitored on a weekly basis. If response rates fall below 80%, we will undertake additional procedures to improve response rate.


Randomization: We have several reasons for randomization by hospital instead of by individual participant. First, it is impractical to randomize nursery staff at a single hospital to receive different training. For the mHealth intervention, it is more feasible to randomize at an individual level, but we felt that the possibility of mothers at the same hospital sharing information would contaminate the results.

Eligibility criteria: Although we acknowledge the important role that fathers and other family members may play in making infant care decisions and while these family members will be encouraged to participate in the intervention, we will be studying the behavioral choices of mothers of newborn infants in this protocol. In addition, although it would be ideal to assess the intervention in non-English-speaking mothers, due to cost and time constraints in developing language-specific curricula, videos, and surveys, and most importantly, because the infants of recent immigrants have lower rates of SIDS and unintentional injury deaths related to the sleep environment than US-born infants, eligibility in this study will be limited to English-speaking mothers.

Validity of maternal report: It is possible that mothers might tell interviewers what they think
researchers want to hear rather than what they actually do at home. This type of reporting bias is always a possibility when there is reliance on self-report of behavior, especially when there may be a perceived negative connotation to a particular response. Ideally one would directly observe the behavior in the home, however, this is not a practical approach for this study. Objective data from the CHIME study demonstrated high correlation between maternal report of infant positioning and positioning detected by sensors. Nonetheless, to address this issue, we designed our survey instruments in a manner such that: 1) particular responses do not seem more "correct" than others; 2) items surveyed include more than just the "recommended practices"; 3) information is not provided to participants that might influence their subsequent behavior, until after key information is collected regarding the behaviors of interest.

**Variation in baseline practice by hospital:** All hospitals have policies regarding breastfeeding and safe sleep promotion. We will be aware of these baseline practices at the beginning of this study from the data obtained in SAFE. In addition, our interventions will be much more comprehensive than any of the baseline hospital practices. Our statistical analyses will account for variations in baseline practice.

**Unforeseen changes in recommended infant care practices:** The possibility that new recommendations will arise is completely unpredictable. We have specifically selected as our outcome measures infant care practices that are soundly based in evidence, such that it is unlikely that recommendations will change drastically. In addition, Drs. Moon and Hauck are members of the AAP Task Force on SIDS, which is the body that determines safe sleep recommendations. Therefore, if changes are anticipated, we will be able to make the necessary adjustments in the study design.

### C12. Study timeline.

Each hospital will have had 2 years of data collected during the SAFE study, which will provide the baseline data used to match hospitals in randomization groups and to serve as the pre-intervention infant care practice survey data. The overall timeline for the key study tasks are provided below.

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<th>Year 1</th>
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<th>Year 3</th>
<th>Year 4</th>
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</table>

The proposed timeline was chosen to spread recruitment and survey activities as smoothly as possible over the 5 year period, which provides the most cost efficient strategy to accomplish recruit subjects and perform surveys on 1600 mothers.

**REFERENCES**


73. MacGregor E, Hughes M. Breastfeeding experiences of mothers from disadvantaged groups: a review. Community Pract 2010;83:30-3.


