Breastfeeding Education Support Tool for Baby (BEST4Baby)

PROTOCOL

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Project Summary/Abstract

A goal of Breastfeeding Education Support Tool for Baby (BEST4Baby) is to conduct exploratory research, primarily through the use of focus groups, to accomplish the following:

- Understand the status of exclusive breastfeeding and other infant feeding practices from the perspective of mothers in a 6-cluster area of Belagavi District, Karnataka, India,
- Assess the acceptability of the use of peer counsellors and their effect on exclusive breastfeeding rates and other breastfeeding practices,
- Assess institutional needs for creating a successful peer counselling model to optimize breastfeeding practices,
- Understand the barriers as well as facilitating factors associated with recruiting and retaining community based peer counsellors,
- Facilitate the design of an effective and culturally-appropriate training curriculum for mothers with breastfeeding experience to prepare them to counsel and support pregnant women and breastfeeding mothers during the BEST4Baby pilot-testing phase,
- Generate information to determine how a mobile technology (mHealth) platform can support peer counsellors and promote their effectiveness and retention over an extended period of time.

Based upon the exploratory research, technological expertise will be applied to the design and implementation of a breastfeeding training program for peer counsellors, which will include multimedia content to aid counsellors in educating and supporting mothers to increase their commitment to exclusively breastfeed their infants to six months and adopt other recommended breastfeeding practices. Orientation to the use of mobile health (mHealth) technology will be integrated into peer counselling training of 24 mothers with breastfeeding experience—or 4 from each of the 6 clusters participating in BEST4Baby. The mothers recruited for training must consent to training, serving as counsellors, and assessing usability and acceptability of the BEST4Baby mHealth platform.

After completing training, each counsellor will be assigned to 5 pregnant women who consent to receiving breastfeeding counselling. Two counselling sessions will be scheduled prior to delivery, and then peer counsellors will visit mothers post-delivery in their homes. Research staff will also visit mothers to collect data on breastfeeding practices and to obtain feedback on the benefit ofBEST4Baby and mHealth tools used during the course of the project. A comparison group of mothers will be utilized to evaluate the influence of peer counselling on breastfeeding practices.

Project Narrative

Breastfeeding is good for mothers, good for babies and an especially cost-effective means for promoting infant survival, healthy growth and development. Yet a very large portion of the world's infants, including those in India, lack the benefit of optimal breastfeeding practices.

Breastfeeding Support Tool for Baby (BEST4Baby) will utilize exploratory research and community involvement to design and integrate mobile technology, culturally-appropriate breastfeeding education, and a community-based approach to increase breastfeeding support to mothers; and the initiative will provide evidence that the BEST4Baby approach can achieve the public health objective of improving rates of exclusive breastfeeding for 6 months and continued breastfeeding for an appropriate time thereafter.

Background

Breastfeeding (BF) reduces morbidity and mortality during the first year of life and decreases the incidence of mal-nutrition, acute and chronic infections, allergy, childhood cancers, childhood-onset diabetes and childhood obesity[1-3]. Breastfeeding also protects against infant mortality, especially during the first six months of life [1-3] and has short-term and long-term effects yielding health benefits which could prevent 13% of all deaths in children under five [4]. The effect of natural feeding in reducing infant mortality is significant[3,5] and has the potential to reduce as many as 156,000 child deaths each year in India and prevent 3.4M respiratory infections, and 3.9M episodes of diarrhea in young children. Global rates of optimal BF practices, especially exclusive breastfeeding (EBF), have remained stagnant over the past decade both in India and in a number of under-resourced countries [6,7.]

Barriers to early initiation, exclusive BF for 6 months, introduction healthful complementary feeding at the appropriate time, and continued BF include demographics (e.g., maternal age, parity, educational status, family size/type), socio-cultural variables (e.g., attitudes, family support, cultural perceptions, customs, etc.), and system factors (e.g., place and 8 type of birth attendant, availability of counselors)[8,9]. Achieving optimal infant feeding practices requires a multi-pronged approach that will not only involve health care providers and policy makers but will also enlist community participation and support[10,11].

One strategy for increasing BF initiation and duration is developing and sustaining community-based programs which utilize peer counselors for breastfeeding support. Such programs have demonstrated effectiveness in both developed and developing countries[6,8,12-14] including India[15-17]. The proposed research will investigate the behavioral, structural, and systemic factors that influence decisions of mothers in India related to exclusive BF and BF duration; findings will be used to develop a comprehensive program using mobile health (mHealth) technology to support peer counselors in their work with lactating mothers. The mHealth application (app) will be integrated into the training of peer counselors, provide multimedia job aids for the counselors' sessions with mothers, and provide an integrated communications network among counselors, local health centers and BF mothers. The goal of the research is to design and develop a comprehensive, culturally-relevant, community-based, peer counselor training program with an mHealth support app called Breastfeeding Education Support Tool for Baby (BEST4Baby) program.

Specific aims of the research are:

Primary Aim 1: Determine the conditions necessary to develop a program to educate and support peer counselors. Four objectives for this aim are:

1.1.Determine the knowledge, attitudes, beliefs, behaviors, motivations and barriers around the initiation and continuation of EBF to 6 months, introduction of healthy complementary foods at the appropriate time, and continued breastfeeding from the perspective of BF mothers and their support networks (i.e., husband, mother-in-law, etc.).

1.2. Assess the acceptability and feasibility of the peer counselor model for improving EBF rates and other BF practices.

1.3. Identify the barriers and facilitators for recruiting and retaining peer counselors.

1.4. Create a culturally appropriate training curriculum for BEST4Baby to prepare peer counselors for their roles.

Primary Aim 2: Evaluate the usability and feasibility of the BEST4Baby's mHealth application to support a community based program utilizing peer counselors to provide breastfeeding support to Indian mothers. Objectives for this aim are:

2.1. Develop the BEST4Baby's mHealth application prototype to support peer counselors.

2.2. Assess the effect size of the BEST4Baby program with 24 peer counselors who each will support 5 breastfeeding mothers (total of 120) from study clusters who deliver their babies during a 9-month pilot by comparing breastfeeding practices among 120 mothers who reside in adjacent communities and have not been provided breastfeeding counseling.

The primary outcome of this research is hypothesized to be an increase in relevant training and capabilities for supporting peer counselors using the BEST4Baby program. A secondary outcome is hypothesized to be an increase in EBF rates at 6 months postpartum among mothers coached by peer counselors. These mothers will learn when to initiate healthful complementary foods and be more likely than the comparison group to express a willingness to continue breastfeeding for an appropriate time when intent is measured prior to the close of this 2-year project. The outcomes for the proposed research are significant due to their focus on sustainable strategies for EBF, a critical infant health intervention. The BEST4Baby methodology is innovative as it involves development of low-cost technology suitable for cell phones and tablets and appropriate for use during training and to support peer counselors as well as mothers. Our highly qualified, inter-disciplinary, international research team has the skills and experience necessary to successfully complete all proposed activities. The team has training experience and expertise, knowledge of lactation practices among Indian women, capabilities in maternal/child health research including community-based participatory research (CBPR), skills in quantitative and qualitative methodology and rich background in leading-edge information and communication technologies.

Significance

Breastfeeding, a natural and safe means of feeding infants, provides nutritional, immunologic, psychological and economic benefits with recognized and unquestionable advantages. Human milk is a complex —species-specific biological fluid, adapted throughout human existence to perfectly satisfy the nutritional and immunological needs of the child[5]. For many years BF has been known to be an important intervention in developing countries to reduce mortality from infectious diseases and malnutrition[3]. However, only 39% of all infants worldwide receive EBF, even when the assessment is made in children less than four months of age [18,19]. Factors such as maternal age >35 years, nulliparity, low birth weight, resuscitation, and delivery by caesarean section contribute to the lack of EBF in settings found in India, where infant and young child feeding practices are not optimal . Studies in India show that EBF drops rapidly from the first month to the sixth month by which time only 20% of children are still being breastfed[20]

Most national and international organizations that monitor health outcomes strongly recommend breastfeeding. Since May 2002, the World Health Organization and UNICEF have jointly developed and supported the Global Strategy for Infant and Young Child Feeding to revitalize global attention on the impact of feeding practices for improving child survival, growth and development . In 2011, the Breast Feeding Promotion Network of India initiated a plan to enhance the practice of BF in the country. The action plan suggested the opening of resource centers, counseling services and communication campaigns [20]. In August 2016, India launched a nationwide program, Mother's Absolute Affection (MAA), to bring undiluted focus on the promotion of BF and to ensure that mothers receive counseling and support by family members and at health facilities. The BEST4Baby program will build upon both these initiatives while focusing on the implementation and sustainability of utilizing peer counselors for breastfeeding support using an mHealth app.

Community-based peer counseling is a cost effective method for increasing the rates of breastfeeding initiation and duration[6,22]. The impact of such counseling on infant feeding patterns is related to the easy accessibility, long standing[12] relationships, and geographical proximity of peer counselors to BF mothers . The effectiveness of peer counseling on EBF has been strongly demonstrated in both developed and developing countries [6-8,12-14,23-24] including India[16.] However, a need remains to identify strategies to enhance sustainability of the peer counselor model.

The BEST4Baby program will recruit peer counselors and integrate recommendations for maintaining programs using community health workers--for example, training for the peer counselor role, mechanisms to sustain morale and motivation, social recognition of BF expertise, supportive supervision, provision of badges and work bags with logos[25,26.] Modest compensation for time and costs associated with participation will also be provided. And importantly, our strategy will involve development of an mHealth application with features to support the peer counselors. Further, we will carefully document and publicize improvements in service delivery and population health that result from the program to the community itself, local providers, and local, regional and national policy-makers. Such efforts will be critical to improve knowledge and maintain support for peer counselors while improving maternal/child health [22,27]

Innovation

The BEST4Baby program, through the use of mHealth technologies will seek to address the challenges found in the available literature related to peer counseling. We propose to maintain a peer support network and an ongoing mobile connection with both peer counselors and public health support organizations. The use of mHealth applications has significant potential to increase access to care and improve health by supporting optimal BF practices[28,29] . India is one of 30 the world's fastest growing markets for mobile technology, reaching over 1 billion mobile subscribers in early 2016 Mobile technologies can both expand the range and increase the efficacy of peer counselors by training and supporting these counselors and by providing additional resources to be shared with BF mothers. The proposed research represents an innovative, substantive departure from the status quo in two key ways:

- Development of a **culturally-relevant, mobile-based** tool that will support the initial training and ongoing learning of peer counselors, with pedagogy such as micro-learning (i.e., bite-size information delivered in 3-5 minutes) to train and provide refresher training, video content to motivate mothers to exclusively breastfeed, and multimedia content to aid during home visits. All content will be created in an accessible format and account for cultural norms and low literacy rates in the target population of mothers.
- Provision of **mobile technology features** to support communication between peer counselors and clinicians at local health centers including responding to technical questions and referrals. This approach will enhance relationships with health workers (i.e., accredited social health activists, or ASHAs) who may also support breastfeeding as a minor part of their overall public health responsibilities.

Specific Aim 1

General Approach. Descriptive, qualitative research will provide information relevant to the four objectives associated with Aim 1. Formative research will be conducted, primarily using focus groups, to understand behavioral, structural, and systemic factors that influence BF decisions and actions. Formative research generates rich, detailed data that leaves the target populations' perspectives intact, provides a context for health behavior, and ensures that programs, training materials, and tools are acceptable and feasible for field testing.

Months 1-3

To address Aim 1 and its four objectives, focus group discussions (FGDs) will be used. This methodology uses in-depth, open-ended questions to help participants explore and clarify their views in a way that is often unattainable in an individual interview and allows flexibility for the research to move in new and unexpected directions[32,33]. FGDs will be held with women who have previously breastfed, members of their support network, and health providers, such as physicians, nurses, midwives, and ASHAs working with the public health system. Each focus group will consist of 8-10 participants and be stratified by key characteristics such as gender, age, and educational level. Focus groups will last approximately 90 minutes. Informed consent will be obtained from all participants. The consent will be read aloud before participants sign to ensure that all participants understand, can ask questions, and knowledgeably provide consent.

The groups will be led by JNMC field research officers who are trained as focus group facilitators. They will recruit participants that match target group characteristics, lead the group discussion, and manage group dynamics. Facilitators will be matched to the key characteristics of the group to avoid potential power dynamics that may affect the openness of the group discussion. Each facilitator will follow a general discussion guide that includes key questions, but also allow flexibility so participants have an opportunity to elaborate and pursue unanticipated but important and relevant topics. All focus group sessions will be audiotaped for transcription and translation into English, and for extraction of key themes.

Specific methodology for each Specific Aim 1, Objectives 1-4 are below.

	Sample: A FGD for mothers in each of six clusters participating in BEST4Baby; at least two FGDs for Target B Population: Target Group A: Mothers who have successfully breastfed at least one child in the past three years. Target Group B: Members of breastfeeding mother's support network (e.g., mother, mothers-in law, etc.) Data Collection Goal: Assess cultural factors that affect BF initiation and maintenance, focusing on: BF practices: knowledge, individual and community attitudes/customs/taboos, intentions, barriers to BF; timing of BF initiation; frequency of EBF; practices related to prelacteal feeds; colostrum; weaning; caregivers for mother/baby while mother is recovering from birth; mother's daily routine Support mechanisms for BF mothers (e.g., relatives, spouse, health care providers, etc.)
	Sample: At least two FGDs with each of two target groups Population: Target Group A: Mothers who successfully have breastfed at least one child in the past three years. Target Group C: Facility- and community-based providers who work with BF mothers in any capacity. Data Collection Goal (Objective 2): Assess cultural factors that affect acceptability of peer counselors focusing on: Perceptions of who qualifies as a peer and the acceptability of receiving BF counseling and advice from such a person Current availability and adequacy of BF information and support to women within the community, and need for acceptance of village women serving as peer counselors Assessment of existing breastfeeding initiatives (nationally, within states and locally) Benefits and challenges of implementing a breastfeeding counseling program Data Collection Goal (Objective 3): Assess cultural factors that affect recruitment/retention of peer counselors focusing on: Role of health workers in the community: their status; type of activities and social organizations for other health workers; future opportunities for peer counselors within the community; barriers to sustaining peer counselors on the community-level; and barriers to involving other health care workers Identification of potential peer counselors, criteria for acceptance of such counselors, and recruitment locations Culturally-appropriate support (social, emotional, other) for retention of peer counselors; ties to community organizations Data Collection Goal (Objective 4): Determine components of a culturally-appropriate training program focusing on: Desirable knowledge and skills (e.g., listening and communicating effectively) of a peer counselor Ideas (e.g., training features, communication tools, etc.) for integration of mHealth technology for support

Months 4-5

Data Analysis of Focus Groups

A three-stage strategy will be used to analyze FGD data. Stage 1 will focus on contextual factors. Descriptive statistics will be used to characterize community, health facility, and participant sociodemographic characteristics.

Thematic analyses will describe the context of each session and conditions that could have affected the perspectives of 34—36 participants, and the social circumstances of the group . Stage 2 will be a within-session analyses. Content and thematic analyses will be conducted for each focus group session. Content analyses will examine how often a topic was mentioned, the emotional tone of member interactions, and how many members talked about a given topic. Thematic analyses will be conducted to identify the types and range of participants' focal concerns related to the research questions. Direct quotations will be cited in the report as representative examples of participants' opinions. Stage 3 will include between target-group comparisons. Responses within each target group will be compared to parallel questions in the protocol for convergence or disagreement on major themes.

Months 6-8

For Specific Aim 1, Objective 4, create a culturally appropriate training curriculum to be used by peer counselors, training content will be based on the WHO breastfeeding counseling course, adapted for cultural relevance and based on FGD findings. Training materials will be developed by Dr. Goudar, Co-Investigator and Research Coordinator, and his staff in consultation with the PI and other Co-Investigators. Multiple educational techniques will be used, including interactive lectures, demonstrations, practical exercises, and discussions based on analysis of focus group results. After development, the curriculum will be translated into Kannada, the most common language in the state of Karnataka. Adequacy of the translated curriculum will be assured by application of strategies identified below:

Linguistic and Cross-cultural Equivalency. Culturally appropriate content is conceptually and technically equivalent to the source language and linguistically appropriate for the target population. To ensure cross-cultural equivalency, two focus groups of Indian mothers (total n= 16) residing in the study area will review BEST4Baby training materials to assess the understandability and relevance of the training content.

Methods for Achieving Linguistic and Cross-cultural Equivalency. Researchers generally agree that using the direct translation technique (also called one-way-translation) is insufficient for translating training content. In developing BEST4Baby training content, we will use translation, back-translation, and review by committee and focus groups to achieve cross-cultural equivalency with individuals from the target population.

Review by Committee. The translations will be reviewed by the project staff for differences in word choice. After this, the translators and project staff will convene a meeting to discuss discrepancies identified in their review, to correct errors in grammar and syntax and to resolve problems of equivalence found among the versions of the content. The review-by-committee approach is useful in neutralizing the cultural, social, and ethnic bias that can be introduced when using only one translator and one back-translator.

Specific Aim 2

For Specific Aim 2, we will create and evaluate an mHealth app for peer counselors, which will include multimedia content to aid in educating and supporting mothers in their desire to exclusively breastfeed.

Months 9-14

Data from the FGDs will inform the requirements for the development phase of the BEST4Baby program. FGDs will facilitate an understanding of cultural and social barriers to breastfeeding, identify breastfeeding resources that may be available online or via mobile devices as well as their use and perceived benefit by FGD participants. Information generated by FGDs will thus help ensure that the BEST4Baby app is well-designed to meet project aims and objectives.

The mHealth app development will include cross-platform mobile technologies (i.e., CSS, HTML5, Javascript, React.JS, and SQLite). The initial mHealth app architecture will include on/off line capabilities to address wireless coverage issues. The team will develop security features, such as strong password protection for authentication, access control, and secure transport of information via Secure Sockets Layer (SSL), to ensure the mHealth app conforms to India's regulations regarding privacy and security of patient data. We will also incorporate usability measurements as part of our prototype development to help monitor the usability of the mHealth app by the peer counselors in the context of antenatal care and postpartum visits. An Agile development methodology, an iterative and incremental software development approach with each iteration called a —sprint,

will be used with approximately five 4-week sprints to develop the functionality of the BEST4Baby€s mHealth app. The core functionality and features design will focus on distribution of prenatal and post-partum training guidelines and support features to peer counselors including:

Micro-learning content. Microlearning is an educational technique centered on the following concepts: (1) time: relatively short sessions lasting 3—10 minutes, (2) content: small, bite-size units of information covered in each session, (3) curriculum: sessions are part of a curriculum, (4) form: all sessions presented in the same format, and (5) 37 flexibility: different time and location for delivery . Users can use micro-learning to master complex topics through many short-length sessions. Content will be based on the WHO breastfeeding counseling course as modified.

Video content. Creation of a video is envisioned for training peer counselors and, as appropriate, during the home visits to improve the knowledge of mothers regarding exclusive breastfeeding and optimal feeding practices[38]. The promotion and educational video will largely consist of brief, realistic interviews citing mother's experiences with BF and the importance of community education and support. The video will be created in a compatible format suitable for viewing on devices purchased for the BEST4Baby program and for placement on social media platforms.

Multimedia content. Multimedia content will be developed based on Social Cognitive Theory (SCT)[39], Theory of Planned Behavior (TPB) [40] and social marketing (e.g., health branding) approaches[41,42] for use by peer counselors for breastfeed during the home visits. Message development will follow active audience engagement methods and be suitable for use by peer counselors to provide information to mothers during antepartum home visits.

Communication features. Timely communication of information based around post-partum time sequence and baby's milestones will be developed to assist the peer counselors in promoting optimal breastfeeding practices. Counselors may be reminded of the need for follow-up via text reminders and communications may support the home visits by providing helpful hints that are introduced in a timely manner. For example, the peer counselors could be prompted to discuss the topic of EBF at 28 weeks GA and at a second visit 1-2 weeks before anticipated delivery.

Months 15-23

For Specific Aim 2, we will pilot test the BEST4Baby program in a real-life setting within the 6 clusters of the larger Global Network research area located in Belagavi District (Karnataka, India). The pilot study will evaluate training for 24 peer counselors recruited from study areas and providing consent; and the study will assess use of the BEST4Baby program to support counselors as well as mothers recruited and consented by research staff to receive peer counseling. Each peer counselor will counsel 5 mothers to achieve a sample adequate to establish an effect size.

Peer Counselors for Breastfeeding Support. The 24 peer counselors will evaluate the usability and acceptability of the mHealth app for the training and support provided. We will perform pre- and post-tests to identify knowledge acquired as a result of peer counselor training and administer a post-training survey on the usability and acceptability of the BEST4Baby program. As peer counselors are being trained, they will receive an ID badge[28], the BEST4Baby mobile application and branded BEST4Baby mobile device to support the training.

New Mothers. New mothers will be advised that if they consent to participate, they will receive support from peer counselors, information either via paper or mobile (text message and/or video using a mobile phone), and follow-up visits from peer counselors during the 6 months post-delivery. After consent, we will allow mothers to be contacted by one of the trained peer counselors.

Intervention and Data Collection Plan. Peer counselors will have a minimum of 9 visits with mothers. Visit 1 and 2 will occur prenatally at which time baseline data will be collected; initial BF education based on appropriate BEST4Baby content will also take place. The counselors will visit the new mothers within 3-5 days after delivery to obtain relevant data (e.g., when breastfeeding was initiated) and provide needed assistance in establishing BF. Another visit will occur again at two-weeks post-partum to record progress and offer support; remaining visits will be based on an agreed upon schedule. Information will be exchanged at visits and potentially between home visits. BF mothers may request additional visits and peer counselors will be available by phone to answer questions and address concerns. Data will be collected to determine usage of the BEST4Baby app during each visit. Standardized data collection sheets for the peer counselors will be developed; and counselors will be trained in writing field notes and documenting their impressions of the visit. At six months postpartum, research staff will query the mother about present and planned BF practices, environmental influences on breastfeeding, level of community support for BF, and overall satisfaction with the BEST4Baby program. At study conclusion, research staff will obtain feedback from the peer counselors on usability of the mHealth app.

Comparison Cohort. To enable effect and sample size calculations, an appropriate comparison cohort will be used. We will obtain baseline and six-month post-partum data from a control group of 120 women delivering in facilities and living a suitable distance from study clusters to avoid contamination. A simple survey will be developed and administered by research staff to collect data comparable to that collected from mothers counseled (e.g., current BF practices and future intentions for continuation of breastfeeding). Women in this comparison cohort will provide informed consent and be provided with a small gift (e.g., a branded carrying bag) to show appreciation for their participation.

Month 24

Data Analysis. For survey, application utilization, and subject data associated with Specific Aim 2, we will conduct bivariate analyses (crosstabs, Chi-square procedures) to examine demographics and other measured variables potentially related to breastfeeding. Changes from baseline to follow-up in breastfeeding and other study outcomes and potential moderating variables (e.g., lifestyle changes due to childbirth and behaviors) will be examined.

We will also document engagement in and use of the BEST4Baby program by both the peer counselors and new mothers. The BEST4Baby program will collect usage data, (e.g., utilization, approximate time spent in use of application during home visits) in the follow-up interviews. These combined process measures will be calculated as a _dosage index' and used as a covariate in subsequent analyses. The dosage index will both 1) document process and 2) serve as an independent variable for multivariate modeling. Dosage measures will include time/counts of activity, intensity, engagement, and satisfaction, and will serve to document the feasibility of the BEST4Baby approach to train the peer counselors as well as to support new mothers to initiate and continue breastfeeding.

We plan to: (1) apply exact logistic regression models to determine if the level of participation in BEST4Baby is associated with an increase in optimal breastfeeding practices, and (2) test mechanisms underlying behavioral outcomes hypothesized in the conceptual model leveraging social cognitive theory, theory of planned behavior, and social marketing. Exact logistic regression models will examine the effect of BEST4Baby dosage, using the dosage index based on pilot test usage and self-report data as independent variables, on 6-month continued breastfeeding. We will calculate odds of exclusive breastfeeding, mixed feeding and use of milk substitutes at follow-up as a function of BEST4Baby dosage based on utilization and process data.

Conclusion: We anticipate that the BEST4Baby program will substantially increase the capacity of the JNMC Women's and Children's Health Research Unit to incorporate mHealth technologies into future use and health care delivery. We plan to utilize findings generated by analysis of BEST4Baby data to develop an application for a fully powered control trial to assess the separate and combined impact of a peer counselor program and mobile applications to support such a program. Cost considerations and greater attention to sustainability will likewise be addressed in that application.

I. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section. Focus groups utilizing trained facilitators will be the primary method for gathering information from subjects that have consented to be participants. Focus groups are considered needed to understand behavioral, structural, or systemic factors that influence decisions and actions of mothers in India related to initiating breastfeeding of their newborns, the nature of breastfeeding between initiation until infants reach 6 months of age (exclusive or not exclusive), and the duration of breastfeeding. Focus groups will also enable assessment of current availability, accessibility, quality and effectiveness of breastfeeding counseling and support within selected community clusters in districts used by the JN Medical College Research Unit to conduct women's and children's health research. Further, focus group data will aid the design of breastfeeding education and mobile health tools that will enhance breastfeeding education and counseling effectiveness.

Some one-on-one interviews, rather than focus groups, will be conducted—for example with fathers scattered among clusters utilized for BEST4Baby. Government officials will also require one-on-one interviews. Either interviews or focus groups will be held to identify and consent women to be trained as counselors using a BEST4Baby educational program and learning processes specified in this application. Those agreeing to be trained will also be consenting to serve as peer counselors who will counsel pregnant women and mothers during the BEST4Baby pilot-testing phase.

Subjects that take the BEST4Baby training will take pre- and post-tests to assess if training increased breastfeeding knowledge; these women will also be asked to provide feedback relative to the acceptability of mHealth technologies and tools developed during the BEST4Baby program and to share perceptions about the perceived feasibility of continuing their use during an extended period of service as a counselor. Mothers will be recruited by research staff and asked to consent to being counseled during home visits and to providing data needed for purposes of BEST4Baby. Research staff will obtain feedback and ask questions to generate information about breastfeeding (e.g., when it was initiated, if exclusive breastfeeding occurred, how long any type of breastfeeding was maintained, and intent to continue breastfeeding beyond the close of BEST4Baby). A group of mothers not receiving peer counseling will also consent and serve as a comparative group to assess if breastfeeding practices are better among peer-counselled mothers compared to mothers not having peer counseling.

It is planned that data generated by the BEST4Baby formative research will be utilized for the design of a clinical trial that can generate definitive findings relative to the effectiveness of mobile technologies to promote optimal breastfeeding and to increase sustainability of a peer counselor model for delivery of breastfeeding support.

Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant. Focus groups will have 8-10 participants and all participants will consent before initiation of focus group discussions. At least two focus groups will be held for each target group described below, except that there will be at least one Target Group A focus group in each of the six clusters selected from among the clusters located within the larger JN Medical College Global Network study area for participation in BEST4Baby. Characteristics of focus group target groups follow.

Target Group A: This group will be comprised of mothers who have breastfed at least one child in the past three years. Other inclusion criteria include: 18 years of age, and willing to provide informed consent. To the extent feasible, mothers representing the diversity that exists in the cluster of residence will be encouraged to participate. A Target Group A focus group will be held in each of the 6 clusters participating in BEST4Baby.

It is also planned that two additional Target Group A focus groups will involve mothers with recent breastfeeding experience. These mothers will assess if the BEST4Baby peer counseling training program, as initially designed, includes relevant content and that the version translated into the local Kannada language is linguistically equivalent to the source language (for example, to a WHO breastfeeding training manual available in English).

Target Group B: This group will be representative of a pregnant woman's social support network (e.g., a mother, mother-in-law, and spouse) as members of such a network affect the level of support a woman receives in her efforts to breastfeed and whether breastfeeding occurs on an exclusive basis or not.

Target Group C: This group will be comprised of health care providers who have in the past or will be responsible for providing advice and support to breastfeeding mothers. We will attempt to interview both facility-based health care providers (both male and female) and community-based health care workers such as the Accredited Health and Social Activists (ASHAs) that are females selected from villages to work as an interface between the community and the public health system, especially for the benefit of facilitating facility births and promoting improved maternal/child health.

Based on our plan for focus groups, it is anticipated that over 100 individuals will participate in focus groups during the course of our project. In addition, some individual interviews will occur—for example, we plan to interview 20 fathers individually to reach those that may be hesitant to participate in a group discussion. Additionally, government officials, representatives of breastfeeding advocacy groups and other breastfeeding stakeholders may be interviewed.

We plan to recruit and train 24 peer counselors, four from each of the six clusters participating in BEST4baby. They will be provided modest consideration for time and costs associated with participation and will ideally live close to mothers they will eventually counsel. They should have had a relatively positive breastfeeding experience and some awareness of breastfeeding recommendations by trusted health organizations and breastfeeding advocacy organizations.

The mothers who will be recruited to receive breastfeeding counseling and support will be women living in study clusters who are in their third trimester of pregnancy and who consent to interaction with the breastfeeding counselor who will contact them prior to delivery and then make home visits for breastfeeding counseling according to an agreed upon schedule and consistent with the BEST4Baby protocol. Peer counselors will be expected to counsel 5 mothers during an approximately 9-month pilot-testing phase. Thus, with 24 counselors, 120 mothers will be counseled. Additionally, 120 mothers from clusters that are not participating in BEST4Baby and not receiving counseling through BEST4Baby will be consented and serve as a comparison group to allow assessment of the influence of peer counseling on breastfeeding practices and intent to continue breastfeeding for the recommended period of time.

Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation. Due to the exploratory nature of the proposed research, there is no rigid sampling plan. Field research staff assigned to recruit subjects for focus groups will be presented criteria for including subjects that have characteristics of the target groups specified above. At the same time, staff will recruit participants that are reasonably representative of the diversity that may characterize a cluster.

Some individuals to be interviewed may be interviewed at location at which they can be found, and which will accommodate a private interview. For example, we anticipate interviewing fathers at a delivery facility they may be visiting prior to discharge of mother and baby. Government officials will be selected due to the need to collect information useful due to their role related to breastfeeding rather than personal characteristics.

For the exploratory research associated with BEST4Baby, mothers will be > 18 years of age. This is due to several reasons: the majority of mothers delivering in India, particularly in Karnataka State, are 18 or older; the preference of the Indian Council of Medical Research that adults be used for research when it's purpose can be achieved without using younger subjects; and the special consent/assent procedures that would be required if females under 18 are used. Funding limitations and a short timeline for project activities suggest that research involving younger pregnant women/ mothers can best be accomplished in a separate study that will enable focus on the diverse needs of such a group. And for some of the same reasons as noted above, we anticipate that all subjects that will be consented for BEST4Baby will be 18 years of age or older.

A very limited time will occur between recruitment for a focus group or an interview; thus, long-term retention of subjects for BEST4Baby research activities should not be a problem. Research staff will be responsible for explaining the purpose of the research activity and providing location and time of the scheduled event to ensure that individuals do NOT consent unless they are willing and adequately motivated to present themselves at the research event.

Pilot-testing requires recruitment of potential counselors and mothers willing to engage in interactions associated with BEST4Baby for a longer period of time, and length of retention from consent to the month prior to study closure will be monitored and noted. Additionally, it is hoped that women engaging in counseling and support of breastfeeding mothers will continue to perform these activities until project end (and ideally beyond). Mothers that are receiving counseling and support will hopefully not withdraw (despite their right to do so) from project participation so that most mothers having infants reaching six months of age before the 24th month of the study can be contacted to ask if they breastfed infants exclusively for six months post-delivery and about other infant feeding practices. Mothers having older babies before the 24th month of the project will be asked if breastfeeding was continued after their infant reached 6 and the introduction of complementary feeding. And prior to the end of BEST4Baby, we will also seek information from mothers still breastfeeding about their intent to continue breastfeeding. An improvement in breastfeeding exclusivity and breastfeeding duration higher than recently reported —baseline data for Karnataka (which can be found in the Rapid Survey of Children, Final Report for 2013-2014 issued by the Ministry of Women and Child Development, Government of India as of April 2016) will suggest that the tools utilized have the potential for influencing improved outcomes and provide the basis for the design of a subsequent clinical trial.

If relevant, explain the rationale or the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. It is possible that pregnant women that have breastfed at least one child in the past three years could be included in focus groups for Target Group A, and some pregnant women will be recruited for the pilot-testing phase of the project. For research designed to explore how to improve breastfeeding exclusivity and duration, it is essential to involve such women. The exploratory research associated with BEST4Baby poses very low risks that are outweighed by the potential health advantages that could be realized by mothers and babies due to achievement of breastfeeding objectives.

It is desirable to involve subjects of diverse socio-economic status in BEST4Baby, including those that may be of lower socio-economic status. Modest compensation based on consideration of time or costs associated with participation in the project will be provided to subjects participating in focus groups or as breastfeeding counselors; however, the compensation will not be substantial enough to represent a means of pressuring lower income subjects to participate.

If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, provide details about all planned interventions such as dose, frequency, and administration. BEST4Baby encompasses exploratory research; thus subjects are not randomly assigned to an intervention or control group. Rather, those that reside in a study cluster or work with a facility serving such a cluster (in the case of a Target Group C) and have characteristics appropriate for a focus group, interview, counselor education and training, or breastfeeding counseling and support will have the opportunity to participate if willing to consent to participation. Mothers (12)) who reside in adjacent communities outside of the six BEST4Baby study clusters and not provided breastfeeding counseling will be asked to consent to serve as a comparison group to the 120 mothers counseled to enable effect size of the influence of peer counseling on breastfeeding practices.

List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected. Research described in this BEST4Baby application will take place within clusters utilized by the Women's and Children's Health Research Unit of the foreign collaborator in this project—JN Medical College. This Research Unit has engaged in research funded by National Institute of Health divisions (primarily the National Institute of Child Health and Human Development) as well as research funded by other public and private entities based in India, the US and elsewhere in the world. The Unit conscientiously adheres to procedures designed to protect privacy and confidentiality rights of subjects. Prior to sharing research data with key personnel of other collaborating institutions, personal identifiers from focus group transcripts and reports of interviews as well as data collected from counselors and mothers will be removed. Only basic characteristics (e.g., cluster of residence, age or age-rang) will be retained. Any research-related documents that JNMC retains per country regulations (e.g., consent forms) will be maintained in limited access areas in locked storage cabinets.

II. Sources of Materials

Describe the research material obtained from living individuals in the form of specimens, records, or data. Source materials are summarized below.

- Focus group data transcribed and translated into English from an electronic copy of focus group audio-recordings that will be in Kannada, the local language most typically spoken in the Belagavi District
- Interview summaries with pre-determined questions and answers provided on a standardized report page
- Pre and post-test scores of counselors recruited for breastfeeding education and performance of breastfeeding
- Data generated when breastfeeding mothers counseled by peer counselors are visited in their homes and interviewed for a period of about 10-15 minutes during which time they are asked questions on breastfeeding practices, the answers of which are relevant to this research
- Data generated from interviews of mothers from communities not in the study area who receive no counseling but agree to be interviewed about breastfeeding practices
- Records with contact information and other necessary data to enable participation in research components of the project and the interactions with and between counselors recruited for breastfeeding education/training and mothers who will receive counseling and support during the pilot testing phase of the project

Describe any data that will be collected from human subjects for the project(s) described in the application. Data, primarily qualitative in nature, to be collected from human subjects is listed below.

- Data related to knowledge, attitudes, beliefs, behaviors, motivations, and barriers that influence breastfeeding practices
- Data useful for assessing if the peer counselor model is a feasible means for increasing exclusive breastfeeding and maintaining breastfeeding for the recommended period of time
- Data related to the barriers and facilitating factors for recruitment and retention of breastfeeding peer counselors
- Data that describes institutional needs for creating a successful peer counseling model and a successful culturally appropriate training curriculum
- Data relevant to the feasibility of using a mobile -based platform to support the peer counselor model for education, counseling and support of mothers
- Data relevant to the feasibility, acceptability and effect size of the BEST4Baby program o Survey data from mothers which includes socio-demographic data; data relevant to breastfeeding and support for breastfeeding; breastfeeding knowledge, attitudes, beliefs, and intentions to continue breastfeeding; and environment influences and factors that support breastfeeding
- Data relevant to the acceptability and use of breastfeeding mobile technology tools
- Names and contact information of subjects recruited to participate in components of the project

Data resulting from querying mothers receiving counseling/support during the pilot testing phase of the project based, for example, on questions related to if and when babies were breastfed exclusively, pre-lacteal feeds given to newborns, when breastfeeding was initiated and when it was stopped, when complementary feeding was initiated.

Indicate who will have access to individually identifiable private information about human subjects AND
Provide information about how the specimens, records, and/or data will be collected, managed, and protected, as well as whether any individually identifiable private information will be collected specifically for the proposed research project:

Due to the exploratory nature of the research associated with BEST4Baby, there is limited need for collection and retention of individually identifiable private information. Some background

information from subjects participating in focus groups and interviews or feedback surveys may be desirable, such as cluster of residence, gender, participant role, and basic socio-demographic information. However, there should be no need to associate the information with a name, birthdate, or other identifier that might jeopardize privacy/confidentiality.

Although it is anticipated that digital audio-recording of focus groups will occur, a method will be used to avoid use of names during the discussions. It should not be necessary to put names on interview forms or staff notes of such interviews. But if access to private information about humans occurs, it would only be JN Medical College research staff that would have access to such information (and then only until data can be de-identified).

As subjects are identified for participation in focus groups, names and contact information may be recorded and retained in locked cabinets at the Research Unit and destroyed subsequent to completion of the focus groups. Subjects recruited for the provision of breastfeeding education/training and participation in the pilot-testing phase of the project will provide contact information (names, addresses, phone numbers). Access to secured records will be only on a —need to know basis,

Any quantifiable data (such as pre- and post-test scores of those receiving breastfeeding education) will be collected and entered into a database by JNMC research staff using only a coded number to indicate subject source; if there is need to keep a log with subject name and code number, the log will be kept in a locked cabinet in a limited access area. Only the Research Coordinator or his designee will be able to access the log.

IIII. Potential Risks

Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects. The research to be carried out in association with BEST4Baby poses no or low-risk of physical, financial, or legal repercussions. However, it's impossible to rule out the potential that a subject might experience psychological distress or embarrassment under certain conditions. For example, focus groups involve multiple participants and researchers cannot guarantee that no one will repeat opinions and information shared during discussions; further, remarks could be attributed to specific individuals even if names are not used during the discussion since participants may know each other. Yet the questions to be asked for the focus groups will likely yield responses resulting in minimal risk to subjects even if discussion is shared. There is also the possibility that a focus group subject could direct unkind remarks toward another participant in the group despite the fact that focus group facilitators will be trained to minimize such an occurrence.

A one-on-one interview between a subject and member of the research staff poses no to low risk if the setting for the interview affords privacy and the researcher is committed to ensuring the subject's rights to privacy and confidentiality.

It is proposed that those recruited to be peer counselors be given a pre- and post-test to assess the effectiveness of the educational strategy to increase breastfeeding knowledge. They will also be asked to participate in a usability survey. No penalty results if a counselor fails to provide evidence of increased knowledge, but there is the possibility of disappointment or self-criticism; also, some individuals experience test-taking anxiety. But these psychological risks would generally not have a serious impact. Nevertheless, research staff will have information to enable the provision of counseling or assistance to a subject experiencing psychological distress or harm due to research participation.

Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research. When alternative treatments or procedures are possible, the rationale for the proposed approach should be clear. NA due to the exploratory nature of the research.

IV. Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent. Subjects will generally reside in a cluster participating in the study or they will be a provider serving a facility in the area. Typically, JNMC maintains contact with the public health facilities and medical directors located in its research area. Often community leaders are known to staff of the Research Unit, and accredited health and social activists (ASHAs) working within study clusters have assisted in the conduct of JNMC research initiatives. Thus, the Research Unit should be able to arrange informational sessions in study clusters or engage in other community sensitization activities to facilitate the identification and recruitment of subjects suitable for participation in BEST4Baby.

Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects ' capacity to consent will be determined and plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. JNMC research staff will visit clusters to identify and recruit subjects. Adequate information will be provided about the type of individual needed for the specific form of research (such as a focus group) and the researcher will provide the potential subject with an explanation of the purpose of BEST4Baby and indicate what is expected of subjects, the type of questions to be asked and data sought, the risks and benefits associated with participation, procedures to be used to generate data, plans for data use and data protection, and other information appropriate for inclusion in a written consent form (such as the subject's right to withdraw from participation). Research staff will conduct a screening per specified protocol procedures to ensure that potential subjects meet inclusion criteria and are willing and able to participate. Children will not participate in research activities; and the subjects to be recruited will be capable of giving informed consent on their own behalf per the judgement of the researcher. Research staff charged with recruiting for focus groups or interviews will be given guidance before initiating recruitment so that adequate numbers of participants are recruited and participants exhibit the desirable balance of subject characteristics.

If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested. No waivers are anticipated for written consents that will be signed. Interviews that meet the Office for Human Research Protections for verbal consent and are approved on this basis by the Ethics Committee of JN Medical College and by a Thomas Jefferson IRB will be conducted after receipt of verbal consent.

b. Protections Against Risk

Describe planned procedures for protecting against or minimizing all potential risks identified, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness. Section I. c. discusses potential risks and indicates that there is low-risk of physical, financial, or legal repercussions but psychological risks cannot be ruled out. The most likely causes of potential risk are the sharing of focus group discussions, unfriendly remarks that may become more common as the number of discussion participants increases, and possible breach in confidentiality that could result if data and/or remarks are attributed to an identified individual,

It is planned that facilitators will undergo training before conducting focus groups and attention will be given to approaches for controlling disruptive behaviors and minimize the use of potentially hurtful language. Additionally, each facilitator will be directed to request participants not to share the focus group discussion with others. Although participants could be asked to sign a pledge to respect privacy and not share the focus group discussion, such a pledge could be ineffective and unwarranted since discussion topics may not be considered overly sensitive by those who agree to take part in the sessions.

Research staff will identify settings that allow privacy during administration of interviews and surveys and implement other means of reducing risk of privacy and confidentiality violations. Personal information will be collected only to the extent necessary and forms and survey instruments with

identifiable data will be kept in locked storage cabinets. Data entered into a database and subsequently analyzed will be de-identified and study identification numbers will replace subject name prior to transmission of data outside of India.

Describe how proposed research involving vulnerable populations meets the additional regulatory requirements described in the HHS regulations, Subparts B, C or D. Refer to HHS regulations, and OHRP guidance. The proposed research is exploratory in nature and involves no clinical intervention. A set of focus groups will involve mothers that have breastfeed at least one child in the past three years. There is no exclusion indicated for subjects due to pregnancy; thus, it is possible that a pregnant woman could participate in a focus group. Additionally, pregnant women are to be recruited for the pilot testing component of BEST4Baby and after consenting, they will be provided breastfeeding counseling prior to delivery. There is no to low-risk to either the pregnant woman or her fetus associated with the pregnant woman's participation in the research or her interaction with a breastfeeding counselor sufficiently educated and trained for her role. And there is the possibility that a peer counselor's contact with the mother while she is pregnant will increase the likelihood that the subject once she delivers will initiate breastfeeding early (ideally within one hour of delivery) and commit to exclusive breastfeeding and appropriate duration of breastfeeding; thus, both the mother and baby may realize benefits from BEST4Baby. Inclusion of pregnant women as subjects within this project designed to promote breastfeeding is thus consistent with the conditions that permit inclusion.

Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects AND
Where appropriate, describe plans for handling incidental findings that may be uncovered as a result of the research, such as incidental findings from research imaging, results of screening tests, or misattributed paternity. BEST4Baby proposes no intervention that should have an adverse event causing the need for medical or professional intervention. However, if peer counselors recruited for BEST4Baby become aware that mothers being counseled have a suspected medical problem or difficulty that warrants referral to a physician or lactation consultant or other appropriate professional, the counselor will have information to enable her to make a referral and she will encourage the mother to seek help.

c. Potential Benefits of the Proposed Research to Human Subjects and Others

Discuss the potential benefits of the research to participants and others. As noted previously, the interaction between the recruited and educated peer counselor with a subject that is recruited to receive breastfeeding education, counseling and support has the potential for increasing the probability that the newborn will be exclusively breastfeed for six months and that the mother adopts other recommended breastfeeding practices. Breastfeeding can increase the probability of newborn survival and provide nutritional, immunological, and developmental benefits to the infant/young child. A breastfed baby has a lower risk of developing Type I diabetes or becoming obese or affected by other chronic conditions. Breastfeeding is also known to increase mother-infant bonding, and it can bring health benefits to the mother such as healthier bones and decreased risk of post-menopausal osteoporosis. Women who breastfeed also burn more calories and tend to lose pregnancy weight more quickly than mothers that don't breastfeed.

Besides the mother-baby dyad, women recruited to serve as breastfeeding counselors have the potential to benefit from improved breastfeeding education and the use of mobile health tools that will result from the research and development activities of the project. Educational tools may also be utilized to provide education to the mother and other family members.

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others. The emphasis of the project on education and training of peer counselors and the possible advantage due to the use of mobile tools represent the reason that anticipated benefits are expected to outweigh potential risks that are judged to be of low magnitude in terms of harm or negative consequences. Modest compensation will be provided to focus participants and breastfeeding counselors in consideration of time and costs associated with participation.

V. Importance of the Knowledge to be Gained

Discuss the importance of the knowledge to be gained as a result of the proposed research. Recruited peer counselors will be educated and trained by utilizing a trusted breastfeeding counseling course developed by WHO and UNICEF and adapting the course to cultural norms and the education program will integrate effective learning processes and mobile technology tools. The course directed at helping those with prior breastfeeding experience will increase knowledge regarding why breastfeeding is important, the process of breastfeeding and the correct latch, composition of milk, psychological benefits of breastfeeding, the risks of prelacteal and artificial feeding, assessing and observing a breastfeeding, listening and learning skills, healthcare practices impeding or facilitating breastfeeding, and helping a mother to breastfeed.

Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result. The BEST4BABy program has the purposes of improving breastfeeding education by improving approaches and promoting the use of mobile health tools. Project staff implementing the project are multidisciplinary and have necessary expertise to carry out the research and development activities as proposed in the project. Additionally, a Breastfeeding Advisory Panel will be utilized to bring additional expertise to the project and assure the provision of guidance as needed. BEST4Baby involves exploratory research to understand barriers to breastfeeding as well as facilitating factors and to assess what can be done to ensure the adequacy of resources for counseling and support. The project also includes the gathering of important information to design effective mobile health tools. Monitoring the project against measures of success, obtaining feedback and performing pilot testing are the means that will allow adjustments to be made if desired results are not obtained. For all the reasons noted, the probability is considered high that education/training of peer counselors will have the desired impact of improving counselor knowledge and skills. Thus, it is unlikely that the project will cause a decline from baseline of breastfeeding education, counseling and support of mothers.

VI. Data and Safety Monitoring Plan

Participation in the pilot due to the intervention presents minimal risks for consenting mothers or their newborns as the intervention--breastfeeding education and support—are generally considered to increase the probability that breastfeeding and other infant feeding practices will comply with recommendations of trusted health organizations. The key members of the research team are responsible for assuring that peer counselors are well-trained and committed to visiting mothers and carrying out their duties—e.g., providing accurate breastfeeding information and tips about proper technique and positioning, education about the benefits of exclusive breastfeeding until an infant reaches 6 months, emotional support as needed, and advice about care-seeking when the peer counselor becomes aware of a maternal or newborn health-related problem likely to require attention from a health care provider. During the pilot, it is expected that JNMC key personnel and Dr. Umesh Charantimath, the pilot study coordinator, will meet at least monthly with the peer counselors providing the intervention. Additionally, peer counselors will complete a data form for each visit made to a mother. Ideally, the reporting form will be completed via cell phone/tablet and transmitted to data personnel at JNMC's Research Unit; otherwise, peer counselors will complete a paper form and the forms will be provided at least every two weeks to the Research Unit. The Study Coordinator will review these forms on an ongoing basis and if he has any concerns, he will discuss concerns with JNMC key persons. Data from the forms will be entered in a data base and a report of the visits will be made available to key personnel of BEST4Baby (in India and the US) each month during the pilot until such time as official study visits between peer counselors and mothers end. When peer counselors complete the form, they will not use a subject's name but rather a study identification number assigned to the mother at the time of consent. Additionally, each counselor will use a study identification number when reporting. Thus, the monthly reports will not include names, but visit data may be aggregated and summarized in a manner to associate the data with a specific peer counselor identified by identification code. Although the data form may contain data relevant to status of breastfeeding, this data will not be included in the monthly monitoring report as the purpose of these reports is primarily to determine if the peer counselors conducted visits consistent with the protocol and used educational tools provided to them, and if they encountered any unanticipated problems.

Inclusion of Women and Minorities

The research and development activities proposed in Breastfeeding Education Support Tool for Baby (BEST4Baby) will include women in all components of the program, including the exploratory research and pilot testing phase of education and training approaches and mobile health technology tools. Women will be recruited from community clusters within the study area utilized by the JNMC Women's and Children's Health Research Unit.

Women are critical to breastfeeding and they are critical to BEST4Baby since it would be impossible without them to gain a better understanding of barriers and facilitating factors that affect achievement of the breastfeeding objectives that are being promoted by the Government of India, its public health system and trusted health organizations such as the World Health Organization and UNICEF. Due to their roles as mothers and their potential for meeting criteria for service as peer counselors, women are also needed to enable design of mobile health tools to enhance breastfeeding education, counseling and support delivered in communities.

The exploratory research that will be conducted will not exclude men as project staff will interview fathers of newborns to assess their knowledge, attitudes and beliefs about breastfeeding; and some men will be involved in the focus groups convened for health providers serving the study clusters.

While it is impractical to implement a recruitment plan for focus groups comprised of 8 -10 participants and ensure that they will be representative of a study cluster's population, field staff will be directed to recruit subjects in a manner to ensure input from diverse members of communities who can provide the type of information being sought to meet the aims of this project. Kannada is the most commonly spoken language in the primarily rural communities of study clusters, so we intend to conduct focus groups and interviews in Kannada.

Inclusion of Children

The exploratory research and development activities proposed in Breastfeeding Education Support Tool for Baby (BEST4Baby) will not include young children nor females of reproductive age unless they are 18 years of age. This project design decision was made for several reasons, including the preference stated in the Indian Council of
Medical Research's document of ethical guidelines that children not be involved in research that could be carried out equally well using adults. Research that meets criteria for involving subjects under 18 must apply complex consent/assent that are specified in the same document, Ethical Guidelines for Biomedical Research on Human Participants (India Council of Medical Research, New Delhi, 2006).

Additionally, while it is desirable that those younger than 18 breastfeed their babies, mothers of this age represent a potentially complex and diverse group and an exceedingly small percent of delivering women. A future study is envisioned for researchers to better understand the approaches for improving attainment of breastfeeding objectives for under 18 mothers.

Timeline

Month(s	Primary Work Tasks
1-2	a) Obtain final approvals from JNMC/TJU IRBs and ICMR (but submissions should occur upon award notification), b) finalize focus group plan/questions, c) have questions and consents translated; d) train facilitators
3-5	a) Recruit and consent subjects; b) hold focus groups which are recorded using electronic recorders Recommendations: Add 2 focus groups with grandmothers resulting in 2 for Obj 1; 8 for Objs 2/3 and 2 for Obj 4 or TOTAL of 10 e Skip the mothers' focus groups originally proposed for month 7; incorporate questions to get desired information into these focus groups
6	Translation of audio-recordings, Kannada-English
7-8.5	a) Review transcripts and analyze b) Convene/ et input from Breastfeeding Advisory Panel
8.5-11	a) BF training development based upon FG results and WHO BF course—training for counselors that will be recruited (no actual training yet) b) Design of micro-learning content, video design, and texting design (messages) Comment: Need clarification of targets (mothers, counselors, both?) for each component of b). Also, will the design work of all components of b have implications for mobile tools (phones, tablets ?
12-14	a) Development using Agile Development—final design of mobile-based platform b Convene/get input from Breastfeeding Advisory Panel
14	Translation of educational materials for BF course and use with mHealth tools
15-23	a) Training/pilot testing of BF course for counselors, and pilot testing of mHealth tools among counselors and mothers b) Data collection/follow-up on BF status among mothers at defined intervals
24	Analyze data and prepare final report

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