Title: Assessment of community perceptions and the feasibility of conducting child mortality and pregnancy surveillance

Child Health and Mortality Prevention Surveillance (CHAMPS) Network

Investigators:

Principal Investigator
- Rob Breiman, MD, MPH, Emory Global Health Institute

    Dr. Breiman will serve as principal investigator for the study. He will be responsible for oversight and final approval of study design, instruments and procedures.

Co-investigators
- Emory University
    - John Blevins, PhD

- Centers for Disease Control and Prevention (CDC)
    - Elizabeth O'Mara Sage, PhD, MPH, MS (SEV 14926)
    - Pratima Raghunathan, PhD, MPH (SEV 4389)
    - Allan Taylor, MD, MPH (SEV 11832)

    CDC Co-investigators will provide technical assistance in tool development, study design, staff training, data analysis and report writing.

- Manhiça Health Research Centre in Mozambique (CISM)
    - Khatia Mungwambe, PhD
    - Inacio Mandomando, MD
- Chris Hani Baragwanath Academic Hospital
    - Shabir Madhi, MD
- CVD-Mali
    - Samba Sow, MD
    - Karen Kotloff, MD

Funding Source

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Background and Significance

Although progress has been made to reduce childhood mortality worldwide, approximately six million children under the age of five (16,000/day) still die every year (World Health Organization [WHO], 2015). Neonatal deaths, in particular, constitute 45% of under-five mortality with rates of stillbirths being almost equal to the number of neonatal deaths (UNICEF et al, 2015; Cousens et al., 2011). Most of these deaths are caused by diseases that are preventable through cost-effective and basic quality-delivered interventions (March of Dimes, PMNCH, Save the Children & WHO, 2012). Understanding global child health and mortality is severely limited by inadequate methods and measurement. Less than 20% of the world's 192 countries have high-quality death registration data, and more than one-third have no cause-specific mortality data at all (Mathers et al., 2005). Tracking under-five mortality is at the forefront of public health, and improving our knowledge of the causes of death will have an impact worldwide.

In low-income countries throughout the world, children often die without being seen by qualified medical personnel; they die without a documented medical history and are often buried before a cause of death determination (CoD) has been conducted. Furthermore, in low-resource countries, deaths that occur in the community are often different from those that occur in the facility and may not be tracked or identified quickly enough for autopsy or postmortem examination. Even for those who die in a health facility setting, the CoD is often difficult to assess, not only due to the fact that post-mortem examinations are seldom performed, but also due to multiple coexisting illnesses, which may lead to diagnostic discrepancies between post-mortem findings and clinical diagnoses (Mushtag & Ritchie, 2005; Gupta et al., 2014). The inability to obtain CoD in health facilities and/or in the community often results in uncertainties in global disease estimations (Lishimpi et al., 2001; Ugiagbe & Osifo, 2012). Uncertainty about the true causes of child death limits the effectiveness of public health programs and often leaves public health policy makers misinformed about the most beneficial allocations of resources and interventions.

Complete diagnostic autopsies (CDA) are recognized as the most comprehensive method to estimate CoD (Fligner et al., 2011). A number of issues make CDAs difficult to execute, however, especially in low-income countries. These include cultural and religious beliefs, financial limitations, and constraints related to public health infrastructure (Turner et al., 2012; Cox et al., 2011; Oluwasola et al., 2009). To this end, the World Health Organization (WHO) recommends the use of verbal autopsy (VA) as a non-invasive alternative (Butler, 2010; Byass, 2014; Gareene, 2014; Jha, 2014). VA involves structured interviews with individuals close to the deceased, through which a CoD is derived. The VA alone as a method to determine CoD, however, is often inaccurate due to lack of diagnostic information, time between death and interview, and diseases with similar clinical presentation (Snow et al., 1992; Soleman et al., 2006). The weakness of VAs in attributing CoD is especially apparent in neonatal deaths, which are often associated with non-specific signs or symptoms.

The imperfections inherent in VA methodology, the impracticality of CDAs in resource-poor settings, and the inaccuracy of clinician ascribed CoD highlight the critical need for an alternative method to better address the causes of death and reduce under five mortality. To this end, the minimally invasive tissue sampling (MITS) procedure was developed to reduce uncertainties regarding causes of death in developing countries (Bassat et al., 2013). The MITS procedure involves extracting tissue specimens from a predefined set of organs and undertaking histopathologic examination. MITS are potentially quicker, less expensive, more acceptable and markedly less invasive than CDAs, and may therefore increase community uptake and participation (Vogel, 2012; Ben-Sasi et al., 2013).

In response to the limitations of currently available data, the Child Health and Mortality Prevention Surveillance (CHAMPS) Network aims to develop a long-term network of sites that collect robust and standardized primary data aimed at understanding and tracking the preventable causes of childhood deaths globally. Timely and accurate data generated by the initiative will inform efforts to address the deaths of children carried out by funding agencies, ministries of health, national public health institutes, scientists, clinicians, government leaders, journalists and the public. The overall CHAMPS Network, when fully realized, has the goal of establishing the scientific evidence needed to dramatically reduce early childhood death and disability, including the factors that may underlie the progression from severe illness to death (malnutrition, electrolyte imbalance, poor access to health care among others).

RATIONALE

Because of its primary emphasis on documenting CoD, CHAMPS Network objectives differ from those of typical surveillance programs and studies focusing on disease etiology. The scope of CHAMPS mortality surveillance[1] is also broad, aiming to capture both perinatal causes of deaths and deaths in infants and children under five years, and deaths caused by both infectious and noninfectious etiologies. MITS methods and advanced laboratory techniques, methods rarely used in settings with high child mortality rates, will be used to attribute cause of death as accurately as possible. In addition, pregnancy surveillance will facilitate identification of stillbirths and neonatal deaths to assist in understanding the causes of these deaths, which are often unaccounted for. The MITS methodology offers the possibility for gathering critical missing data to determine the causes of under-five mortality; however, because the procedure is carried out on the body of a recently deceased child, a wide-range of complex religious, cultural, and ethical questions inevitably arise. Widespread acceptability of child mortality surveillance incorporating MITS will require a profound understanding of cultural and religious norms and practices to determine the feasibility and understand the perceptions of MITS and pregnancy surveillance prior to implementation. For example, beliefs about death and the afterlife, opposition to and concerns about body disfigurement, difficulties in obtaining consent from grieving families, inadequate involvement/endorsement of community leaders, lack of community awareness, suspicion of researchers, and burial practices are some of the factors underlying autopsy refusal. Understanding these kinds of cultural norms and practices will be essential to the acceptability and sustainability of CHAMPS activities[2] in relation to both child mortality and pregnancy surveillance.

JUSTIFICATION FOR THIS FORMATIVE RESEARCH

In order to assess the feasibility of child mortality surveillance and pregnancy surveillance that uses MITS, formative research is necessary to understand specific cultural, religious and socio-behavioral factors that may increase or decrease acceptability of MITS on children under five, and the factors that may influence care-seeking behaviors during pregnancy, labor and delivery, and in the newborn period. These data will ultimately help determine the overall feasibility of MITS in the context of child mortality and pregnancy surveillance as well as to determine the nature and scope of behavior/belief modification efforts through community engagement, and communication with religious, traditional, thought/opinion, and political leaders.

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[1] Child mortality surveillance refers to the process of identifying and reporting the death of a child under the age of five years in the catchment community; this includes CHAMPS activities and procedures such as consent, clinical procedures (MITS, laboratory diagnostic procedures, etc.), incentives, family and community feedback, etc.

[2] CHAMPS activities involve socio-behavioral sciences (formative research and community engagement) and surveillance programs focusing on mortality, pregnancy, demographics and possibly severe diseases in children under 5 years old.

Formative research will also be employed to assess the contexts in which families grieve, to identify how and which family members participate in pregnancy and postpartum processes (including rituals), to determine which family member(s) and how members should be approached when introducing the MITS procedure, and to identify other community members (e.g. religious leaders, healthcare providers) who could act as positive influences when deciding whether to accept child mortality surveillance and MITS. In addition, formative research will help determine whether and in what context incentives, such as assistance with funeral costs or recognition of the family's participation, would be ethically feasible, effective or appropriate for encouraging MITS acceptance and participation. Finally, formative research will complement and guide community engagement activities and help to assess the effectiveness of these activities and how they should be modified to optimize acceptance of child mortality surveillance including the MITS procedure and other CHAMPS activities.

HYPOTHESIS (narrative)
It is anticipated that this formative research will help identify, specifically: (1) the *facilitators and barriers* for undertaking child mortality surveillance, including conducting MITS when patients die within healthcare facilities and at home or elsewhere within communities; (2) the *facilitators and barriers* to care-seeking, access to care and perceptions of pregnancy, labor/birth, and the postnatal period; and, (3) what incentives, if any, would be ethically feasible, effective and appropriate for encouraging participation in child mortality surveillance with MITS.

EXISTING FACTORS TO BE CONSIDERED IN THE FORMATIVE RESEARCH
Formative research will examine and assess key factors related to the feasibility and perceptions of CHAMPS surveillance procedures. These factors include: 1) religious beliefs, 2) cultural norms, 3) political conditions, 4) economic conditions, 5) disease prevalence/incidence, and 6) environmental factors. Any examination of these factors will require intentional, ongoing, respectful partnerships with community members and community leaders, including religious and traditional leaders. Such partnerships are essential for establishing the conditions on which trust can be built and strengthened over time. Methods for community assessment and engagement with community members and leaders are spelled out in subsequent sections of this document.

Religious beliefs about death and related practices that demonstrate faithful care for the body of a deceased loved one will undoubtedly impact community perceptions and beliefs about MITS. Studies on the perceptions of autopsies in low and middle income countries name religious beliefs as the most frequent cause of suspicion of and refusal to consent to either autopsies or post-mortem examinations (Gurley et al., 2009; Lishimpi et al., 2001). Religious beliefs on these issues vary tremendously across and within traditions because they are often blended with other cultural factors that affect beliefs and practices within the local context; moreover, religious practice is rarely a simple expression of a singular belief system, but is itself a hybrid mixture of various traditions (Bhabha, 1994). For some people of faith, the invasive nature of MITS may pose a fundamental challenge to beliefs about the nature of the body, God's providence, respect for the deceased, one's own place in the family and community, and the afterlife. As such, suspicion of MITS protocols may be quite high. At the same time, religious traditions may support participation in child mortality surveillance activities if they are understood to generate knowledge that could eventually be used to treat the causes of death of children. The formative research of the CHAMPS network will assess religious beliefs and practices, recognizing that such assessments must be adapted to disparate cultural and geographic contexts. Such assessments will aid in framing the design of the formative research and other activities carried out across the network in ways meaningful to community stakeholders. Demonstrating respectful appreciation of religious beliefs

will in turn help foster trust to find common ground and better understand the ethical issues involved in community buy-in and individual consent.

Cultural norms beyond religion may also influence perceptions of child mortality, pregnancy and neonatal surveillance and care for and burial of young children. For example, expectations and experiences of parenthood are embedded within longstanding and powerful cultural frameworks which are gendered, creating different expectations for men and women as to their appropriate parental roles and responsibilities. Traditional beliefs surrounding pregnancy may also affect when a women discloses pregnancy, care seeking during pregnancy, and how and where a women delivers. In addition, cultural beliefs related to the child's age at death, disease causality and fatalism are likely to influence perceptions of the relative meaning or value of CHAMPS protocols involving child mortality and pregnancy surveillance. In particular, similar to the earlier mentioned crucial role of religion, cultural norms will be key determinants of community perceptions and beliefs about MITS. Formative research examining cultural norms will allow the in-country CHAMPS teams the opportunity to develop surveillance activities in ways that align with local norms and to address key ethical tensions between cultural values and CHAMPS procedures that could not be ascertained through the laboratory and clinical protocols alone.

Political conditions affect the social relations across communities and among community members. They may contribute to an ethos of cooperation and trust among members of a community despite cultural, religious, ethnic, class, or economic differences or they may exacerbate those differences, leading to tension or violence. Community perceptions of political leaders and governmental alliances and programs (at both the local and national levels) will influence perceptions of the CHAMPS activities, especially in relation to the role of the Ministry of Health in each specific country. Finally, perceptions of global political issues may impact perceptions about the involvement of international researchers associated with CHAMPS. By assessing these political conditions (both historical and current), the formative research protocol aims to gain insights into the influence of these broader political forces on acceptability of CHAMPS activities.

Economic conditions are a primary social determinant of poor health and health inequity (WHO 2008). Formative research that assesses the economic conditions among stakeholder communities will be instrumental in understanding the connections between this social-structural factor and the causes of under-five mortality. In resource-poor settings, economic conditions may impact food security and lessen the availability of and access to health facilities and services. These inter-related issues could in turn influence perceptions of CHAMPS surveillance activities, particularly if residents in these settings believe that services for their children were lacking when they were alive, but that CHAMPS personnel are eager to carry out MITS protocols after their child has died. In addition, information on economic circumstances in communities can help to gauge the possibility of an undue influence of incentives for participation in CHAMPS activities. Similarly environmental factors can impact childhood morbidity and mortality. Assessing environmental conditions at the stage of formative research will be useful in understanding how these factors contribute to food availability, air quality and nutritional sustainability for children.

EXISTING STUDIES AND LIMITATIONS
MITS was first proposed in the literature in 1995 by Avrahami et al. These initial papers were focused on the use of laparoscopy and thoracoscopy as an alternative to conventional autopsy, which were found to be accurate and easy to perform and highly sensitive for victims of trauma. Since then, multiple studies have explored the use of MITS to understand its clinical value and its potential for replacing conventional

autopsy. While most studies have focused on developed countries and non-infectious causes of death, e.g. birth defects (Sebire et al., 2012; Fan et al., 2010; Breeze et al., 2011; Weustink et al., 2009), several recent projects are working to validate the technique in developing countries (Bassat et al., 2013).

Globally, neonatal deaths constitute 45% of under 5 mortality (UNICEF, WHO, World Bank, UN Population Division, 2015) and stillbirths are nearly equal to the number of neonatal deaths (Cousens et al, 201). Trends in both neonatal mortality and stillbirth rate reduction lag behind progress being made in reducing under-five deaths (Cousens et al., 2011; UNICEF et al., 2015). Pregnancy surveillance is an essential element needed for identification of perinatal and infant deaths. Identification of perinatal deaths, however, is highly dependent on cultural practices. For example, cultural norms can influence the timing of when and with whom a woman communicates that she is pregnant, is in labor and gives birth, or has a pregnancy or neonatal loss. Understanding the norms around these critical life events is fundamental to designing and implementing a pregnancy surveillance system that captures complete birth outcomes and perinatal deaths. Finally, it is only through a pregnancy surveillance system that pregnancy outcomes can be successfully tracked and stillbirths and neonatal deaths can be accurately identified and counted.

Due to the limitations of the current CoD methodologies, there is a pressing need for additional research to determine the best method to determine CoD in developing countries, especially among children under five. Today, the global health community lacks consistent, accurate, and timely infectious disease epidemiology and surveillance data to inform strategy and enable critical decisions for reducing childhood mortality. A lack of quality primary data across key geographies has led to large gaps in knowledge and has prompted an over-reliance on modeling. Data that are available are gathered through non-standardized processes into siloed systems, limiting stakeholders' ability to integrate, analyze, compare, make inferences and take timely actions. Furthermore, available data offer limited insight into etiology in high mortality countries. Finally, the availability of primary data is often delayed for years due to misaligned incentives among stakeholders, resulting in a lagging view of evolving epidemiology. This combination of factors restricts the ability of global stakeholders as well as national leaders to make evidence-based decisions such as prioritizing product development, targeting interventions appropriately, measuring the impact of interventions, and refining strategies to address changing epidemiology.

Goals/Aims

GOALS

The overall goal of the CHAMPS Network is to provide accurate, timely and reliable data on the causes of death for children under age five. A unique aspect of CHAMPS will be the collection of tissue samples, by pathologists, from recently deceased children. While this is a sensitive topic, it is crucial to determining causes of child mortality to inform policy and program decisions aimed at reducing child deaths. **To this end, this formative research will aim to evaluate the feasibility (i.e. acceptability, practicality and implementation) and ethical considerations of child mortality surveillance in different cultural, social, religious and geographical contexts.**

Another important and overlapping goal of the CHAMPS Network is to conduct pregnancy surveillance to help support complete identification of birth outcomes, stillbirths and neonatal deaths in communities by monitoring live births up to 2 months after delivery. **As a secondary objective, this formative research will also aim to explore perceptions of pregnancy, birth and the postpartum period to inform the development and implementation of pregnancy surveillance systems aimed to identify**

stillbirths and neonatal deaths, as well as to understand acceptability of pregnancy surveillance among those who would be participating.

PRIMARY OBJECTIVES

- To describe cultural, social, and religious norms, rituals and practices involving the death of a child (stillbirth, newborn, infant and child)
- To examine the role of socio-cultural attitudes and traditions on communities' views on child mortality surveillance
- To examine facilitators and barriers related to consent for MITS
- To determine factors affecting acceptability of child mortality surveillance, including motivators and barriers, by the relatives of the deceased child, community leaders and other community members involved
- To identify factors motivating the acceptance and refusal to perform child mortality surveillance both theoretically and in actuality
- To inform tools and approaches for ongoing CHAMPS activities and to adapt approaches as community awareness and perceptions evolve and relationships with communities are strengthened
- To assess the success of community engagement efforts and identify approaches aimed to increase both general acceptability of MITS, and acceptance by parents who are requested to allow a MITS to be performed on a deceased son or daughter.

SECONDARY OBJECTIVES

- To examine the role of socio-cultural attitudes and traditions on communities' views on pregnancy, birth, postpartum and newborn care and pregnancy loss
- To document the facilitators and barriers of identifying stillbirth and neonatal deaths

SPECIFIC AIMS

Specific Aim 1: Examine and assess factors associated with the overall feasibility (acceptability, practicality and implementation) of child mortality surveillance on patients (deceased) identified in facilities and in the community with a focus on the following factors:

    a. Beliefs about child death and corpse, religions and traditions, confidentiality, family issues, perceived need and appropriateness, etc.
    b. Desire/willingness to consent and gain knowledge of the cause of death
    c. Relevant cultural practices
    d. Rituals and grieving (age, gender and community)
    e. Stigma associated with stillbirths and neonatal deaths
    f. Beliefs about the incentives that may play a role in CHAMPS activities (i.e. child mortality and pregnancy surveillance), history of incentives in target communities
    g. Beliefs about early pregnancy loss, still birth and neonatal death (i.e. religious and traditional beliefs, confidentiality, family issues, MITS being unnecessary and inappropriate)
    h. Requirements for health systems to accept and participate in child mortality surveillance utilizing MITS, including reluctance and competing priorities
    i. Collaborations and relationships with MOHs and other relevant government and non-government agencies
    j. Community understanding and acceptance of public health initiatives such as CHAMPS including a general history of public health interventions in the target communities

k. Training needs for those involved in CHAMPS activities (i.e. community engagement leaders, epidemiologists, clinicians, etc.)

Specific Aim 2: Identify and respond to known and unanticipated perceptions, concerns, barriers and opportunities that will/could arise through CHAMPS activities:
a. Incentives
   i. Influence on acceptance of child mortality surveillance incorporating MITS
   ii. Effect on participants' perceptions of the cultural and ethical issues involved
   iii. Knowledge of incentives on community perceptions of participants
   iv. Perceptions of the individual, community, and social benefits of child mortality surveillance
   v. Influence on participation in pregnancy surveillance
b. Legal considerations
   i. Issues that impact CHAMPS activities in the countries where the surveillance activities will be implemented
      a. Reporting requirements for deaths involving trauma or violence, reportable disease requirements, partner notification requirements
   ii. Role of governmental authorities (e.g., Ministries of Health) in CHAMPS activities
c. Researcher concerns
   i. Researcher communication about the value of child mortality surveillance and MITS without inappropriately influencing pre-existing perceptions during formative data gathering
d. Health care worker concerns
   i. Clinicians may feel threatened by results from MITS if the message given to parents is different than what they transmitted or if the message suggest that there was an error in clinical decision-making and actions that missed opportunities to prevent (or hastened) death
   ii. Alternatively, clinicians might view MOITS as a way to improve clinical management and raise concerns about the limited geographical or age-based scope of CHAMPS

Specific Aim 3: Examine and assess community entry and engagement approaches and requirements with focus on the following:
a. Approaches for identifying the key community stakeholders that should be involved in examining community entry
b. Approaches/methodologies to researching the barriers, facilitators, gaps and needs of community engagement
c. Methodologies for assessing and developing approaches for community sensitization of pregnancy and child mortality surveillance
d. Methodologies for identifying the benefits of CHAMPS activities on the existing clinical and laboratory infrastructure/services in the community as a value-added outcome
e. How to conduct monitoring of acceptability and address rumor control
f. Approaches for involving the community during CHAMPS implementation
g. Awareness of rituals and grieving (variable by age, gender or community) and the appropriate ways to address them in community engagement

Specific Aim 4: Explore the perceptions involving pregnancy, birth, postpartum and newborn care practices that facilitate or impede notification of births, stillbirths and neonatal deaths.

      a. Patterns associated with pregnancy notification, care-seeking behaviors, delivery planning including location of delivery and desired birth attendants, birth notification, and postpartum practices

      b. Barriers associated with access to care involving ANC, health facility delivery and newborn care, and postnatal care,

      c. Community perceptions about the capacity and quality of ANC and delivery

      d. Facility capacities in pregnancy dating, skilled birth attendant coverage and postpartum and newborn exams

      e. Provider perceptions regarding ANC policies, preferences, and improvements related to ANC and postnatal and newborn care

Formative Research Design

The CHAMPS social behavioral component will employ a qualitative design based on sociological and anthropological approaches, namely ethnography and phenomenology. The core qualitative approach will be ethnography, which is an iterative, cumulative process resulting in the scientific description and interpretation of cultural behavior. Over an extended time period, the socio-behavioral science team interacts directly with members of the local communities in their own natural and daily environment (Hammersley et al., 1983). This approach will first allow members of the site socio-behavioral science[3] team to explore the cultural and social phenomena (i.e., "death") in its broader context. This approach will also lend to understand local meaning before looking more deeply into the specific research questions (i.e., *acceptability of child mortality surveillance including MITS* and *perceptions of pregnancy in relation to notification of births and deaths*). In addition, an ethnographic approach will help strengthen relations between the members of the CHAMPS site socio-behavioral science teams and community members and leaders, which may facilitate the trust needed to optimize acceptability of child mortality surveillance. Phenomenology is an approach to understand first-hand experiences of those involved in a phenomenon of interest to the research question (i.e., being pregnant, caring for a child with severe illness, or losing a child) (Starks, 2007). This approach will enable the team to move from the more theoretical leanings on potential factors influencing the acceptability of the CHAMPS program into understanding how these factors play in actuality. It will also contribute, in real time, to the achievement of the aim of assessing the success of community engagement efforts and identifying approaches for making them more effective towards acceptance of MITS in principle, and when parents are requested to allow a MITS to be performed.

The methods for this formative research will involve a combined phased approach of semi-structured interviews (SSIs), key informant in-depth interviews, focus group discussions (FGDs) and participant observations. This multi-method approach will facilitate data triangulation needed to validate information collected across different data sources regarding the feasibility and perceptions of CHAMPS activities. This procedure assumes that different data collection approaches enhance the nature and integrity of inferences drawn from diverse data. By Please refer to Appendix G for an example timeframe reflective of the formative research process.

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[3] Members of the CHAMPS site socio-behavioral science team include a lead socio-behavioral scientist and other socio-behavioral researchers (and assistants) to assist with data collection, analysis and community engagement activities. These individuals may also be referred to as "interviewers" in this protocol and will be responsible for data collection.

FORMATIVE RESEARCH SETTINGS

Formative research will take place at potential CHAMPS surveillance sites selected by the CHAMPS Program Office. Initially, the sites will include Manhiça District, Mozambique; Bamako, Mali; and Soweto Township within Johannesburg, South Africa. Additional sites will be included as the CHAMPS Network expands.

Manhiça District is a rural area located 80 km north of Maputo (Mozambique's capital) with a population of about 165.000. The Manhiça Health Research Centre (CISM) manages a Health Demographic Surveillance System that has progressively expanded to cover most of the population since 1996. Life expectancy at birth is 57.1 years and child mortality rate is 76.1/1000 live births. The district is served by a district hospital and 14 rural health centers. Shangaans constitute the dominant ethnic group, with very strong patriarchal social structures and cultural aspects that are similar to other ethnic groups within the Southern region of Africa. Christianity and different forms of animism are the main belief systems in this area, and a minority of the population is Muslim (Manhiça HDSS 2015).

In Johannesburg, the capital of South Africa, formative research will be conducted in Soweto, a township with peri-urban characteristics, inhabited predominantly by a low-income community of 1.4 million people, of whom 125 000 are under-5 years of age. The main ethnic groups are the Zulus, Xhosas and Sothos (STATS-SA 2012). The community is severely affected by HIV, with a prevalence of HIV infection in women attending antenatal clinics in Soweto that has stabilized at 30% since 2005 (The 2012 National Antenatal Sentinel HIV & Herpes Simplex Tissue Type-2 Prevalence Survey in South Africa). However, vertical mother-to-child transmission (MTCT) of HIV has declined from 8-12% in 2007 to less than 2% by 2010 (Barron et al., 2013).

Bamako, the capital of Mali, has a population of approximately 2 million inhabitants. The Centre for Vaccine Development (CVD) in Mali established a HDSS. According to The World Factbook, life expectancy at birth is 55 years and child mortality is 102 deaths/1000 live births (2013-14). Based on DHS 2013 data, during the past five years, of 1000 births, 56 die before reaching their first birthday. Of 1,000 children a year, 41 do not reach their fifth birthday. Overall, the risk of dying between birth and the fifth birthday is 95 to 1,000 live births (DSH, 2012-13). Hôpital Gabriel Touré is the main tertiary level teaching hospital in Bamako. Within the DSS, 3 Centres de Santé Communautaire (CSComm) or health centers provide the health care services in the area. Among the 10 existing main ethnic groups, the Bambara, the Sonrais, the Fulani and the Soninke predominate. The main religion is Islam (94.8% of the population), and 2.4% of the population adheres to Christian beliefs. Traditional spiritual beliefs are also common among adherents of both Islam and Christianity.

FORMATIVE RESEARCH PARTICIPANTS

A combination of nomination and snowball sampling techniques will be used to identify potential respondents. It is important that broad representations of the different segments and sectors of the communities involved in the program be approached and invited to take part in the formative research. To this end, each site must carefully consider the views, interests, needs, priorities, expectations and concerns of individuals and communities when identifying participants. In addition, sites must assess any potential negative impact on certain individuals and/or communities caused by social, cultural, economic, political and/or environmental circumstances. Each site will define study respondents and the participant inclusion and exclusion criterion in accordance with local norms and relevance to the formative research objectives.

Examples of community and health members or representatives with the following characteristics could be considered to participate in interviews (sites to include additional categories/subcategories as appropriate). Data collection approaches and sample sizes are also suggested (see following sections for detailed information on recruitment and field data collection approaches).

Table 1: Examples of community representatives, methods and sample sizes

Community Representatives	Data Collection Approach	Expected Participant Range
Knowledgeable leaders in the community (notables, elders, matrons)	key informant in-depth interviews Focus groups (2)	3-6 10-16 (total participants)
Community level health care providers (public, private, and traditional, including traditional healers and birth attendants)	key informant in-depth interviews Focus groups (2)	3-6 10-16 (total participants)
Professionals involved in proceedings related to death and dying (e.g., mortuary attendants, body preparers, burial/cemetery workers)	Key informant in-depth interviews	2-5
Religious leaders (including representatives of world religious traditions and indigenous religions)	Key informant in-depth interviews	6-10
Local community members representing the potential participants in CHAMPS, including parents and/or next of kin	Semi-structured interviews	8-10
Participants in vigil, burial, or cremation ceremonies, and other grieving or mourning rituals	Key informant in-depth interviews	2-5
Political representatives	Semi-structured interviews	4-6
Village chiefs or other traditional authorities	Key informant in-depth interviews	6-10
Health/Policy Representatives	**Data Collection Approach**	**Sample Range**
Policy makers from the health, legal, vital registration, etc.	Key informant in-depth interviews	3-6
Public health practitioners (staff from governmental health programs, MCH specialists, representatives of key international NGOs/FBOs, etc.)	Focus groups (2)	10-16 (total participants)
Representatives of clinical and medical professional organizations	Semi-structured interviews	3-6
Clinicians (pediatricians, pathologists, medical officers) (outside of the community)	Semi-structured interviews	6-8
Researchers (demographers, biomedical researchers, epidemiologists, etc.)	Semi-structured interviews	3-6

RECRUITMENT

The formative research will be an iterative process, whereby recruitment will start from central level institutions down to local level institutions, less formal organizations and individuals.

At the level of institutions (government, the private sector, research institutions, health facilities), a list of the departments and sectors within the institutions will be requested, from which the senior-most and at least one executive or practitioner within the sector will be purposively selected. A meeting between the appropriate member of the site socio-behavioral science team and the potential participant will be requested in person in order to invite the potential participant to take part. Snowball recruitment will also take place. In other words, participants being interviewed may refer to other people who, in their opinion, would be better suited to discuss particular issues with the research team. Those newly nominated people will also be invited to participate.

At the community level, meetings with Community Advisory Boards (CAB), local Health Committees (HC) and community representatives will serve to produce the key sampling frame. During the meetings, the different interest groups will be mapped, and a list of contacts for the participants will be generated. One to two individuals representing each interest will then be purposively selected and contacted to be interviewed. Snowball sampling may also occur until it is felt that sufficient data has been collected to meet the desired objectives of this protocol.

During the interviews with community representatives, the community level health care providers, entities involved in proceedings related to death, and the knowledgeable people will be mapped out. As much as possible, information about where to find those entities will be obtained from those conducting the interviews. The site socio-behavioral science team will purposively select at least two representatives from each group, stratified by geographical area, and approach them for inclusion in this formative research. Because MITS will occur both in clinical and community settings, parents and relatives of children who have experienced severe illness must be recruited from both contexts in order to ascertain their perceptions.

The procedure for recruitment from clinical settings will be carried out as follows: children (from 0-5 years of age) who experienced severe illness in the previous 30 days, or those children who have died, will be listed from health facility records; and, parents and relatives of these children will be identified with the aid of the health facility records and data from the Health Demographic Surveillance System (HDSS) in place in each site. If no HDSS is in place, identification will be through health facility records alone. The CHAMPS protocol will identify specific criteria for defining severe illness. A list of children along with their respective parents or relatives will be generated and a subset will be will be randomly selected and visited at home for inclusion.

The procedure for recruitment from community settings will vary depending on existing systems in each country. The Social Behavioral Science (SBS) lead in each country with work with the CHAMPS Program Office SBS team to develop a protocol for community recruitment after assessing those systems. Some examples for possible recruitment would include: using HDSS to determine children who died at home and visiting their parents (feasible only in countries with active an HDSS); interviewing community health workers to identify families in the local community that have had a child experience severe illness and visiting those families regarding possible inclusion in the study (may not be feasible in light of confidentiality laws); and working with traditional healers and religious leaders to identify families that have had a child experience severe illness and visiting those families.

COMMUNITY PARTICIPATION

The formative research component will be implemented with a community entry and engagement strategy. The two approaches will use mutual feedback since the successful implementation of formative research requires that community representatives (and the community they represent) be adequately informed. Community engagement at the start of the formative research will be essential for reaching consensus with key community stakeholders on the proposed objectives and approaches of the formative research. In addition, formative research results will inform on-going community engagement activities to help establish trust between CHAMPS staff and the community as a whole. Such trust provides a basis for creating sustainable, shared commitments that align and further CHAMPS objectives and the communities´ views, interests, needs, desires, priorities, expectations and concerns.

A dedicated on-site Community Liaison Officer (CLO) will act as the interface between the research team, the community members, and the community representatives and will be responsible for the mutual feedback between research findings and the community as a whole in order to improve the community entry and engagement strategy.

Community participation will focus on eliciting feedback from community members-at-large and from representative community leaders.

Community members-at-large

The CHAMPS community participation strategy for community members-at-large is based on established qualitative methodologies in community-based participatory research and action (CBPR/A). The method, Participatory Inquiry into Community Health Assets (PICK-CHAMP) (Blevins et al., 2012), employs an asset-based framework adapted from the model of Participatory Rural Appraisal (PRA) developed by Robert Chambers (Chambers, 1998). PICK-CHAMP was named as a best practice model for community engagement for activities carried out under the US President's Emergency Plan for AIDS Relief (PEPFAR) (Jaskiewicz, et. al., 2009). PICK-CHAMP brings together community members to participate in workshops designed to describe community members' perspectives and priorities on a selected topic. Therefore, the community entry dialogue and additional community engagement opportunities will help promote and provide context to the topics to be explored in the specific aims (see previous section).

PICK-CHAMP will serve three purposes: 1) it will serve as the first community participation activity, setting the stage for building relationships with PICK-CHAMP participants over the course of CHAMPS activities, 2) qualitative data from PICK-CHAMP on community perceptions beliefs, practices, and perceptions related to childhood death will be incorporated into KI and FGD interview guides, and 3) the same qualitative data will provide feedback on possible modifications to child mortality surveillance, MITS procedures and protocols. PICK-CHAMP participants will be invited to stay in communication with the CHAMPS site in country so that findings can be shared and feedback elicited over the course of the CHAMPS surveillance initiative. In addition, participants will be invited to be part of regular community meetings to be held as part of the community participation activities over the course of the CHAMPS program. Appendix F contains the PICK-CHAMP curriculum that will be used.

Community leaders

In sites where Community Advisory Boards (CABs) or local Health Committees (HCs) (or their equivalent)

are in place, these structures will constitute key entry points for this aspect of this formative research. Through meetings between site socio-behavioral science teams and CAB or HC, this protocol and objectives will be discussed and suggestions from board or committee members will be incorporated into the formative research Standard Operational Procedures. Additionally, individual or group meetings (where appropriate) will be held with community-level religious, cultural, political/ administrative representatives as well as local-level health and/or psycho-social service professionals from the public, private, faith-based, and traditional sectors. Findings from the community members-at-large workshops will be shared with community members to begin discussion on community perceptions and priorities. The discussions in the meetings center on the following issues:

- What are the suitable characteristics and appropriate conduct of research team members when approaching and interacting with community members
- How CHAMPS activities can align with and support the existing clinical and public health infrastructure
- How to enter the locations where proceedings related to death take place
- How to best approach and invite family members to participate in formative research (and ultimately CHAMPS surveillance)
- How to recognize family members´ contribution to the formative research (and ultimately CHAMPS surveillance)
- What are the best channels and approaches to feed back the information gleaned from the community assessments for CHAMPS activities to community members

Regarding feedback of the results, the same channels used for community entry will be used to share the outcomes of the formative research and discuss implications. In addition, during the data collection process, a specific question on how each participant would like to learn about the results of the formative research will feature as a topic for discussion. The dissemination approach and channels used will be based on the suggestions of the CAB, community representatives and individual participants.

FIELD DATA COLLECTION METHODS
Qualitative data will be collected through semi-structured interviews, key informant in-depth interviews, focus group discussions and observations, which are detailed below.

Semi-structured interviews (SSI)
The SSI is a qualitative method of oral inquiry which allows a verbal interchange between an interviewer and the respondent based on a written interview guide consisting of pre-determined open questions (see Appendix B for an example SSI guide). The questions are presented in a predetermined format and sequence, but allowing some flexibility in the way the topics are addressed by both interviewer and respondent. Specifically, despite having some degree of structure, the respondent is encouraged to develop his/her ideas, rather than giving "yes" or "no" type of answers (Longhurst, 2010).

This method will be used to obtain and register information on the views, concerns and expectations of individuals representing entities or institutions that implement or use mortality surveillance with MITS (policy makers, public health patricians, researchers, clinicians, community-level health care providers, etc.). SSIs will also be carried out among parents of children who have experienced severe illness or have died and pregnant women. For planning purposes, minimal sample sizes for each target group

were anticipated (as seen in table 1), based on experiences from past studies. However, a reduced or additional number or participants per target groups may be recruited depending on the saturation point. Although indicative minimal sample size has been provided (table 1), participants should be recruited until theoretical saturation for each research question is reached, which is the point when no new insights are generated through the data (McLafferty, 2004; Onwuegbuzie et al., 2009). However, it will be necessary to continue collecting and analyzing data after the initial formative research analysis to readdress certain community perceptions and potential changes in methods. Data collection and analysis will be performed in a cyclical way in order to monitor theoretical saturation.

These interviews will be conducted individually, face-to-face and will be audio recorded with the permission of the participant (respondent). Each SSI will take approximately 45 to 60 minutes and will be audio-recorded according to the comfort and permission of the participant. Interviews will also be translated from local language to English, French or Portuguese and transcribed. The interviewer will take notes during the interviews which will later be translated and entered into a spreadsheet. Data will be entered in NVivo, a qualitative text-organizing software.

Key informant in-depth interviews
Key informant interviews are qualitative in-depth interviews with those who have firsthand knowledge of the community. Key informant interviews are typically less structured, open-ended sets of verbal questions based on an interview topic guide that orients the interviewer on the overall issues to be discussed. The topics are very broad and within each topic, the format, order, and depth of each question is formulated by the interviewer (Longurst, 2010) (see Appendix C for an example IDI guide).

Key informant interviews will include, for example: political, religious, traditional authorities, notables, elders, matrons and others especially those involved in proceedings related to severe disease avoidance, notification and treatment. In addition, key informants may also involve those involved in events around a death in order to gain an in-depth understanding of cultural, social and religious norms. Key informant interviews will also be conducted to explore informants' roles in the local processes surrounding death, their opinions about performing MITS to deceased children and the best way to proceed if MITS were to be offered at the health facility and in the community. Others areas of key informant interviews may also focus on pregnancy and severe illness as related to CHAMPS. Participants should be recruited until theoretical saturation for each research question is reached, which is the point when no new insights are generated through the data (McLafferty, 2004; Onwuegbuzie et al., 2009). However, it may be necessary to continue collecting and analyzing data after the initial formative research analysis to readdress certain community perceptions and potential changes in methods. Data collection and analysis will be performed in a cyclical way in order to monitor theoretical saturation.

Each key informant interview will take approximately 1 hour. The interviews will be audio-recorded according to the comfort and permission of the participant and translated from local language to English, French or Portuguese and transcribed. The interviewer will take notes during the interviews which will later be translated and entered into a spreadsheet. Data will be entered in NVivo, a qualitative text-organizing software.

Focus group discussions (FGDs)
FGDs are semi-structured forms of verbal exchange between the researcher and the respondents, who are convened to take part in a group interview (Longhurst, 2010). When required and/or appropriate, the above information will be collected through focus group discussion because there may be instances when participants may be more comfortable discussing the topic in a group and/or where a more

productive and robust conversation occurs due to group dynamics. Each FGD will take no longer than 1.5 hours. All contents of the FGD will be audio-recorded with permission from participants (see Appendix D for an example FGD guide). Two note-takers will take notes during each FGD which will later be translated and entered in NVivo for data coding.

Sample and sample size: Focus group discussions (interviews) will include, for example: knowledgeable leaders in a community including religious, traditional authorities, notables, elders, matrons and others especially those involved in proceedings related to severe disease avoidance, notification and treatment. Discussions may also be compromised of those involved in events around a death in order to gain an in-depth understanding of cultural, social and religious norms. Focus group discussions will also be conducted to explore community healthcare and public health provider perceptions regarding the local processes surrounding death, their opinions about performing MITS to deceased children and the best way to proceed if MITS were to be offered at the health facility and in the community. Focus group discussions may also emphasize pregnancy and severe illness as related to CHAMPS.

Each focus group discussion will take approximately 1 hour. The discussions will be audio-recorded according to the comfort and permission of the participant and translated from local language to English, French or Portuguese and transcribed. The discussions will be facilitated by a member of the site social behavioral science team and a minimum of two additional transcribers will take notes during the discussions (which will later be translated). Data will be entered in NVivo, a qualitative text-organizing software.

Observations

Designated members of the site social sciences team will contact and ask permission to community leaders to accompany the procedures, rituals, customs and traditions around death at the community (health centers, funeral homes, religion services, funerals, etc.). Community leaders will intercede with the family and the community in order to allow the research team to explore attitudes, behaviors and relationships in this context and to understand the local norms and practices around death. This approach will help to elucidate appropriate ways of enrolling and involving potential participants.

Once MITS are introduced in the health facility and after they have been introduced in the community, it will be important to gain direct insights of interactions between health workers and family members of the deceased. In addition, it is important to understand family members' attitudes and coping strategies when facing the task of asking/ giving consent to perform MITS; a skilled social scientist will be present to observe the entire informed consent process. There will be no direct interaction between the social scientist and the health worker or with the family members in order to minimize interference with the decision-making process.

Hospital- and community-based health professionals performing MITS will be under observation while performing their routine activities in order to determine which procedures are acceptable by them and which strategies and approaches are the most appropriate for a future implementation of MITS techniques. The observation sessions will take as long as the procedure being observed lasts. Field notes will be the main source of recording the information. Appendix E provides a template for field notes; using this template will help ensure consistency in what is collected across sites.

INFORMED CONSENT PROCEDURES

When recruited individuals arrive for a semi-structured interview, a key informant in-depth interview or a focus group, the interviewer will read a verbal consent script (see Appendices A, B and C respectively).

Each potential participant will be informed about the purpose of the formative research, the procedures to be followed, risks and benefits anticipated, their rights as a participant, and that participation is voluntary. Informed consent will be adapted according to site-specific requirements. Potential participants will be informed that:

1) The interview is audio recorded to best capture an accurate record of his/her perspective and experiences; the interviewer will begin by conducting a short test of the recording capacity to screen out ambient noise. If recording is not feasible because of such noise or because of mechanical failure of the recording device, the interviewer will take notes as the interview proceeds;
2) The participant may refuse to answer any question, or may stop the interview at any time; if the participant stops the interview, s/he will be asked if the recording of the unfinished interview might be used for analysis. If not, it will be destroyed as per the participant's request;
3) The audio recordings will be transcribed in-country, and saved to a cloud-based storage system until data analysis is completed as reference. This system will be encrypted and password-protected to ensure security of data.
4) Their decision to participate in the interview (or not) and their decision to answer specific questions (or not) will not impact their ability to receive health care services in the future.

Any questions will be answered and verbal consent for participation will be sought, but signature documentation will not be requested.

Justification for Waiver of Documentation of Informed Consent
A waiver of documentation of informed consent is being requested as allowed under US CFR 45.46.117, which states that the requirement for the investigator to obtain a signed consent form for some of all or the subjects may be waived under the following conditions:

1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; and,
2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Both of the above conditions are met in this formative research. Therefore, no written documentation of informed consent will be sought. An unsigned copy of the verbal consent script will be provided to all participants. Separate verbal consent scripts for participation in individual interviews (both SSIs and IDIs) and FGDs are included in Appendices A, B and C respectively.

For those who are not able to read or read with difficulty, an independent individual with reading skills will be asked to read out the participant information sheet. After this, time will be allowed for questions, which will be answered by the site socio-behavioral science team members. Participants who still have doubts will be allowed time to consult others (i.e., family members). Participation in the formative research will be voluntary, and confidentiality will be preserved in accordance with the national legislation regarding data protection, or in the absence of this, in accordance with the GCP ICH norms.

Protection of Privacy and Confidentiality
All interviews will be conducted in private locations. If any names happen to be used in the focus groups and interviews, they will later be stripped from transcripts and replaced by generic distinguishing codes

that correspond to the focus group discussion number and the gender of the participant.

Only socio-behavioral science team members will have access to data collected. All forms will be stored in locked cabinets in site socio-behavioral science team offices. All databases and computers will be password-protected and maintained in secure buildings.

Potential Risks

Participation in this formative research is not anticipated to expose participants to substantial risk or harm. We will collect no identifying information at any time, and the formative research involves only minimal or no risk to participants. We will therefore apply for exemption from the requirements for full IRB review set forth in 45CFR 46 (United States Code of Federal Regulations) and will apply for a similar exemption from the IRBs or ethics oversight committees of participating sites as required.

The members of the socio-behavioral science team and focus group discussion assistants must consider risk and harm throughout individual and/or focus group interactions. For example, a mother may impart traditional (cultural) preterm care practices that could potentially be harmful to the baby. Careful consideration of how to react to this type of ethical dilemma will be discussed among the researcher and assistants prior to the focus group sessions.

Risks
Risks from participation in this formative research are limited to possible embarrassment at some sensitive questions and at voluntary disclosure of sensitive information to other participants in focus group discussions.

Protection against risks
These risks will be minimized by the voluntary nature of participation. In addition, it will be made clear to participants that they may decline to answer any question or divulge any information at any time.

Participant names will not be recorded, either at the time of recruitment or during the conduct of focus groups or interviews. During the focus groups and interviews, participants will be instructed to refrain from mentioning any specific names (their own or other people's). In our experience, some individuals will choose to use their true first name despite such instruction. Therefore, as added protection against inadvertent disclosure, any potential identifiers in the interview data will be eliminated during the transcription process by replacing specific names of people, places, or organizations, with general terms or pseudonyms. Participants will be distinguished from one another by arbitrary, generic codes in transcripts, which will be assigned in such a way that participants' comments may be distinguished from one another but that participants cannot be otherwise identified. We will keep all data confidential. All information pertaining to the formative research will be stored in locked filing cabinets in office of the local collaborating institution, and all electronic files will be encrypted. Audio recordings will be destroyed after accuracy of transcription is verified and after the corresponding digital files have been securely stored.

Risk/benefit ratio
The risk/benefit ratio for this formative research is appropriate. There is little risk involved with participating in this formative research. There are also no more than minimal benefits to participants. What we learn will be used to help implement more effective strategies for communicating and

implementing CHAMPS activities directly in the communities from which participants come. Therefore, participants and their communities will benefit indirectly.

Benefits

There are no direct benefits to the participants. This is in accordance with the US Code of Federal Regulations for studies with minimal risk. The participants may feel a sense of pride or purpose in knowing that their participation may indirectly benefit their community in the future. For example, the information gained around the concepts of health seeking behavior, cultural practices, and perceived barriers to care has the potential to inform programmatic decision-making by national and sub-national ministry of health and non-governmental organization staff. This may ultimately improve access to and quality of maternal and newborn health services. Moreover, this formative research will provide crucial information about the feasibility of CHAMPS surveillance activities in the formative research site settings which will inform the implementation of these activities using culturally acceptable methods.

Compensation

Participants will not be financially compensated for their time and effort in order to avoid the perception of coercion. A small item, such as a bar of soap or sack of flour, may be provided as a token of appreciation to all subjects who are offered participation in the formative research based on the acceptability of this practice as determined by each site. Participants may also be compensated for transportation costs by reimbursing each participant for the median cost for in-town public transportation. Some type of refreshment (i.e., soda, juice) will be provided for each participant when culturally appropriate.

Data Analysis

Only members of the CHAMPS site and Program Office socio-behavioral science team will have access to data collected. All forms will be stored in locked cabinets in the offices of socio-behavioral science members. All databases and computers will be password-protected and maintained in secure buildings. Members of the site socio-behavioral science teams will be trained on data management, security, collection, standard coding and data analysis prior to data collection.

Each member of the socio-behavioral science team will complete data summary sheets on a daily basis to document main themes derived from the discussions and/or observations. If required, members of the site socio-behavioral science teams will recourse to the audio recordings to complete the information. By the end of each week, data collectors will be required to complete a spreadsheet based on data from the summary sheets. This spreadsheet will summarize socio-demographic characteristics of participants involved in the formative research and the main themes emerging from the discussions (content analysis). This spreadsheet will provide the capacity to monitor the saturation point. Additionally, a descriptive analysis will be performed for quantitative indicators (ex: quantifiable variables from the semi-structured interviews) by frequency distribution.

All data collected (i.e. key informant in-depth interviews, semi-structured interviews, focus group discussions) will be digitally recorded and later transcribed. Audio contents of interviews and focus group discussions of pregnant women and next-of-kin experiences will be transcribed verbatim into MS Word by dedicated trained transcriptionists. If conducted in local language, transcripts will be locally translated by the same transcriptionists to a formally written language (i.e., Portuguese, English or

French, depending on the site). Supervisors at sites will perform quality checks of transcripts by listening to 25% of the audio recordings against the respective transcripts. Field notes taken during interviews and observations will also be transcribed. Roughly 30% of transcripts in Portuguese and French will be translated into English for subsequent analysis by team members from the CHAMPS Program Office for the purposes of quality control. Data analysis will therefore be performed by the CHAMPS site research team in-county. Analysis training and trouble-shooting will be consistently monitored through technical assistance provided by Socio-Behavioral Scientists located in the CHAMPS Program Office.

After all quality checks have been completed, Word documents will be imported into NVivo, version 10; a software that facilitates the management and coding of large sets of qualitative data. Transcripts, observation reports and field notes will be coded locally by the research team, which will work collaboratively across the sites to develop the coding frame. A generic outline of nodes and codes will be developed (coding tree) which will have the flexibility of including emerging themes from specific sites (grounded theory). As the emerging themes are incorporated, they will be shared with the investigators of the 3 sites and in that way the coding tree will be continuously updated. Coded text will be translated and shared with the other sites for multisite analysis.

Plans for Monitoring the Formative Research for Safety

All audio files will be securely stored with password protection and kept for 5 years beyond the end-date of data collection. After that period, data will be destroyed. Transcripts will be kept securely in the same manner, but they will be kept in electronic format as source documents for at least 10 years beyond the end-date of analysis. NVivo project containing all the transcripts will be kept in the server and can be used in the future for training and academic purposes.

All data collected in the formative research including audio files, transcripts, and interview notes will be digitized and downloaded into a formative research database on a password protected computer at each formative research site. A copy of each digital file will be sent by encrypted electronic mail to the site socio-behavioral science lead. Hard copies and original files on audio devices will be erased or destroyed immediately after the site socio-behavioral science lead confirms receipt of the files. The formative research database will be kept on both the computers of the site socio-behavioral science lead and those responsible for data collection and transcriptions, which will be password-protected and located in a 24-hour security-controlled building. A back-up copy of the database will be kept on an external, encrypted hard-drive in a locked file cabinet of the site socio-behavioral science lead, which is also in a 24-hour security-controlled building. The CHAMPS Program Office and site socio-behavioral science team will be the only people to have direct access to the data. Limited and segmented access to the data files will be granted to data analysis technicians, as needed.

Confidentiality

Actions will be taken to maintain privacy and confidentiality throughout the data collection and analysis phases of the formative research. Individual and focus group discussion interviews will be conducted in private settings that minimize the ability and likelihood of non-participants overhearing or viewing the conversations. Subjects will not be identified personally, nor will personal information about subjects be collected beyond age, gender, and category (e.g., pregnant women). For protection of subjects, verbal consent will be collected as opposed to a written consent form. Furthermore, all formative research

facilitators and note-takers will receive training on maintaining confidentiality and will be required to sign a confidentiality agreement form prior to conducting interviews. Following consent procedures at the onset of focus group discussions, the importance of confidentiality will be discussed with participants. A verbal agreement not to discuss information shared with others outside the group will be required prior to participation.

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Appendix A: Consent

Verbal Consent

Date (dd/mm/yyyy): __ __ /__ __/__ __ __ __

Introduction

Thank you for participating in this interview. I am _____ from _____.

What is this interview?

This is an interview we are asking members of your community to participate in. This is part of a bigger effort to better understand what members of your community do when: 1) a woman becomes pregnant, 2) she experiences problems during her pregnancy, or 3) when a child dies. The results of the interview will help us better understand the causes of child deaths so that we can help to reduce preventable deaths in the future. Your participation is voluntary (your choice). If you do not want to participate in the interview, it will not affect your job, your ability to access health care, or your participation in CHAMPS activities, now or in the future.

What are the possible risks and benefits?

You will be asked to give at most 1.5 hours of your time and you can choose to stop at any time even if the interview is not complete. We will also give you a form you can send in later if you change your mind and want us to remove your information from our records. We will not record your name, but we will record some simple information about you such as your gender, age, and the country you live in. The only foreseeable risk to you is a potential loss of privacy. However your privacy is very important to us and we will be very careful with your information. The only people who will have access to the information shared in the interview will be the members of the CHAMPS socio-behavioral science team and they will not share individual results with anyone else for any reason. When the CHAMPS social-behavioral science team shares findings from these interviews, all information that could identify any individual who was interviewed will be removed before the findings are shared.

There will be no direct benefit to you or your family members from participating in this interview. However, the information that you provide may ultimately help us to improve the health of babies and children in your country in the future.

If you have any further questions about this interview or your participation in this study, please ask now or contact the following individual: [Name of site lead Socio-Behavioral Scientist]. We can send you a copy of this information, if you would like.

Contact Information

If, at any time, you have questions about this screening process, your rights as a research participant, or if you have questions, you may contact the Emory University Institutional Review Board at +01 404-712-0720 or toll-free at +01 877-503-9797 or by email at irb@emory.edu

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes   No

If Yes:

_____
Name of Participant

_____
Name of Legally-Authorized Representative (if non-treatment study, must be parent/legal guardian of minor, or have Power of Attorney for Research)

_____
Relationship of Legally-Authorized Representative to Participant

_____
Signature of Person Conducting Informed Consent Discussion   Date   Time

_____
Name of Person Conducting Informed Consent Discussion

Appendix B: Semi-Structures Interview Guide (example)

Please note that the purpose of this guide is to provide examples for semi-structured interview consent and questions reflective of the specific aims listed in the protocol. These should be modified to satisfy the cultural norms, timing and sensitivities in each site accordingly. Interviewing strategies involving question sequencing, probing structure, timing and transition should also be designed based on each site's current methodologies. It is anticipated that 8 to 10 questions will take approximately 1 hour using a semi-structured method.

Example Types of Interview Questions

Demographic information

Topic 1: Death and related practices (feasibility)
Example questions for the general sample population:
1. Please describe what happens when a child dies in [name of community].
    Probes:
    - Ask about cultural practices and rituals
    - What happens to the corpse?
2. When a child dies, what happens to the child's spirit and what does the family or the community do to help this happen?
    Probes:
    - Why are those things done? What happens if they're not done?
    - Are there specific things done in the family? Are they done in private? How does the family tell the community that the child has died? When do they tell?
3. What helps a woman to be healthy during her pregnancy? What causes her to lose her child during pregnancy? Are the common beliefs and practices around early pregnancy loss, stillbirth, or neonatal death?
    Probes:
    - If she loses her child, what does she do?
    - What does the community do?
    - Are there specific things done in the family? Are they done in private? How does the family tell the community that the child has died? When do they tell?
4. People are often sad when a child dies. How do people in your community show their sadness?
    Probes:
    - Does a family member do anything specifically? Does the mother?
    - How does the community support the family?
    - Is anything done long after the child has died (e.g., at the anniversary of the child's death)?
    - What things are done to show sadness when a mother loses her child during pregnancy?
5. Do you feel there is value in knowing the cause of death?
    Probes:
    - Explore the desire/willingness to consent.

- How much or what information would be valued?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions):
1. What are some of the requirements for the health system (i.e. medical facilities) to conduct MITS procedures?
     Probes:
       - What might be the level of current knowledge (about MITS and/or other CHAMPS activities)?
       - Explore the acceptability of MITS among health care workers.

Example questions for next of kin and/or parents (can be used with conjunction with general questions):
1. Do you feel there is value in knowing the cause of death of your [child, niece, nephew, grandchild, etc.]?
     Probes:
       - Explore the desire/willingness to consent.
       - How much information would be valued?

Topic 2: Ethical Considerations
Example questions for the general sample population:
1. Do you think people should be offered something for taking part in a health-related activity?
     Probes:
       - Have you had any past experiences with receiving food or money by participating in [example health activity] (receiving incentives)?
       - If something were offered to members of your community when they take part in this activity, how would people respond?
2. We want to find out what causes children to die so that we can do something about those things and have fewer deaths of children. Do you think finding out this information would be valuable?
     Probes:
       - If it's valuable, why? If not, why not?
3. [Follow-on to question #2] To find out this information, we have to gather some tissue and fluids from the body of the child after they die so they we can know what caused the child to die. We need to do that within 24 hours after a child dies. We would only do it if the child's parents agreed. How would your community feel about this being done?
     Probes:
       - Explore any concerns from the perspective of the community.
       - Explore any concerns from the perspective of the family.
       - Is there anyone in your community
4. Should women in the community talk with our project staff so that the staff can find out about the things that women face when they're pregnant and learn about the things that can make pregnancy difficult? Doing this would only involve us talking with women and we would only talk with them with their permission.
     Probes:
       - If yes, why? If no, why not?
       - Do you think that families in your community would be willing for the wife/mother to do this?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions):

1. What is the role of the government, if any, when a child dies?
    Probes:
    - What are the reporting requirements?
    - Are there any investigations conducted (i.e. if there is suspicion of intentional injury causing the death)?
2. What is the process for reporting deaths in [facility name or community]?
    Probes:
    - Do clinicians feel threatened by results of MITS if different from their diagnosis?
    - Would others (i.e. clinical personnel) see MITS as helpful?

Topic 3: Community Entry and Engagement
Example questions for the general sample population:

1. What places do people go to most often for healthcare?
    Probes:
    - Which facilities in your community are most often used?
    - Which facilities or health providers are most trusted?
    - Outside of health facilities, who do people see for their health (e.g., a faith healer, a traditional healer)?
2. We want to find out what causes children to die so that we can do something about those things and have fewer deaths of children. Do you think finding out this information would be valuable?
    Probes:
    - If it's valuable, why? If not, why not?
3. [Follow-on to question #2] To find out this information, we have to gather some tissue and fluids from the body of the child after they die so they we can know what caused the child to die. We need to do that within 24 hours after a child dies. We would only do it if the child's parents agreed. How would your community feel about this being done?
    Probes:
    - Explore any concerns from the perspective of the community.
    - Explore any concerns from the perspective of the family.
    - Is there anyone in your community
4. If tissue and fluids from the body of a child who dies were to be collected with the parents' permission, what kinds of rumors might start in the community?
    Probes:
    - Do you have any suggestions about ways we could work in your community to address those rumors if they started?
5. People are often sad when a child dies. How do people in your community show their sadness?
    Probes:
    - Does a family member do anything specifically? Does the mother?
    - How does the community support the family?
    - Is anything done long after the child has died (e.g., at the anniversary of the child's death)?
    - What things are done to show sadness when a mother loses her child during pregnancy?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions)

1. Who are the most important people that need to be involved in activities related to community entry [describe community entry]?
   Probes:
   - Religious leader?
   - Village chiefs?
2. What do you think would be the best method of educating the community about MITS?
   Probes:
   - Explore facility and community discussions.
3. What are some of the best ways to speak with and involve community leaders in CHAMPS activities [describe CHAMPS activities]?
   Probes:
   - Explore rituals and traditional practices.

Topic 4: Pregnancy and Birth (perceptions)
Example questions for the general sample population:

1. Please describe how pregnant women receive care during their pregnancy.
   Probes:
   - How do women share the news of their pregnancy? When does this usually occur?
   - Do women typically go to an antenatal care facility or receive care at home?
   - Who provides the care for pregnant women (at home and/or in a facility)?
   - Where do women go to deliver? Who provides the care during delivery?
2. What are some barriers to seeking care?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions)

1. What are the current capacities in this [facility or community] to date pregnancies and postpartum and newborn exams?
   Probes:
   - Explore types of care and quality of care.
2. Can you describe any policies related to antenatal care?
   Probes:
   - Explore strengths and weaknesses of antenatal care.

Appendix C: Key Informant In-Depth Interview Guide (example)

Please note that the purpose of this guide is to provide examples for key informant in-depth interview consent and questions reflective of the specific aims listed in the protocol. These should be modified to satisfy the cultural norms, timing and sensitivities in each site accordingly. Interviewing strategies involving question sequencing, probing structure, timing and transition should also be designed based on each site's current methodologies.

Example Types of Interview Questions

Topic 1: Death and related practices (feasibility)
Example questions for the general sample population:
1. Please describe what happens when a child dies in [name of community].
   Probes:
   - Ask about cultural practices and rituals
   - What happens to the corpse?
2. When a child dies, what happens to the child's spirit and what does the family or the community do to help this happen?
   Probes:
   - Why are those things done? What happens if they're not done?
   - Are there specific things done in the family? Are they done in private? How does the family tell the community that the child has died? When do they tell?
3. Who are the people who take the lead in doing these things in your community
   Probes:
   - What do religious or spiritual leaders do? Is there more than one type of religious leader in your community?
   - What do healthcare workers do?
   - What do women do? What do men do? What do children do?
4. Can you tell me what happens to the body of a child who dies?
   Probes:
   - How is the body cared for after death?
   - How is the body buried?
   - Who prepares the body?
   - Is there a religious service or some activity the community does together when the child's body is buried? If so, who leads it?
5. Are these things always done for everybody or do people decide that some things don't have to be done?
   Probes:
   - How important is it to carry out these activities?
   - Imagine that these activities weren't carried out. What would happen?
6. What helps a woman to be healthy during her pregnancy? What causes her to lose her child during pregnancy?
   Probes:
   - If she loses her child, what does she do?
   - What does the community do?

- Are there specific things done in the family? Are they done in private? How does the family tell the community that the child has died? When do they tell?

7. Is someone or something to blame for the death of a child or the loss of a child during pregnancy?
    - Probes:
        - If so, who is it? What is it?
        - What does the community do in response?

8. People are often sad when a child dies. How do people in your community show their sadness?
    - Probes:
        - Does a family member do anything specifically? Does the mother?
        - How does the community support the family?
        - Is anything done long after the child has died (e.g., at the anniversary of the child's death)?
        - What things are done to show sadness when a mother loses her child during pregnancy?

9. Do you feel there is value in knowing what caused a child to die?
    - Probes:
        - Why would this be valuable?
        - Explore the desire/willingness to consent.
        - How much or what information would be valued?

10. Our project wants to work collaboratively and respectfully with your community? Do you have any suggestions for helping us to do that?
    - Probes:
        - How can we be mindful and respectful of mothers' and families' needs after the death of a child?
        - How can we be mindful and respectful of the community's needs after the death of a child?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions):

1. What are some of the requirements for the health system (i.e. medical facilities) to conduct MITS procedures?
    - Probes:
        - What might be the level of current knowledge (about MITS and/or other CHAMPS activities)?
        - Explore the acceptability of MITS among health care workers.

2. Having named those requirements, which of them are in place in your health system?
    - Probes:
        - What would need to be put in place in regard to facilities? Equipment? Personnel?

3. What role could your health system play in carrying out MITS?
    - Probes:
        - Could MITS be carried out in your health facilities?
        - Could your healthcare workers go out into the community to carry out MITS?

4. What role could your health system play in carrying out pregnancy surveillance?
    - Probes:
        - Could pregnancy surveillance be carried out in your health facilities?

- Could your healthcare workers go out into the community to carry out pregnancy surveillance?
- Do you have access to an existing disease surveillance database that could provide data for pregnancy surveillance

5. How can CHAMPS activities work with the existing health priorities and activities in the community?
    Probes:
    - How can CHAMPS activities integrate with and/or support the activities of your health system?
    - How can CHAMPS contribute to the public health infrastructure of your community?

Example questions for next of kin and/or parents (can be used with conjunction with general questions):
1. Do you feel there is value in knowing the cause of death of your [child, niece, nephew, grandchild, etc.]?
    Probes:
    - Explore the desire/willingness to consent.
    - How much information would be valued?
2. What is most important for us to do in showing our respect to your family during this difficult time?

Topic 2: Ethical Considerations
Example questions for the general sample population:
1. Do you think people should be offered something for taking part in a health-related activity?
    Probes:
    - Have you had any past experiences with receiving food or money by participating in [example health activity] (receiving incentives)?
    - If something were offered to members of your community when they take part in this activity, how would people respond?
2. We want to find out what causes children to die so that we can do something about those things and have fewer deaths of children. Do you think finding out this information would be valuable?
    Probes:
    - If it's valuable, why? If not, why not?
3. [Follow-on to question #2] To find out this information, we have to gather some tissue and fluids from the body of the child after they die so they we can know what caused the child to die. We need to do that within 24 hours after a child dies. We would only do it if the child's parents agreed. How would your community feel about this being done?
    Probes:
    - Explore any concerns from the perspective of the community.
    - Explore any concerns from the perspective of the family.
    - Is there anyone in your community who would need to give their approval to allow community members to take part in CHAMPS?
4. Should women in the community talk with our project staff so that the staff can find out about the things that women face when they're pregnant and learn about the things that can make pregnancy difficult? Doing this would only involve us talking with women and we would only talk with them with their permission.
    Probes:

- If yes, why? If no, why not?
- Do you think that families in your community would be willing for the wife/mother to do this?

5. You described for us things that are important in the community to do when a child dies. We've described for you the importance for CHAMPS of identifying the things that cause children to die so that we can do something about those things. How important are each of these things to your community?
    Probes:
    - If community activities are more important, why?
    - If CHAMPS objective is more important, why?

6. Do you think that it's possible to do the things that are important in the community when a child dies **AND** to gather the tissue and fluid samples from the child's body?
    Probes:
    - If no, please describe the reasons why both aren't possible in your opinion
    - If yes, please describe the ways that both can be done

7. How can CHAMPS be respectful of and build the trust of community members?
    Probes:
    - Can you think of anything we might do accidentally that would be offensive to the community?
    - What are the best ways for us to work with the community? What are the best ways to share what we find?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions):

1. What is the role of the government, if any, when a child dies?
    Probes:
    - What are the reporting requirements?
    - Are there any investigations conducted (i.e. if there is suspicion of intentional injury causing the death)?

2. What is the process for reporting deaths in [facility name or community]?
    Probes:
    - Do clinicians feel threatened by results of MITS if different from their diagnosis?
    - Would others (i.e. clinical personnel) see MITS as helpful?

Topic 3: Community Entry and Engagement
Example questions for the general sample population:

1. What places do people go to most often for healthcare?
    Probes:
    - Which facilities in your community are most often used?
    - Which facilities or health providers are most trusted?
    - Outside of health facilities, who do people see for their health (e.g., a faith healer, a traditional healer)?

2. We want to find out what causes children to die so that we can do something about those things and have fewer deaths of children. Do you think finding out this information would be valuable?
    Probes:
    - If it's valuable, why? If not, why not?

3. [Follow-on to question #2] To find out this information, we have to gather some tissue and fluids from the body of the child after they die so they we can know what caused the child to die. We need to do that within 24 hours after a child dies. We would only do it if the child's parents agreed. How would your community feel about this being done?
    Probes:
    - Explore any concerns from the perspective of the community.
    - Explore any concerns from the perspective of the family.
    - Is there anyone in your community

4. If tissue and fluids from the body of a child who dies were to be collected with the parents' permission, what kinds of rumors might start in the community?
    Probes:
    - Do you have any suggestions about ways we could work in your community to address those rumors if they started?

5. People are often sad when a child dies. How do people in your community show their sadness?
    Probes:
    - Does a family member do anything specifically? Does the mother?
    - How does the community support the family?
    - Is anything done long after the child has died (e.g., at the anniversary of the child's death)?
    - What things are done to show sadness when a mother loses her child during pregnancy?

6. How can CHAMPS be respectful of and build the trust of community members?
    Probes:
    - Can you think of anything we might do accidentally that would be offensive to the community?
    - What are the best ways for us to work with the community? What are the best ways to share what we find?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions)
1. Who are the most important people that need to be involved in activities related to community entry [describe community entry]?
    Probes:
    - Religious leader?
    - Village chiefs?
    - Others?

2. What do you think would be the best method of educating the community about MITS?
    Probes:
    - Explore facility and community discussions

3. What are some of the best ways to speak with and involve community leaders in CHAMPS activities [describe CHAMPS activities]?
    Probes:
    - Explore rituals and traditional practices.

Topic 4: Pregnancy and Birth (perceptions)
Example questions for the general sample population:

1. Please describe how pregnant women receive care during their pregnancy.
   Probes:
   - How do women share the news of their pregnancy? When does this usually occur?
   - Do women typically go to an antenatal care facility or receive care at home?
   - Who provides the care for pregnant women (at home and/or in a facility)?
   - Where do women go to deliver? Who provides the care during delivery?
3. What are some barriers to seeking care?

2. What are some barriers to care for women who are pregnant?

3. What do people in the community do when they find out a woman is pregnant?
   Probes:
   - What happens among women when they find out another woman is pregnant?
   - What happens among men when they find out a man's wife is pregnant
   - What happens in the family when the mother finds out she's pregnant?
   - What happens in your faith communities when the members find out that a woman in the community is pregnant?

Example questions for community health care providers, public health practitioners, clinicians, policy and political representatives, researchers, etc. (can be used with conjunction with general questions)
1. What are the current capacities in this [facility or community] to date pregnancies and postpartum and newborn exams?
   Probes:
   - Explore types of care and quality of care.
2. Can you describe any policies related to antenatal care?
   Probes:
   - Explore strengths and weaknesses of antenatal care.
3. How could CHAMPS activities be aligned with and complement your current antenatal and postpartum services?

Appendix D: Focus Group Discussion Guide (example)

Please note that the purpose of this guide is to provide examples for focus group consent and questions reflective of the specific aims listed in the protocol. These should be modified to satisfy the cultural norms, timing and sensitivities in each site accordingly. Interviewing strategies involving question sequencing, probing structure, timing and transition should also be designed based on each site's current methodologies.

Example Types of Focus Group Discussion Questions

Topic 1: Death and related practices (feasibility)
Example questions for the general sample population (i.e. community health care leaders and providers, public health practitioners, clinicians, etc.)

1. Please describe what happens when a child dies in [name of community].
   Probes:
   - Ask about cultural practices and rituals
   - What happens to the corpse?

2. Can you tell me what happens to the body of a child who dies?
   Probes:
   - How is the body cared for after death?
   - How is the body buried?
   - Who prepares the body?
   - Is there a religious service or some activity the community does together when the child's body is buried? If so, who leads it?

3. Are these things always done for everybody or do people decide that some things don't have to be done?
   Probes:
   - How important is it to carry out these activities?
   - Imagine that these activities weren't carried out. What would happen?

4. What helps a woman to be healthy during her pregnancy? What causes her to lose her child during pregnancy?
   Probes:
   - If she loses her child, what does she do?
   - What does the community do?
   - Are there specific things done in the family? Are they done in private? How does the family tell the community that the child has died? When do they tell?

5. Our project wants to work collaboratively and respectfully with your community? Do you have any suggestions for helping us to do that?
   Probes:
   - How can we be mindful and respectful of mothers' and families' needs after the death of a child?
   - How can we be mindful and respectful of the community's needs after the death of a child?

6. What are some of the requirements for the health system (i.e. medical facilities) to conduct MITS procedures?
   Probes:

- What might be the level of current knowledge (about MITS and/or other CHAMPS activities)?
- Explore the acceptability of MITS among health care workers.
7. Having named those requirements, which of them are in place in your health system?
    - Probes:
        - What would need to be put in place in regard to facilities? Equipment? Personnel?
8. What role could your health system play in carrying out MITS?
    - Probes:
        - Could MITS be carried out in your health facilities?
        - Could your healthcare workers go out into the community to carry out MITS?
9. What role could your health system play in carrying out pregnancy surveillance?
    - Probes:
        - Could pregnancy surveillance be carried out in your health facilities?
        - Could your healthcare workers go out into the community to carry out pregnancy surveillance?
        - Do you have access to an existing disease surveillance database that could provide data for pregnancy surveillance
10. How can CHAMPS activities work with the existing health priorities and activities in the community?
    - Probes:
        - How can CHAMPS activities integrate with and/or support the activities of your health system?
        - How can CHAMPS contribute to the public health infrastructure of your community?

Topic 2: Ethical Considerations
Example questions for the general sample population (i.e. community health care leaders and providers, public health practitioners, clinicians, etc.):
1. Do you think people should be offered something for taking part in a health-related activity?
    - Probes:
        - Have you had any past experiences with receiving food or money by participating in [example health activity] (receiving incentives)?
        - If something were offered to members of your community when they take part in this activity, how would people respond?
2. Should women in the community talk with our project staff so that the staff can find out about the things that women face when they're pregnant and learn about the things that can make pregnancy difficult? Doing this would only involve us talking with women and we would only talk with them with their permission.
    - Probes:
        - If yes, why? If no, why not?
        - Do you think that families in your community would be willing for the wife/mother to do this?
3. Do you think that it's possible to do the things that are important in the community when a child dies **AND** to gather the tissue and fluid samples from the child's body?
    - Probes:
        - If no, please describe the reasons why both aren't possible in your opinion
        - If yes, please describe the ways that both can be done
4. How can CHAMPS be respectful of and build the trust of community members?

Probes:
- Can you think of anything we might do accidentally that would be offensive to the community?
- What are the best ways for us to work with the community? What are the best ways to share what we find?

3. What is the role of the government, if any, when a child dies?
Probes:
- What are the reporting requirements?
- Are there any investigations conducted (i.e. if there is suspicion of intentional injury causing the death)?

4. What is the process for reporting deaths in [facility name or community]?
Probes:
- Do clinicians feel threatened by results of MITS if different from their diagnosis?
- Would others (i.e. clinical personnel) see MITS as helpful?

Topic 3: Community Entry and Engagement
Example questions for the general sample population (i.e. community health care leaders and providers, public health practitioners, clinicians, etc.):

1. What places do people go to most often for healthcare?
Probes:
- Which facilities in your community are most often used?
- Which facilities or health providers are most trusted?
- Outside of health facilities, who do people see for their health (e.g., a faith healer, a traditional healer)?

2. If tissue and fluids from the body of a child who dies were to be collected with the parents' permission, what kinds of rumors might start in the community?
Probes:
- Do you have any suggestions about ways we could work in your community to address those rumors if they started?

3. People are often sad when a child dies. How do people in your community show their sadness?
Probes:
- Does a family member do anything specifically? Does the mother?
- How does the community support the family?
- Is anything done long after the child has died (e.g., at the anniversary of the child's death)?
- What things are done to show sadness when a mother loses her child during pregnancy?

4. How can CHAMPS be respectful of and build the trust of community members?
Probes:
- Can you think of anything we might do accidentally that would be offensive to the community?
- What are the best ways for us to work with the community? What are the best ways to share what we find?

5. Who are the most important people that need to be involved in activities related to community entry [describe community entry]?
Probes:
- Religious leader?

- Village chiefs?
- Others?
6. What do you think would be the best method of educating the community about MITS?
   Probes:
   - Explore facility and community discussions
7. What are some of the best ways to speak with and involve community leaders in CHAMPS activities [describe CHAMPS activities]?
   Probes:
   - Explore rituals and traditional practices.

Topic 4: Pregnancy and Birth (perceptions)
Example questions for the general sample population (i.e. community health care leaders and providers, public health practitioners, clinicians, etc.):
1. Please describe how pregnant women receive care during their pregnancy.
   Probes:
   - How do women share the news of their pregnancy? When does this usually occur?
   - Do women typically go to an antenatal care facility or receive care at home?
   - Who provides the care for pregnant women (at home and/or in a facility)?
   - Where do women go to deliver? Who provides the care during delivery?
2. What are some barriers to care for women who are pregnant?
3. What do people in the community do when they find out a woman is pregnant?
   Probes:
   - What happens among women when they find out another woman is pregnant?
   - What happens among men when they find out a man's wife is pregnant
   - What happens in the family when the mother finds out she's pregnant?
   - What happens in your faith communities when the members find out that a woman in the community is pregnant?
4. What are the current capacities in this [facility or community] to date pregnancies and postpartum and newborn exams?
   Probes:
   - Explore types of care and quality of care.
5. Can you describe any policies related to antenatal care?
   Probes:
   - Explore strengths and weaknesses of antenatal care.
6. How could CHAMPS activities be aligned with and complement your current antenatal and postpartum services?

Appendix E: Field Notes Template for Observation Data

Please note that the purpose of this guide is to provide examples for observation opportunities reflective of the specific aims listed in the protocol. These should be modified to satisfy the cultural norms, timing and sensitivities in each site accordingly.

1. **As best you can, provide a brief description of the ritual**
   - Source of this information: (e.g., subjective impression, discussion with someone present)

2. **What does the ritual signify?**
   - Source of this information: (e.g., subjective impression, discussion with someone present)

3. **Where is the ritual being held?**
   - What is the significance of the site, if any?
     - Source of this information: (e.g., subjective impression, discussion with someone present)

4. **Who is present for the ritual?**
   - What are the various roles of those present?
   - Who is the leader/leaders?
   - Are there any variations in roles based on characteristics such as gender, age, relationship to person who died?
   - Is anyone absent?
     - Source of this information: (e.g., subjective impression, discussion with someone present)

5. **What are the elements of the ritual? What activities are performed?**
   - Do the various activities signify anything in particular?
     - Source of this information: (e.g., subjective impression, discussion with someone present)

6. **When is the ritual carried out?**
   - What time of day?
   - How long after the death of the child?
   - What events occur before or after these events?
   - Is timing important?
     - Source of this information: (e.g., subjective impression, discussion with someone present)

Template for Observation of Discussion with Family for Possible Participation in MITS

1. What CHAMPS team member(s) spoke with the family?
- Who did they speak to? Primarily the husband? Primarily the wife? Both? Did they acknowledge all family members?

2. What was said?
- Did the CHAMPS team member say anything before discussing MITS? If so, what did s/he say? (be detailed here. If necessary, continue this on the back of the sheet)
- How did the CHAMPS team member broach the subject of the family consenting to MITS? What did s/he say (again, be as detailed as possible)
- Was there any form of non-verbal communication? (e.g., eye contact, a touch on a family member's hand, etc)

3. What was the family's response?
- What did they say specifically?
- What questions did they ask?
- What were the responses back from the CHAMPS team member?
- Did the family display emotion? If so, what emotion was displayed?

4. Did the family consent
- If so, what elements of the conversation were most important for eliciting their consent, in your opinion?

Appendix F: PICK-CHAMP Workshop Curriculums

Community Members Workshop

- Exercise 1: Perceptions of Pregnancy
    - o Task: Identify community members' perspectives of the things that cause problems in pregnancy and the things that contribute to a healthy pregnancy
    - o Output: A participant driven list of factors that impact pregnancy

- Exercise 2: Perceptions of Childhood Health and Illness
    - o Task: Identify community members' perspectives of the things that contribute to healthy children and the things that cause childhood illness and death.
    - o Output: A participant driven list of factors that impact childhood health, illness, and death.

- Exercise 3: Participants' Perception of the Death of a Child
    - o Task: Participants develop a list of community activities undertaken when a child dies.
    - o Output: A list of most important things done in the community when a child dies generated by each individual participant.

- Exercise 4: Community Responses to Childhood Death
    - o Task: Participants decide upon the most important things done in their community when a child dies.
    - o Output: A ranked list of things done in the community with the most important 4-6 listed.

- Exercise 5: Commonalities Between CHAMPS Objectives and Community Priorities
    - o Task: Identify commonalities between community priorities and norms and the objectives of CHAMPS
    - o Output: A participant-driven list of messages based on community norms and language that re-enforce the objectives of CHAMPS with the three most powerful messages identified.

- Exercise 6: Relationship Between Community Responses to Childhood Death and CHAMPS Activities
    - o Task: Assess the level of alignment or tension between CHAMPS activities and community responses to childhood death.
    - o Output: A ranked matrix of alignment and tension between CHAMPS activities and community activities.

- Exercise 7: Community Organizations That Could Support CHAMPS Activities
    - o Task: Generate a list of valued community organizations and leaders in the community that could support CHAMPS.
    - o Output: A participant driven list of local community organizations that are important resources for the community to respond to the death of a child that participants also identify as potentially supporting one or more CHAMPS activities.

Community Leaders Workshop

- Exercise 1: A History of Our Community
    - Task: Develop a timeline of key social, political and health events in the local community over the last 50 years.
    - Output: A timelines that reflects important historical events and show historical trends that have shaped the current health, social, and political environments.

- Exercise 2: Commonalities Between CHAMPS Objectives and Community Priorities
    - Task: Identify commonalities between community priorities and norms and the objectives of CHAMPS
    - Output: A participant-driven list of messages based on community norms and language that re-enforce the objectives of CHAMPS with the three most powerful messages identified.

- Exercise 3: Perceptions About CHAMPS Activities
    - Task: Assess the level of alignment or tension between CHAMPS activities and community responses to childhood death.
    - Output: A matrix of alignment and tension between CHAMPS activities and community activities.

- Exercise 4: Building Support for CHAMPS
    - Task: Use the key messages created in exercise 2 to create/strengthen alignment between community activities and CHAMPS activities
    - Output: A participant driven list of action steps (and champions) that align with community messages that could be undertaken to build support for CHAMPS

- Exercise 5: Creating a Spiderweb
    - Task: Identify the relationships among key organizations that could support CHAMPS as identified in the community members workshop.
    - Output: A participant developed social network map and contact information for potential community partners of CHAMPS.

Activities	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Protocol Adaption (at site)												
Review all materials and forward implementation plan for review	X	X	X									
Finalize protocol and implementation requirements			X	X								
Finalize all training materials			X									
IRB Approvals												
IRB approval			X	X								
Submit amendments as required			X	X	X							
Community Entry and Engagement Workshops (PICK-CHAMP)												
Set dates for the workshop		X										
Recruit participants			X	X								
Conduct workshops			X	X								
Semi-Structured Interviews (SSIs)												
Train research assistants				X	X							
Identify incentives and participant transportation				X	X							
Identify participants				X	X							
Refine interview questions			X	X								
Conduct interview pre-test (pilot)				X								
Refine interview questions again				X	X							
Conduct interviews				X	X	X	X	X	X	X	X	X
Key Informant In-Depth Interviews												
Identify participants				X	X							
Refine interview questions				X								
Conduct interview pre-test (pilot)				X	X							
Refine interview questions again				X	X							
Conduct interviews				X	X	X	X	X	X	X	X	X
Focus Group Discussions (FDGs)												
Identify and arrange site locations for focus groups				X	X							
Identify participants				X	X							
Register participants				X	X							
Develop focus groups questions			X	X	X							
Conduct focus group in [insert area]				X	X	X	X	X	X	X	X	X
Conduct focus group in [insert area]				X	X	X	X	X	X	X	X	X
Analysis												
Analyze data for SSIs and key informant in-depth interviews						X	X	X	X	X	X	X
Analyze data for FGDs						X	X	X	X	X	X	X

Draft preliminary reports												
Post activities												
Conduct evaluation												
Finalize reports and continue to inform community engagement and CHAMPS activities												