FULL RESEARCH PROPOSAL

The Mbereko+Men Model: a community based intervention to improve care-seeking for maternal, newborn and child health services and care and support in the home in Manicaland, Zimbabwe

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RESEARCH OUTLINE

Rationale	Available data indicate that maternal, newborn and child health (MNCH) in Zimbabwe is being compromised by low uptake of services along the continuum of care over the critical 1,000-day period covering pregnancy and the first two years of life. Multiple interrelated demand-side barriers constrain the capacity of rural Zimbabwean women to seek health care. Previous research and program experience, from Zimbabwe as well as other low- and middle-income country contexts, has identified social support, women's economic empowerment, and men's positive engagement in family health as important enablers at the community level that can support women to access essential MNCH services. A community based intervention to support care-seeking among rural Zimbabwean women has the potential to substantially improve health outcomes for women, infants and children. Furthermore, an evidence-based intervention that was demonstrated to be effective could be scaled to other areas in Zimbabwe and adapted for use in other country contexts.
Aim	The study aims to assess the effectiveness, feasibility and acceptability of a novel, gender-synchronised, community based intervention to improve care-seeking for a package of essential MNCH services and care and support in the home in an underserved rural area of Zimbabwe.
Objectives	The research objectives are: 1. To assess the effect of a novel, gender-synchronised, community based intervention on uptake of MNCH services and care and support in the home; 2. To assess the feasibility of implementation of an intervention that synchronises men's discussion forums with women's groups; 3. To assess the acceptability of men's increased engagement in family health to women and men; and 4. To explore how men perceive male engagement in family health following an intervention designed to encourage men's involvement in family health.
Design	We propose a two-arm cluster-randomised controlled trial, with four clusters per arm. The clustering unit will be the rural health clinic catchment area. The arms comprise no intervention (normal standard care) and full intervention (Mbereko+Men Project). The proposed study, which is designed to test the Mbereko+Men Model, will be fully integrated with implementation of the Mbereko+Men Project. We intend to nest a cluster-randomised controlled trial within planned program activities. Additional qualitative and quantitative routine data generated throughout the project will also be analysed retrospectively.
Study population	Primary study population: women resident in study sites for at least 12 months who have given birth within 0-6 months. Additional study populations: men resident in study sites for at least 12 months whose partners have given birth within 0-6 months or who have a child aged 0-6 months; male and female target beneficiaries who participate in Mbereko+Men Project activities; and project implementers and key stakeholders (Village Health Workers, Health Care Committee members; facility-based health care workers, male champions, village leaders and policymakers).
Study duration	The duration of the proposed study is three years. The intended study implementation period is January 2016 – December 2018.

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GLOSSARY OF ABBREVIATIONS AND TERMS

Abbreviation	Term
ANC	Antenatal care
CMD	Common mental disorders
DHS	Demographic and Health Survey
EPDS	Edinburgh Postnatal Depression Scale
HCC	Health Centre Committee
HCW	Health care worker
HIV	Human immunodeficiency virus
MICS	Multiple Indicator Cluster Survey
MNCH	Maternal, newborn and child health
MOHCC	Ministry of Health and Child Care, Zimbabwe
OPHID	Organisation for Public Health Interventions and Development
PPTCT	Prevention of parent-to-child transmission of HIV
RHC	Rural health clinic
VHW	Village health worker

Term	Definition
Mbereko	Local dialect Shona for the cloth wrap that holds to baby next to the mother in the first two years of life

BACKGROUND AND SIGNIFICANCE

Available data indicate that maternal, newborn and child health (MNCH) in Zimbabwe is being compromised by low uptake of services along the continuum of care over the critical 1,000-day period covering pregnancy and the first two years of life. Multiple interrelated demand-side barriers constrain the capacity of rural Zimbabwean women to seek health care. Previous research and program experience, from Zimbabwe as well as other low- and middle-income country contexts, has identified social support, women's economic empowerment, and men's positive engagement in family health as important enablers at the community level that can support women to access essential MNCH services. A community based intervention to support care-seeking among rural Zimbabwean women has the potential to substantially improve health outcomes for women, infants and children. Furthermore, an evidence-based intervention that was demonstrated to be effective could be scaled to other areas in Zimbabwe and adapted for use in other country contexts.

MATERNAL AND INFANT MORTALITY IS UNACCEPTABLY HIGH IN ZIMBABWE

The most recent Zimbabwe Multiple Indicator Cluster Survey (MICS) survey (2014)[1] indicates that 18% of women are delivering their babies outside of the healthcare system, and that Zimbabwe still has an unacceptably high maternal mortality ratio of 581 per 100,000 live births with 26% of deaths attributable to HIV. Additionally, Zimbabwe has an under five mortality ratio of 75 per 1,000 live births[2] with one in five deaths in children aged under-five attributable to HIV, with additional deaths caused by pneumonia, diarrhoea and tuberculosis which may be associated with HIV. Undernutrition is also a leading contributor to child deaths.

Maternal and infant mortality are particularly high in the proposed study site, Mutasa District in Manicaland Province. Manicaland Province is the second most populated province in Zimbabwe with a population of 1,752,698. The majority (83%) of the population lives in rural settings where distance and resource constraints compromise access to health services.[3] Mutasa District has the highest infant mortality rate in Manicaland, at 87 deaths per 1,000 live births,[4] substantially higher than the national average of 55 deaths per 1,000 live births.[4]

LOW UPTAKE OF ESSENTIAL MNCH SERVICES

In Zimbabwe, more than two-thirds of all childhood deaths occur within the critical 1,000 days between the time a woman learns she is pregnant and her child's second birthday.[2] With high HIV-related maternal and infant mortality, poor nutrition outcomes and large number of deaths due to preventable infections and delay in care seeking, it is widely acknowledged that increasing uptake along an integrated continuum of essential maternal, newborn and child health (MNCH) services can significantly improve maternal and child survival.[5]

Zimbabwean rural mother-baby pairs have low uptake of the continuum of essential health services known to improve MNCH, including: four or more ANC appointments, couples HIV testing in ANC and PPTCT, facility-based delivery, prompt postnatal care for mothers and infants, exclusive breastfeeding and post-partum family planning, among others.[2] Rather than complete disengagement from care, many mother-baby pairs access services 'cafeteria style',

making use of some services (such as ANC), while missing many essential services altogether (such as facility delivery).[6] Improving maternal and child health requires consistent uptake of essential health services over the first 1,000 days.

THE ROLE OF DEMAND-SIDE BARRIERS TO ACCESSING MNCH SERVICES

Multiple barriers constrain demand for health care among Zimbabwean rural mother-baby pairs. Existing evidence indicates that rural women, women with higher parity, women with limited education and women facing resource constraints have lower uptake of essential MNCH services in Zimbabwe.[2]

Lack of social support for rural women of childbearing age: Social support has been identified as important for improved health outcomes among women and children.[7] In settings with high HIV prevalence, social support has been demonstrated as a protective factor for depression among women.[8] The Organisation for Public Health Interventions and Development (OPHID) has previously demonstrated the important role of social support groups for increasing access to family health services by HIV-affected children in rural Zimbabwe.[9]

Resource constraints act as barriers to service uptake: Resources required to access and pay for health services, transport required to reach health facilities, and opportunity costs (e.g. lost productivity at household level) associated with accessing care have been identified as major barriers to uptake of maternal health services among poor women.[10]

Lack of awareness of key services and planning to overcome barriers to uptake over the first 1,000 days: Previous work completed by OPHID has demonstrated that failure to set goals for service uptake and limited advanced planning impede service uptake, and that limited social recognition for achieving sustained MNCH service uptake in rural communities contributes to low demand for sustained uptake along the continuum of care.[11]

Gender inequality and lack of female decision-making: Among married women aged 15-49, women in Manicaland Province are the least likely compared with women from other provinces in Zimbabwe to report making specific decisions regarding their own health care (67.5%), major purchases (79.5%) or visits to relatives (79.9%) either by themselves or jointly with their husband; with only 54.3% of women participating in all three decisions.[2] Gender inequality, lack of women's empowerment, and attitudes and experience of gender-based violence among women are shown to decrease MNCH service uptake and outcomes over the first 1,000 days. In Zimbabwe, women who believe that wife beating is not justified for any reason are more likely than other women to use any method of contraception, receive antenatal care, delivery care from a skilled provider and postnatal check-ups within the first two days following delivery than women who agree it is justified. Children of women who participate in one to two household decisions have an under-5 mortality rate (110 deaths per 1,000 live births) that is higher than those of children of mothers who participate in three decisions (64 deaths per 1,000 live births).[2]

Lack of male involvement: Male involvement in family health is associated with improved maternal health outcomes in developing countries[12] and particularly important for improving

coverage and infant outcomes in PPTCT programs.[13] Despite this, male participation in Zimbabwe's PPTCT program remains below target.[14]

STRATEGIES TO ADDRESS DEMAND-SIDE BARRIERS

The established barriers to uptake of MNCH services in Zimbabwe indicate that measures to support women at both individual and social level, and to link women to community level actors and resources to support their decisions and actions on health, are required to improve uptake of essential MNCH services over the first 1,000 days. A recent systematic review highlighted the value of integrating maternal and newborn care in community settings through a series of interventions, which can be packaged effectively for delivery through a range of community health workers and health promotion groups.[15]

Provision of quality health services: Ensuring rural health care workers have the required skills and competencies to provide quality MNCH services is critical to ensuring that supply can match any increases in demand for services, in order to achieve improved maternal and child health.[16] Accordingly, assessing existing capacities, identifying skills gaps and providing necessary training and on-site mentorship are critical first steps prior to generating demand for services as a strategy for reducing maternal and infant morbidity and mortality.

Women's empowerment groups: The ability of women to access information, make decisions, and act effectively in their own interest, or in the interest of those who depend on them, are essential aspects of the empowerment of women. If women, who in the study setting are generally the primary caretakers of children, are empowered, then the health and survival of their infants will be enhanced as will their own health and survival. The information, social support, group problem solving and skills development achieved through participation in women's groups in low income settings have been demonstrated to have a powerful effect upon maternal and child health in low income settings. In areas with high coverage of groups (where over 30% of pregnant women participated in women's groups) this was associated with a 55% fall in maternal mortality and a 33% reduction in neonatal mortality.[17] Accordingly, the World Health Organization has made formal recommendations about the use of women's groups using the participatory learning and action cycle in efforts to reduce maternal and child morbidity and mortality.[18]

Income generation and access to financial services: Increasing women's access to financial resources within their decision-making powers has been linked to increased service uptake and improved maternal and child health.

Planning and goal-setting: Through previous collaboration, OPHID and Burnet Institute have demonstrated that engaging rural women in a process of identifying and problem solving barriers to MNCH service uptake using the Action Birth Card, resulted in a significant increase in underutilised maternal health services compared to previous pregnancies without the use of the goal-setting tool.[19] Such findings build on existing evidence that engaging recipients in an active process of making specific plans, writing them down, and problem-solving obstacles to service uptake improves health service utilisation.[20]

Male engagement in family health: Male involvement in planning for health service uptake has been linked to increased utilisation of multiple maternal and child health services including facility based delivery, PMTCT services and child health services.[12, 21] Through previous collaboration, OPHID and Burnet Institute found that women in rural Zimbabwe identified their husbands/male partners as the people in their social network who were most helpful for overcoming barriers to service uptake.

EXPECTED CONTRIBUTION OF THIS STUDY

Community based approaches to address barriers and support enablers to increase uptake of essential MNCH services are urgently required, not only in Zimbabwe but also in other low- and middle-income country settings. The proposed study aims to test a scalable model that works at the community level to address barriers and support enablers to improve care-seeking for essential MNCH services and care and support in the home for mother-baby pairs. If proven effective, this model could be replicated to improve MNCH care-seeking, and health outcomes for women and children, in rural areas in Manicaland Province and beyond.

ALIGNMENT WITH EXISTING GOVERNMENT STRATEGIES

OPHID programs are embedded within existing Zimbabwe Ministry of Health and Child Care (MOHCC) structures and designed in collaboration with National, Provincial and District health authorities. This unique position ensures that activities implemented by OPHID are in line with MOHCC priorities, and ensures rapid translation of project outcomes and lessons learned into on-going MOHCC policy and planning, increasing potential for scale.

Specifically, the proposed study responds to national public health priorities as outlined in the following strategic documents:

- *Maternal and Neonatal Health Road Map (2007-2015)*, which calls for a three-quarter reduction in the maternal mortality ratio and a two-thirds reduction in under-5 mortality;
- *Zimbabwe Agenda for Sustainable Socio-Economic Transformation (2013-2018)*, which focuses on poverty reduction;
- *Zimbabwe HIV Care and Treatment Strategic Plan 2013-2017*, Objective 4, 'To strengthen community based initiatives and systems in the provision of ART with Meaningful participation of PLHIV'; and
- *Strategic Plan for the Elimination for New HIV infections in Children and Keeping Mothers and Families Alive (2011-2015)*, Objective 6, 'To strengthen the involvement and participation of communities and their leaders in PMTCT and paediatric HIV care and treatment'.

STUDY AIM AND OBJECTIVES

AIM

The study aims to assess the effectiveness, feasibility and acceptability of a novel, gender-synchronised, community based intervention to improve care-seeking for a package of essential MNCH services, and care and support provided in the home to mother-baby pairs, in an underserved rural area of Zimbabwe.

OBJECTIVES

1. To assess the effect of the Mbereko+Men Model on uptake of MNCH services and care and support in the home;
2. To assess the feasibility of implementation of an intervention that synchronises men's discussion forums with women's groups;
3. To assess the acceptability of men's increased engagement in family health to women and men; and
4. To explore how men perceive male engagement in family health following an intervention designed to encourage men's involvement in family health.

INTERVENTION DESCRIPTION

INTERVENTION ACTIVITIES

The Mbereko+Men Project will improve health outcomes among mother-baby pairs in Mutasa District, Manicaland Province by empowering mothers and creating an enabling environment to support women to seek and adhere to high quality essential MNCH services at eight rural health clinics (RHCs).

To achieve this, the project will:

1. Improve community-facility linkages and provision of quality, integrated essential MNCH services at eight RHCs by strengthening community engagement with RHCs through monthly Health Centre Committee (HCC) meetings that bring together community leaders and health facility staff to review clinic performance and community health outcomes.
2. Empower women to make positive decisions for family health by supporting the formation of an expected 160 Mbereko groups in eight RHC catchment areas over three years. These groups will provide women with training in income generation and internal savings and lending, facilitate problem identification and problem-solving at group and individual level to address barriers to uptake of 10 essential MNCH services using the Action Birth Card, and provide information about how to promote family health within the home (e.g. quality maternal nutrition, infection control, care-seeking for child illness).
3. Increase men's capacity to support family health and women's decision-making by holding monthly male engagement community dialogue forums in eight RHC catchment areas.

Project activities will be implemented in four RHC catchment areas in the first and second year, and will be scaled up to the remaining four RHC catchment areas in the second year of the project. Lessons learned from implementing the project in the first four RHC catchment areas will inform how the project is implemented in the remaining RHC catchment areas in the second year. New initiatives to engage men in women's and children's health require intensive support and close monitoring, which will be provided through this phased approach to project implementation.[22]

Community mobilisation through facilitated participatory learning and action cycles with women's groups is recommended by the World Health Organisation to improve maternal and newborn health, particularly in rural settings with low access to health services.[22] Mbereko groups are informed by a specific participatory learning and action cycle that is known to be effective,[23] and were implemented successfully by OPHID in Chimanimani and Buhera Districts, Manicaland Province, in 2012-2015.

This project will also extend the Action Birth Card goal-setting and planning tool for increasing uptake of essential MNCH services to include key postnatal services to two years of age.[19] The Action Birth Card was used successfully in Mashonaland Central in 2012-2015 to support increased uptake of underutilised maternal health services from the antenatal period to the early postnatal period.

OPHID has gathered experience in demand generation for health services through a number of community-based models, with the Mbereko groups proving to be the most successful one.

Comparable women's groups, based on the same concept, have been documented as a low cost intervention to successfully reduce maternal and neonatal mortality by up to 40%.[23]

Engaging with men as allies to address barriers to women's health service utilisation is recommended by the World Health Organization[22] and has a basis in programming experience and evaluations from Zimbabwe[24, 25] and elsewhere.[26-29] Working with women's and men's discussion groups has previously been successful in increasing health service utilisation.[30] Due to very high mobility among men in rural Manicaland, it is practical and efficient to engage men at community level through public meetings rather than attempting to work only with male partners of women in Mbereko groups.

INTERVENTION OBJECTIVES AND ANTICIPATED OUTCOMES

The project is designed to achieve four strategic objectives:

1. RHCs in project areas provide quality, integrated essential MNCH services to women and children and are responsive to community health needs.
2. Women who participate in Mbereko groups, and their newborn or infant children, increase uptake of an essential package of MNCH services during the 1,000-day window covering pregnancy and the first two years of life. This essential package of services includes prevention of parent to child transmission of HIV (PPTCT), antenatal care, facility birth, postnatal care for mother and newborn, nutrition counselling and support, child immunisations and family planning.
3. Women who participate in Mbereko groups are empowered with health information, improved access to financial services, access to credit and savings and psychosocial support, and are able to make informed decisions about family health.
4. Men in communities that host men's discussion forums are empowered to support family health, and to question gender norms and roles that reinforce inequitable gender relations and constrain women's decision-making autonomy.

Successfully achieving these strategic objectives is expected to result in the following health and development outcomes:

- Increased uptake of essential package of MNCH services, including facility birth;
- Improved health outcomes for women, newborns and children, including maternal mental health;
- Improved care and support in the home for women, newborns and infants;
- Increased women's economic empowerment;
- Increased couple communication and improved couple relationships; and
- Reduced maternal workload and increased maternal nutrition and rest during pregnancy.

SUSTAINABILITY CONSIDERATIONS

The project's approach to building community capacity for the support and monitoring of community demand, uptake and adherence to PPTCT, HIV and MNCH services is intended to ensure ownership and sustainability of activities. Income generation and internal savings and lending help to ensure Mbereko groups are financially self-sufficient. Group leadership using existing community health cadres (VHWs) is intended to ensure continuation of groups

following the end of project cycle. Finally, the Participatory Learning and Action cycle model for Mbereko group activities ends with groups developing their own sustainability plans.

CONDUCTING RESEARCH THROUGH INTERVENTION IMPLEMENTATION

Nested within the Mbereko+Men Project will be a research study to test the Mbereko+Men Model.

The delivery of the Mbereko+Men Project will be phased, to provide an opportunity for careful testing of how to implement the model as well as an opportunity to assess its effects. The research study will align with phased implementation of the project to conduct a two-arm cluster-randomised controlled trial. After testing and assessment of the Mbereko+Men Model, the intervention will be implemented in the control arm. The four RHC catchment areas where the project is implemented starting in the first year will comprise the intervention arm. The four RHC catchment areas where the project is implemented starting in the second year will comprise the control arm.

PARTNERSHIP ARRANGEMENTS

IMPLEMENTATION ARRANGMENTS

In-country partner OPHID will be responsible for local implementation of the Mbereko+Men Project, with Burnet Institute providing technical and programmatic oversight. Working embedded within MOHCC structures, the project will be implemented with full participation of District and site level MOHCC stakeholders.

OPHID will be responsible for project implementation including sensitisation and/or training of all MOHCC stakeholders including Health Care Workers (HCWs), Health Centre Committee (HCC) Members, Village Health Workers (VHWs) and community leaders, on-going monitoring and evaluation, providing health sites with supportive supervision and facilitation of Mbereko group meetings and men's discussion forums.

ROLES AND RESPONSIBILITIES

Table 1 Roles and responsibilities of partner organisations

	MOHCC	OPHID	Burnet Institute
Study design		√	√
Designing of tools		√	√
Funding			√
Pretesting of tools		√	
Study implementation and coordination	√	√	
Data capturing, analysis and reporting	√	√	√
Dissemination of results		√	√

RESEARCH DESIGN

STUDY DESIGN

We propose a two-arm cluster randomised controlled trial, with four clusters in each arm. The arms comprise no intervention (normal standard care) and intervention (Mbereko+Men Model).

Four of the selected RHC catchment areas will be randomly allocated to the intervention arm, where the project will be implemented starting in the first year, and the remaining four catchment areas will be allocated to the control arm, where the project will be implemented starting in the second year.

Within this model, all eight RHC catchment areas will receive the intervention by the end of the study, and whether an RHC catchment area receives the intervention in the first or the second year is determined at random. This approach is also expected to facilitate the practical and logistical implementation of the intervention, since the intervention will not be introduced simultaneously in all study sites.

We also propose to conduct retrospective analyses of qualitative and quantitative routine data generated through project implementation in all sites.

RESEARCH METHODS

Community-based surveys

We propose to conduct a community-based survey using a quantitative survey instrument at baseline (prior to project implementation) and midline (following 18 months' project implementation).

They are intended to collect information from women and men in all study sites about: socio-demographic characteristics; male engagement in family health; women's empowerment; care-seeking for essential MNCH services; care and support in the home; and MNCH outcomes, including maternal mental health.

Mbereko members' registers

Through routine project activities, VHWs will maintain a register of MNCH service utilisation among members of Mbereko groups. There will be one register per Mbereko group. This data will be collected by OPHID project staff and analysed retrospectively.

These registers are primarily intended to support project activities, but will also capture information from women directly participating in the intervention about care-seeking for essential MNCH services.

Men's charters for family health

Through routine project activities, men's discussion forums will develop charters for family health. There will be one charter per discussion forum. This data will be collated by OPHID project staff and subsequently analysed.

These charters are primarily intended to support project activities, but will also capture information from men directly participating in the intervention about men's perceptions of how they can engage with family health.

Additional routine data collection

Subject to resource availability and emerging information needs, during project implementation some additional data may be collected through focus group discussions (FGDs) and key informant interviews held with project implementers and key stakeholders.

If conducted, these research activities will be intended to capture information about the feasibility and acceptability of project implementation from people who are either directly involved in project implementation or who have a direct stake in the project.

STUDY POPULATION

Community-based surveys

The primary study population is women who meet the following inclusion criteria:

- Has given birth within the previous 0-6 months;
- Resident in study site for a minimum of 12 months;
- Aged 16 years and older; and
- Able to give informed consent.

Additionally, male participants who meet the inclusion criteria listed below will be eligible to respond to the community-based baseline and midline surveys:

- Has a child aged 0-6 months, or female partner has given birth within the previous 0-6 months;
- Resident in study site for a minimum of 12 months;
- Aged 16 years and older;
- Able to give informed consent; and
- Female partner or mother of his child has provided consent for the man to be surveyed.

Married and unmarried women and men will be eligible to participate. Women and men who are no longer in an ongoing relationship with the father or mother of their child will be eligible to participate.

Mbereko members' registers

Since this data is collected through routine project activities, the study population will be all women who join Mbereko groups and attend group meetings. These women will meet the following inclusion criteria to be eligible to participate in Mbereko groups:

- Currently resident in study site; and
- In the 1,000-day window covering pregnancy and the first two years of their child's life.

Exclusion criteria will include people who are not able or willing to give informed consent for their data to be included in the study. Women who do not provide consent for their data to be used in the study will still be eligible to participate in Mbereko groups.

Men's charters for family health

Since this data is collected through routine project activities, the study population will be all men who participate in developing men's charters for family health. All male community members will be invited to attend, and no exclusion criteria will be applied.

Additional routine data collection

Subject to resource availability and emerging information needs, participants will be purposively recruited to capture information about the feasibility and acceptability of project implementation, in order to refine project activities and inform scale-up of the project to all sites in the second year. These participants will be 16 years or older and include the following groups of project implementers and key stakeholders:

- VHWs who have not previously been involved with Mbereko groups;
- HCC members;
- Facility-based HCWs;
- VHWs responsible for Mbereko groups;
- Male champions who have been involved in facilitating men's discussion forums;
- Village leaders; and
- Policymakers.

Exclusion criteria will include people who are not able or willing to give informed consent.

STUDY SETTING

We propose to conduct the study in eight RHC catchment areas within Mutasa District, Manicaland Province, Zimbabwe (Figure 1).

Manicaland Province, the second most populated province in Zimbabwe, has a population of 1,752,698, with the majority (83%) living in rural settings where distance and resource constraints compromise access to health services.[3] MNCH outcomes in Manicaland are generally poorer than the national average, as described below.

The 2014 MICS indicates that while ANC rates from a skilled provider are high (91.1%), Manicaland Province has the lowest rate of ANC uptake in Zimbabwe. Women in Manicaland Province are also less likely to deliver with a skilled birth attendant (72.2%) and more likely to give birth before 18 years of age (34% aged 20-24%) than national average.[1]

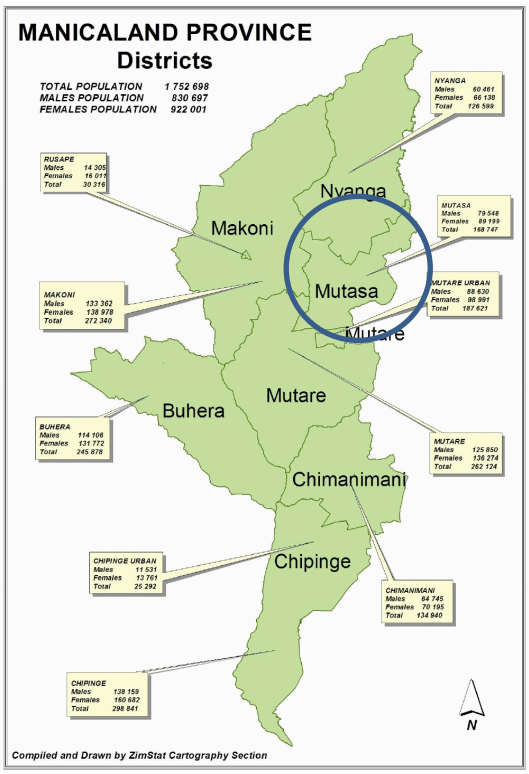

Figure 1 Map of proposed study setting

The province has a large membership to Apostolic faith groups, known to have early, often polygamous marriages, and reduced access to maternal health services.[31] More women in Manicaland deliver with traditional birth attendants than in any other province and fewer women in Manicaland deliver with a skilled attendant, 72.2% vs. 80% nationally.

The infant mortality rate has been estimated at 69 deaths per 1,000 births.[3] The 2010/11 Zimbabwe DHS demonstrated that infants in Manicaland are the least likely to be breastfed within one hour of birth (52.5%) and only 34.8% aged 0-5 months are exclusively breastfed. Almost one-third of children in Manicaland do not have their births registered, a critical element of child health and survival, with the highest mortality countries demonstrated to have the lowest birth registration.[32] Timely health-care seeking for infections is poor, with treatment sought for only half of children aged 0-11 months with diarrhoea in the last two weeks. The compounding effects of poor maternal and infant health in Manicaland, compared to other provinces in Zimbabwe, can be attributed to Manicaland having the highest rate of under-5 stunting (34%) in Zimbabwe.

Manicaland has the largest proportion of individuals living with HIV, and the lowest coverage of maternal antiretroviral therapy at 58%. 14% of male partners receive an HIV test during pregnancy, which is well below the national target of 20%.[14]

Mutasa District, the setting for the proposed study, has the highest infant mortality rate in the province, at 87 deaths per 1,000 live births[4], substantially higher than the national average of 55 deaths per 1,000 live births.[4]

STUDY PROCEDURES

SITE SELECTION AND SAMPLING

The study will be conducted in eight RHC catchment areas within Mutasa District, Manicaland Province, Zimbabwe.

For the cluster randomised controlled trial, eight clusters, each comprising a single RHC catchment area from the study population of all RHC catchment areas in Mutasa District, will be randomly selected in a blinded manner. The eight clusters will be randomly assigned to have the Mbereko+Men Project introduced after the baseline data collection (intervention arm; four clusters) or after 18 months' project implementation (control arm; four clusters).

The HCC, VHWs and community leaders in each of the eight RHC catchment areas selected will be consulted through OPHID program staff, and the purpose and process of the Mbereko+Men Project as well as the proposed study will be explained.

We will attempt to recruit all eligible women in each cluster, working with VHWs, HCC members and community leaders to sensitise the community prior to data collection and develop a sampling frame of all women who have recently given birth in order to facilitate recruitment. Based on available data for Mutasa District for the number of facility-based and home births, the number of women enrolled in ANC, and the number of infants vaccinated, the anticipated sample size for each cluster is 55 women, and 220 women for each study arm.

We will attempt to recruit all eligible men in each cluster. We will work with VHWs, HCC members and community leaders to sensitise the community prior to data collection and will use the sampling frame of women as the sampling frame for men. By using the sampling frame of eligible women, male partners of eligible women or fathers of the children of eligible women will be selected.

TOOL DEVELOPMENT

Data collection tools have been developed in draft form and will be comprehensively pre-tested prior to use, to ensure that they are locally comprehensible and appropriate. Several rounds of pre-testing may occur prior to data collection. The following draft data collection tools are included as appendices:

- Baseline questionnaire;
- Mbereko members' register;
- Men's charter discussion guide; and
- Midline questionnaire.

The process for further development of the data collection tools via pre-testing is described below. It is also anticipated that additional items may be added to the midline questionnaire in order to capture information that emerges as relevant during project implementation. After pre-testing, translation, and any revision, all data collection tools will be resubmitted for ethical review prior to use.

The working language for the development of data collection tools is English. Before pre-testing, data collection tools will be translated and back translated into and out of the local language used by the study population (Shona). This process will be used to guide the forms of language and expressions used, to ensure that words and expressions are widely understood in the study sites. Additionally, members of the research team responsible for data collection will be well trained and will understand the broader purpose of questions or phrases included in data collection tools.

Due to the high cost of travel to eligible study sites, pre-testing of data collection tools may be conducted either away from the study sites during the training of data collectors, or in the same district as the study sites (Mutasa District) shortly preceding actual data collection. The timing and location of pre-testing will be at the discretion of the in-country research lead.

Pre-testing will be used to explore a range of issues associated with the content of the data collection tools, including the identification of topics that will require particular sensitivity. Respondents will be asked to respond to the data collection tools, but also requested to provide comments on the clarity and acceptability of questions used and the way in which questions are asked. At the end of pre-testing, the data collection team will meet with the in-country research lead to review the data collection tools and resolve any problems arising. These results will be incorporated into the revised data collection tools.

TRAINING OF DATA COLLECTION TEAM

Training of data collectors will be conducted by senior OPHID staff members under the supervision of the in-country principal investigator. The content to be covered in training will be agreed between the principal investigator and the in-country principal investigator. At minimum, all data collectors will be trained in:

- Discussing sensitive topics, including mental health and gender roles, in a locally and culturally appropriate way;
- Gender- and age-sensitive practices for collecting data;
- Data safety and management, including the specific procedures to be used in this study;
- Maintaining ethical principles in conducting research; and
- Referral procedures for illegal, reportable activities and acute health conditions, as appropriate to available referral options at each study site.

OPHID staff members will also provide training and on-going feedback and coaching to VHWs in filling out the Mbereko members' register, as part of the intervention.

Enumerators for the community-based surveys will be trained prior to data collection. In addition, OPHID project staff will provide feedback and coaching to enumerators in the field during data collection. Enumerators will be directed to ensure that surveys are not administered in ways that are potentially harmful for pregnant women. Specifically, this means that enumerators will be directed to:

- Not expect participants to stand for long periods of time;
- Administer surveys in locations where participants can sit comfortably;
- Encourage participants to sit, stand and/or move as they wish during data collection;

- Complete data collection in a timely manner;
- Ensure that participants are provided with light refreshments and water if needed; and
- Remind participants that they can pause or stop at any time.

OPHID project staff will conduct data collection for men's charters for family health, and for any FGDs and key informant interviews.

DATA COLLECTION

Community-based surveys

Community-based surveys will be conducted at baseline and midline in all study sites. The same procedures will be followed for the baseline and midline surveys in order to ensure that data are comparable.

Prior to the survey, OPHID project staff will work within existing lines of communication set up during project planning and implementation to advise VHWs, HCC members and community leaders of upcoming surveys, and will request that these people sensitise the community at each RHC catchment area. OPHID project staff will also work with VHWs and community leaders to develop a list of women who have given birth in the previous 0-6 months, which provides the sampling frame for selection of women and men.

All eligible women and men will be invited to participate in these surveys. Recruitment will be conducted in a location that is convenient and comfortable for potential participants, and will be integrated with project activities where feasible. Women and men may be requested to gather at a predefined location agreed between OPHID project staff and VHWs or community leaders, and may also be recruited through household visits by OPHID project staff. The precise location of recruitment will be determined by OPHID project staff in consultation with VHWs and community leaders. Women and men will be assessed for eligibility and recruited if they are eligible. Procedures used to recruit male participants for the community-based surveys will not allow data from their female partners to be re-identified, and vice versa. During recruitment, a member of the research team will read out the participant information sheet and clarify any questions about the study. The research team member will check understanding of the study and the information provided. Informed consent for the study will be obtained from eligible participants who agree to participate. Written consent will be sought from all participants, however those participants who give consent but are disinclined to sign the consent form or are illiterate will be given the option to have the data collector certify that verbal consent was granted.

Following recruitment and the granting of informed consent, survey enumerators will verbally administer a brief structured survey and record participants' responses in pen or pencil on the survey form. Surveys will be administered by individuals of the same sex as the participant. The survey will be administered verbally in a private location and participants' responses will be confidential. This survey will collect quantitative data on: socio-demographic characteristics; male engagement in family health; women's empowerment; care-seeking for essential MNCH services; care and support in the home; and MNCH outcomes, including maternal mental health. Each participant will be given a randomly generated unique

identifier. This code will only be known to senior members of the research team and all other personal identifying information will be de-linked from the survey. Men's surveys will include a record of the unique identifier for their female partner or the mother of their child in order to allow matching of responses.

We anticipate that completion of the survey will take approximately 20 minutes. All involvement will be voluntary. Participants may be provided with light refreshments. For ethical reasons, other forms of remuneration will not be provided.

Surveys will be administered by an enumerator of the same sex as the participant. Once a survey has been administered, the completed questionnaire will be physically held for the rest of the day by the enumerator who administered the survey, stored in such a way that participants' responses are not visible (such as in a closed bag or closed folder). This means that on the day of data collection, men's and women's completed questionnaires will not be held in the same location, and all completed questionnaires will be under the direct supervision of enumerators. At the end of each day of data collection, completed questionnaires will be stored under lock and key, for example in lockable folders within a locked vehicle. Men's and women's completed questionnaires will be stored separately, for example in separate lockable folders. The supervisor of the data collection team will hold the key(s). Data will be stored under lock and key until it leaves the field.

Mbereko members' registers

Routine monitoring data on health service utilisation by Mbereko group members will be collected by trained VHWs during monthly Mbereko group meetings. Each VHW responsible for an Mbereko group will maintain a members' register, which will be updated at each monthly meeting to record which essential MNCH services women have accessed since the previous meeting. When recording a woman's service uptake, the VHW will cross check with the woman's ANC card where this is available. As part of routine project activities, OPHID project staff will review members' registers to check the quality of data collection and provide feedback, coaching and support to VHWs.

Eligible women will be asked to provide their informed consent, at the point of enrolment in the Mbereko group, for their de-identified service utilisation data to be extracted and analysed. If a woman provides consent then she will be asked by the VHW to sign on the Mbereko members' register to indicate that she has provided consent. If a woman does not provide consent then she will not sign the register, and in the absence of a signature her data will not be extracted by OPHID project staff. During routine project activities, no distinction will be made within Mbereko groups between study participants and those women who have chosen not to participate in the study.

Women attending Mbereko groups will receive a unique 'member ID' that is not linked with any study ID given to Mbereko group members who also participate in the community-based survey. The Mbereko member register will list women's 'member IDs' together with their names and other identifying information. This register is a tool that is used to assist in implementing the intervention and contains only information that is publicly discussed within each Mbereko group. When data is extracted from this tool by a data collector, women's

'member IDs' will be extracted but their names and other identifying information will not be extracted. Extracted data will be physically held by the data collector and stored in such a way that data is not visible (such as in a closed bag or closed folder) until it is stored under lock and key (for example in lockable folders within a locked vehicle). Extracted data will be stored under lock and key until it leaves the field.

Men's charters for family health

Men's discussion forums will be held monthly during project implementation. In the sixth monthly discussion forum in each study site, the group will work together to develop a men's charter for family health. A male OPHID project staff member will be present at all men's discussion forums, and will facilitate (or co-facilitate with a discussion forum member) discussion to develop an agreed set of principles that describe how men in the community commit to supporting family health in the future. These principles will be recorded by community members in a physical document, which becomes the men's charter for family health.

During facilitated discussion, the OPHID project staff member will request community consent from a nominated community representative to record the men's charter. Prior to data collection, all members of the discussion group will have the opportunity to raise concerns about collection of this data and to discuss these with the group leaders privately. If a community does not provide consent then the men's charter for that community will not be recorded. If a community does provide consent for the men's charter to be recorded, then the OPHID project staff member will request signed consent from the nominated community representative to take one or more digital photographs to record the men's charter.

Additional routine data collection

During routine project activities, OPHID project staff will meet with MOHCC stakeholders and community members who are engaged in project implementation or who have a stake in project activities. Subject to resource availability and emerging information needs, these meetings may be used as opportunities to conduct FGDs or key informant interviews.

Any FGDs conducted will be implemented according to the following data collection procedures. Participants will be identified by OPHID project staff in consultation with VHWs, HCC members and community leaders. Recruitment procedures will be tailored to the group of project implementers or key stakeholders being targeted and may include recruitment at HCC meetings, RHCs, or village meetings. During recruitment, an OPHID project staff member will read out the participant information sheet and clarify any questions about the study. The research team member will check understanding of the study and the information provided. Informed consent for the study will be obtained from eligible participants who agree to participate. Informed consent to take notes and record the FGD will also be obtained from all participants. Written consent will be sought from all participants, however those participants who give consent but are disinclined to sign the consent form or are illiterate will be given the option to have the facilitator certify that verbal consent was granted. It will be clearly explained to each potential participant in the FGDs that agreement to be recorded during the

group discussion is a requirement for participation and that they can refuse to participate if they do not want to be recorded.

Each FGD will comprise between 7 and 12 participants who are members of the same group of project implementers or key stakeholders, as defined above (e.g. VHWs, male champions, etc.) Each participant will be given a randomly generated unique identifier. At the commencement of the FGD, once audio-recording has begun, each participant will list his/her unique identifier, together with a pseudonym of his/her choice. Participants will be asked to refer to each other by these pseudonyms during the FGD. We anticipate that FGDs will take approximately 90 minutes. All involvement will be voluntary. Participants may be provided with light refreshments. Where participants have travelled to participate in the FGD, they may be reimbursed for transport and related expenses. For ethical reasons, other forms of remuneration will not be provided.

Any key informant interviews conducted will be implemented according to the following data collection procedures. Participants will be identified by OPHID project staff in consultation with VHWs, HCC members and community leaders. Recruitment procedures will be tailored to the key informant being targeted and may include direct phone or email contact, or outreach via VHWs, HCC members and community leaders. Interviews may be conducted in person, or remotely via telephone or Skype if an in-person interview is not possible. For telephone or Skype interviews research team members will: approach the person involved and explain the study; email them the participant information sheet and informed consent; go through the participant information sheet on the phone clarifying any questions that emerge; and ask the person to fax, or scan and email a signed copy of the informed consent form. Once this document has been received, the interview will be conducted remotely. During recruitment, a member of the research team will read out the participant information sheet and clarify any questions about the study. The research team member will check understanding of the study and the information provided. Informed consent for the study will be obtained from eligible participants who agree to participate. Informed consent to take notes and record the key informant interview will also be obtained from all participants. Written consent will be sought from all participants, however those participants who give consent but are disinclined to sign the consent form will be given the option to have the interviewer certify that verbal consent was granted. Participants can decline to have the interview recorded, or ask that the recording be paused or stopped, at any time and without providing a reason. Each participant will be given a randomly generated unique identifier. At the commencement of the key informant interview, once audio-recording has begun, each participant will list his/her unique identifier.

We anticipate that each key informant interview will take up to one hour. All involvement will be voluntary. Participants may be provided with light refreshments, or reimbursement for lunch. For ethical reasons, other remuneration will not be provided. The location of key informant interviews will be determined separately for each interview by the research team with reference to potential sensitivities and risks relevant to each participant, and may include participants' workplaces and community centres.

STUDY ENDPOINTS AND STATISTICAL CONSIDERATIONS

The primary endpoint for the proposed study is difference in mean score on the Edinburgh Postnatal Depression Scale (EPDS) (validated Shona-language version) between intervention and control arms among enrolled women after 18 months of intervention implementation. Participants will be in their first 6 months after childbirth. This endpoint corresponds to the primary research objective of the proposed study: to assess the effect of the Mbereko+Men Model on uptake of MNCH services and care and support in the home.

Based on a study population of women who have given birth within 0-6 months prior to data collection (n=55 per cluster, 220 per arm), the study is powered to detect a difference in mean EPDS score of 3.5 points between the two study arms. A difference of 3.5 points is likely to be 44% of 1 standard deviation for this population.[35]

EPDS is a reasonable measure for the study population. EPDS can measure perinatal common mental disorders (CMD), defined as CMD during pregnancy or in the year after giving birth.[33] EPDS detects but does not distinguish between symptoms of depression and anxiety, so can be considered a marker for CMD.[33] Prevalence of EPDS >11 has been measured as stable within a cohort between 6-8 weeks and 6 months postpartum, which suggests that it is meaningful to measure EPDS among women who have given birth within 0-6 months prior to data collection.[34] A Shona-language version of the EPDS has been validated among HIV-positive and HIV-negative women aged 18 years and over in urban Zimbabwe.[35, 36] Mean EPDS score for a cohort of 210 women in urban Zimbabwe with a child aged 6-7 weeks (women aged 18 years and over, including both HIV-positive and HIV-negative women, recruited when attending 6-week postnatal check-up) was 10.41 (SD, 7.9).[35] The prevalence of perinatal CMD among women in urban Zimbabwe has previously been measured at 33% (women at 6-7 weeks postpartum assessed with DSM-IV).[37]

It is reasonable to expect that the intervention will have a moderate-to-large effect on maternal mental health. A large cluster randomised controlled trial in India (36 clusters, total 19,030 births) tested the effect of women's participatory learning and action groups on birth outcomes and maternal depression, and found significant differences in the third year: significant increase in no or mild depression (95% intervention, 90% control, AOR 2.33 (1.25–4.38) and significant decrease in moderate depression (5% intervention, 10% control, AOR 0.43 (0.23–0.80)).[38] Additionally, a small cohort study (27 women) of a six-week group counselling intervention for postpartum women with moderate depression found a change from mean EPDS score of 17.3 (SD, 3.7) at baseline (6-7 weeks postpartum) to 8.22 (SD, 3.6) after the six-week intervention.[37] One aspect of this intervention was to improve the quality of intimate partners' support to women (as in the proposed study),[37] although this component was not separately assessed.

Secondary endpoints include:

- Difference in proportion of women scoring 11 or more on the EPDS between intervention and control arms, measured among enrolled women after 18 months of intervention implementation;
- Difference in proportion of women not involved in any of three key measures of household decision-making between intervention and control arms, measured separately

among enrolled men and enrolled women after 18 months of intervention implementation;

- Difference in mean Gender Equitable Men (GEM) score between intervention and control arms, measured among enrolled men after 18 months of intervention implementation;
- Difference in proportion of men who provide pre-defined support to mother-baby pairs, measured separately among enrolled men and enrolled women after 18 months of intervention implementation; and
- Difference in proportion of women accessing pre-defined essential MNCH services, measured among Mbereko group participants at baseline and after 18 months of intervention implementation.

DATA MANAGEMENT AND ANALYSIS

DATA MANAGEMENT PROCEDURES

Consent forms

Signed informed consent forms will be kept separately from completed surveys, extracted register data, men's charters and digital photographs of men's charters. Signed consent forms will be stored securely at all times in locked document storage facilities such as lockable folders or filing cabinets. Only authorised research team members will have access to the signed consent forms.

Signed Mbereko registers will be retained by the responsible VHW, as described below.

Community-based surveys

Completed baseline and midline surveys will be kept secure at all times in locked document storage facilities such as lockable folders or filing cabinets. Only authorised research team members will have access to the completed surveys. No personal identifiers will be recorded on the surveys. Data captured by the surveys will be entered electronically into a database, with entries defined by the unique identifier previously assigned to each participant rather than by any personal information. The electronic database will be password-protected and stored securely on Dropbox, or another secure file-sharing platform. Only authorised research team members will have access to the file-sharing folder containing survey data. For verification purposes, scanned copies of the questionnaires may also be stored in the same file-sharing folder. Scanned copies of the questionnaires will be defined by the unique identifier previously assigned to each participant rather than by any personal information, and no identifying information will be included in the scanned copies of the questionnaires.

Mbereko members' register data

OPHID project staff will review each member's register with the VHW responsible for maintaining the register during routine project activities, initially once per month and later decreasing in frequency to once every three-to-six months. Immediately following this review, OPHID project staff will extract data from the register and enter it into an electronic database. Personal identifying information will not be extracted from the members' register. Each members' register will be retained by the responsible VHW and will not be stored together with the electronic database.

The electronic database will be password-protected and stored securely on Dropbox, or another secure file-sharing platform. Only authorised team members will have access to the file-sharing folder containing extracted register data.

Men's charters for family health

An OPHID project staff member will be present when each men's charter for family health is developed during routine project activities. Shortly after each charter has been developed, the OPHID staff member will take one or more digital photographs of the charter that clearly

capture all text and images included in the charter. These photographs will be stored securely on Dropbox or another secure file-sharing platform. The original charter will be retained by the men's discussion forum at community level.

It is unlikely that any charter will contain personally identifiable data. If no personally identifiable data is present on a charter, then photographs of that charter may be made publicly available and shared with relevant local stakeholders following the granting of community consent.

Additional routine data

As described above, additional data collection through routine project activities is subject to resource availability and emerging information needs. If FGDs and/or key informant interviews are conducted, the resulting data will be managed according to the processes outlined below.

Any FGDs and/or key informant interviews conducted will be audio-recorded with a digital voice recorder. All digital audio files and any notes taken during FGDs and interviews will be stored securely in password protected electronic files on a study investigator's hard drive. For verification purposes, these electronic files may also be stored on Dropbox or another secure file-sharing platform. Paper copies of field notes will be stored securely at all times in locked document storage facilities such as lockable folders or filing cabinets and will only be accessible to authorised members of the research team. Audio files and notes will be defined by the unique identifier previously assigned to each participant rather than by any information that could identify the participants. Only authorised research team members will have access to the folder containing the recordings and notes. Once audio files have been stored electronically on a study investigator's hard drive and backed up, and their quality has been confirmed, the original files on the voice recorder will be erased. Until these files have been erased, the voice recorder will be stored securely in locked storage facilities such as lockable folders or filing cabinets.

QUANTITATIVE DATA ANALYSIS

A detailed statistical analysis plan will be developed to guide analysis to be conducted for baseline and midline survey data. A statistician with substantial expertise in data-analysis using STATA, including advanced skills in the analysis of datasets using cluster sampling designs, will contribute to and have oversight of the final data analysis plans. Statistical analyses will be appropriately adjusted for the cluster sampling design and small number of clusters. Analysis will be conducted using STATA 12.1 or similar software and developed using verifiable syntax records (do-files).

Analysis of baseline data will assess the associations between socio-demographic characteristics, indicators of women's empowerment, indicators of male engagement in family health and MNCH outcomes. Univariate exploratory and descriptive analyses will be undertaken to estimate prevalence and distributions of key factors both overall and by study arm. This will produce a basic description of the key variables of interest. Cross tabulations

(bivariate analysis) will be used to explore whether there are significant associations among variables of interest.

Analysis of midline data will compare indicators of women's empowerment, indicators of male engagement in family health and MNCH outcomes across study arms, controlled for potential confounders. Baseline data will be used to inform statistical adjustment for potential confounders. This analysis will be used to assess the effect of the Mbereko+Men Model on care-seeking for MNCH services and care and support in the home.

Additionally, retrospective analysis of routine project data (Mbereko members' registers) will be conducted to assess changes in service utilisation among Mbereko group members over the three-year project implementation period. This will form part of the endline assessment for the Mbereko+Men Project. Endline data will be compared with baseline data to assess the effect of project activities on target beneficiaries during the three-year project implementation period.

QUALITATIVE DATA ANALYSIS

We will conduct inductive thematic analyses of men's charters at two time points. First, analysis will be conducted of all charters developed in the intervention arm during the first year of project implementation. Subsequently, analysis will be conducted of all charters developed in the control arm following scale-up of the intervention to all study sites after 18 months' project implementation. At each time point, senior members of the research team will review the charters to develop a provisional coding framework. The coding framework will be informed by predefined lines of enquiry relating to gender norms and roles, and existing literature that describes key domains of interest for men's engagement in family health. Critically, however, the coding framework will not be limited to these predefined lines of enquiry. Once the coding framework has been developed, manual coding will be used to identify themes and sub-themes and to code the charters; care will be taken to identify any additionally emerging codes and to identify any counter-findings for themes and sub-themes. Two senior members of the research team will conduct this exercise independently and compare results. Discrepancies will be resolved by discussion. Additional codes identified through this process will be added to the coding framework. Key points for each theme and sub-theme will be summarised, and illustrated with primary data, e.g. text-based quotes and diagrams. This process will be conducted separately for each of the two time points. The coding framework developed for the analysis of charters developed in the control arm will be informed by but not restricted to the coding framework previously developed for the analysis of charters developed in the intervention arm. Once analysis has been completed for charters in all study sites, the two coding frameworks will be compared and may be unified into a single coding framework; care will be taken to identify any differences between charters developed in the intervention arm and charters developed in the control arm. Results will be compared with the global literature on interventions that work with men to address issues relating to MNCH in order to begin isolating what new information this study contributes.

Additionally, subject to resource availability and emerging information needs we may conduct qualitative analysis of routine project data (FGDs and key informant interviews with project

implementers and key stakeholders). The approach to qualitative analysis of routine project data is described below. Following each FGD or key informant interview, facilitators and note-takers will complete field notes to record and reflect on key themes arising from the FGD or interview. All notes will be provided to the in-country principal investigator at the end of each week of field data collection for review. Debriefing sessions among OPHID staff will also address FGD content and these discussions will be documented. Thematic analysis of field notes and documents from debriefings will be conducted against a pre-defined framework of themes and sub-themes. Care will be taken to identify counter-findings for themes and sub-themes, where these exist. Care will also be taken to ensure that both men's and women's views are reported in qualitative findings.

ETHICAL CONSIDERATIONS

ETHICAL APPROVAL

Before participants are recruited into data collection, ethical approval will be sought from the appropriate ethical committee(s) in both Zimbabwe and Australia.

In Zimbabwe, OPHID will submit a study protocol to the Medical Research Council of Zimbabwe and all foreign researchers will be registered with the Research Council of Zimbabwe prior to commencing study activities. This study protocol will include both Shona- and English-language versions of data collection tools, informed consent forms, and participant information sheets.

In Australia, Burnet Institute will submit a study protocol to The Alfred Hospital Human Ethics Committee with English-language data collection tools, informed consent forms, and participant information sheets.

In addition, regulatory approvals from local authorities will be sought where necessary.

As detailed above, all data collection tools will be pre-tested, translated into Shona and back-translated into English, and it is expected that they will be revised as a result of this process. Following pre-testing, translation and back-translation, revised English-language tools will be resubmitted for ethical review prior to use in the field.

METHODS FOR DEALING WITH ADVERSE EVENTS

No adverse events are anticipated, as no drugs or biologic agents are used.

METHODS FOR DEALING WITH ILLEGAL, REPORTABLE ACTIVITIES

Any illegal, reportable activities (e.g. child abuse) encountered through implementation of this study will be reported to the appropriate authorities (e.g. Zimbabwe Republic Police, Ministry of Social Welfare) in accordance with existing OPHID and Burnet Institute child protection policies and local health institution protocols for management of such events.

CONFIDENTIALITY

Measures will be taken to ensure the privacy, respect and dignity of all participants. Identities of study participants will remain anonymous. All members of the research team will receive intensive training in research ethics, including confidentiality. A statement agreeing to maintain confidentiality will be included as part of the participant consent forms and will be explained to participants verbally prior to requesting their informed consent. Furthermore, before any FGDs that are conducted, facilitators will remind all participants of the participants' own obligation to maintain confidentiality and not disclose information discussed during the FGD to others. During any FGDs conducted, participants will be asked to avoid referring to each other by name. Data collection will be conducted in a private location and no identifying details will be recorded on data collection forms, digital recordings or field notes.

The collection of personal identifying information (i.e. real names) will be restricted to the signing of informed consent forms and not used at any other point. Informed consent forms will be delinked from all data collected and will be stored separately.

Data collected in the course of routine project implementation (e.g. Mbereko members' register) may include some personal identifying information, such as real names and ANC card number. Data to be analysed will be extracted from project documents by OPHID staff members, and stored separately from project documents in a de-identified dataset.

All documents and recordings will be stored securely in lockable document storage facilities, such as locked folders or locked filing cabinets, and password protected documents accessible only to authorised members of the research team. Any electronic audio files collected through FGDs or key informant interviews will be deleted from the recording device immediately after files have been stored electronically on a study investigator's hard drive and backed up, and their quality has been confirmed.

When information is published or shared, it will not be possible to identify participants because their names and other identifying information will not be used. Care will be taken to ensure that individual participants cannot be identified.

Any breach of confidentiality will be reported to the principal investigator or the in-country principal investigator, and all major breaches will be reported to the Medical Research Council of Zimbabwe, the Research Council of Zimbabwe and the Alfred Hospital Human Ethics Committee.

The study population is largely comprised of current or future target beneficiaries of OPHID programs, which are specifically designed to provide public health and development programs to marginalised and under-served populations in poor and/or rural settings. There is therefore a pre-existing dependent relationship between participants and OPHID. The research team will manage the ethical issues arising from this dependent relationship by ensuring that the confidentiality of participants is protected. It will also be clearly explained during participant recruitment that consent or refusal to participate in data collection will not affect current or future interaction with OPHID and that all information provided during data collection is confidential.

All primary data collected through research will be destroyed within five years, or within seven years if unpublished. Individual names will not be used in any written reports or publications that result from this research. Only authorised members of the research team will have access to the research data.

When destroying primary data, the following procedures will be followed:

- For information stored electronically, the research team will use only file-sharing platform(s) that offer an option for permanent disposal, and will follow the required steps to ensure permanent disposal so that information is irretrievable;
- Information stored in paper copy will be shredded; and

- Information stored digitally on audio-recorders will be deleted directly from the audio-recording device immediately after files have been stored electronically on a study investigator's hard drive and backed up, and their quality has been confirmed.

INFORMED CONSENT

Care will be taken to prepare culturally appropriate and comprehensible explanations about the study, including aims and objectives, any potential risks and benefits, and particular emphasis on the participants' right to withdraw from participation at any time. Researchers will also discuss the use of digital recorders to create a record of any FGDs and key informant interviews with participants at the start of each consultation, prior to obtaining consent. Written consent will be sought from all individuals from whom individual or community consent is sought, however those participants who give consent but are disinclined to sign the consent form or are illiterate will be given the option to have the data collector certify that verbal consent was granted. For eligible participants aged 16-17 years, a parent or another person aged 18 years or older, and nominated by the participant, will provide written consent and the participant aged 16-17 years will additionally provide written or verbal assent. Designated research team members will further explain to eligible participants being recruited for the study that non-participation will not affect their current or future interactions with OPHID, nor will it influence their accessing of health and social services.

In each men's discussion group, community consent will be sought from a nominated community representative to record the men's charter. Prior to data collection, all members of the discussion group will have the opportunity to raise concerns about collection of this data and to discuss these with the group leaders privately. If a community does not provide consent then the men's charter for that community will not be recorded. If a community does provide consent for the men's charter to be recorded, then the OPHID project staff member will request signed consent from the nominated community representative to take one or more digital photographs to record the men's charter.

The original signed consent form for each participant will be stored securely in lockable document storage facilities, such as locked folders or locked filing cabinets, and will be stored separately from other study documentation. Signed Mbereko registers will be retained by the responsible VHW as part of routine project activities.

RISKS AND BENEFITS

Risks and benefits for study participants

Women who participate in Mbereko groups are expected to benefit directly from the intervention, through increased social support from Mbereko groups, increased access to financial services, and increased support at community level to access MNCH services. Women resident in study sites who do not participate in Mbereko groups may also benefit indirectly from the study, through increased support at community level to access MNCH services.

Men who participate in men's discussion forums are expected to benefit directly from the intervention, through becoming more informed and empowered in their capacity to support family health. Men may also improve their relationships with their female partners and children, and other men in their community, and thereby receive additional social support. Men resident in study sites who do not participate in men's discussion forums may also benefit indirectly from the study, through increased support at community level to engage in family health.

As with any health or development program that aims to change behaviour, there is a risk that women and men who change their behaviour (e.g. women who increase their uptake of MNCH services, men who provide increased care and support for female partners in the home) may be perceived as acting in ways that are contrary to existing social norms. This can lead to increased tension within households and communities. This tension is not inherently risky and is integral to any process of social change. However, care will be taken to minimise risk associated with changes in behaviour that are encouraged by the project. The participatory nature of Mbereko groups and men's discussion forums means that community members drive the process of identifying changes that they would like to see in their own community, which ensures that identified changes are within acceptable and feasible bounds for each Mbereko group or men's discussion forum.

Because the Mbereko+Men Project is designed to engage men in discussion around gender roles and norms, there is a risk that any existing harmful gender roles and norms could be reinforced through discussion facilitated by the study. This risk will be rigorously minimised. Messages discussed during men's discussion forums will be pre-tested with women to ensure that they are gender-sensitive and to identify any potential perverse outcomes. A male OPHID staff member who has been well trained in gender issues and facilitation will be present at every men's discussion forum to provide support and co-facilitate as appropriate.

The risks of participating in data collection include a potential breach of confidentiality, and embarrassment or discomfort discussing sensitive issues. To minimise these risks, experienced researchers will receive training in research ethics, including conducting research relating to sensitive issues. The approaches to be taken to minimise a breach of confidentiality have been discussed in detail above. Participants may withdraw from data collection at any time and will not be required to answer questions they do not want to. Counselling and referral for locally relevant, accessible, professional services will be provided as appropriate to any participant who is distressed, who reports harms such as intimate partner violence or child abuse, or who is assessed through data collection as being at high risk of severe depression or self-harm.[1] Training will be conducted with all research team members involved in field research on how to provide referral and what to do in case of disclosure by study participants during the interviews. The interviewers will be trained to respect the participants' comments, values, beliefs, decisions and choices.

Through participation in data collection, participants may become aware of a range of services available through Mbereko+Men project activities that may be of benefit to their health and

[1] Survey instruments for baseline and midline data collection will include validated screening tools for symptoms of depression and anxiety.

wellbeing. Additionally, participation in data collection may provide benefits in terms of increased self-awareness, knowledge, understanding and decision-making capacity.

Risks and benefits for society

Because project activities include training and support provided to district- and site-level staff at rural health clinics, communities within study sites will benefit from additional training and support provided to health care workers that are based at the health facility catchment area.

There is a risk of stigmatisation of communities from the reporting of results. Care will be taken in reporting results to avoid characterising communities by the data collected – for example, it will be explained that the data collected do not describe all relevant features of a community. Care will also be taken not to rank study sites, or to describe one study site as 'better' or 'worse' than another.

COSTS AND COMPENSATION

Study participants will not receive any financial compensation for their participation. Participants are not expected to assume any additional costs as a result of participation in this study. Where participants have travelled to participate in the study, they may be reimbursed for transport and related expenses. Participants may also receive light refreshments during recruitment and/or data collection. The appropriate amount of any reimbursement for transport and related expenses, and the appropriateness of providing any light refreshments during recruitment and/or data collection, is to be determined by the in-country principal investigator. For ethical reasons, other forms of remuneration will not be provided.

CONFLICT OF INTEREST

There are no conflicts of interest for investigators participating in this study.

INTENDED USE OF FINDINGS

The aim of the proposed research is to document the effectiveness, feasibility and acceptability of the Mbereko+Men Model as a community-based intervention to support care-seeking among rural Zimbabwean women and improve care and support in the home for mother-baby pairs. If proven effective, this model would be a culturally appropriate, scalable and low-cost strategy to increase care-seeking and improve MNCH outcomes in rural Zimbabwe, with the potential to be adapted to other settings.

The results from the proposed study will be presented to relevant MOHCC stakeholders. A plain-language summary of key results and recommendations will be prepared in English and Shona. This summary will be disseminated to participating men and women and their communities, including participating HCCs and VHWs. The summary may also be disseminated to in-country and international stakeholders. Additionally, results from the proposed study will be submitted for publication in peer-reviewed journals and as abstracts for relevant conference presentations, in order to contribute to the larger evidence base on supporting women to access essential MNCH services.

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