Chamas for Change: Validating the effect of a community-based women's health education program on facility-based delivery and other maternal, newborn, and child health outcomes

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Introduction

Worldwide, women and children in poor and rural communities face the challenges of pregnancy and infancy without supports in the home, community, or facility. Reflecting this, maternal mortality is the leading cause of death among women of childbearing age in Kenya and 1 in every 19 infants dies before their first birthday. Women bear the primary responsibility of gathering fuel, food and water as well as managing the livelihoods of their families. Thus, the majority of women struggle to care for their own and their children's health. Maintaining breastfeeding past the first few months is particularly challenging; exclusive breastfeeding (EBF) is uncommon, lasting a median of 2.6 months in Kenya. The protective effect of EBF on infant mortality is well established: an exclusively breastfed child is 14 times less likely to die in the first six months.[1] From an equity perspective, these figures are not evenly distributed across socioeconomic strata. Access to care is generally correlated with economic accessibility, and this is particularly true in Kenya. Poorer women have greater barriers to accessing care, receive lower quality care, and are disproportionately constrained by the demands of providing for their families.[2]

We seek to address the inequities that drive maternal and infant mortality in sub-Saharan Africa by validating an intervention that builds community empowerment in MNCH and facilitates processes of accountability using Community Health Volunteer (CHV)-led women's groups. ***Chamas for Change*** (*Chamas*) is a peer-support model that groups together pregnant women in the same community. Translated from kiswahili as 'groups', *chamas* have a longstanding presence in East Africa.[3] They are

[1] Black R., Allen LH, et al. (2008) "Maternal and child undernutrition: global and regional exposures and health consequences", (Maternal and Child Undernutrition Series 1). *The Lancet* Vol 371 (9608): 243 – 260.

[2] Kenya National Bureau of Statistics (KNBS) and ICF Macro (2010). Kenya Demographic and Health Survey 2008-09. Calverton, Maryland: KNBS and ICF Macro.

[3] Karega Mwatha, R. "Women's groups: From Welfare to Small-Scale Business in Kenya". In *Small Enterprise Development*, Volume7, Number 1, March 1996, pp. 31-41(11).

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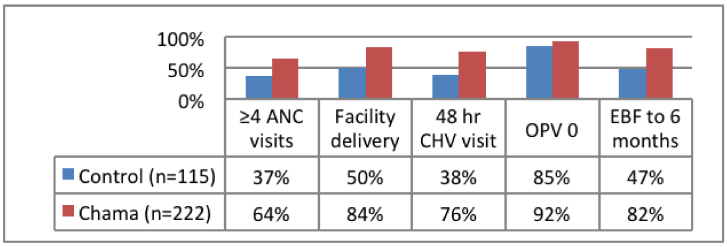
highly gendered institutions that women have relied on for survival to pool resources.[4] Using this existing cultural script, we have developed *chamas* tailored to the needs of pregnant women. Central to our approach is the integration of health, social and financial literacy education with a savings/loans program. *Chamas* are designed to improve MNCH by generating positive peer support for women to advocate for themselves and account for the care they receive. We combined best practices from women's health groups and microfinance programs to design an integrated service delivery platform that is low-cost, self-sustaining and self-managed. *Chamas* do not rely on a major financial institution to manage their funds or their group. They depend on women gaining the agency necessary to own their futures. Members become shareholders in each other's futures not only by the disbursement of loans but by keeping each other accountable to healthy practices and relationships for themselves and their families.

Background

In 2012, 32 Government of Kenya (GoK) CHVs recruited 400 pregnant and breastfeeding women to 16 *chamas* of 20-30 women. These groups met bi-weekly, employed participatory approaches to developing their group charter and were supported by local chiefs. Upon joining, women pledge to participate for one year and uphold the goals of the *chama*: support each other, save and become entrepreneurs, attend ANC, deliver in a facility, breastfeed exclusively (EBF) for 6 months, and adopt long-term family planning (FP). During meetings, women discuss social and health topics, learn accounting and safekeeping skills and receive mentorship from their peers to engage in income generating activities. Groups initiated in 2012 are currently in their fourth cycle (year), focusing on information and supports needed for child growth, education, development, positive parenting and relationship practices. Since 2012, this community strategy within Busia County has continued to recruit pregnant women each year. There are currently 68 CHWs that lead 42 groups, with 12 CHV service managers and 690 active members.



	≥4 ANC visits	Facility delivery	48 hr CHV visit	OPV 0	EBF to 6 months
Control (n=115)	37%	50%	38%	85%	47%
Chama (n=222)	64%	84%	76%	92%	82%

To evaluate the effect, acceptability, and sustainability of *chamas*, we performed a prospective cohort study. We compared data from 222 *chama* women and 115 non-*chama* women matched for age, parity, and location of prenatal care who were pregnant in 2012-13. Compared to controls, *chama* women were 73% more likely to attend 4 prenatal visits, 67% more likely to deliver in facility, 75% more likely to breastfeed exclusively to 6 months and 98% more likely to receive a CHV home visit <48hrs of birth compared with controls. All of these outcomes were statistically significant ($p<0.001$). Further analysis with multiple logistic regression modeling showed that *chama* women compared to control women had five times the odds of delivering in a facility (OR = 5.07, 95% CI: 2.74-9.39) and five times the odds of receiving a CHV home-visit (OR = 4.91, 95% CI: 2.76-8.72) even when controlling for age, parity, marital status, education, employment, prior facility delivery and current facility delivery. These positive effects have been replicated in *chama* women recruited in 2013-2014. Among pregnant women, 98% delivered in a facility, and 91% breastfed

[4] Kitetu, C. (2013). *Organizational Networks of Kenyan Female Migrants in England: The Humble Chama Now Operating at Higher International Levels*. London: United Kingdom. http://codesria.org/IMG/pdf/CATHERINE_KITETU.pdf (accessed 26 June 2014)

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exclusively to 6 months. Among all *chama* women in 2014, 70% decided to use a long-term family planning method (i.e. intrauterine device or hormonal implant).

Significance
We have shown that *chamas* can be tailored to increase the uptake of health services in pregnancy and infancy, sustain themselves beyond the period of funding and become integrated within a county's health strategy. However, further investment is warranted to validate this intervention in a new region to ensure the positive effects on MNCH are a result of *chamas* and can be replicated.

Purpose: To demonstrate that *chamas* is an effective, acceptable, and feasible model for improving women's and children's health and well-being in western Kenya.

Objectives: Investigators of this study aim to assess if women living in clusters randomized to participate in the first year of *chamas* have:

1. Higher health services uptake, as measured by:
    a. Our primary outcome: facility-based deliveries, and
    b. Secondary outcomes: attendance of 4 or more ANC visits, visit by a CHV within 48 hours of birth, exclusive breastfeeding to 6 months postpartum, immunization uptake at 12 months-of-age, contraceptive method uptake
2. Higher levels of self-reported empowerment, as well as decreased parental stress and use of harsh punishment to discipline children
3. Received the program as it was intended to be delivered, measured through process evaluations (e.g. attendance records, GISHE participation, re-enrollment)
4. Engaged in a cost-beneficial program as measured by the costs and benefits/person
5. Lower levels of maternal and infant morbidity as measured by eclampsia, low birth weight, poor growth, diarrhea in the last month, preterm deliveries
6. Lower levels of maternal, perinatal, neonatal and infant mortality
7. A positive experience in *chamas*, qualitatively measured through interviews and focus group discussions with women, participating CHVs, male partners of *chamas* participants, and health authority figures (i.e. MOH representatives)

Research Question: Is participating in *chamas* associated with improved health and social outcomes, including facility-based deliveries, compared to receiving the standard of care (monthly home-visits)?

Hypotheses:
Hypothesis 1: Pregnant women who participate in *chamas* are more likely to demonstrate improved health outcomes, namely: deliver in a health facility, as well as attend at least four ANC visits, receive a 48-hour CHV home-visit, exclusively breastfeed to 6 months, fully-immunize their infants by 12 months of age, and choose a contraceptive method for family planning when compared with women receiving the current standard of care.
Hypothesis 2: Women who participate in *chamas* will have higher levels of financial and decision-making autonomy, increased peer support and lower levels of parental stress when compared with women receiving the current standard of care.
Hypothesis 3: Women who participate in *chamas* will find the program acceptable and feasible.
Hypothesis 4: *Chamas* will be more cost-effective (as in cost the health system less by averting negative health outcomes per person) than the standard or care.

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Methods and Statistics:

Study Design: Cluster Randomized Controlled Trial

We have chosen a cluster randomized controlled design because our intervention is delivered in groups based within Community Health Units (CUs). We know some of the positive effects of *chamas* expand to the community surrounding the *chama*. By randomizing clusters, we will hope to isolate these communities to understand the individual-level effects of *chamas*. Clusters will be randomized 1:1 to each study arm using a random number generator. Clusters will not be matched or stratified. We will mask all investigators, data collectors, and analysts to cluster allocation. We will evaluate individual-level outcomes for all women who complete the trial at 12-months follow-up.

Study Outcomes and Endpoints:

Our primary and secondary outcomes are summarized in Table 1. The *chama* intervention will run for one year and all outcomes will be measured 12-months following the start of *Chamas* sessions or monthly home-visits. At the end of the first year, women in *chamas* can choose whether they re-enroll in the intervention at that time.

Table 1: Primary Outcome
• Facility-based deliveries (defined as deliveries attended by skilled birth attendants in facilities)
Secondary Outcomes
• Changes in care-seeking behaviors: attending at least four ANC visits, receiving a CHV home-visit within 48 hours postpartum, exclusively breastfeeding for at least six months, accepting a modern method of contraception, and immunizing infants (OPV0, Measles I, Fully Immunizing per WHO and Republic of Kenya MOH standards) • Maternal and Infant Morbidity: Eclampsia; Preterm labor, Low birth weight • Mortality: Perinatal, Infant, Maternal • Changes in maternal and child well-being: Women's Empowerment; Peer Support, Financial Status, Parental Stress, and Harsh Punishment • Lived experiences of pregnant women related to access to and utilization of health services • Process outcomes: Attendance (individual-level), GISHE participation, Re-enrollment

Sampling & Randomization:

We will randomize all CUs with an active presence of CHVs trained by AMPATH through the Kenyan Community Health Strategy. There are 77 eligible CUs from which participants will be recruited. Each CU has approximately 5000 households. Since there are 86 inactive CUs and 1 active CU throughout the region of our selected CUs, there will be buffer areas scattered throughout to reduce contamination between intervention and control CUs. Randomization will be performed in PASS 11 using random number generator operated by the trial manager. We will randomize clusters after women have agreed to participate and have been enrolled. Each CU will be allocated one of two possible number combinations. The study population will be recruited from all 60 GOK antenatal clinics in the 4 sub-counties over a 3-4-month period. The County Health leadership has agreed to select clinic staff not involved in clinical duties to help with initial recruitment. We will mask data collectors, investigators, and analysts to cluster allocation throughout the trial; however, both arms will be identifiable to participants and CHVs by design.

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Study Setting:
This study will be carried out in Trans-Nzoia County, which has 198 community units (CUs) in 5 sub-counties, Kiminini, Endebess, Kwanza, Saboti and Cherangany. We will eliminate Endebess Sub-county, which leaves us with 77 active CUs in 4 sub-counties. Endebess sub-county has many ADC farms on which individuals reside and work. As a result, access to health care is not comparable to the other four sub-counties. Trans-Nzoia has a population of 956,559 with 480,857 women and 154,963 children under-five (MOH 2015). It has on-going Maternal, Newborn and Child Health (MNCH) activities led by the GOK and supported by AMPATH in both the community and MOH facilities. Trans-Nzoia county 115 health facilities (DHIS June 2016), 2 district hospitals, 2 sub-district hospitals, 33 dispensaries, 7 health centres, 28 medical clinics and 6 nursing homes. In our 4 sub-counties, there are 60 MOH facilities (level 2, 3, and 4). All the subcounties subside primarily on agriculture and raising livestock. Kitale, part of Saboti sub-county, is urban, Kiminini sub-county is peri-urban, and Cherangany and Kwanza are rural. Agribusiness, real estate and comercial buisnesses are increasing in all the areas.

Trans Nzoia has varying health outcomes among sub-counties, but overall has poor health indicators. Only 56.9% of children are fully immunized, and 58.3% of pregnant women deliver in health facilities. The infant mortality rate is 58 per 1,000 live-births compared to a national average of 39 per 1,000 live-births (KDHS 2014). Furthermore only 29.3% of women receive FP commodities compared to a national average of 58%. (KDHS 2014). Finally, only 17.4% of women have attended the recommended 4 or more antenatal visits. Approximately 6.3% of women of reproductive health age are pregnant at any one time (KDHS 2014).

The trial will be implemented by the AMPATH Maternal and Child Health innovations group in collaboration with the Kenyan MOH. As part of AMPATH, Moi University is ideally positioned to meet the objectives of this proposal. We have an established record managing large MNCH programs and scaling them within the Kenyan MOH.

Study Population & Eligibility:
The target population will be pregnant and recently postpartum women, of any age, living across four sub-counties (Saboti, Cherangany, Kwanza, Kiminini) in Trans Nzoia County, Western Province, Kenya. Pregnant women will be recruited from eligible CUs based on the following criteria:

Participant Eligibility Criteria:

A. Any pregnant woman who:
    a. Presents for her first ANC visit at one of the recruiting health facilities
    b. Is less than or equal to 32 weeks gestation during her first ANC visit
    c. Resides in an intervention or control CU

Cluster Eligibility Criteria:

- Community Health Unit in one of four recruiting sub-counties (Cherangany, Saboti, Kwanza, Kiminini) in Trans Nzoia County, Western Province, Kenya
- Have a workforce of CHVs trained by AMPATH under the Kenyan Community Health Strategy

Intervention Activities:
The *chama* intervention seeks to empower and educate women to improve the health and well-being of their families. Our theory of change is constructed on a framework that focuses on providing women

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peer support, financial literacy and health and social education will empower them to work as a group to improve the health of the communities within which they live.

All clusters randomized to the intervention arm will be invited to participate in *chamas*. Each group will consist of two CHVs, two mentor mothers (i.e. post-menopausal women who have completed child-rearing) and 15-20 pregnant women. These groups will meet bi-weekly and use participatory approaches to develop their individualized group charter/constitution. Upon joining, women pledge to participate for one year and uphold the goals chosen by the *chama*. During each meeting, two CHVs facilitate a 60-90 minute discussion on health and social topics relevant to the antenatal, intrapartum, and postpartum periods. After this discussion, women will have the option to participate in the Group Integrated Savings for Health and Empowerment (GISHE) program. GISHE is a table banking program that gives women an opportunity to save money, pool money together to serve as a social or humanitarian fund and take loans from one another. Throughout the year, they will learn accounting and safekeeping skills and receive mentorship from their peers to engage in income generating activities. CHVs will not be invited to be a member of the GISHE group.

If the CHVs choose to continue the intervention, each community unit will be facilitated to form a new *chama* of pregnant women every 12 months. In addition, women who have completed their first year can choose to participate in a second and third year. After three years of the *chama* program, women will graduate and be encouraged to continue to meet as a group without CHV facilitations.
CHVs have been trained by the MOH and AMPATH to provide services to women and children under five. In addition to providing a refresher training on important MNCH topics covered by the Community Health Strategy, we will also train CHVs facilitating *chamas* on the program and equip them with skills to facilitate groups using a participatory learning approach. We will do this by providing training orientation sessions preceding the trial. In addition, our group will visit each *chama* on a minimum of a quarterly basis to allow them opportunities for feedback and support.

Control Group Activities
GOK community strategy focuses on care provision by community health volunteers (CHVs) who provide standard Ministry of Health (MOH) activities including promoting good nutrition, sanitation, and hygiene and linking families to essential MOH services. In 2014, AMPATH partnered with the county government to train the CHVs on important health topics including maternal, neonatal and infant health.

The CHVs in the control group will be given refresher training on health roles they are supposed to play according to the standard MOH activities. This includes visiting mothers throughout pregnancy, within 48 hours of delivery and in early childhood by conducting home-visits on a monthly basis. We will provide quarterly mentorship meeting for the CHVs to monitor their activities and ensure similar contact with our clinical staff as the implementation groups. If the study shows that *chamas* are beneficial to women and their infants, we will pledge to scale-up the intervention to the control group.

Stratification & Power:
We estimated sample size using methods described by *Rutterford et al*. for a proposed mixed effects regression analysis using derived baseline estimates. Assuming a mean cluster size of 20 individuals, 77 clusters (equally allocated between arms), intra-cluster correlation coefficient (ICC) of 0.44 (based on pilot data), and 20% attrition, we calculated a total of 1,280 individuals would be needed to detect a 4.7% difference on the risk difference scale with 80% power at a (two-tailed) significance level of 0.05.

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To determine our recruitment timeline, we assumed 6.3% of all women of reproductive age would be pregnant at any given time (or roughly 50 women per CU annually). We determined an enrollment period of roughly 3-4 months adequate to recruit our estimated sample size.

Data Collection & Storage

Data collection will occur by enumerators who do not participate in providing maternal and child health services and who do not have a working knowledge of the intervention and where it is being implemented. The same data collection protocol will be used for both intervention and the control groups. Enumerators will be recruited from the health facilities where recruitment takes place and trained to perform detailed interviews.

Data will be collected in two phases: at baseline and at 12-months following the initiation of *chamas* and monthly home-visits. Baseline data will be collected on all women who agree to participate in the study during enrollment. Data collectors will ask women attending their first ANC in health facilities if they consent to be contacted for enrollment; at that time, data collectors will record locator information such as the participant's address and/or phone number. CHVs and data collectors will then attempt to contact women in their communities to formally enroll them in the trial and will collect baseline socio-demographic and reproductive health data at that point in time. Data collectors will visit all women across trial arms in their homes to collect end-line data 12-months later. Data will be collected by interview on paper and/or tablet at both baseline and endline and entered into an encrypted RedCap database.

Paper data will be stored in a locked cabinet in the MNCH offices at AMPATH Primary Care Building. Data entered will be stored under password protection in a database accessible to the Data Management Team and Co-investigators only. All data will be entered into RedCap and stored on a password-protected device with antiviral and security software. All study participants will be given a unique identifier. Only the Data manager and the PIs will have access to the de-identified database.

Impact Evaluation

Prospective outcome data will be collected by enumerators. Enumerators will collect data at baseline and endline. At baseline, we will collect data on demographics of the respondents and their partners, household assets and income, reproductive history and child outcomes. At endline, we will collect data on maternal and child outcomes, utilization of reproductive health services, maternal well-being, and microfinance. We will attempt to collect outcome data on all women who enrolled in the study. CHVs will collect M&E data reported monthly. The data will be used for project monitoring and process evaluation. They will also keep records of financial information on the microfinance component of the *chama*. These records will be submitted to the research assistant at the end of the *chama* cycle, where data on microfinance performance of the *chama* will be mined from the records. Please see the figure below to better understand the flow of implementation and evaluation.

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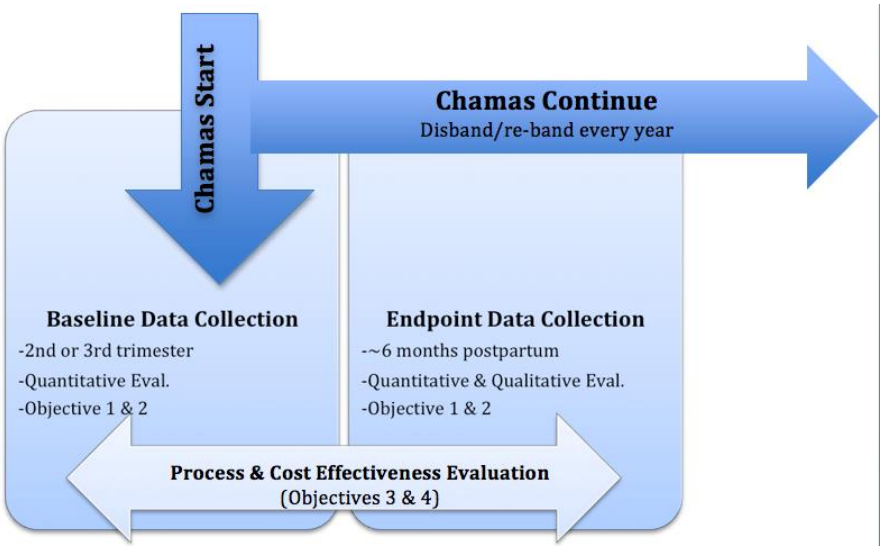

Process Evaluation

We will meet with selected CHVs quarterly in intervention and control sites to provide mentorship and support. In addition, CHVs will record process data on paper on a monthly basis to report on details of their work throughout the year. GOK and program registers will be used to determine adherence level and quality of implementation of the intervention. The Monthly Reporting Tool is included in the Appendix.

Qualitative Analysis

To meet the second research objective, specifically to better understand experiences with *chamas* and understand how *chamas* affect peer support, focus group discussions (FGDs) and key informant interviews (KIIs) will be carried out with women enrolled in the study, CHVs involved in community strategy in intervention and cluster CUs, male partners of women attending chama, and health authority figures (i.e. Sub-County Public Health Nurses - SCPHN). We plan to conduct FGDs with women and CHVs at baseline, and FGDs/KIIs with women, CHVs, male partners, and SCPHNs at endline.

At study baseline, we expect to interview a total of 20 CHVs, 10 from intervention and 10 from control. To assess acceptability of the program, we also intend to hold 4 focus group discussions (FGDs) composed of women in intervention clusters/4 FGDs from control clusters. To avoid homogeneity in the composition of the groups, we will stratify women into two groups based on age (>25 yo or =< 25 yo). We expect to reach saturation point in holding 2 FGDs with younger mothers and 2 FGDs with older mothers from the intervention and control clusters. We will also conduct up to four FGDs with women in the 2017 cohort who were never followed up (for a total of 12 FGDs).

During our endline assessment, we will also conduct FGDs with women enrolled in the chamas intervention group, CHVs that participated in the study between 2017-2019, as well as male partners that attended chama sessions. We also plan to conduct KIIs with health authority figures (i.e. SCPHNs) from each sub-county. During these discussions, we plan to explore themes including perceptions of effectiveness of chamas, experiences with maternal and child health related outcomes, health service utilization outcomes, as well as experiences with service disruptions.

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We anticipate we will conduct 4 endline FGDs with chama women, 4 FGDs with CHVs, 2 FGD with male partners and 4-8 KIIs with health authority figures. We will also conduct 2 FGDs with women who were in the original cohort, which was not recruited into chamas. Women (10-12 per FGD) will be selected from the total sample of enrolled women using a computerized random sampling technique. 4 CHV representatives will be selected from each of the four sub-counties in which we work. We will ensure 2 CHV representatives from each sub-county are allocated to each FGD group (i.e. 2 sub-county representatives from each sub-county in each FGD). We will use a convenience sampling technique to generate our group male partner FGD participants. Women who consistently attend chamas (>50% of total sessions) and who are not selected to participate in FGDs themselves will be asked to invite their male partners to participate. We will enroll the first 10-12 male partners who agree and consent to participation and who have attended at least 3 chama sessions themselves. Lastly, we will conduct 4 KIIs with SCPHNs – one representative per study sub-county. These SCPHNs have been actively involved throughout the duration of the chama study. We will consent all FGD and KII participants prior to conducting interviews.

Economic Evaluation

All intervention costs will be managed and recorded by Research Sponsored Projects Office (RSPO) through AMPATH Transformational Project (ATP) an online accounting system. This will include start-up and maintenance costs throughout the study period. We will be a developing an addendum to this proposal with a plan for a cost effectiveness analysis.

Data Management & Quality

Data Analysis

Intention-to-treat analysis will be used to deal will loss to follow-up, provide unbiased comparisons among the treatment groups and ensure conclusions drawn from the findings is based on information about the potential effects of a treatment policy rather than on the potential effects of specific treatment. Individual level data analysis will be employed controlling for design effect for all outcomes. Details of our analysis plan are delineated in our *Statistical Analysis Plan*. We will additionally conduct a process evaluation to monitor the intervention and control arms, as well as address quality of services throughout the year.

Qualitative data will be coded for themes and used to triangulate quantitative results. A code structure will be developed for the KIIs and FGDs with theory driven content analysis using the constant comparative approach to consolidate codes into a unified structure. Once the coding team has reviewed all the material and a final coding structure has been established by consensus, all the KIIs and FGDs will be recoded in MS Word Tracked Changes using the final structure. The coded material will be synthesized into a narrative format with extensive quotations organized thematically. In all cases, rival explanations will be noted and developed into alternative conclusions in the final analysis.

Ethical Considerations

We will obtain ethical approval through the Institutional Research and Ethics Committee at Moi University School of Medicine and Moi Teaching and Referral Hospital (Kenya) and Indiana University (Indianapolis, IN, USA). In preparation for this proposed intervention, we have obtained signed approval from Trans Nzoia County leadership.

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There will be little risk to women participating in this study and participation is by choice only. The intervention is a supplemental service delivery mechanism that incorporates all aspects of the current gold standard of care. It is not meant to replace the MOH community strategy, but to complement and improve it. Furthermore, in addition to participating in the intervention, women will still receive the GOK standard of care in their homes.

The primary risk of this study is therefore the loss of confidentiality of patient-identifiable information or information that could identify an interview subject or focus group participant with her/his recorded information. The study will employ all standard operating procedures of the AMPATH Research offices and Informatics program in order to ensure that patient data is kept securely in study databases with all appropriate encryption and password protection. All study participants will be given a unique identifier. Loss of confidentiality of the focus group participants and interview subjects will be minimized by restricting the number of investigators that have access to the audio recordings, by de-identifying subjects on the transcripts, and storing the recordings and the subject key in an encrypted and password-protected computer file.

Benefits to the subjects

Since the study provides an intervention aimed to supplement the current care cascade, there may be benefits to women who participate in the intervention. They may have more contact with CHVs and obtain more education than women not in *chamas*. It is unclear whether this will lead to a benefit in health outcomes, which is why we are performing this study. Women will participate voluntarily and will not receive any monetary or non-monetary gifts for their participation. Furthermore should this study show benefit to women and children in the intervention group, we will commit to scaling up the project to the control region should funding be available.

For the qualitative portion of the study, participants in these interviews may benefit from having their ideas and suggestions implemented in the design of future interventions in the communities and facilities. Furthermore, they will receive reimbursement of their transport to the interview and snacks during their session, in keeping with local research practices.

Informed consent

We will obtain informed consent from each woman who enrolls in the intervention and control groups. During the consent process, we will consent women to follow-up on pregnancy and health service utilization outcomes during end-line. CHVs work in the community collecting patient data for Ministry of Health registers. They are from the community and usually during their regular work, they visit pregnant and breastfeeding women to check their ANC status, Immunization status and Family Planning as they give other services. The enumerators will consent women who show up at the facility when they visit for any ANC visit by 32 weeks gestation. We will obtain the consent of the parent or guardian of the infant participating in the evaluation from both the control and intervention groups. The children are under the age of five so obtaining their assent will be difficult, but we will stop the evaluation should a child be vocalizing their assent by crying or refusing to participate in the evaluation.

Additional informed consent of all individuals participating in in-depth interviews and focus group discussions will also be obtained. Separate written consent forms have been included in this application for all individuals participating in the qualitative assessment in the focus group discussions and in-depth interviews.

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All data will be collected by an enumerator being paid by the project. The enumerator will not have an understanding of the intervention being conducted nor will he/she be participating in the intervention or community health service delivery. All our research assistants are trained on the protocols and importance of consent and confidentiality. All of our enumerators will be taught about consent and confidentiality and will sign a statement agreeing to maintain confidentiality.

Confidentiality

All study participants will be assigned a unique ID at the beginning of the study to ensure confidentiality. For those participating in KIIs and FGDs, no one outside of the Principal Investigators, Co-Investigators or research staff will have access to the names of the individuals recorded in the focus group discussions or the interviews. A transcriptionist will be able to hear the voices of individuals on audio recordings, but will not have access to the names or any other identifying information of the individuals in the study. Encryption will be used on all electronic devices that are used to store recorded audio from focus group discussions and interviews. Access to the encrypted data will require a password.

Only the study personnel listed above will have access to the names of all the study participants and their identifiable information. CHVs implementing the *chamas* or conducting their work will not have access to the data collected. Enumerators collecting the data will not have access to the database or to the data they have collected after their point of contact.

Only the Principal Investigators, Co-Investigators, and research staff will have access to the password or the encrypted data. Only de-identified data will be shared outside of AMPATH and only for the purpose of data analysis or for dissemination of the aggregate results of the study.

Study implications

This study is evaluating an innovation in maternal and infant health services in the community, specifically the use of a group-based women's health education model. If data analysis of this care program shows improvement of community-based service delivery, facility-based uptake of services and maternal and newborn health outcomes, there is great potential to expand this program to other regions of Kenya. The evaluation will be used to inform CHV best practices within all of AMPATH Primary Health Care. If the PHC *Chamas for Change* project is found to be acceptable and beneficial, then it is possible that funding can be secured in order to implement *chamas* throughout western Kenya. Expanding *chamas* may facilitate CHVs to improve the delivery of community-based services from HIV to diabetes care. Furthermore, this project may help to provide women around the world a voice in order to keep their communities accountable to their mothers and children.

Project Budget:

This study is funded by Saving Lives at Birth through Grand Challenges Canada. The project budget is 250,000 CAD to be used over 2 years. We are using the funding to both implement the program and to perform the evaluation.

Project Deliverables:

The analyzed data and quarterly data will be submitted in a report to Grand Challenges Canada as required by the grant agreement. We will compile the final data analysis into a manuscript that will be submitted to a journal that is yet to be decided. We may also present analyzed data in the form of posters and presentations at academic conferences.

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