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The role of a decision-support smartphone application in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-experimental research protocol

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Abstract:

Introduction;

Improving maternal and newborn survival remain major aspirations for many countries in the global south. Slum settlements, a result of rapid urbanization in many developing countries including Kenya, exhibit high levels of maternal and neonatal mortality. There are limited referral mechanisms for sick neonates and their mothers from the community to health care facilities with ability to provide adequate care. In this study we specifically plan to develop and assess the added value of having community health volunteers (CHVs) use smartphones to identify and track mothers and children in a bid to reduce pregnancy-related complications and newborn deaths in the urban slums of Kamukunji sub-County in Nairobi, Kenya.

Methods and analysis;

A quasi-experimental study. We are implementing an innovative, m-health application known as mPAMANECH which uses dynamic mobile phone and web-portal solutions, to enable CHVs make timely decisions on the best course of action in their management of mothers and newborns at community level. The application is based on existing guidelines and protocols in use by CHVs. Currently, CHVs, conduct weekly home visits and make decisions from memory or using unwieldy manual tools, and thus prone to making errors. mPAMANECH has an in-built algorithm that makes it easier, faster and more likely for CHVs to make the right management decision. We are working with a network of selected CHVs and maternity centres to pilot test the tool. To measure the impact of the intervention, baseline, midline and endline surveys will be conducted in addition to systematic monitoring and documentation. Data will be obtained through qualitative and quantitative methods.

Ethics and dissemination.

Ethical approval for the study was obtained from the African Medical Research Foundation. Key messages from the results will be packaged and widely disseminated through meetings, conference presentations, reports, factsheets and academic publications to facilitate uptake by policy makers.

Keywords: Decision-Support; Community Health Volunteers, Maternal and Newborn Health; Slums; Kenya

Article focus

We hypothesise that usage of a CHV decision-support module does not have an effect on utilization of MNH services or MNH outcomes in informal settlements.

Key messages

- The study's findings will generate evidence on the effectiveness of public- private partnerships in improving maternal, newborn and child health services and outcomes in urban slums.

-If successful, the study will provide a model of public-private engagement for adoption by the local and central governments, for under-served populations, in other developing countries.

Strengths and Limitations

- The project seeks to address a critical challenge in the health care system in a slum context: identification and referral of ill mothers and newborns.

- It utilises the existing CHV work tools and mobile phone technology to show how an evidence based intervention can improve health outcomes at community level.

-A potential harmful unintended consequence stems from the fact that CHVs are not medically trained and as such could make a decision to treat at home, rather than refer (even when the system advises otherwise) with possible negative health consequences for the mothers and their newborns.

-However, since the system allows health workers to access this data, they will be in-charge of following up on such cases to avoid unnecessary delays and such unintended consequences.

1. Introduction:

Improving maternal, newborn and child survival remain major aspirations for many countries in the global south. Annually, close to 300,000 women die from maternal causes, 3.3 million children are stillborn while an additional 3.3 million die within the first month of life, [1-3]. A vast majority of these deaths occur in sub-Saharan African and South Asia. Most maternal deaths are due to causes directly related to pregnancy and childbirth; unsafe abortion and obstetric complications such as severe bleeding, infection, hypertensive disorders, and obstructed labour, [1]. A small group of neonatal conditions are responsible for the high neonatal mortality, and these include: sepsis, pneumonia, birth trauma/asphyxia, congenital malformations and prematurity, [2, 4]. Most of these causes are preventable with existing cost-effective interventions. Kenya has made some progress in improving maternal and newborn survival over the years. Maternal mortality has progressively reduced from 488/100,000 to 362/100,000 between 2008/09 and 2014. Neonatal mortality has reduced from 31 to 22 deaths per 1000 live births, between 2008/9 and 2014, [5, 6]. Neonatal deaths account for about 60% of all infant deaths in Kenya, [6]. Given that the majority of maternal deaths happen during labour while most child deaths happen during the neonatal period, increasing women's access to healthcare during pregnancy and childbirth and improving the quality of intrapartum care would serve to reduce most of these preventable causes. Despite the existence and knowledge about simple strategies and techniques to reduce maternal and newborn deaths, these interventions are not up to scale due to inadequacy of health care facilities, trained personnel, information, poor referral systems and pervasive poverty.

Community Health Volunteers

The need to ensure universal health coverage amidst a global health care workers crisis saw the identification of community health volunteers (CHVs) as a critical alternative and workforce at

the community level, [7]. CHVs are volunteers identified from communities that they reside in and offered a few days' basic training based on a set curriculum before they are assigned community health promotion roles. CHVs belong to established community units with a responsibility of making weekly home visits to households within designated geographical areas. The visits are targeted to households with pregnant women, newborns, infants and other children under the age of five years. During these visits, CHVs are supposed to identify those cases that need referral for preventive services, those that need medical attention, and those that need simple remedies. Their work tools include many paper based registers and counselling cards that they refer to in order to make management decisions. Like many other developing countries, Kenya suffers a shortage of healthcare workers, [8]. CHVs were identified under Kenya's Community Health Strategy as a means of alleviating the healthcare worker crisis. To date, CHVs continue to bridge the critical gap between communities and the formal health system, and many positive lessons have been learned in Kenya and other parts of the world, [9-11]. CHVs in Kenya, like in many emerging economies, are responsible for the majority of grassroots health care delivery, and as such, continue to play a very critical role in primary health care delivery.

Decision-support systems

Clinical decision support (CDS) refer to tools used to improve decision-making in the patient care workflow, [12]. CDS provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care, [13, 14]. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually

relevant reference information, among other tools, [15]. They are beneficial in reducing errors, increasing quality of care and improving efficiency.

Mobile technology for health

Mobile technologies have the potential to bridge systemic gaps needed to improve access to and use of health services, particularly among underserved populations, [16]. Worldwide, the use of mobile and/or electronic devices to support both medical and public health practice and research (mHealth) is increasingly being appreciated. Over the last one decade, there has been global enthusiasm and interest among development agencies, researchers, and policy makers resulting in the rapid proliferation of mHealth solutions many countries. mHealth has the important role of connecting people in real time while reducing delays in health-related decision making and access to quality care, [17]. The growing coverage of mobile networks has enabled development of various mHealth initiatives especially targeted for underserved populations in developing countries, [18]. The use of mobile and electronic technology is increasingly valued in health care delivery, especially in low and middle income countries, [17-20]. The high and ever growing mobile penetration coupled with investments from technology companies that provide accessible platforms onto which innovations can establish and offer value-based products, [18]. Innovations include mobile phone platforms/applications and micro-insurance packages. Given the nature and tight timeframes of most obstetric and neonatal emergencies, which more often than not demand quick access to quality care at short notice, mobile phone innovations are a cheap and fast solution especially in areas with poor healthcare infrastructure which have shown improvements in maternal and child health outcomes, [20, 21]. The majority of innovations on the market are tailored towards promoting reproductive, maternal, and child health, [17, 22]. In addition, various projects have been designed and evaluated on CHVs use of mobile technology

to deliver interventions, [23, 24]. Decision-support systems have been highlighted as a critical factor in reducing errors in evidence-based clinical practice. For clinicians, studies have demonstrated that computerized decision support systems can be used to improve compliance to practice guidelines [13, 14]. Given the limited training obtained and skills that the CHVs possess, coupled with the distances they work from the clinical settings mobile information technologies tools enable them to provide much needed health services.

Over the last decade, more mobile and electronic information tools have been developed, tested and implemented with CHVs to support their work roles. The tools help the CHVs in surmounting challenges such as lack of appropriate work tools and inadequate supportive supervision and training [23, 24]. These tools have been instrumental in improving access to care by marginalized population groups subjected to stigma and those in hard to reach areas by reducing both time and cost of travel. As such, research on CHVs' use of mHealth tools in important. Several pilot projects, utilizing multiple designs and measures have been implemented. The projects have reported improvements in services rendered by CHVs and the related health outcomes for communities. In sub-Saharan Africa, most of the interventions have demonstrated improvements in the CHVs' delivery of maternal, newborn and child health, Tuberculosis and sexual and reproductive health services, among others, [21, 23]. The innovations largely use SMS and hotlines enabling mothers to access vital information and timely referrals as a result of better and faster communication and transport. Available evidence shows the usefulness of mHealth tools in facilitation of compliance with practice guidelines and process improvement, [23]. However, many of the interventions have been limited methodologically by their inability to demonstrate effectiveness and or impact related to patient

outcomes. In addition a lack of use of nationally accepted guidelines and open source tools limits the scalability of these interventions. In addition, available literature does not provide cost estimates necessary for delivery of program targets. Furthermore, a top to bottom approach that does not incorporate the ideas of the CHVs in the development of the tools is a major impediment as successful projects use the CHVs as experts in the design and management of their interventions, [23]. The recently developed mHealth Evidence Reporting and Assessment (mERA) checklist whose aim is to assist authors in reporting mHealth-research, to guide reviewers and policymakers in synthesising high-quality evidence is expected to indirectly improve the quality of mHealth evidence in the literature, [16, 25]

The African Population and Health Research Center (APHRC) has implemented a health systems strengthening project, Partnership for Maternal, Newborn and Child Health (PAMANECH) in Korogocho and Viwandani informal settlements of Nairobi, Kenya, [26]. The project sought to strengthen the healthcare delivery system in the urban informal settlements to be more responsive to the health needs of mothers and their children through enhanced service delivery public-private partnerships. In a bid to improve the health management information system, an innovative mHealth application, was developed. The mPAMANECH application was developed as an integrated data capture tool running as a mobile app with selected reporting forms for CHVs in Kenya. It operates in an interconnected network of CHVs and health facilities within a defined local system. It is designed to replace the numerous paper-based forms that do not allow integration of patient data from the community to the health facility and back for better referral

and management of patients. This system has been seen to improve the reporting abilities of CHVs as it is less cumbersome than the paper-based system and enhanced data quality as it has a function that limits saving data until all necessary fields are filled in. In addition, the CHEW can access a CHV's data remotely without having to wait for the end of the month for the CHV summaries. The desire to improve the functionality of the existing system to include a decision support function provides the basis on the new project.

This project attempts to bridge this gap by incorporating CHV views, utilizing the tools approved by the Ministry of Health and allowing for assessment of health outcomes in the design and implementation of the project. The decision support system is developed from open source tools. In addition, a cost effectiveness analysis would be conducted to inform county and national implementation plans regarding the necessary investments for set up and maintenance.

2. Methods and Analysis

Research Objectives

The overall objective of the proposed work is to develop and validate a decision-support algorithm within a mHealth application in improving maternal and newborn health outcomes in urban slums in Kamukunji sub-County in Nairobi, Kenya. The project seeks to assess the added value of using a CHV decision-support module of mPAMANECH in reducing prenatal and postnatal maternal complications and newborn deaths.

Specifically the project will assess (i) the feasibility and acceptability of using a decision-support module of mPAMANECH and (ii) whether decision-support platform contributes to increase in utilization of MNH services, and reduction of MNH complications and deaths. We will measure several outcomes, *figure 1* related to the two specific objectives, above.

Conceptual framework, Theory of Change and Operationalization

Our innovation centres around enhancing the functionality and utility of the current mPAMANECH application to include a community decision support tool to be used within a local system comprised of CHVs and five maternity centres serving five slum settlements in Nairobi. The decision-support module in the mPAMANECH application will supplement the existing MNCH data capture modules and help in the identification of high risk facing pregnant women, new mothers and newborns with complications, and to make timely and correct decisions on referral for cases that need intervention. The main beneficiaries are pregnant women (over 24 weeks), mothers in the immediate post-partum period and their newborns (up to 28 days old).

The use of CHVs in delivering the mobile phone based intervention and follow up by the SCHMT will ensure sustained support and adherence to the intervention during pregnancy, immediate postpartum and in the neonatal period. The mPAMANECH has the official 503 and 504 forms in use by CHVs and Community Health Extension Workers (CHEWs), who supervise the CHVs. A dedicated team of CHEWs will ensure that the intervention is delivered as expected and non-adherence captured and documented.

The attributes of the solution include: 1) Use of any android devices - the entire application is operable on phones, tablets or desktops/laptops; 2) Within a linked local system – messaging is delivered internally via the portal and no extra network charges are required for messaging; 3) The application is bandwidth light and takes about 100 Kenya shillings a month per user, based on local data bundle charges. The application can work offline and auto-synchronize as soon as network connectivity is re-established; 4) Updates are automated and there is no need for an IT

expert to have physical access to the device to execute a software patch or change; 5) The application has security features that protect users' confidentiality and limit access to a closed but linked local system of health facilities and CHVs with varied access rights; 6) It has the ability to limit use of other phone functionality to only allow this application to run. This helps prevent abuse of the device and promote saving on bandwidth. We aim to enhance the functionality and utility of the current mPAMANECH application to include a community decision support tool to be used within a local system comprised of selected CHVs and five maternity centres serving slum settlements in Nairobi. In the 'Operationalisation' section, we describe more on how the decision support system is expected to work.

From our proposed theory of change, *figure 2*, we anticipate that the decision support module of mPAMANECH will assist the CHVs in the identification of high risk pregnant women, new mothers and newborns with complications, and to make timely and correct decisions on referral for cases that need intervention. With the improved knowledge and skills possessed by the CHVs more women and neonates in need of health care will be identified and referred to the necessary health facilities. As a result, there will be increase utilisation of maternal and neonatal health services and reduced maternal and neonatal complications and deaths.

Operationalisation of the Decision Support System

The mobile decision support system (mDSS) mobile application (app) is an Android app that installs from the phone and runs as an application, *figure 3*. The app will be hosted at Google store and is accessible for download via the internet automatically to the user handset.

Once installed, the handset and the application will be configured with the credentials of the CHV including username and password, which are linked with the operating phone number. This setup allows the system to register and associate collected records to the respective CHV; useful for reporting and analysis purposes.

The CHVs will be provided with a mobile phone running the mHealth App for data collection which is then relayed to the head office at APHRC Campus. When visiting households for data collection, by initiating a new record the system automatically picks the geolocation of the household and associates it with the record.

The CHV will complete the respective form and save the information at any stage on the handset. This method allows the CHV to continue collecting more information and only submit the completed form to the server over the internet. Where the handset detects that internet connectivity is not available for one reason or the other, the completed forms will be stored in the phone and only be relayed to the server when the connectivity is established. Because the application is in communication with the server in real-time, any update of the data is immediately available to the CHVs. The application is preconfigured with danger signs for both mothers and newborns as defined by the WHO. When any of the danger signs is picked by the system, the CHV is immediately prompted to refer the patient to a facility within the network.

The system is to be set up in such a way that the CHV will not be allowed to proceed and complete the forms until the referral is done. The patient's information will be available to all the facilities within the network and he/she will be able to visit any of the networked facilities for treatment. This information is also relayed to the rest of the other facilities and a record of the visit is kept in the server. Within 24 hours if the patient has not been seen in any of the

networked facilities, an SMS message is relayed to the respective CHV handset. At this point, the CHV should follow up with the patient to inquire about their condition and whether they chose to honour the referral to a facility outside the network or not.

When the patient visits a facility within the network, using the household number and the name he/she will be easily identified and treated. The clinician is able to record the treatment in the patient's information, which is recorded in the server.

Both the CHV and the clinician's information are available to a reviewer in real time from the web. The reviewer's role would be to assess the CHV's reason for referral and the clinician's final diagnosis for correctness. The feedback from the reviewer will be available and shared on a monthly basis during review meetings. Every week, the CHEW, will randomly sample referrals made by each CHV to assess their correctness. This will be compared with the 'reviewers' summary.

mDSS Solution- Key Features (*figure 4*)

CHV (mobile App)

Through this app, the mDSS data collection tools are accessible on the CHV mobile handset. It allows for completion and submission of the information to the mDSS Server.

mDSS Server

A database driven web application that acts as a host for the collected information. It also has a web interface for data manipulation by the facility healthcare worker(s) and reviewer.

The mDSS server application incorporates an application logic component that connects with the SMS and email gateways. This allows for real-time communication of certain critical indicators

to the respective recipients. For example, where a patient has not shown up at the referred facility, the CHV will be alerted.

Facility (web access)

This module is accessible at the facility via the web. The application allows the clinician to treat the patient and record the treatment. The facility portal is accessible by facility staff to manage referrals. The "Messages" to alert the CHVs are to be integrated with WhatsApp for effective message delivery over the same mobile phone.

Reviewer (web access)

This module is also accessible via the web, and provides the reviewer a view to assess both the CHV referral report and the clinician's diagnosis. It is based on this analysis that a decision is measured.

Null hypothesis:

Usage of a CHV decision-support module does not have an effect on utilization of MNH services or MNH outcomes.

Study Design and Sampling Strategy

a. **Study Design**

To answer the question on effect of the decision support system, we will use a quasi-experimental design with pre and post assessments to determine the impact, if any, on the MNH services and selected health indicators.

We will work with three community units (CUs) from which a group of 50 CHVs will serve as the intervention group. Three CUs in Embakasi sub-County, with 50 CHVs will serve as the

control. The CUs in the control group will be geographically distant from the intervention site to limit contamination. The control group will be facilitated within the normal standard of practice which includes paper-based reporting. The idea is to compare access to MNH services, referral practices and MNH outcomes between those with a decision-support tool with those working with traditional paper-based tools.

We will conduct a baseline survey and an end-line at least one year after the full implementation of the intervention. The control group will be assessed at the same time as the surveys are being conducted in the intervention group. To strengthen the case for causal inference we will also do a systematic monitoring and documentation of the intervention based on our theory of change. The monitoring and documentation will also capture any other contextual factors that may influence the same outcomes as our intervention.

To answer the question on feasibility, we will conduct a mixed methods assessment of the CHVs and CHEWs. Qualitative assessments of their current work experiences with the paper based system as well as after the introduction of the mobile based system will be conducted. We will assess ease of use, challenges experienced and opportunities for improvement. These will be triangulated with their HMIS reports (paper and electronic).

b. **Study Setting**

The intervention site covers informal settlements in Kamukunji sub County, which, like other slums, are characterized by poverty, poor coverage of social services and poor health outcomes. We will identify CUs and 5 facilities that serve the CUs. Embakasi sub-County will serve as the control site. We will identify three CUs to serve as controls.

c. **Sampling**

The CUs in the intervention group will be purposively selected based on discussions with the sub-County community strategy coordinator for Kamukunji. We will select CUs with the worst health indicators for both the intervention and control groups, including those serving informal settlements, and with more likelihood to benefit from the intervention.

For the population based surveys:

➢ **Quantitative study**

- *Study population*

The project will target households with women of reproductive age (15-49 years) in the informal settlements of Kamukunji. It will also target health care providers in five selected health facilities as well as the sub-County Health Management teams of Kamukunji, Embakasi, Makadara and Nairobi City County.

A quantitative survey will be conducted focussing mainly on maternal and newborn health and family planning services.

- *Sample size estimation*

The key outcome of interest is correct referral practices. Using proportion of neonates with at least one danger sign referred by CHVs as the indicator, since it is representative of the target population, the total sample size for each group has been estimated as 173 (346 in total). Using a difference in proportion 13.3 % for neonates with danger signs referred (rising from 16.7 to 30%), at 95% CI for 80% power and sample proportions of 50% in the intervention and 40% in the control groups, respectively, we came up with a sample size of 315. Accounting for a potential non-response rate of 10% based on previous studies in similar study populations, the effective sample size is 346. Using correct decisions made by CHVs (one of the indicators to be measured), the sample size was estimated as 199. 346 is therefore an appropriate sample size.

- *Sampling procedure*

To measure feasibility and acceptability, all the CHVs in the intervention site will be assessed, in addition to an audit of the functionality of the system. We will measure the percentage time for which the system is down on a monthly basis **(Numerator:** Number of times (in minutes) when the system is down. **Denominator**: Total active time in a month. Down time defined as 30 minutes of hanging and Active time as time without hitches), proportion of CHVs effectively using the decision support system (Within the system, on a quarterly basis we will be able to generate reports on decisions, correct or otherwise, made by the CHVs. These will also be compared to the control site that will only have a paper based system of data collection), and the experiences of the CHVs and the mothers with the mobile based system. These will be compared to the investment.

To answer the question on effect of the system on utilisation of services, the data above will be triangulated with data from the **mPAMANECH application which already has an integrated data collection module**, the data generated by the CHVs and participating health facilities will be retrieved, cleaned and analyzed to derive estimates of the main outcome of interest – correct referral practices. In addition, these data will be triangulated with other sources such as the CHV monthly reports and health facility HMIS. A system of random numbers generated using STATA will be used to select the respondents based on a sampling frame that is going to be informed by an updated household register in the selected community units.

➢ **Qualitative study**

We will use focus group discussions (FGDs) and in-depth interviews among the direct project beneficiaries and CHVs, and key informant interviews with key actors (sCHMTs, health

providers, CHVs and community leaders). Participants will be purposively selected to represent the different stakeholders as well as different health service user categories (users and non-users).

Data from the quantitative survey will be used to identify women who have or not used specific MNH services and these will be approached to participate in the focus group discussions or in-depth interviews. Other respondents will be identified based on their position in the community and their role in the project.

Data Collection, Management and Analysis

Data collection:

We will conduct a baseline survey and an end-line at least one year after the full implementation of the intervention. The control group will be assessed at the same time as the surveys are being conducted in the intervention group. To strengthen the case for causal inference we will also do a systematic monitoring and documentation of the intervention based on our theory of change. The monitoring and documentation will also capture any other contextual factors that may influence the same outcomes as our intervention. The effects and impact of the project will be determined by triangulating data and information from different sources, examining trends where possible, and trying to find and support explanations for the observed findings.

Our key data sources will be the following: household surveys, routine HMIS data and qualitative assessments (interviews and focus group discussions).

We will conduct simple and multiple logistic regression analyses comparing differences in the proportions of women in reproductive age and children under-five at baseline and end line for variables like antenatal coverage, vaccination coverage, skilled birth attendance, among others,

(See figure 1 for key indicators). These analyses will control for any differences in the samples (if any) at the two time points as well as the contribution of contextual factors that may have occurred in the course of the implementation.

mPAMANECH data: Descriptive data in terms of referrals by, diagnostic decisions, among others, will be summarised using means and standard deviations for the parametric continuous data and medians with inter-quartile ranges for the non-parametric data. Categorical data such as referrals by age and gender will be summarised using proportions and percentages.

Qualitative data: Qualitative data will be transcribed and saved in Word format. Transcribed word files will be imported into NVIVO software (QSR International Pty Ltd) for coding and further analysis. Analysis across all transcripts will be conducted using a constant comparative method to identify themes and their repetitions and variations. The analysis will also aim to identify changes (if any) in various indicators that could be attributed to the intervention.

3. Ethics and Dissemination

The study was reviewed internally by APHRC's internal scientific review committee. Ethical approval for the project was obtained from the African Medical Research Fund's Ethical and Scientific Review Committee (AMREF-ESRC P279/2016). The research team has undergone the NIH training on protecting human research participants. We shall seek informed consent from all study participants. All survey data will be collected in privacy and will be treated with confidentiality. It will be made clear to participants from the onset that participation in the study is voluntary and that they may choose to withdraw from the study at any time and for whatever reasons without fear of penalty. The mPAMANECH datasets will be available to users (CHVs, clinicians, CHEWs, among others) based on assigned, but limited, rights to protect the identity of

study participants. Only the core research team will have access to all of this information. The entire dataset will be stored in the APHRC server.

The potential risks for study participants are limited to (i) data breaches ii) time spent on the interview and (iii) discomfort experienced due to particular questions that respondents may perceive as upsetting or personal. These potential risks will be carefully explained to each participant during the process of obtaining informed consent.

For the data collected on the phones and computers, once it is saved the data is relayed in real time to the APHRC server and no information is saved on the phone or the computer. The users will only be able to see summary data, without the participants' details. To further minimise the risk attached to data breaches following the loss of a smartphone, each phone will have a 4-digit pass code to enable the CHVs log into the phone. This code will become active after 3 minutes on non-use. The third level of security is the username and password on each device.

Plan for Communicating Findings of the Study:

Results obtained through this study will be made available to those who contributed information; the communities of Kamukunji and Embakasi. In addition,

i. The study team will conduct one major dissemination workshop in Kenya to share research findings with development partners, local NGOs, healthcare providers, activists, media houses, health professional societies, and policymakers.
ii. Findings of the study will be shared at local and international conferences with researchers and policy makers.
iii. We also expect to publish 3 peer-reviewed articles in Open Access scientific journals.

iv. The Policy Engagement and Communications (PEC) unit at APHRC will also use the findings of this study to produce policy briefs, fact sheets, and working papers, as well as newsletters, which will be shared with a wide range of stakeholders.

v. The findings of the study will also be shared through APHRC's website.

4. Discussion

Maternal and neonatal health are both national and global priorities given that maternal and neonatal health indicators have not appreciably improved over the Millennium Development Goals life-span. They remain aspirations in the Sustainable Development agenda. CHVs are a critical component of the health workforce bridging the gap between communities and the formal health system. They not only improve coverage and access to basic health services but are also usually available in locations where and at times when formal health services are unavailable or inadequate. Quality healthcare is largely supported by quality data. Kenya still faces challenges with its Health Management Information System. Inaccurate data as a result of poor documentation impair the country's planning processes. This project accords APHRC and its partners an opportunity to utilize funds that have been identified to respond to Kenya's needs; to improve maternal and newborn health.

The next steps of the project if the experiments under this grant are successful will include sharing the findings with the Nairobi City County and the funder and agreeing on the next phase

of implementation. The Ministry of Health, Nairobi, is keen to roll out the system county-wide subject to availability of funding. The project team will work with the consortium to generate evidence to support decision-making at whatever stage of implementation. These may include effectiveness in reducing adverse maternal and neonatal outcomes at national level, cost-effectiveness, process issues such as CHV motivation and efficiency among others.

Potential impediments to the intervention include possible technology failure, loss of equipment (phones) and CHV turnover; all of which could require revisions and adaptations in the work plan (e.g., quality assurance, insurance, and training). A potential harmful unintended consequence stems from the fact that CHVs are not medically trained and as such could make a decision to treat at home, rather than refer (even when the system advises otherwise) with possible negative health consequences for the mothers and their newborns. However, since the system allows health workers to access this data, they will be in-charge of following up on such cases to avoid unnecessary delays and such unintended consequences.

5. Conclusion

The study outlined in this protocol will assess the added value of using a CHV decision-support module of mPAMANECH in reducing maternal complications and newborn deaths in the informal settlements of Nairobi, Kenya. The study's findings will contribute to the body of knowledge on the effectiveness of mHealth innovations in improving maternal, newborn and child health services and outcomes in urban informal settlements. Successful execution of the protocol will generate evidence on the effectiveness, if any, of the system. Based on the positive lessons learned, this project will provide a system for adoption by the local and central governments, for resource limited communities.

6. Competing interests statement:

None declared.

7. Authors' contributions:

PB, CK, EK, AKZ conceived the project and its design and participated in refining the manuscript. MO contributed to the refining of the design. PB drafted the manuscript. All authors read and approved the final manuscript.

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Figure 1, Key Outcomes:

Domain of Inquiry	Key Outcome Indicators
Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	- Percentage time for which the system is down on a monthly basis - Number of CHVs effectively using the decision support tool - Proportion of CHVs able to identify at least 4 danger signs among neonates - Proportion of CHVs able to identify at least 2 post-partum complications - Percentage of correct referral decisions by CHVs for post-partum mothers with complications - Percentage of correct referral decisions by CHVs for neonates with danger signs - Proportion of pregnant women referred for ANC by CHVs - Proportion of mothers referred for PNC by CHVs
Determine the decision-support platform's effect on utilization of MNH services and MNH complications and deaths	- Proportion of women attending at least 4 ANCs - Proportion of all mothers attending at least 2 PNCs - Proportion of deliveries assisted by trained personnel - Percentage of women who accessed first ANC within the 1st trimester - Proportion of women referred for post-partum family planning - Proportion of newborns with at least one danger sign referred by CHVs - Proportion of low birth weight newborns referred - Proportion of women lost during follow up - Proportion of newborns lost during follow up

Figure 2, Theory of Change

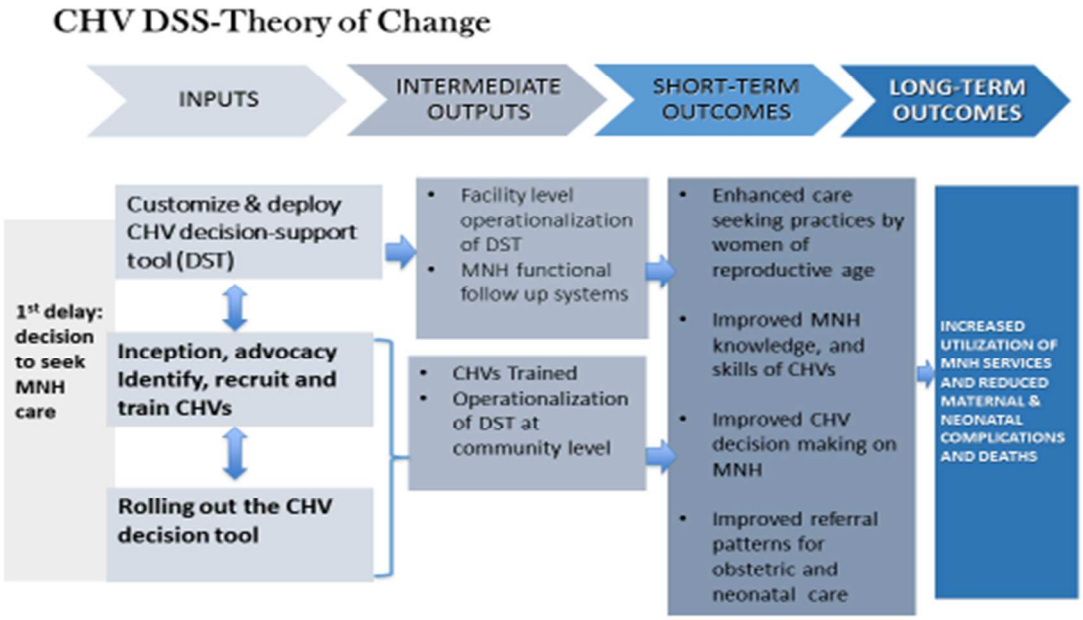

Figure 3, Mobile Data Gathering Platform

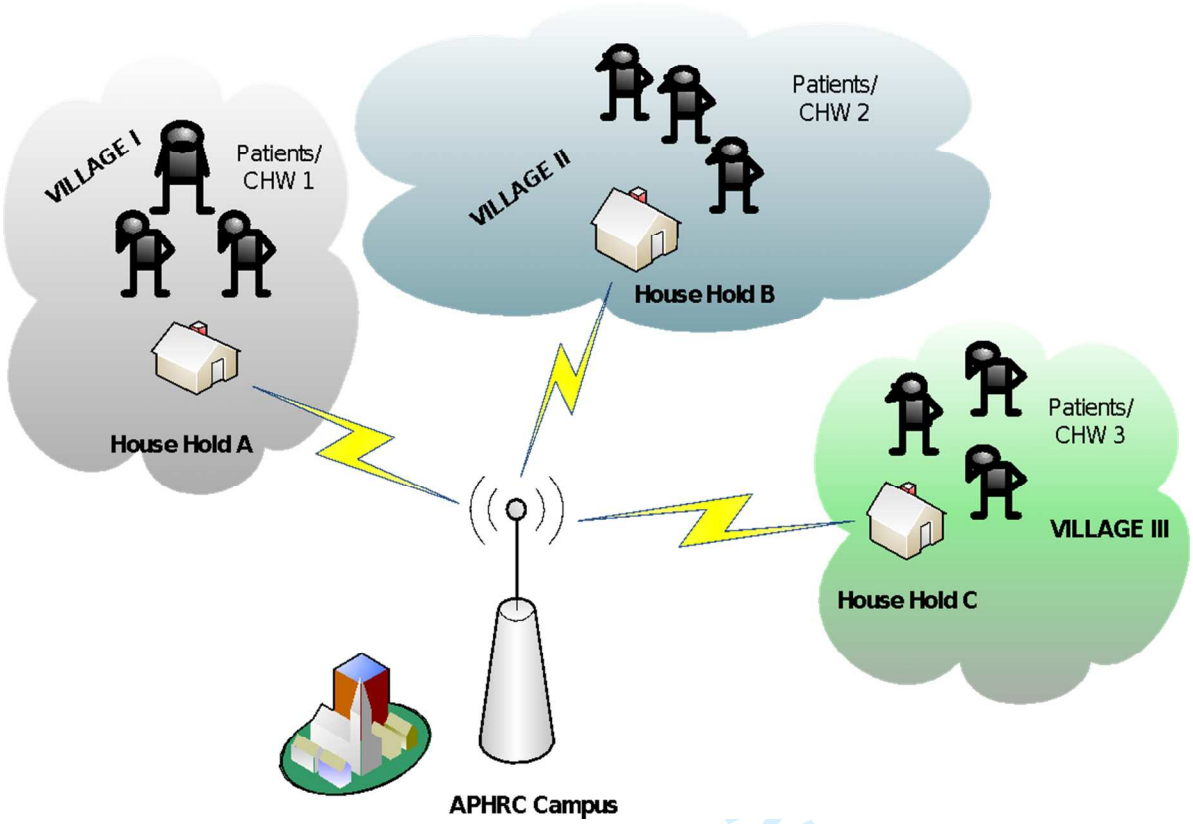

Figure 4: How the system works

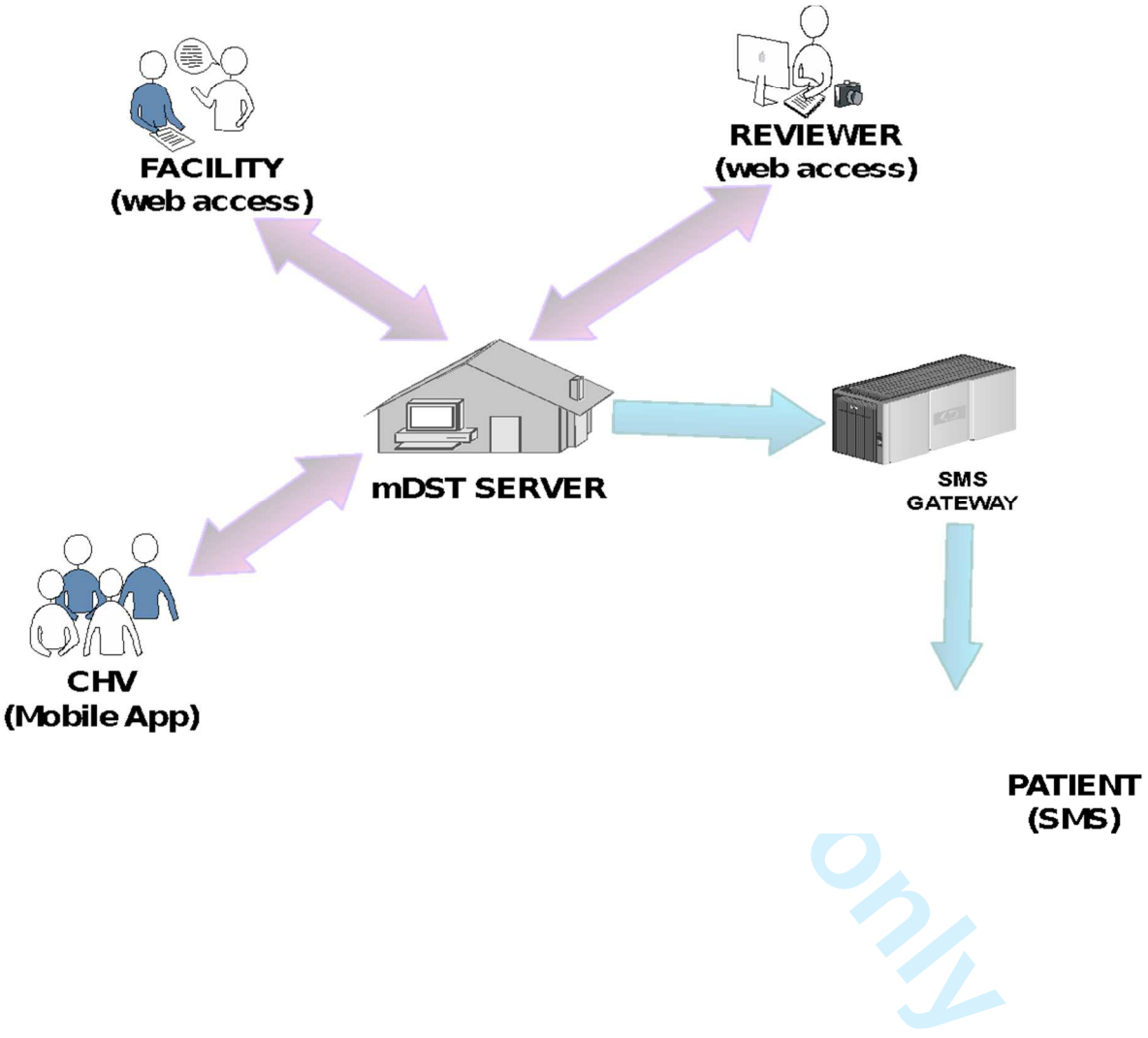

Figure 5, Project timeline

CHV Decision Support Application: Pilot study							
			2016	2017			
Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**
Inception period	■						
Seek ethical approval		■					
Baseline			■				
Recruit & train field team			■				■
Conduct Baseline			■				
Conduct Endline			■				■
Data cleaning			■				■
Data analysis and interpretation			■				■
Scientific write up on baseline			■				■
Scientific write up on endline			■				■
Develop Decision Support System		■	■				
Training of CHWs			■				
Training of DHMTs			■				

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The role of a decision-support smartphone application in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-experimental research protocol

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The role of a decision-support smartphone application in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-experimental research protocol

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Abstract:

Introduction;

Improving maternal and newborn survival remain major aspirations for many countries in the global south. Slum settlements, a result of rapid urbanization in many developing countries including Kenya, exhibit high levels of maternal and neonatal mortality. There are limited referral mechanisms for sick neonates and their mothers from the community to health care facilities with ability to provide adequate care. In this study we specifically plan to develop and assess the added value of having community health volunteers (CHVs) use smartphones to identify and track mothers and children in a bid to reduce pregnancy-related complications and newborn deaths in the urban slums of Kamukunji sub-County in Nairobi, Kenya.

Methods and analysis;

A quasi-experimental study. We are implementing an innovative, m-health application known as mobile-Partnership for Maternal, Newborn and Child Health (mPAMANECH) which uses dynamic mobile phone and web-portal solutions, to enable CHVs make timely decisions on the best course of action in their management of mothers and newborns at community level. The application is based on existing guidelines and protocols in use by CHVs. Currently, CHVs, conduct weekly home visits and make decisions from memory or using unwieldy manual tools, and thus prone to making errors. mPAMANECH has an in-built algorithm that makes it easier, faster and more likely for CHVs to make the right management decision. We are working with a network of selected CHVs and maternity centres to pilot test the tool. To measure the impact of the intervention, baseline, midline and endline surveys will be conducted. Data will be obtained through qualitative and quantitative methods.

Ethics and dissemination.

Ethical approval for the study was obtained from the African Medical Research Foundation. Key messages from the results will be packaged and disseminated through meetings, conference presentations, reports, factsheets and academic publications to facilitate uptake by policy makers.

Keywords: Decision-Support; Community Health Volunteers, Maternal and Newborn Health; Slums; Kenya

Strengths and Limitations

- The project seeks to address a critical challenge in the health care system in a slum context: identification and referral of ill mothers and newborns.

- It utilises the existing CHV work tools and mobile phone technology to show how an evidence based intervention can improve health outcomes at community level.

-A potential harmful unintended consequence stems from the fact that CHVs are not medically trained and as such could make a decision to treat at home, rather than refer (even when the system advises otherwise) with possible negative health consequences for the mothers and their newborns.

-However, since the system allows health workers to access this data, they will be in-charge of following up on such cases to avoid unnecessary delays and such unintended consequences.

1. Introduction:

Annually, close to 300,000 women die from maternal causes, 3.3 million children are stillborn while an additional 3.3 million die within the first month of life [1-3]. A vast majority of these deaths occur in sub-Saharan African and South Asia. Most maternal and newborn deaths are due to causes directly related to pregnancy and childbirth [1, 2, 4]. Most of these causes are preventable with existing cost-effective interventions. Kenya has made some progress in improving maternal and newborn survival over the years. Maternal mortality has progressively reduced from 488/100,000 to 362/100,000 between 2008/09 and 2014. Neonatal mortality has reduced from 31 to 22 deaths per 1000 live births, between 2008/9 and 2014, [5, 6]. Neonatal deaths account for about 60% of all infant deaths in Kenya [6]. Despite the existence and knowledge about simple strategies and techniques to reduce maternal and newborn deaths, these interventions are not up to scale due to inadequacy of health care facilities, trained personnel, information, poor referral systems and pervasive poverty.

Community Health Volunteers

The need to ensure universal health coverage amidst a global health care workers crisis saw the identification of community health volunteers (CHVs) as a critical alternative and workforce at the community level [7]. CHVs are volunteers identified from communities that they reside in and offered a few days' basic training based on a set curriculum before they are assigned community health promotion roles. CHVs belong to established community units with a responsibility of making weekly home visits to households within designated geographical areas. CHVs were identified under Kenya's Community Health Strategy as a means of alleviating the healthcare worker crisis. To date, CHVs continue to bridge the critical gap between communities and the formal health system, and many positive lessons have been learned in Kenya and other

parts of the world [8-10]. CHVs in Kenya, like in many emerging economies, are responsible for the majority of grassroots health care delivery, and as such, continue to play a very critical role in primary health care delivery.

Decision-support systems

Clinical decision support (CDS) refer to tools used to improve decision-making in the patient care workflow [11]. CDS provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care [12, 13]. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools [14]. They are beneficial in reducing errors, increasing quality of care and improving efficiency.

Mobile technology for health

Mobile technologies have the potential to bridge systemic gaps needed to improve access to and use of health services, particularly among underserved populations [15]. Worldwide, the use of mobile and/or electronic devices to support both medical and public health practice and research (mHealth) is increasingly being appreciated [16-19]. The high and ever growing mobile penetration coupled with investments from technology companies that provide accessible platforms onto which innovations can establish and offer value-based products [17]. Innovations include mobile phone platforms/applications and micro-insurance packages. Given the nature and tight timeframes of most obstetric and neonatal emergencies, which more often than not demand quick access to quality care at short notice, mobile phone innovations are a cheap and fast solution especially in areas with poor healthcare infrastructure which have shown

improvements in maternal and child health outcomes [19, 20]. The majority of innovations on the market are tailored towards promoting reproductive, maternal, and child health [16, 21]. In addition, various projects have been designed and evaluated on CHVs use of mobile technology to deliver interventions [22, 23]. Decision-support systems have been highlighted as a critical factor in reducing errors in evidence-based clinical practice. For clinicians, studies have demonstrated that computerized decision support systems can be used to improve compliance to practice guidelines [12, 13]. Given the limited training obtained and skills that the CHVs possess, coupled with the distances they work from the clinical settings mobile information technologies tools enable them to provide much needed health services.

Over the last decade, more mobile and electronic information tools have been developed, tested and implemented with CHVs to support their work roles. The tools help the CHVs in surmounting challenges such as lack of appropriate work tools and inadequate supportive supervision and training [22, 23]. These tools have been instrumental in improving access to care by marginalized population groups subjected to stigma and those in hard to reach areas by reducing both time and cost of travel. As such, research on CHVs' use of mHealth tools in important. Several pilot projects, utilizing multiple designs and measures have been implemented. The projects have reported improvements in services rendered by CHVs and the related health outcomes for communities. In sub-Saharan Africa, most of the interventions have demonstrated improvements in the CHVs' delivery of maternal, newborn and child health, Tuberculosis and sexual and reproductive health services, among others [20, 22]. The innovations largely use SMS and hotlines enabling mothers to access vital information and timely referrals as a result of better and faster communication and transport. Available evidence

shows the usefulness of mHealth tools in facilitation of compliance with practice guidelines and process improvement [22]. However, many of the interventions have been limited methodologically by their inability to demonstrate effectiveness and or impact related to patient outcomes. In addition a lack of use of nationally accepted guidelines and open source tools limits the scalability of these interventions. In addition, available literature does not provide cost estimates necessary for delivery of program targets. Furthermore, a top to bottom approach that does not incorporate the ideas of the CHVs in the development of the tools is a major impediment as successful projects use the CHVs as experts in the design and management of their interventions [22].

The African Population and Health Research Center (APHRC) has implemented a health systems strengthening project, Partnership for Maternal, Newborn and Child Health (PAMANECH) in Korogocho and Viwandani informal settlements of Nairobi, Kenya [24]. The project sought to strengthen the healthcare delivery system in the urban informal settlements to be more responsive to the health needs of mothers and their children through enhanced service delivery public-private partnerships. In a bid to improve the health management information system, an innovative mHealth application, was developed. The mPAMANECH application was developed as an integrated data capture tool running as a mobile app with selected reporting forms for CHVs in Kenya. It operates in an interconnected network of CHVs and health facilities within a defined local system. It is designed to replace the numerous paper-based forms that do not allow integration of patient data from the community to the health facility and back for better referral and management of patients. This system has been seen to improve the reporting abilities of

CHVs as it is less cumbersome than the paper-based system and enhanced data quality as it has a function that limits saving data until all necessary fields are filled in [25]. In addition, the CHEW can access a CHV's data remotely without having to wait for the end of the month for the CHV summaries. The desire to improve the functionality of the existing system to include a decision support function provides the basis on the new project.

This project attempts to bridge this gap by incorporating CHV views, utilizing the tools approved by the Ministry of Health and allowing for assessment of health outcomes in the design and implementation of the project. The decision support system is developed from open source tools. In addition, a cost effectiveness analysis would be conducted to inform county and national implementation plans regarding the necessary investments for set up and maintenance.

2. Methods and Analysis

Research Objectives

The overall objective of the proposed work is to develop and validate a decision-support algorithm within a mHealth application in improving maternal and newborn health outcomes in urban slums in Kamukunji sub-County in Nairobi, Kenya. The project seeks to assess the added value of using a CHV decision-support module of mPAMANECH in reducing prenatal and postnatal maternal complications and newborn deaths.

Specifically the project will assess (i) the feasibility and acceptability of using a decision-support module of mPAMANECH and (ii) whether decision-support platform contributes to increase in utilization of MNH services. We will measure several outcomes, *figure 1* related to the two specific objectives, above. The outcome measures have been used in different studies assessing CHV abilities to assess and make referrals [26, 27].

Conceptual framework, Theory of Change and Operationalization

Our innovation centres around enhancing the functionality and utility of the current mPAMANECH application to include a community decision support tool to be used within a local system comprised of CHVs and five maternity centres serving five slum settlements in Nairobi. The decision-support module in the mPAMANECH application will supplement the existing MNCH data capture modules and help in the identification of high risk facing pregnant women, new mothers and newborns with complications, and to make timely and correct decisions on referral for cases that need intervention. The main beneficiaries are pregnant women (over 24 weeks), mothers in the immediate post-partum period and their newborns (up to 28 days old).

The use of CHVs in delivering the mobile phone based intervention and follow up by the SCHMT will ensure sustained support and adherence to the intervention during pregnancy, immediate postpartum and in the neonatal period. The mPAMANECH has the official 100, 513, 514 and 515 forms in use by CHVs and Community Health Extension Workers (CHEWs), who supervise the CHVs [28, 29]. A dedicated team of CHEWs will ensure that the intervention is delivered as expected and non-adherence captured and documented. CHV adherence will be measured by the CHEWs who will provide additional support, correcting CHVs but not forms. They will be used to sample some of the CHVs' work. For each woman or newborn with referral symptom, seen at household level, we will compare the CHEW's assessment to that of the CHV in regard to the proportion of cases for whom CHWs identified and indicated correctly on their forms as requiring a referral, and the proportion for whom a written referral was provided. This is beneficial because the review meetings are at the end of the month. The sampling of the work

will enable on-going supportive supervision in order to improve the quality of the CHVs work. In addition, more assessment will be made for those referrals that will be seen at health facility level, comparing danger signs identified by the CHV to those seen by the clinician.

The attributes of the solution include: 1) Use of any android devices - the entire application is operable on phones, tablets or desktops/laptops; 2) Within a linked local system – messaging is delivered internally via the portal and no extra network charges are required for messaging; 3) The application is bandwidth light and takes about 100 Kenya shillings a month per user, based on local data bundle charges. The application can work offline and auto-synchronize as soon as network connectivity is re-established; 4) Updates are automated and there is no need for an IT expert to have physical access to the device to execute a software patch or change; 5) The application has security features that protect users' confidentiality and limit access to a closed but linked local system of health facilities and CHVs with varied access rights; 6) It has the ability to limit use of other phone functionality to only allow this application to run. This helps prevent abuse of the device and promote saving on bandwidth. We aim to enhance the functionality and utility of the current mPAMANECH application to include a community decision support tool to be used within a local system comprised of selected CHVs and five maternity centres serving slum settlements in Nairobi. In the 'Operationalisation' section, we describe more on how the decision support system is expected to work.

From our proposed theory of change, *figure 2*, we anticipate that the decision support module of mPAMANECH will assist the CHVs in the identification of high risk pregnant women, new mothers and newborns with complications, and to make timely and correct decisions on referral for cases that need intervention. With the improved knowledge and skills possessed by the CHVs more women and neonates in need of health care will be identified and referred to the necessary health facilities. As a result, there will be increase utilisation of maternal and neonatal health services and reduced maternal and neonatal complications and deaths.

Operationalisation of the Decision Support System

The mobile decision support system (mDSS) mobile application (app) is an Android app that installs from the phone and runs as an application, *figure 3*. The app will be hosted at Google store and is accessible for download via the internet automatically to the user handset.

Once installed, the handset and the application will be configured with the credentials of the CHV including username and password, which are linked with the operating phone number. This setup allows the system to register and associate collected records to the respective CHV; useful for reporting and analysis purposes.

The CHVs will be provided with a mobile phone running the mHealth app for data collection which is then relayed to the head office at APHRC Campus. When visiting households for data collection, by initiating a new record the system automatically picks the geolocation of the household and associates it with the record.

The CHV will complete the respective form and save the information at any stage on the handset. This method allows the CHV to continue collecting more information and only submit the completed form to the server over the internet. Where the handset detects that internet connectivity is not available for one reason or the other, the completed forms will be stored in the phone and only be relayed to the server when the connectivity is established. Because the application is in communication with the server in real-time, any update of the data is immediately available to the CHVs. The application is preconfigured with danger signs for both mothers and newborns as defined by the WHO [30]. When any of the danger signs is picked by the system, the CHV is immediately prompted to refer the patient to a facility within the network.

The system is to be set up in such a way that the CHV will not be allowed to proceed and complete the forms until the referral is done. The patient's information will be available to all the facilities within the network and he/she will be able to visit any of the networked facilities for treatment. This information is also relayed to the rest of the other facilities and a record of the visit is kept in the server. Within 24 hours if the patient has not been seen in any of the networked facilities, an SMS message is relayed to the respective CHV handset. At this point, the CHV should follow up with the patient to inquire about their condition and whether they chose to honour the referral to a facility outside the network or not.

When the patient visits a facility within the network, using the household number and the name he/she will be easily identified and treated. The clinician is able to record the treatment in the patient's information, which is recorded in the server.

Both the CHV and the clinician's information are available to a reviewer in real time from the web. The reviewer's role would be to assess the CHV's reason for referral and the clinician's final diagnosis for correctness. The feedback from the reviewer will be available and shared on a monthly basis during review meetings. Every week, the CHEW, will randomly sample referrals made by each CHV to assess their correctness. This will be compared with the 'reviewers' summary.

mDSS Solution- Key Features (*figure 4*)

CHV (mobile App)

Through this app, the mDSS data collection tools are accessible on the CHV mobile handset. It allows for completion and submission of the information to the mDSS Server.

mDSS Server

A database driven web application that acts as a host for the collected information. It also has a web interface for data manipulation by the facility healthcare worker(s) and reviewer.

The mDSS server application incorporates an application logic component that connects with the SMS and email gateways. This allows for real-time communication of certain critical indicators to the respective recipients. For example, where a patient has not shown up at the referred facility, the CHV will be alerted.

Facility (web access)

This module is accessible at the facility via the web. The application allows the clinician to treat the patient and record the treatment. The facility portal is accessible by facility staff to manage

referrals. The "Messages" to alert the CHVs are to be integrated with WhatsApp for effective message delivery over the same mobile phone.

Reviewer (web access)

This module is also accessible via the web, and provides the reviewer a view to assess both the CHV referral report and the clinician's diagnosis. It is based on this analysis that a decision is measured.

Null hypothesis:

Usage of a CHV decision-support module does not have an effect on utilization of MNH services.

Study Design and Sampling Strategy

a. **Study Design**

To answer the question on effect of the decision support system, we will use a quasi-experimental design with pre and post assessments to determine the impact, if any, on the MNH services and selected health indicators.

We will work with three community units (CUs) from which a group of 50 CHVs will serve as the intervention group. Three CUs in Embakasi sub-County, with 50 CHVs will serve as the control. The CUs in the control group will be geographically distant from the intervention site to limit contamination. The control group will be facilitated within the normal standard of practice which includes paper-based reporting. The idea is to compare access to MNH services, referral practices and MNH outcomes between those with a decision-support tool with those working with traditional paper-based tools.

We will conduct a baseline survey and an end-line at least one year after the full implementation of the intervention. The control group will be assessed at the same time as the surveys are being conducted in the intervention group. To strengthen the case for causal inference we will also do a systematic monitoring and documentation of the intervention based on our theory of change. The monitoring and documentation will also capture any other contextual factors that may influence the same outcomes as our intervention.

To answer the question on feasibility, we will conduct a mixed methods assessment of the CHVs and CHEWs. Qualitative assessments of their current work experiences with the paper based system as well as after the introduction of the mobile based system will be conducted. We will assess ease of use, challenges experienced and opportunities for improvement. These will be triangulated with their HMIS reports (paper and electronic).

b. **Study Setting**

The intervention site covers informal settlements in Kamukunji sub County, which, like other slums, are characterized by poverty, poor coverage of social services and poor health outcomes. We will identify CUs and 5 facilities that serve the CUs. Embakasi sub-County will serve as the control site. We will identify three CUs to serve as controls.

c. **Sampling**

The CUs in the intervention and control groups will be purposively selected based on discussions with the sub-County community strategy coordinators for Kamukunji and Embakasi. We will select CUs with the worst health indicators for both the intervention and control groups, including those serving informal settlements, and with more likelihood to benefit from the intervention.

For the population based surveys:

➢ **Quantitative study**

- *Study population*

The project will target households with women of reproductive age (15-49 years) in the informal settlements of Kamukunji and Embakasi. It will also target health care providers in five selected health facilities as well as the sub-County Health Management teams of Kamukunji, Embakasi, Makadara and Nairobi City County.

A quantitative survey will be conducted focussing mainly on maternal and newborn health and family planning services.

- *Sample size estimation*

The key outcome of interest is correct referral practices. Using proportion of neonates with at least one danger sign referred by CHVs as the indicator, since it is representative of the target population, the total sample size for each group has been estimated as 173 (346 in total). Using a difference in proportion 13.3 % for neonates with danger signs referred (rising from 16.7 to 30%), at 95% CI for 80% power and sample proportions of 50% in the intervention and 40% in the control groups, respectively, we came up with a sample size of 315. Accounting for a potential non-response rate of 10% based on previous studies in similar study populations, the effective sample size is 346. Using correct decisions made by CHVs (one of the indicators to be measured), the sample size was estimated as 199. 346 is therefore an appropriate sample size.

- *Sampling procedure*

To measure feasibility and acceptability, all the CHVs in the intervention site will be assessed, in addition to an audit of the functionality of the system. We will measure the percentage time for which the system is down on a monthly basis **(Numerator:** Number of times (in minutes) when the system is down. **Denominator**: Total active time in a month. Down time defined as 30

minutes of hanging and Active time as time without hitches), proportion of CHVs effectively using the decision support system (Within the system, on a quarterly basis we will be able to generate reports on decisions, correct or otherwise, made by the CHVs. These will also be compared to the control site that will only have a paper based system of data collection), and the experiences of the CHVs and the mothers with the mobile based system. These will be compared to the investment.

To answer the question on effect of the system on utilisation of services, the data above will be triangulated with data from the **mPAMANECH application which already has an integrated data collection module**, the data generated by the CHVs and participating health facilities will be retrieved, cleaned and analyzed to derive estimates of the main outcome of interest – correct referral practices. In addition, these data will be triangulated with other sources such as the CHV monthly reports and health facility HMIS. A system of random numbers generated using STATA will be used to select the respondents based on a sampling frame that is going to be informed by an updated household register in the selected community units.

➢ **Qualitative study**

We will use focus group discussions (FGDs) and in-depth interviews among the direct project beneficiaries and CHVs, and key informant interviews with key actors (sCHMTs, health providers, CHVs and community leaders). Participants will be purposively selected to represent the different stakeholders as well as different health service user categories (users and non-users).

Data from the quantitative survey will be used to identify women who have or not used specific MNH services and these will be approached to participate in the focus group discussions or in-

depth interviews. Other respondents will be identified based on their position in the community and their role in the project.

Data Collection, Management and Analysis

Data collection:

We will conduct a baseline survey and an end-line at least one year after the full implementation of the intervention. The control group will be assessed at the same time as the surveys are being conducted in the intervention group. To strengthen the case for causal inference we will also do a systematic monitoring and documentation of the intervention based on our theory of change. The monitoring and documentation will also capture any other contextual factors that may influence the same outcomes as our intervention. The effects and impact of the project will be determined by triangulating data and information from different sources, examining trends where possible, and trying to find and support explanations for the observed findings.

Our key data sources will be the following: household surveys, routine HMIS data and qualitative assessments (interviews and focus group discussions).

We will conduct simple and multiple logistic regression analyses comparing differences in the proportions of women in reproductive age and children under-five at baseline and end line for variables like antenatal coverage, vaccination coverage, skilled birth attendance, among others, (See figure 1 for key indicators). These analyses will control for any differences in the samples (if any) at the two time points as well as the contribution of contextual factors that may have occurred in the course of the implementation.

mPAMANECH data: Descriptive data in terms of referrals by, diagnostic decisions, among others, will be summarised using means and standard deviations for the parametric continuous data and medians with inter-quartile ranges for the non-parametric data. Categorical data such as referrals by age and gender will be summarised using proportions and percentages.

Qualitative data: Qualitative data will be transcribed and saved in Word format. Transcribed word files will be imported into NVIVO software (QSR International Pty Ltd) for coding and further analysis. Analysis across all transcripts will be conducted using a constant comparative method to identify themes and their repetitions and variations. The analysis will also aim to identify changes (if any) in various indicators that could be attributed to the intervention.

3. Ethics and Dissemination

The study was reviewed internally by APHRC's internal scientific review committee. Ethical approval for the project was obtained from the African Medical Research Fund's Ethical and Scientific Review Committee (AMREF-ESRC P279/2016). The research team has undergone the NIH training on protecting human research participants. We shall seek informed consent from all study participants. All survey data will be collected in privacy and will be treated with confidentiality. It will be made clear to participants from the onset that participation in the study is voluntary and that they may choose to withdraw from the study at any time and for whatever reasons without fear of penalty. The mPAMANECH datasets will be available to users (CHVs, clinicians, CHEWs, among others) based on assigned, but limited, rights to protect the identity of study participants. Only the core research team will have access to all of this information. The entire dataset will be stored in the APHRC server.

The potential risks for study participants are limited to (i) data breaches ii) time spent on the interview and (iii) discomfort experienced due to particular questions that respondents may perceive as upsetting or personal. These potential risks will be carefully explained to each participant during the process of obtaining informed consent.

For the data collected on the phones and computers, once it is saved the data is relayed in real time to the APHRC server and no information is saved on the phone or the computer. The users will only be able to see summary data, without the participants' details. To further minimise the risk attached to data breaches following the loss of a smartphone, each phone will have a 4-digit pass code to enable the CHVs log into the phone. This code will become active after 3 minutes on non-use. The third level of security is the username and password on each device.

Plan for Communicating Findings of the Study:

Results obtained through this study will be made available to those who contributed information; the communities of Kamukunji and Embakasi. In addition,

i. The study team will conduct one major dissemination workshop in Kenya to share research findings with development partners, local NGOs, healthcare providers, activists, media houses, health professional societies, and policymakers.
ii. Findings of the study will be shared at local and international conferences with researchers and policy makers.
iii. We also expect to publish 3 peer-reviewed articles in Open Access scientific journals.
iv. The Policy Engagement and Communications (PEC) unit at APHRC will also use the findings of this study to produce policy briefs, fact sheets, and working papers, as well as newsletters, which will be shared with a wide range of stakeholders.

v. The findings of the study will also be shared through APHRC's website.

4. Discussion

Maternal and neonatal health are both national and global priorities given that maternal and neonatal health indicators have not appreciably improved over the Millennium Development Goals life-span. They remain aspirations in the Sustainable Development agenda. CHVs are a critical component of the health workforce bridging the gap between communities and the formal health system. They not only improve coverage and access to basic health services but are also usually available in locations where and at times when formal health services are unavailable or inadequate. Quality healthcare is largely supported by quality data. Kenya still faces challenges with its Health Management Information System. Inaccurate data as a result of poor documentation impair the country's planning processes. This project accords APHRC and its partners an opportunity to utilize funds that have been identified to respond to Kenya's needs; to improve maternal and newborn health.

The next steps of the project if the experiments under this grant are successful will include sharing the findings with the Nairobi City County and the funder and agreeing on the next phase of implementation. The Ministry of Health, Nairobi, is keen to roll out the system county-wide subject to availability of funding. The project team will work with the consortium to generate evidence to support decision-making at whatever stage of implementation. These may include

effectiveness in reducing adverse maternal and neonatal outcomes at national level, cost-effectiveness, process issues such as CHV motivation and efficiency among others.

Potential impediments to the intervention include possible technology failure, loss of equipment (phones) and CHV turnover; all of which could require revisions and adaptations in the work plan (e.g., quality assurance, insurance, and training). A potential harmful unintended consequence stems from the fact that CHVs are not medically trained and as such could make a decision to treat at home, rather than refer (even when the system advises otherwise) with possible negative health consequences for the mothers and their newborns. However, since the system allows health workers to access this data, they will be in-charge of following up on such cases to avoid unnecessary delays and such unintended consequences.

5. Conclusion

The study outlined in this protocol will assess the added value of using a CHV decision-support module of mPAMANECH in reducing maternal complications and newborn deaths in the informal settlements of Nairobi, Kenya. The study's findings will contribute to the body of knowledge on the effectiveness of mHealth innovations in improving maternal, newborn and child health services and outcomes in urban informal settlements. Successful execution of the protocol will generate evidence on the effectiveness, if any, of the system. Based on the positive lessons learned, this project will provide a system for adoption by the local and central governments, for resource limited communities.

6. Competing interests statement:

None declared.

7. Authors' contributions:

PB, CK, EK, AKZ conceived the project and its design and participated in refining the manuscript. MO contributed to the refining of the design. PB drafted the manuscript. All authors read and approved the final manuscript.

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Figure 1, Key Outcomes:

Domain of Inquiry	Key Outcome Indicators
Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	- Percentage time for which the system is down on a monthly basis - Number of CHVs effectively using the decision support tool - Proportion of CHVs able to identify at least 4 danger signs among neonates - Proportion of CHVs able to identify at least 1 danger sign among neonates - Proportion of CHVs able to identify at least 2 post-partum complications - Percentage of correct referral decisions by CHVs for post-partum mothers with complications - Percentage of correct referral decisions by CHVs for neonates with danger signs - Proportion of pregnant women referred for ANC by CHVs - Proportion of mothers referred for PNC by CHVs
Determine the decision-support platform's effect on utilization of MNH services	- Proportion of women attending at least 4 ANCs - Proportion of all mothers attending at least 2 PNCs - Proportion of deliveries assisted by trained personnel - Percentage of women who accessed first ANC within the 1st trimester - Proportion of women referred for post-partum family planning - Proportion of newborns with at least one danger sign referred by CHVs - Proportion of low birth weight newborns referred - Proportion of women lost during follow up - Proportion of newborns lost during follow up

Figure 1: Key Outcome measures

30x39mm (300 x 300 DPI)

Figure 2, Theory of Change

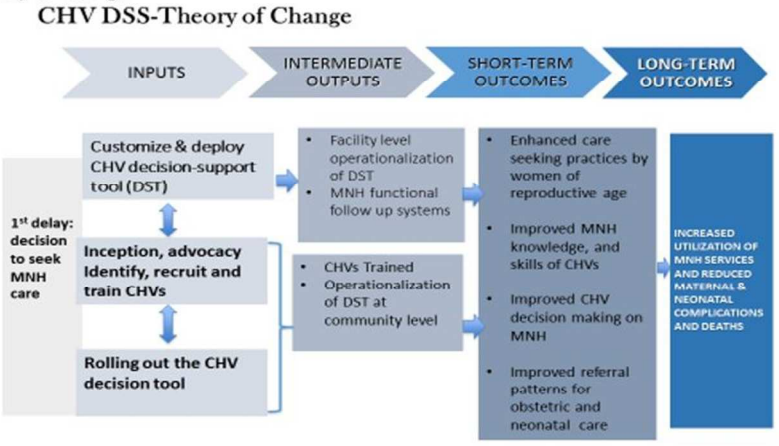

Figure 2: Theory of change

78x40mm (300 x 300 DPI)

Figure 3, Mobile Data Gathering Platform

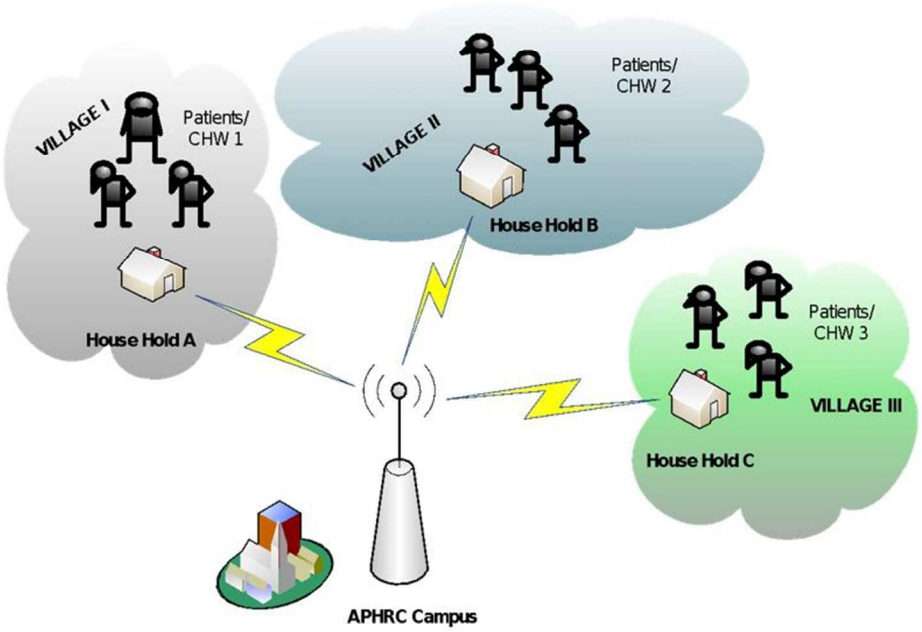

Figure 3: The system

72x53mm (300 x 300 DPI)

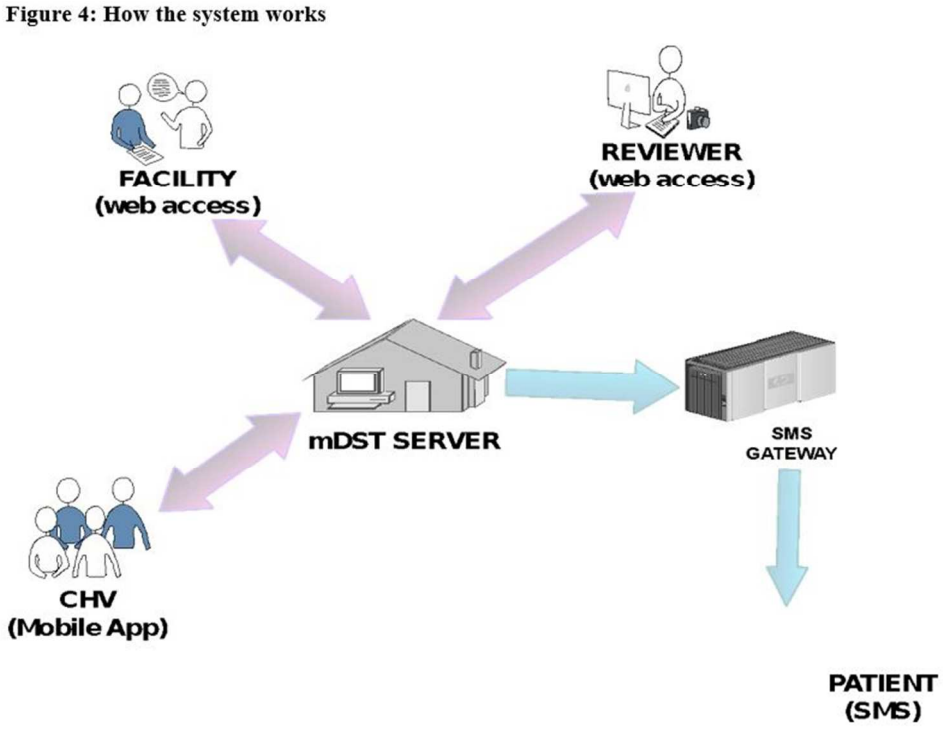

Figure 4: How the system works

70x53mm (300 x 300 DPI)

Figure 5, Project timeline

CHV Decision Support Application: Pilot study

			2016	2017			
Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**
Inception period							
Seek ethical approval							
Baseline							
Recruit & train field team							
Conduct Baseline							
Conduct Endline							
Data cleaning							
Data analysis and interpretation							
Scientific write up on baseline							
Scientific write up on endline							
Develop Decision Support System							
Training of CHWs							
Training of DHMTs							

Figure 5: Project timeline

54x48mm (300 x 300 DPI)

Project Title	Using a Decision-Support Smartphone application to enhance Community Health Volunteers' effectiveness in reducing Maternal complications and reducing Newborn Deaths in the informal settlements of Nairobi,	
	Objectively Verifiable Indicators	
Domain of inquiry	**Indicators**	**Method of calculation**
1. Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	Percentage time for which the system is down on a monthly basis	**(Numerator:** Number of times (in minutes) when the system is down **Denominator**: Total active time in a month. Down time defined as 30 minutes of hanging and Active time as time without hitches) * 100
	Number of CHVs effectively using the decision support tool	**Numerator:** Number of CHVs able to either correctly refer or manage clients at home (target is 50 CHVs). Within the system, on a quarterly basis we will be able to generate reports on decisions made by the CHVs. These will also be compared to the control site that will only have a paper based system of data collection
	Proportion of CHVs able to identify at least 4 danger signs among neonates	**Numerator:** Number of CHVs able to identify at least 4 danger signs among neonates (aged upto 28 days). **Denominator:** Total number of CHVs in the selected CUs (total 50 CHVs).
	Proportion of CHVs able to identify at least 2 post-partum complications	**Numerator:** Number of CHVs able to identify at least 2 post-partum complications. **Denominator :** Total number of CHVs in selected Cus (total 50 CHVs)
	Percentage of correct referral decisions by CHVs for post-partum mothers with complications	**(Numerator:** Number of correct referrals by CHVs for post-partum mothers with complications. **Denominator:** Total number of postpartum women referred.)*100
	Percentage of correct referral decisions by CHVs for neonates (aged upto 28 days) with danger signs	**(Numerator:** number of correct referrals by CHVs for neonates (aged upto 28 days) with danger signs. **Denominator:** Total number of neonate referrals)*100
	Proportion of pregnant women referred for ANC by CHVs	**Numerator:** Number of pregnant women referred for ANC to selected health facilities by CHVs **Denominator:** Total number of women-pregnant seen by CHVs
	Proportion of mothers referred for PNC by CHVs	**Numerator:** Number of post-delivery women referred for PNC to selected health facilities by CHVs. **Denominator:** Total number of deliveries in selected facilities and at home
2. Determine the decision-support platform's effect on utilization of MNH services		
	Proportion of women attending at least 4 ANCs	**Numerator:** Number of pregnant women attending 4 or more ANC visits in project sites. **Denominator:** Total number of pregnant women seeking ANC services in the selected health facilities
	Proportion of all mothers attending at least 2 PNCs	**Numerator:** Number of mothers attending at least 2 PNCs in project sites. **Denominator:** Total number of postpartum women seeking PNC services in the selected health facilities.
	Proportion of deliveries assisted by trained personnel	**Numerator:** Number of assisted deliveries by trained personnel (at home or at the facility). **Denominator:**Total number of deliveries in the facilities and CUs covered by project
	Percentage of women who accessed first ANC within the 1st trimester	**(Numerator:** Number of women attending the first ANC within the first semester. **Denominator:** Total number of women attending ANC in project sites)*100
	Proportion of women referred by CHVs for post-partum family planning	**Numerator:** Number of post-partum women referred and seen at facilities for family planning. **Denominator:**Total number of women referred in the facilities and Cus in project sites
	Proportion of newborns (aged upto 28 days) with atleast one danger sign referred by CHV	**Numerator:** Number of CHVs able to identify at least 4 danger signs among neonates (aged upto 28 days). **Denominator:** Total number of CHVs in the selected CUs (total 50 CHVs).
	Proportion of low birth weight newborns (< 2500g) referred	**Numerator:** Number of low birth weight newborns (< 2500g) referred to selected health facilities. **Denominator:** Total number of live birth weighted in selected facilities
	Proportion of women lost during follow up	**Numerator:** Number of women referred by CHVs who fail to report to the selected facilities. **Denominator:** Total number of women referred by CHV
	Proportion of newborns (aged upto 28 days) lost during follow up	**Numerator:** Number of newborns (aged upto 28days) who failed to report to selected facilities. **Denominator:** Total number of newborns (aged upto 28 days) referred by CHVs

BMJ Open

The role of a decision-support smartphone application in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-experimental research protocol

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The role of a decision-support smartphone application in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-experimental research protocol

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Abstract:

Introduction;

Improving maternal and newborn survival remain major aspirations for many countries in the global south. Slum settlements, a result of rapid urbanization in many developing countries including Kenya, exhibit high levels of maternal and neonatal mortality. There are limited referral mechanisms for sick neonates and their mothers from the community to health care facilities with ability to provide adequate care. In this study we specifically plan to develop and assess the added value of having community health volunteers (CHVs) use smartphones to identify and track mothers and children in a bid to reduce pregnancy-related complications and newborn deaths in the urban slums of Kamukunji sub-County in Nairobi, Kenya.

Methods and analysis;

A quasi-experimental study. We are implementing an innovative, m-health application known as mobile-Partnership for Maternal, Newborn and Child Health (mPAMANECH) which uses dynamic mobile phone and web-portal solutions, to enable CHVs make timely decisions on the best course of action in their management of mothers and newborns at community level. The application is based on existing guidelines and protocols in use by CHVs. Currently, CHVs, conduct weekly home visits and make decisions from memory or using unwieldy manual tools, and thus prone to making errors. mPAMANECH has an in-built algorithm that makes it easier, faster and more likely for CHVs to make the right management decision. We are working with a network of selected CHVs and maternity centres to pilot test the tool. To measure the impact of the intervention, baseline and endline surveys will be conducted. Data will be obtained through qualitative and quantitative methods.

Ethics and dissemination.

Ethical approval for the study was obtained from the African Medical Research Foundation. Key messages from the results will be packaged and disseminated through meetings, conference presentations, reports, factsheets and academic publications to facilitate uptake by policy makers.

Keywords: Decision-Support; Community Health Volunteers, Maternal and Newborn Health; Slums; Kenya

Strengths and Limitations

- The project seeks to address a critical challenge in the health care system in a slum context: identification and referral of ill mothers and newborns.

- It utilises the existing CHV work tools and mobile phone technology to show how an evidence based intervention can improve health outcomes at community level.

-A potential harmful unintended consequence stems from the fact that CHVs are not medically trained and as such could make a decision to treat at home, rather than refer (even when the system advises otherwise) with possible negative health consequences for the mothers and their newborns.

-However, since the system allows health workers to access this data, they will be in-charge of following up on such cases to avoid unnecessary delays and such unintended consequences.

1. Introduction:

Annually, close to 300,000 women die from maternal causes, 3.3 million children are stillborn while an additional 3.3 million die within the first month of life [1-3]. A vast majority of these deaths occur in sub-Saharan African and South Asia. Most maternal and newborn deaths are due to causes directly related to pregnancy and childbirth [1, 2, 4]. Most of these causes are preventable with existing cost-effective interventions. Kenya has made some progress in improving maternal and newborn survival over the years. Maternal mortality has progressively reduced from 488/100,000 to 362/100,000 between 2008/09 and 2014. Neonatal mortality has reduced from 31 to 22 deaths per 1000 live births, between 2008/9 and 2014, [5, 6]. Neonatal deaths account for about 60% of all infant deaths in Kenya [6]. Despite the existence and knowledge about simple strategies and techniques to reduce maternal and newborn deaths, these interventions are not up to scale due to inadequacy of health care facilities, trained personnel, information, poor referral systems and pervasive poverty.

Community Health Volunteers

The need to ensure universal health coverage amidst a global health care workers crisis saw the identification of community health volunteers (CHVs) as a critical alternative and workforce at the community level [7]. CHVs are volunteers identified from communities that they reside in and offered a few days' basic training based on a set curriculum before they are assigned community health promotion roles. CHVs belong to established community units with a responsibility of making weekly home visits to households within designated geographical areas. CHVs were identified under Kenya's Community Health Strategy as a means of alleviating the healthcare worker crisis. Under the strategy, CHVs are supervised by Community Health Extension Workers (CHEWs). To date, CHVs continue to bridge the critical gap between

communities and the formal health system, and many positive lessons have been learned in Kenya and other parts of the world [8-10]. CHVs in Kenya, like in many emerging economies, are responsible for the majority of grassroots health care delivery, and as such, continue to play a very critical role in primary health care delivery.

Decision-support systems

Clinical decision support (CDS) refer to tools used to improve decision-making in the patient care workflow [11]. CDS provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care [12, 13]. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools [14]. They are beneficial in reducing errors, increasing quality of care and improving efficiency.

Mobile technology for health

Mobile technologies have the potential to bridge systemic gaps needed to improve access to and use of health services, particularly among underserved populations [15]. Worldwide, the use of mobile and/or electronic devices to support both medical and public health practice and research (mHealth) is increasingly being appreciated [16-19]. The high and ever growing mobile penetration coupled with investments from technology companies that provide accessible platforms onto which innovations can establish and offer value-based products [17]. Innovations include mobile phone platforms/applications and micro-insurance packages. Given the nature and tight timeframes of most obstetric and neonatal emergencies, which more often than not demand quick access to quality care at short notice, mobile phone innovations are a cheap and

fast solution especially in areas with poor healthcare infrastructure which have shown improvements in maternal and child health outcomes [19, 20]. The majority of innovations on the market are tailored towards promoting reproductive, maternal, and child health [16, 21]. In addition, various projects have been designed and evaluated on CHVs use of mobile technology to deliver interventions [22, 23]. Decision-support systems have been highlighted as a critical factor in reducing errors in evidence-based clinical practice. For clinicians, studies have demonstrated that computerized decision support systems can be used to improve compliance to practice guidelines [12, 13]. Given the limited training obtained and skills that the CHVs possess, coupled with the distances they work from the clinical settings mobile information technologies tools enable them to provide much needed health services.

Over the last decade, more mobile and electronic information tools have been developed, tested and implemented with CHVs to support their work roles. The tools help the CHVs in surmounting challenges such as lack of appropriate work tools and inadequate supportive supervision and training [22, 23]. These tools have been instrumental in improving access to care by marginalized population groups subjected to stigma and those in hard to reach areas by reducing both time and cost of travel. As such, research on CHVs' use of mHealth tools in important. Several pilot projects, utilizing multiple designs and measures have been implemented. The projects have reported improvements in services rendered by CHVs and the related health outcomes for communities. In sub-Saharan Africa, most of the interventions have demonstrated improvements in the CHVs' delivery of maternal, newborn and child health, Tuberculosis and sexual and reproductive health services, among others [20, 22]. The innovations largely use SMS and hotlines enabling mothers to access vital information and

timely referrals as a result of better and faster communication and transport. Available evidence shows the usefulness of mHealth tools in facilitation of compliance with practice guidelines and process improvement [22]. However, many of the interventions have been limited methodologically by their inability to demonstrate effectiveness and or impact related to patient outcomes. In addition a lack of use of nationally accepted guidelines and open source tools limits the scalability of these interventions. In addition, available literature does not provide cost estimates necessary for delivery of program targets. Furthermore, a top to bottom approach that does not incorporate the ideas of the CHVs in the development of the tools is a major impediment as successful projects use the CHVs as experts in the design and management of their interventions [22].

The African Population and Health Research Center (APHRC) has implemented a health systems strengthening project, Partnership for Maternal, Newborn and Child Health (PAMANECH) in Korogocho and Viwandani informal settlements of Nairobi, Kenya [24]. The project sought to strengthen the healthcare delivery system in the urban informal settlements to be more responsive to the health needs of mothers and their children through enhanced service delivery public-private partnerships. In a bid to improve the health management information system, an innovative mHealth application, was developed. The mPAMANECH application was developed as an integrated data capture tool running as a mobile app with selected reporting forms for CHVs in Kenya. It operates in an interconnected network of CHVs and health facilities within a defined local system. It is designed to replace the numerous paper-based forms that do not allow integration of patient data from the community to the health facility and back for better referral

and management of patients. This system has been seen to improve the reporting abilities of CHVs as it is less cumbersome than the paper-based system and enhanced data quality as it has a function that limits saving data until all necessary fields are filled in [25]. In addition, the CHEW can access a CHV's data remotely without having to wait for the end of the month for the CHV summaries. The desire to improve the functionality of the existing system to include a decision support function provides the basis on the new project.

This project attempts to bridge this gap by incorporating CHV views, utilizing the tools approved by the Ministry of Health and allowing for assessment of health outcomes in the design and implementation of the project. The decision support system is developed from open source tools. In addition, a cost effectiveness analysis would be conducted to inform county and national implementation plans regarding the necessary investments for set up and maintenance.

2. Methods and Analysis

Research Objectives

The overall objective of the proposed work is to develop and validate a decision-support algorithm within a mHealth application in improving maternal and newborn health outcomes in urban slums in Kamukunji sub-County in Nairobi, Kenya. The project seeks to assess the added value of using a CHV decision-support module of mPAMANECH in reducing prenatal and postnatal maternal complications and newborn deaths.

Specifically the project will assess (i) the feasibility and acceptability of using a decision-support module of mPAMANECH and (ii) whether decision-support platform contributes to increase in utilization of MNH services. We will measure several outcomes, *figure 1* related to the two specific objectives, above. The outcome measures have been used in different studies assessing

CHV abilities to assess and make referrals [26, 27]. Supplementary files 1, 2 and 3 show the quantitative and qualitative measures under study.

Conceptual framework, Theory of Change and Operationalization

Our innovation centres around enhancing the functionality and utility of the current mPAMANECH application to include a community decision support tool to be used within a local system comprised of CHVs and five maternity centres serving five slum settlements in Nairobi. The decision-support module in the mPAMANECH application will supplement the existing MNCH data capture modules and help in the identification of high risk facing pregnant women, new mothers and newborns with complications, and to make timely and correct decisions on referral for cases that need intervention. The main beneficiaries are pregnant women (over 24 weeks), mothers in the immediate post-partum period and their newborns (up to 28 days old).

The use of CHVs in delivering the mobile phone based intervention and follow up by the SCHMT will ensure sustained support and adherence to the intervention during pregnancy, immediate postpartum and in the neonatal period. The mPAMANECH has the official 100, 513, 514 and 515 forms in use by CHVs and CHEWs, who supervise the CHVs [28, 29]. A dedicated team of CHEWs will ensure that the intervention is delivered as expected and non-adherence captured and documented. CHV adherence will be measured by the CHEWs who will provide additional support, correcting CHVs but not forms. They will be used to sample some of the CHVs' work. For each woman or newborn with referral symptom, seen at household level, we will compare the CHEW's assessment to that of the CHV in regard to the proportion of cases for whom CHWs identified and indicated correctly on their forms as requiring a referral, and the

proportion for whom a written referral was provided. This is beneficial because the review meetings are at the end of the month. The sampling of the work will enable on-going supportive supervision in order to improve the quality of the CHVs work. In addition, more assessment will be made for those referrals that will be seen at health facility level, comparing danger signs identified by the CHV to those seen by the clinician.

The attributes of the solution include: 1) Use of any android devices - the entire application is operable on phones, tablets or desktops/laptops; 2) Within a linked local system – messaging is delivered internally via the portal and no extra network charges are required for messaging; 3) The application is bandwidth light and takes about 100 Kenya shillings a month per user, based on local data bundle charges. The application can work offline and auto-synchronize as soon as network connectivity is re-established; 4) Updates are automated and there is no need for an IT expert to have physical access to the device to execute a software patch or change; 5) The application has security features that protect users' confidentiality and limit access to a closed but linked local system of health facilities and CHVs with varied access rights; 6) It has the ability to limit use of other phone functionality to only allow this application to run. This helps prevent abuse of the device and promote saving on bandwidth. We aim to enhance the functionality and utility of the current mPAMANECH application to include a community decision support tool to be used within a local system comprised of selected CHVs and five maternity centres serving slum settlements in Nairobi. In the 'Operationalisation' section, we describe more on how the decision support system is expected to work.

From our proposed theory of change, *figure 2*, we anticipate that the decision support module of mPAMANECH will assist the CHVs in the identification of high risk pregnant women, new mothers and newborns with complications, and to make timely and correct decisions on referral for cases that need intervention. With the improved knowledge and skills possessed by the CHVs more women and neonates in need of health care will be identified and referred to the necessary health facilities. As a result, there will be increase utilisation of maternal and neonatal health services and reduced maternal and neonatal complications and deaths.

Operationalisation of the Decision Support System

The mobile decision support system (mDSS) mobile application (app) is an Android app that installs from the phone and runs as an application, *figure 3*. The app will be hosted at Google store and is accessible for download via the internet automatically to the user handset.

Once installed, the handset and the application will be configured with the credentials of the CHV including username and password, which are linked with the operating phone number. This setup allows the system to register and associate collected records to the respective CHV; useful for reporting and analysis purposes.

The CHVs will be provided with a mobile phone running the mHealth app for data collection which is then relayed to the head office at APHRC Campus. When visiting households for data collection, by initiating a new record the system automatically picks the geolocation of the household and associates it with the record.

The CHV will complete the respective form and save the information at any stage on the handset. This method allows the CHV to continue collecting more information and only submit the completed form to the server over the internet. Where the handset detects that internet connectivity is not available for one reason or the other, the completed forms will be stored in the phone and only be relayed to the server when the connectivity is established. Because the application is in communication with the server in real-time, any update of the data is immediately available to the CHVs. The application is preconfigured with danger signs for both mothers and newborns as defined by the WHO [30]. When any of the danger signs is picked by the system, the CHV is immediately prompted to refer the patient to a facility within the network.

The system is to be set up in such a way that the CHV will not be allowed to proceed and complete the forms until the referral is done. The patient's information will be available to all the facilities within the network and he/she will be able to visit any of the networked facilities for treatment. This information is also relayed to the rest of the other facilities and a record of the visit is kept in the server. Within 24 hours if the patient has not been seen in any of the networked facilities, an SMS message is relayed to the respective CHV handset. At this point, the CHV should follow up with the patient to inquire about their condition and whether they chose to honour the referral to a facility outside the network or not.

When the patient visits a facility within the network, using the household number and the name he/she will be easily identified and treated. The clinician is able to record the treatment in the patient's information, which is recorded in the server.

Both the CHV and the clinician's information are available to a reviewer in real time from the web. The reviewer's role would be to assess the CHV's reason for referral and the clinician's final diagnosis for correctness. The feedback from the reviewer will be available and shared on a monthly basis during review meetings. Every week, the CHEW, will randomly sample referrals made by each CHV to assess their correctness. This will be compared with the 'reviewers' summary.

mDSS Solution- Key Features (*figure 4*)

CHV (mobile App)

Through this app, the mDSS data collection tools are accessible on the CHV mobile handset. It allows for completion and submission of the information to the mDSS Server.

mDSS Server

A database driven web application that acts as a host for the collected information. It also has a web interface for data manipulation by the facility healthcare worker(s) and reviewer.

The mDSS server application incorporates an application logic component that connects with the SMS and email gateways. This allows for real-time communication of certain critical indicators to the respective recipients. For example, where a patient has not shown up at the referred facility, the CHV will be alerted.

Facility (web access)

This module is accessible at the facility via the web. The application allows the clinician to treat the patient and record the treatment. The facility portal is accessible by facility staff to manage

referrals. The "Messages" to alert the CHVs are to be integrated with WhatsApp for effective message delivery over the same mobile phone.

Reviewer (web access)

This module is also accessible via the web, and provides the reviewer a view to assess both the CHV referral report and the clinician's diagnosis. It is based on this analysis that a decision is measured.

Null hypothesis:

Usage of a CHV decision-support module does not have an effect on utilization of MNH services.

Study Design and Sampling Strategy

a. **Study Design**

To answer the question on effect of the decision support system, we will use a quasi-experimental design with pre and post assessments to determine the impact, if any, on the MNH services and selected health indicators.

We will work with three community units (CUs) from which a group of 50 CHVs will serve as the intervention group. Three CUs in Embakasi sub-County, with 50 CHVs will serve as the control. The CUs in the control group will be geographically distant from the intervention site to limit contamination. The control group will be facilitated within the normal standard of practice which includes paper-based reporting. The idea is to compare access to MNH services, referral practices and MNH outcomes between those with a decision-support tool with those working with traditional paper-based tools.

We will conduct a baseline survey and an end-line at least one year after the full implementation of the intervention. The control group will be assessed at the same time as the surveys are being conducted in the intervention group. To strengthen the case for causal inference we will also do a systematic monitoring and documentation of the intervention based on our theory of change. The monitoring and documentation will also capture any other contextual factors that may influence the same outcomes as our intervention.

To answer the question on feasibility, we will conduct a mixed methods assessment of the CHVs and CHEWs. Qualitative assessments of their current work experiences with the paper based system as well as after the introduction of the mobile based system will be conducted. We will assess ease of use, challenges experienced and opportunities for improvement. These will be triangulated with their HMIS reports (paper and electronic).

b. **Study Setting**

The intervention site covers informal settlements in Kamukunji sub County, which, like other slums, are characterized by poverty, poor coverage of social services and poor health outcomes. We will identify CUs and 5 facilities that serve the CUs. Embakasi sub-County will serve as the control site. We will identify three CUs to serve as controls.

c. **Sampling**

The CUs in the intervention and control groups will be purposively selected based on discussions with the sub-County community strategy coordinators for Kamukunji and Embakasi. We will select CUs with the worst health indicators for both the intervention and control groups, including those serving informal settlements, and with more likelihood to benefit from the intervention.

For the population based surveys:

➢ **Quantitative study**

- *Study population*

The project will target households with women of reproductive age (15-49 years) in the informal settlements of Kamukunji and Embakasi. It will also target health care providers in five selected health facilities as well as the sub-County Health Management teams of Kamukunji, Embakasi, Makadara and Nairobi City County.

A quantitative survey will be conducted focussing mainly on maternal and newborn health and family planning services.

- *Sample size estimation*

The key outcome of interest is correct referral practices. Using proportion of neonates with at least one danger sign referred by CHVs as the indicator, since it is representative of the target population, the total sample size for each group has been estimated as 173 (346 in total). Using a difference in proportion 13.3 % for neonates with danger signs referred (rising from 16.7 to 30%), at 95% CI for 80% power and sample proportions of 50% in the intervention and 40% in the control groups, respectively, we came up with a sample size of 315. Accounting for a potential non-response rate of 10% based on previous studies in similar study populations, the effective sample size is 346. Using correct decisions made by CHVs (one of the indicators to be measured), the sample size was estimated as 199. 346 is therefore an appropriate sample size.

- *Sampling procedure*

To measure feasibility and acceptability, all the CHVs in the intervention site will be assessed, in addition to an audit of the functionality of the system. We will measure the percentage time for which the system is down on a monthly basis **(Numerator:** Number of times (in minutes) when the system is down. **Denominator**: Total active time in a month. Down time defined as 30

minutes of hanging and Active time as time without hitches), proportion of CHVs effectively using the decision support system (Within the system, on a quarterly basis we will be able to generate reports on decisions, correct or otherwise, made by the CHVs. These will also be compared to the control site that will only have a paper based system of data collection), and the experiences of the CHVs and the mothers with the mobile based system. These will be compared to the investment.

To answer the question on effect of the system on utilisation of services, the data above will be triangulated with data from the **mPAMANECH application which already has an integrated data collection module**, the data generated by the CHVs and participating health facilities will be retrieved, cleaned and analyzed to derive estimates of the main outcome of interest – correct referral practices. In addition, these data will be triangulated with other sources such as the CHV monthly reports and health facility HMIS. A system of random numbers generated using STATA will be used to select the respondents based on a sampling frame that is going to be informed by an updated household register in the selected community units.

➢ **Qualitative study**

We will use focus group discussions (FGDs) and in-depth interviews among the direct project beneficiaries and CHVs, and key informant interviews with key actors (sCHMTs, health providers, CHVs and community leaders). Participants will be purposively selected to represent the different stakeholders as well as different health service user categories (users and non-users).

Data from the quantitative survey will be used to identify women who have or not used specific MNH services and these will be approached to participate in the focus group discussions or in-

depth interviews. Other respondents will be identified based on their position in the community and their role in the project.

Data Collection, Management and Analysis

Data collection:

We will conduct a baseline survey and an end-line at least one year after the full implementation of the intervention. The control group will be assessed at the same time as the surveys are being conducted in the intervention group. To strengthen the case for causal inference we will also do a systematic monitoring and documentation of the intervention based on our theory of change. The monitoring and documentation will also capture any other contextual factors that may influence the same outcomes as our intervention. The effects and impact of the project will be determined by triangulating data and information from different sources, examining trends where possible, and trying to find and support explanations for the observed findings.

Our key data sources will be the following: household surveys, routine HMIS data and qualitative assessments (interviews and focus group discussions).

We will conduct simple and multiple logistic regression analyses comparing differences in the proportions of women in reproductive age and children under-five at baseline and end line for variables like antenatal coverage, vaccination coverage, skilled birth attendance, among others, (See figure 1 for key indicators). These analyses will control for any differences in the samples (if any) at the two time points as well as the contribution of contextual factors that may have occurred in the course of the implementation.

mPAMANECH data: Descriptive data in terms of referrals by, diagnostic decisions, among others, will be summarised using means and standard deviations for the parametric continuous data and medians with inter-quartile ranges for the non-parametric data. Categorical data such as referrals by age and gender will be summarised using proportions and percentages.

Qualitative data: Qualitative data will be transcribed and saved in Word format. Transcribed word files will be imported into NVIVO software (QSR International Pty Ltd) for coding and further analysis. Analysis across all transcripts will be conducted using a constant comparative method to identify themes and their repetitions and variations. The analysis will also aim to identify changes (if any) in various indicators that could be attributed to the intervention. Figure 5 shows the study's timeline.

3. Ethics and Dissemination

The study was reviewed internally by APHRC's internal scientific review committee. Ethical approval for the project was obtained from the African Medical Research Fund's Ethical and Scientific Review Committee (AMREF-ESRC P279/2016). The research team has undergone the NIH training on protecting human research participants. We shall seek informed consent from all study participants. All survey data will be collected in privacy and will be treated with confidentiality. It will be made clear to participants from the onset that participation in the study is voluntary and that they may choose to withdraw from the study at any time and for whatever reasons without fear of penalty. The mPAMANECH datasets will be available to users (CHVs, clinicians, CHEWs, among others) based on assigned, but limited, rights to protect the identity of study participants. Only the core research team will have access to all of this information. The entire dataset will be stored in the APHRC server.

The potential risks for study participants are limited to (i) data breaches ii) time spent on the interview and (iii) discomfort experienced due to particular questions that respondents may perceive as upsetting or personal. These potential risks will be carefully explained to each participant during the process of obtaining informed consent.

For the data collected on the phones and computers, once it is saved the data is relayed in real time to the APHRC server and no information is saved on the phone or the computer. The users will only be able to see summary data, without the participants' details. To further minimise the risk attached to data breaches following the loss of a smartphone, each phone will have a 4-digit pass code to enable the CHVs log into the phone. This code will become active after 3 minutes on non-use. The third level of security is the username and password on each device.

Plan for Communicating Findings of the Study:

Results obtained through this study will be made available to those who contributed information; the communities of Kamukunji and Embakasi. In addition,

i. The study team will conduct one major dissemination workshop in Kenya to share research findings with development partners, local NGOs, healthcare providers, activists, media houses, health professional societies, and policymakers.
ii. Findings of the study will be shared at local and international conferences with researchers and policy makers.
iii. We also expect to publish 3 peer-reviewed articles in Open Access scientific journals.
iv. The Policy Engagement and Communications (PEC) unit at APHRC will also use the findings of this study to produce policy briefs, fact sheets, and working papers, as well as newsletters, which will be shared with a wide range of stakeholders.

v. The findings of the study will also be shared through APHRC's website.

4. Discussion

Maternal and neonatal health are both national and global priorities given that maternal and neonatal health indicators have not appreciably improved over the Millennium Development Goals life-span. They remain aspirations in the Sustainable Development agenda. CHVs are a critical component of the health workforce bridging the gap between communities and the formal health system. They not only improve coverage and access to basic health services but are also usually available in locations where and at times when formal health services are unavailable or inadequate. Quality healthcare is largely supported by quality data. Kenya still faces challenges with its Health Management Information System. Inaccurate data as a result of poor documentation impair the country's planning processes. This project accords APHRC and its partners an opportunity to utilize funds that have been identified to respond to Kenya's needs; to improve maternal and newborn health.

The next steps of the project if the experiments under this grant are successful will include sharing the findings with the Nairobi City County and the funder and agreeing on the next phase of implementation. The Ministry of Health, Nairobi, is keen to roll out the system county-wide subject to availability of funding. The project team will work with the consortium to generate evidence to support decision-making at whatever stage of implementation. These may include effectiveness in reducing adverse maternal and neonatal outcomes at national level, cost-effectiveness, process issues such as CHV motivation and efficiency among others.

Potential impediments to the intervention include possible technology failure, loss of equipment (phones) and CHV turnover; all of which could require revisions and adaptations in the work plan (e.g., quality assurance, insurance, and training). A potential harmful unintended consequence stems from the fact that CHVs are not medically trained and as such could make a decision to treat at home, rather than refer (even when the system advises otherwise) with possible negative health consequences for the mothers and their newborns. However, since the system allows health workers to access this data, they will be in-charge of following up on such cases to avoid unnecessary delays and such unintended consequences.

5. Conclusion

The study outlined in this protocol will assess the added value of using a CHV decision-support module of mPAMANECH in reducing maternal complications and newborn deaths in the informal settlements of Nairobi, Kenya. The study's findings will contribute to the body of knowledge on the effectiveness of mHealth innovations in improving maternal, newborn and child health services and outcomes in urban informal settlements. Successful execution of the protocol will generate evidence on the effectiveness, if any, of the system. Based on the positive lessons learned, this project will provide a system for adoption by the local and central governments, for resource limited communities.

6. Competing interests statement:

None declared.

7. Authors' contributions:

PB, CK, EK, AKZ conceived the project and its design and participated in refining the manuscript. MO contributed to the refining of the design. PB drafted the manuscript. All authors read and approved the final manuscript.

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Figure 1, Key Outcomes:

Domain of Inquiry	Key Outcome Indicators
Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	- Percentage time for which the system is down on a monthly basis - Number of CHVs effectively using the decision support tool - Proportion of CHVs able to identify at least 4 danger signs among neonates - Proportion of CHVs able to identify at least 1 danger sign among neonates - Proportion of CHVs able to identify at least 2 post-partum complications - Percentage of correct referral decisions by CHVs for post-partum mothers with complications - Percentage of correct referral decisions by CHVs for neonates with danger signs - Proportion of pregnant women referred for ANC by CHVs - Proportion of mothers referred for PNC by CHVs
Determine the decision-support platform's effect on utilization of MNH services	- Proportion of women attending at least 4 ANCs - Proportion of all mothers attending at least 2 PNCs - Proportion of deliveries assisted by trained personnel - Percentage of women who accessed first ANC within the 1st trimester - Proportion of women referred for post-partum family planning - Proportion of newborns with at least one danger sign referred by CHVs - Proportion of low birth weight newborns referred - Proportion of women lost during follow up - Proportion of newborns lost during follow up

Figure 1: Key Outcome measures

30x39mm (300 x 300 DPI)

Figure 2, Theory of Change

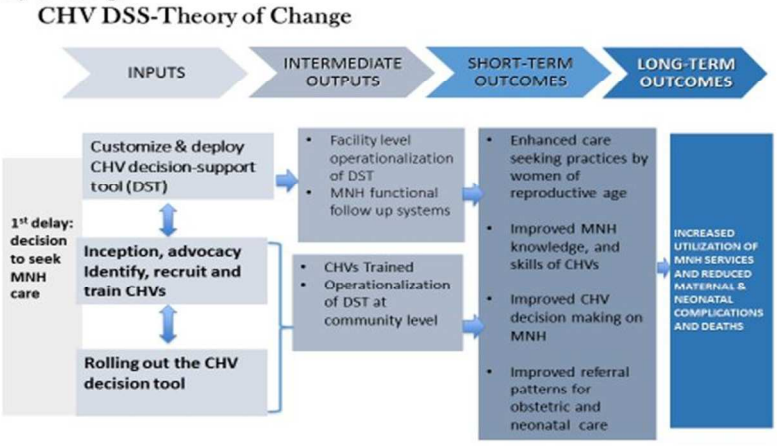

Figure 2: Theory of change

78x40mm (300 x 300 DPI)

Figure 3, Mobile Data Gathering Platform

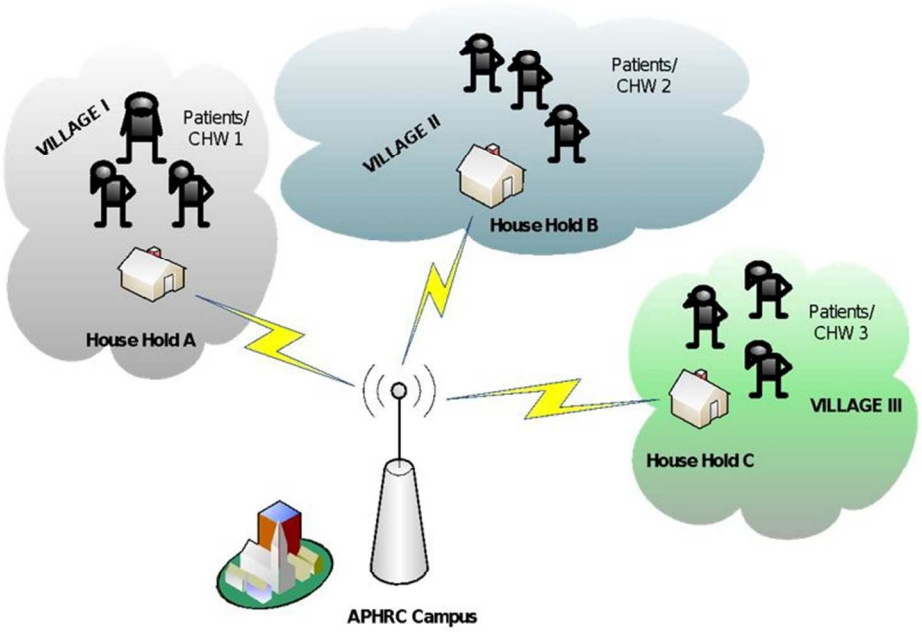

Figure 3: The system

72x53mm (300 x 300 DPI)

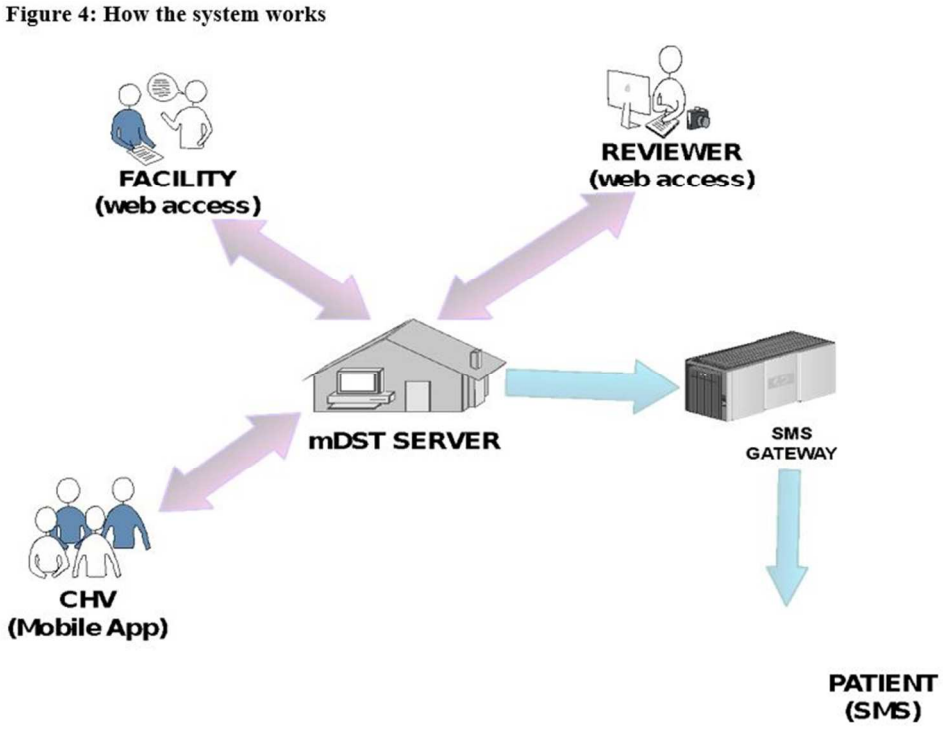

Figure 4: How the system works

70x53mm (300 x 300 DPI)

Figure 5, Project timeline

CHV Decision Support Application: Pilot study							
			2016	2017			
Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**
Inception period	■						
Seek ethical approval		■					
Baseline			■				
Recruit & train field team			■				■
Conduct Baseline			■				
Conduct Endline			■				■
Data cleaning			■				■
Data analysis and interpretation			■				■
Scientific write up on baseline			■				■
Scientific write up on endline			■				■
Develop Decision Support System		■	■				
Training of CHWs			■				
Training of DHMTs			■				

Figure 5: Project timeline

54x48mm (300 x 300 DPI)

Project Title	Using a Decision-Support Smartphone application to enhance Community Health Volunteers' effectiveness in reducing Maternal complications and reducing Newborn Deaths in the informal settlements of Nairobi,	
	Objectively Verifiable Indicators	
Domain of inquiry	**Indicators**	**Method of calculation**
1. Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	Percentage time for which the system is down on a monthly basis	**(Numerator:** Number of times (in minutes) when the system is down **Denominator**: Total active time in a month. Down time defined as 30 minutes of hanging and Active time as time without hitches) * 100
	Number of CHVs effectively using the decision support tool	**Numerator:** Number of CHVs able to either correctly refer or manage clients at home (target is 50 CHVs). Within the system, on a quarterly basis we will be able to generate reports on decisions made by the CHVs. These will also be compared to the control site that will only have a paper based system of data collection
	Proportion of CHVs able to identify at least 4 danger signs among neonates	**Numerator:** Number of CHVs able to identify at least 4 danger signs among neonates (aged upto 28 days). **Denominator:** Total number of CHVs in the selected CUs (total 50 CHVs).
	Proportion of CHVs able to identify at least 2 post-partum complications	**Numerator:** Number of CHVs able to identify at least 2 post-partum complications. **Denominator :** Total number of CHVs in selected Cus (total 50 CHVs)
	Percentage of correct referral decisions by CHVs for post-partum mothers with complications	**(Numerator:** Number of correct referrals by CHVs for post-partum mothers with complications. **Denominator:** Total number of postpartum women referred.)*100
	Percentage of correct referral decisions by CHVs for neonates (aged upto 28 days) with danger signs	**(Numerator:** number of correct referrals by CHVs for neonates (aged upto 28 days) with danger signs. **Denominator:** Total number of neonate referrals)*100
	Proportion of pregnant women referred for ANC by CHVs	**Numerator:** Number of pregnant women referred for ANC to selected health facilities by CHVs **Denominator:** Total number of women-pregnant seen by CHVs
	Proportion of mothers referred for PNC by CHVs	**Numerator:** Number of post-delivery women referred for PNC to selected health facilities by CHVs. **Denominator:** Total number of deliveries in selected facilities and at home
2. Determine the decision-support platform's effect on utilization of MNH services		
	Proportion of women attending at least 4 ANCs	**Numerator:** Number of pregnant women attending 4 or more ANC visits in project sites. **Denominator:** Total number of pregnant women seeking ANC services in the selected health facilities
	Proportion of all mothers attending at least 2 PNCs	**Numerator:** Number of mothers attending at least 2 PNCs in project sites. **Denominator:** Total number of postpartum women seeking PNC services in the selected health facilities.
	Proportion of deliveries assisted by trained personnel	**Numerator:** Number of assisted deliveries by trained personnel (at home or at the facility). **Denominator:**Total number of deliveries in the facilities and CUs covered by project
	Percentage of women who accessed first ANC within the 1st trimester	**(Numerator:** Number of women attending the first ANC within the first semester. **Denominator:** Total number of women attending ANC in project sites)*100
	Proportion of women referred by CHVs for post-partum family planning	**Numerator:** Number of post-partum women referred and seen at facilities for family planning. **Denominator:**Total number of women referred in the facilities and Cus in project sites
	Proportion of newborns (aged upto 28 days) with atleast one danger sign referred by CHV	**Numerator:** Number of CHVs able to identify at least 4 danger signs among neonates (aged upto 28 days). **Denominator:** Total number of CHVs in the selected CUs (total 50 CHVs).
	Proportion of low birth weight newborns (< 2500g) referred	**Numerator:** Number of low birth weight newborns (< 2500g) referred to selected health facilities. **Denominator:** Total number of live birth weighted in selected facilities
	Proportion of women lost during follow up	**Numerator:** Number of women referred by CHVs who fail to report to the selected facilities. **Denominator:** Total number of women referred by CHV
	Proportion of newborns (aged upto 28 days) lost during follow up	**Numerator:** Number of newborns (aged upto 28days) who failed to report to selected facilities. **Denominator:** Total number of newborns (aged upto 28 days) referred by CHVs

Using a Decision-Support Smartphone application to enhance Community Health Volunteers' effectiveness in reducing maternal complications and reducing newborn Deaths in the informal settlements of Nairobi, Kenya

Thematic Interview Guide with suggestions to questions

FGD CHVs

INTRODUCTION AND WARM UP (2 mins)

- The moderator introduces him/herself and explains the purpose of the study
- The moderator explains that the discussion is open, not an exam and there is no wrong or right answer. Explain that the information given by each participant is confidential.
- Encourage the respondent to give honest opinions.
- Talk not just for yourself but also what you know your friends think.
- Explain the use of the recorder.

A. Experience working in the community

Probes

a) How many households are you allocated and how often do you visit them?
b) What are some of the activities conducted in the household? (Counselling, Referral)
c) How do you collect/report information collected from households?
d) How do you handle maternal, neonates and children complications, deliveries?
e) Do you have a way of identifying any danger signs in newborns and mothers and how easy it?
f) At what point do you refer complicated cases?
g) What do you think should be improved?

B. Health facilities in the area

Probes

a) Which health facilities do you refer your patients?
b) How do you follow up patients referred to ensure they go to the health facilities?
c) Do you get feedback on referrals done?
d) Are the services offered in the facilities affordable and responsive to the needs of the community?
e) In your opinion are the patients satisfied with the services?
f) Perceived quality, accessibility and affordability regarding the existing FP and maternal health services, effectiveness of referral system, and barriers to utilization of the health services.
g) Challenges and Opportunities (how to assist mothers and children to access care), improve their work lives (reporting, knowledge and skills)

C. Data collection/reporting and follow-up tools

Probes

a) Generally how do you feel about the data collection/reporting system currently in use
b) On average how much time does it take to collect data from one household
c) How often is your work reviewed and by who?
d) What are the advantages and disadvantages/challenges of the current system?
e) How in your opinion do you think it can be improved?
a) If you have heard of any health related mobile applications used in this community, what is your opinion?
b) What are your views on the use of a decision support tool for CHVs to collect/report information & make referrals/ follow-ups?

IDI Postnatal women's interview guide

a. Tell me about your childbirth experience?
b. Have you heard of the term “dignity”? What do you understand by the term dignity? How would you describe dignity?
c. While at home, did you have any thoughts about how your dignity will be affected in the labour ward?

- If so, what these thoughts were and where they came from?

d. Did you feel that the labourward would affect your dignity?
    a. If so, how?
e. Do you feel that the attending midwives affected your dignity during the childbirth process?

- If so, how?

f. During childbirth, were there any moments that you feel that you lost, or could have lost, your dignity?

- If yes, explore the following;
    - What was the situation?
    - Was the situation related to your condition, treatment or care?
    - What were your feelings at the time?
    - Did you feel that the midwives tried to do anything to keep your dignity?
    - Did the labourward staff make the situation better or worse? If so, how?
    - Is there anything else you would have liked the attending staff to do in this situation?

g. Is there anything else you would like to say about your dignity as a patient on the labourward?

FGD: Women of Reproductive Age

INTRODUCTION AND WARM UP (2 mins)

- The moderator introduces him/herself and explains the purpose of the study
- The moderator explains that the discussion is open, not an exam and there is no wrong or right answer. Explain that the information given by each participant is confidential.
- Encourage the respondent to give honest opinions.
- Talk not just for yourself but also what you know your friends think.
- Explain the use of the recorder.

A. Now I would like us to talk about your views on CHVs work in this community.
Probes

a) Are you aware of any CHVs in this community and are you conversant with their roles?
b) Have you ever been visited by the CHV & for what reasons
c) Have you sought any services from the CHVs and what services
d) Do you generally find the services of the CHVs useful?

B. I would like to talk about the reporting/data collecting mechanism used by the CHVs;
Probes
a) What kind of information do the CHVs collect from you? How is it done?
b) How do you think it can be improved?

C. Now I would like to ask about the Health facilities visited by you or any mother in the community;

Probes

a) Which facilities do you visit frequently and what services do you most seek.
b) Are you able to get quality care from these health facilities
c) Do you get referred by the CHVs to these facilities
d) Overall, what are your views on the referral system by CHVs and services offered by the health facilities in the community, please tell me more
e) How do you think it can be improved?
f) Perceived quality, accessibility and affordability regarding the existing FP and maternal health services, effectiveness of referral system, and barriers to utilization of the health services.
g) Challenges and Opportunities (how to assist mothers and children to access care)

KII: CHEWs and Health Providers

Tell me about your roles as a CHEW/Clinician in provision of health services to people in this community

Probes

a) Health status of the community
b) Interaction with the CHVs
c) Experiences working with the CHVs

A. Now I would like to ask about the services offered by health facilities in this area
   a) Which facilities do residents of this community visit frequently and what services do they mostly seek.
   b) Are they able to get quality care from these health facilities
   c) Are they referred by the CHVs to these facilities
   d) Overall, what are your views on the referral system by CHVs and services offered by the health facilities in the community, please tell me more
   e) How do you think it can be improved?

B. Now I going to talk about the reporting tools used to collect information/report and refer by the CHVs
   a) What tools are used to collect data in this community? Generally how do you feel about the data collection/reporting system currently in use?
   b) On average how much time does it take the CHVs to collect data from one household
   c) How often do you review CHVs' work?
   d) What are the advantages and disadvantages/challenges of the current system?
   e) How in your opinion do you think it can be improved?
   f) In your opinion what would you say about mobile app in data collection and reporting process?

KII Health Providers

A. Tell me about your roles as a Clinician in provision of health services to people in this community

Probes

a) Health status of the community
b) Interaction with the CHVs
c) Interaction with DHMTs

B. Now I would like to ask about the services offered by health facilities in this area

Probes

a. What services do they utilize mostly?
b. Are they able to get quality care from these health facilities
c. Are they referred by the CHVs to these facilities
d. Overall, what are your views on the referral system by CHVs and health facilities? please tell me more
e. How do you think it can be improved?

C. Reporting tools used to collect information/report and refer by the CHVs

a. What tools are used to collect data in this community? Generally how do you feel about the data collection/reporting system currently in use?
b. What are the advantages and disadvantages/challenges of the current system?
c. How in your opinion do you think it can be improved?
d. In your opinion what would you say about mobile app in data collection and reporting process?

D. What do you understand by the term "dignity"?

Threats to dignity:

E. Have you ever felt that a woman's dignity was lost, or threatened at any point during the childbirthing period?

- If so, what do you feel caused this to happen?
- What effect do you feel you had on the situation? Do you feel that you improved or worsened the situation, and how?
- How do you feel other staff improved or worsened the situation, and how?
- Do you feel that you or any other staff could have done anything else to promote the woman's dignity in this situation, and if so, what could you have done?

Promotion of dignity:

F. Do you feel that women keep their dignity during their care/treatment/childbirth?

- What do you feel helped promote the women's dignity?
- What was your role in promoting the women's dignity?

Effect of the ward environment:

G. Do you feel that the ward environment affects women's dignity?

- Is there is anything more that could be done to the ward environment to promote a woman's dignity?
- Is there anything else you would like to say about women's dignity on the labourward?

KII: Sub County focal person

A) Tell me about your roles as a sub-county focal person in this community

B) What can you say about the services offered by the health facilities in this community?

Probes:

a) The cost, quality of care, available to mothers and children
b) Do you know of any challenges that are faced by the mothers and children in this community to access health facilities?
c) In your opinion do you think that the engagement of the CHVs in the community is of help, what are your views on the services offered by the CHVs
Probes; task shifting, improved care?

C) Please tell more on your experiences working with the SCMOH,

Probe:

- Perceived quality, accessibility and affordability regarding the existing FP and maternal health services, effectiveness of referral system, and barriers to utilization of the health services.
- Challenges and Opportunities (how to assist mothers and children to access care), reporting, compliance with regulations by health facilities and CHVs

D) Are there any activities that you have been involved in this sub-County, please clarify;

Probes; Running of meetings, Trainings, support supervisions and any community engagements (specify)

E) In your opinion what would you say about mobile app in data collection and reporting process? Please tell me more

KII: SCMOH

A) Tell me about your work in this community

Probes: support supervision, sub county meetings & stakeholder forums

B) Tell me more about your engagement with the CHVs and how the experience has been
C) Experience working with health facilities

Probes: reporting, compliance with regulations

D) How effective are the CHVs in the community?

Probes;

- Perceived quality, accessibility and affordability regarding the existing FP and maternal health services, effectiveness of referral system, and barriers to utilization of the health services.
- Challenges and Opportunities (how to assist mothers and children to access care), reporting, compliance with regulations by health facilities and CHVs

E) In your opinion do you think a CHV decision support tool would be make CHV perform duties and responsibilities effectively? How is that?

	AFRICAN POPULATION AND HEALTH RESEARCH CENTER **HEALTH CHALLENGES AND SYSTEMS PROGRAM** **Using a Decision-Support Smartphone application to enhance Community Health Volunteers' effe** **reducing Maternal complications and reducing Newborn Deaths in the informal se** *Questionnaire for community health volunteers*	
	START TIME (24hrs Format)	
	DATE OF INTERVIEW (DD/MM/YYYY)	
	FIs CODE	
	NAME OF CHV	
	COMMUNITY HEALTH UNIT CHV IS LINKED TO	
	HEALTH FACILITY CHV IS LINKED TO	
1	**BACKGROUND**	
1.1	RESPONDENT'S DATE OF BIRTH (DD/MM/YYYY)	
1.2	RESPONDENT'S AGE (COMPLETED YEARS)	
1.3	Have you ever attended school?	YES…… NO……
1.4	What is the highest level of education that you have completed?	Primary school …… Secondary …… College/university deg
1.5	What grade/class did you attain?	
2.0	**COMMUNITY SERVICES** **I would like us to discuss about the community services you are involv** **some questions might require you to refer to your registers**	
2.1	How many years have you served this community as a community health volunteer (CHV)?	Less than 1 year…… 1 - 2 years…… 2 - 4 years…… More than 5 years…..

2.2	As a CHV, what are your roles? *FW instructions:* *Circle All that apply* *Do not Prompt or read the options*	HH Health education Proper nutrition durin Breast feeding…… Birth plan…… Health facility based c ANC…… PNC for mother …… Vaccination…… Danger signs in pregn Danger signs in postn Danger signs in newb Height measurments.. Weight measurements Referrals…… Growth monitoring of Distribution of FP cor Community mobilizat Identification of wom Others (Specify)……
2.3	How many households are allocated /assigned to you?	☐☐☐
2.4	In the allocated households in Qn 2.3, how many have? *FW Instruction:* *Ask about counts in each category*	Non pregnant wome Pregnant women How many of the pr categorized as havin Newborns (0-28 day Infants (29 days to 1 Children (12 months
	Would you categorize pregnant women with the following conditions as having high risk pregnancies. *FW Instructions: Read out the options.* *Multiple response allowed*	Carrying twins and h multiples Gestestional diabete HIV positive wome High blood pressure Pregnacy in teens < Pregnancy in wome Overweights/ obese History of miscarria
	NOW, I would like us to discuss about services that you have offered in the l ***Some questions may require you refer to your records/registers***	

	Reference month	
2.5	How many of the following have you visited in the last one month	Non pregnant wome Pregnant women Newborns (0-28 day Infants (29 days to 1 Children (12 months
2.6	In the last month, how many women have you referred to the nearest heatlh facility for the following services	Family planning Pregnancy tests ANC Pregnancy danger si Facility based devliv PNC for mothers Postpartum women
	FW : REFER TO QUESTION 2.6 , If women were referred for ANC , danger signs a if not, skip to section 3	
2.7	Among the women referred for ANC in the last one month, how many were for	1st ANC visits At least 4th ANC vi
2.8	Kindly identify danger signs in pregnant women *FW instructions:* *Circle All that apply* *Do not Prompt or read the options*	High fever Vaginal bleeding Baby not moving Weight loss Swelling in hands or f Bad headache High blood Pressure Blurred vision Severe abdominal pai Difficulty breathing Painful urination Convulsions/fits Loss of consciousness Heavy vaginal dischar A lot of vomiting

		Very pale palms of hands or nail bed Genital ulcers Other, specify _____
2.9	Kindly identify danger signs in postpartum women *FW instructions:* *Circle All that apply* *Do not Prompt or read the options*	Fever without chills Fever with chills Heavy bleeding after l Bad abdominal pain High blood pressure Convulsions Abnormal discharge Loss of conciousness Headaches, dizziness/ Blurry vision Difficulty breathing Difficulty paiing urine Palm og hands and fe than normal Other (Specify)_____
1.2	In the last 3 months, how many pregnant and postpartum women have you refered with danger signs?	Pregnant women Post-partum comen
2.11	Kindly identify danger signs in newborns **CIRCLE ALL MENTIONED**	Preterm birth Preterm lowbirth we Term lowbirth weig Jaundice Skin in palm and so of feet turn blue Yellow sole Breathing difficultie Fever (temperature Low temperature (3 Lethargy Failure to feed Convulsions or fits s Drowsy Fast breathing (60 b more in 1 minute co Chest indrawing Movement only on s

		or no movement ev on stimulation Signs of local infect umbilicus red or dr skin boils and eyes c Excessive weight lo Other (Specify)_____
2.10	In the last 3 months, how many newborns have you referred to the nearest heatlh facility for the following services	Routine medical che Vaccinations Seek medical care fo
3.0	**DATA DOCUMENTATION** Now I would like us to discuss about how you currently collect data	
3.1	How do you collect data during home visits	Manually using MO Electronically using or electronic devices Others specify
3.2	How do you determine if a woman/newborn has a danger sign and needs urgent medical attention ?	By referring to coun From memory I call someone to ref I guess I don't know Other specify _____
3.3	Are you satisfied with the current method of data collection ?	Yes …… No…… D/K……
3.4	Do you think the current method of identifying danger signs in women and newborns is effective and efficient	**Y** Effective 1 Efficient 1
3.5	In your opinion, do you think an electronic / mobile data capture system will	Make work easier

	Fill with the correct response 1=Yes 2=No 98=Do not know	Shorten time in HHs Assist in correct identification of dan signs Increase timely refe Reduce misdiagnosi community level Others specify
3.6	Have you been trained on mobile /electronic data collection	Yes…… No……
	FW INSTRUCTION : THANK THE PARTICIPANT FOR PARTICIPATION AND **RECORD ANY GENERAL COMMENTS ABOUT THE INTERVIEW/R**	
	_____	
	_____	
	_____ **END TIME (24 Hrs Format)**	

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ask the following question

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END THE INTERVIEW

ESPONDENT