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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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3 **The role of a decision-support smartphone application in enhancing Community Health**
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5 **Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-**
6 **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

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

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10 - The study's findings will generate evidence on the effectiveness of public- private partnerships in
11
12 improving maternal, newborn and child health services and outcomes in urban slums.
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15 -If successful, the study will provide a model of public-private engagement for adoption by the local and
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17 central governments, for under-served populations, in other developing countries.
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20 **Strengths and Limitations**

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23 - The project seeks to address a critical challenge in the health care system in a slum context:
24
25 identification and referral of ill mothers and newborns.
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29 - It utilises the existing CHV work tools and mobile phone technology to show how an evidence based
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31 intervention can improve health outcomes at community level.
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35 -A potential harmful unintended consequence stems from the fact that CHVs are not medically trained
36
37 and as such could make a decision to treat at home, rather than refer (even when the system advises
38
39 otherwise) with possible negative health consequences for the mothers and their newborns.
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42 -However, since the system allows health workers to access this data, they will be in-charge of following
43
44 up on such cases to avoid unnecessary delays and such unintended consequences.
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55 **1. Introduction:**

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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.

51 **Community Health Volunteers**

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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

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2
3 the community level, [7]. CHVs are volunteers identified from communities that they reside in
4 and offered a few days' basic training based on a set curriculum before they are assigned
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6 community health promotion roles. CHVs belong to established community units with a
7
8 responsibility of making weekly home visits to households within designated geographical areas.
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10 The visits are targeted to households with pregnant women, newborns, infants and other children
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12 under the age of five years. During these visits, CHVs are supposed to identify those cases that
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14 need referral for preventive services, those that need medical attention, and those that need
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16 simple remedies. Their work tools include many paper based registers and counselling cards that
17
18 they refer to in order to make management decisions. Like many other developing countries,
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20 Kenya suffers a shortage of healthcare workers, [8]. CHVs were identified under Kenya's
21
22 Community Health Strategy as a means of alleviating the healthcare worker crisis. To date,
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24 CHVs continue to bridge the critical gap between communities and the formal health system, and
25
26 many positive lessons have been learned in Kenya and other parts of the world, [9-11]. CHVs in
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28 Kenya, like in many emerging economies, are responsible for the majority of grassroots health
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30 care delivery, and as such, continue to play a very critical role in primary health care delivery.
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39 **Decision-support systems**

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41 Clinical decision support (CDS) refer to tools used to improve decision-making in the patient
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43 care workflow, [12]. CDS provides clinicians, staff, patients or other individuals with knowledge
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45 and person-specific information, intelligently filtered or presented at appropriate times, to
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47 enhance health and health care, [13, 14]. These tools include computerized alerts and reminders
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49 to care providers and patients; clinical guidelines; condition-specific order sets; focused patient
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51 data reports and summaries; documentation templates; diagnostic support, and contextually
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3 relevant reference information, among other tools, [15]. They are beneficial in reducing errors,
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5 increasing quality of care and improving efficiency.
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8 **Mobile technology for health**

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10 Mobile technologies have the potential to bridge systemic gaps needed to improve access to and
11 use of health services, particularly among underserved populations, [16]. Worldwide, the use of
12 mobile and/or electronic devices to support both medical and public health practice and research
13 (mHealth) is increasingly being appreciated. Over the last one decade, there has been global
14 enthusiasm and interest among development agencies, researchers, and policy makers resulting
15 in the rapid proliferation of mHealth solutions many countries. mHealth has the important role of
16 connecting people in real time while reducing delays in health-related decision making and
17 access to quality care, [17]. The growing coverage of mobile networks has enabled development
18 of various mHealth initiatives especially targeted for underserved populations in developing
19 countries, [18]. The use of mobile and electronic technology is increasingly valued in health care
20 delivery, especially in low and middle income countries, [17-20]. The high and ever growing
21 mobile penetration coupled with investments from technology companies that provide accessible
22 platforms onto which innovations can establish and offer value-based products, [18]. Innovations
23 include mobile phone platforms/applications and micro-insurance packages. Given the nature
24 and tight timeframes of most obstetric and neonatal emergencies, which more often than not
25 demand quick access to quality care at short notice, mobile phone innovations are a cheap and
26 fast solution especially in areas with poor healthcare infrastructure which have shown
27 improvements in maternal and child health outcomes, [20, 21]. The majority of innovations on
28 the market are tailored towards promoting reproductive, maternal, and child health, [17, 22]. In
29 addition, various projects have been designed and evaluated on CHVs use of mobile technology
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3 to deliver interventions, [23, 24]. Decision-support systems have been highlighted as a critical
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5 factor in reducing errors in evidence-based clinical practice. For clinicians, studies have
6
7 demonstrated that computerized decision support systems can be used to improve compliance to
8
9 practice guidelines [13, 14]. Given the limited training obtained and skills that the CHVs
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11 possess, coupled with the distances they work from the clinical settings mobile information
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13 technologies tools enable them to provide much needed health services.
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20 Over the last decade, more mobile and electronic information tools have been developed, tested
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22 and implemented with CHVs to support their work roles. The tools help the CHVs in
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24 surmounting challenges such as lack of appropriate work tools and inadequate supportive
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26 supervision and training [23, 24]. These tools have been instrumental in improving access to care
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28 by marginalized population groups subjected to stigma and those in hard to reach areas by
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30 reducing both time and cost of travel. As such, research on CHVs' use of mHealth tools in
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32 important. Several pilot projects, utilizing multiple designs and measures have been
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34 implemented. The projects have reported improvements in services rendered by CHVs and the
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36 related health outcomes for communities. In sub-Saharan Africa, most of the interventions have
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38 demonstrated improvements in the CHVs' delivery of maternal, newborn and child health,
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40 Tuberculosis and sexual and reproductive health services, among others, [21, 23]. The
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42 innovations largely use SMS and hotlines enabling mothers to access vital information and
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44 timely referrals as a result of better and faster communication and transport. Available evidence
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46 shows the usefulness of mHealth tools in facilitation of compliance with practice guidelines and
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48 process improvement, [23]. However, many of the interventions have been limited
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50 methodologically by their inability to demonstrate effectiveness and or impact related to patient
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3 outcomes. In addition a lack of use of nationally accepted guidelines and open source tools limits
4 the scalability of these interventions. In addition, available literature does not provide cost
5 estimates necessary for delivery of program targets. Furthermore, a top to bottom approach that
6 does not incorporate the ideas of the CHVs in the development of the tools is a major
7 impediment as successful projects use the CHVs as experts in the design and management of
8 their interventions, [23]. The recently developed mHealth Evidence Reporting and Assessment
9 (mERA) checklist whose aim is to assist authors in reporting mHealth-research, to guide
10 reviewers and policymakers in synthesising high-quality evidence is expected to indirectly
11 improve the quality of mHealth evidence in the literature, [16, 25]
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32 The African Population and Health Research Center (APHRC) has implemented a health systems
33 strengthening project, Partnership for Maternal, Newborn and Child Health (PAMANECH) in
34 Korogocho and Viwandani informal settlements of Nairobi, Kenya, [26]. The project sought to
35 strengthen the healthcare delivery system in the urban informal settlements to be more
36 responsive to the health needs of mothers and their children through enhanced service delivery
37 public-private partnerships. In a bid to improve the health management information system, an
38 innovative mHealth application, was developed. The mPAMANECH application was developed
39 as an integrated data capture tool running as a mobile app with selected reporting forms for
40 CHVs in Kenya. It operates in an interconnected network of CHVs and health facilities within a
41 defined local system. It is designed to replace the numerous paper-based forms that do not allow
42 integration of patient data from the community to the health facility and back for better referral
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3 and management of patients. This system has been seen to improve the reporting abilities of
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5 CHVs as it is less cumbersome than the paper-based system and enhanced data quality as it has a
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7 function that limits saving data until all necessary fields are filled in. In addition, the CHEW can
8
9 access a CHV's data remotely without having to wait for the end of the month for the CHV
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11 summaries. The desire to improve the functionality of the existing system to include a decision
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13 support function provides the basis on the new project.
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17 This project attempts to bridge this gap by incorporating CHV views, utilizing the tools approved
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19 by the Ministry of Health and allowing for assessment of health outcomes in the design and
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21 implementation of the project. The decision support system is developed from open source tools.
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23 In addition, a cost effectiveness analysis would be conducted to inform county and national
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25 implementation plans regarding the necessary investments for set up and maintenance.
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32 **2. Methods and Analysis**

33 **Research Objectives**

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35 The overall objective of the proposed work is to develop and validate a decision-support
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37 algorithm within a mHealth application in improving maternal and newborn health outcomes in
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39 urban slums in Kamukunji sub-County in Nairobi, Kenya. The project seeks to assess the added
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41 value of using a CHV decision-support module of mPAMANECH in reducing prenatal and
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43 postnatal maternal complications and newborn deaths.
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48 Specifically the project will assess (i) the feasibility and acceptability of using a decision-support
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50 module of mPAMANECH and (ii) whether decision-support platform contributes to increase in
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52 utilization of MNH services, and reduction of MNH complications and deaths. We will measure
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54 several outcomes, *figure 1* related to the two specific objectives, above.
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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

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3 expert to have physical access to the device to execute a software patch or change; 5) The
4 application has security features that protect users' confidentiality and limit access to a closed
5 but linked local system of health facilities and CHVs with varied access rights; 6) It has the
6 ability to limit use of other phone functionality to only allow this application to run. This helps
7 prevent abuse of the device and promote saving on bandwidth. We aim to enhance the
8 functionality and utility of the current mPAMANECH application to include a community
9 decision support tool to be used within a local system comprised of selected CHVs and five
10 maternity centres serving slum settlements in Nairobi. In the 'Operationalisation' section, we
11 describe more on how the decision support system is expected to work.
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15 From our proposed theory of change, *figure 2*, we anticipate that the decision support module of
16 mPAMANECH will assist the CHVs in the identification of high risk pregnant women, new
17 mothers and newborns with complications, and to make timely and correct decisions on referral
18 for cases that need intervention. With the improved knowledge and skills possessed by the CHVs
19 more women and neonates in need of health care will be identified and referred to the necessary
20 health facilities. As a result, there will be increase utilisation of maternal and neonatal health
21 services and reduced maternal and neonatal complications and deaths.
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44 **Operationalisation of the Decision Support System**

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47 The mobile decision support system (mDSS) mobile application (app) is an Android app that
48 installs from the phone and runs as an application, *figure 3*. The app will be hosted at Google
49 store and is accessible for download via the internet automatically to the user handset.
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3 Once installed, the handset and the application will be configured with the credentials of the
4 CHV including username and password, which are linked with the operating phone number. This
5 setup allows the system to register and associate collected records to the respective CHV; useful
6 for reporting and analysis purposes.
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13 The CHVs will be provided with a mobile phone running the mHealth App for data collection
14 which is then relayed to the head office at APHRC Campus. When visiting households for data
15 collection, by initiating a new record the system automatically picks the geolocation of the
16 household and associates it with the record.
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23 The CHV will complete the respective form and save the information at any stage on the
24 handset. This method allows the CHV to continue collecting more information and only submit
25 the completed form to the server over the internet. Where the handset detects that internet
26 connectivity is not available for one reason or the other, the completed forms will be stored in the
27 phone and only be relayed to the server when the connectivity is established. Because the
28 application is in communication with the server in real-time, any update of the data is
29 immediately available to the CHVs. The application is preconfigured with danger signs for both
30 mothers and newborns as defined by the WHO. When any of the danger signs is picked by the
31 system, the CHV is immediately prompted to refer the patient to a facility within the network.
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45 The system is to be set up in such a way that the CHV will not be allowed to proceed and
46 complete the forms until the referral is done. The patient's information will be available to all the
47 facilities within the network and he/she will be able to visit any of the networked facilities for
48 treatment. This information is also relayed to the rest of the other facilities and a record of the
49 visit is kept in the server. Within 24 hours if the patient has not been seen in any of the
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3 networked facilities, an SMS message is relayed to the respective CHV handset. At this point,
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5 the CHV should follow up with the patient to inquire about their condition and whether they
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7 chose to honour the referral to a facility outside the network or not.
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11 When the patient visits a facility within the network, using the household number and the name
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13 he/she will be easily identified and treated. The clinician is able to record the treatment in the
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15 patient's information, which is recorded in the server.
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19 Both the CHV and the clinician's information are available to a reviewer in real time from the
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21 web. The reviewer's role would be to assess the CHV's reason for referral and the clinician's
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23 final diagnosis for correctness. The feedback from the reviewer will be available and shared on a
24
25 monthly basis during review meetings. Every week, the CHEW, will randomly sample referrals
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27 made by each CHV to assess their correctness. This will be compared with the 'reviewers'
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29 summary.
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32 33 **mDSS Solution- Key Features (*figure 4*)**

34 35 **CHV (mobile App)**

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37 Through this app, the mDSS data collection tools are accessible on the CHV mobile handset. It
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39 allows for completion and submission of the information to the mDSS Server.
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45 46 **mDSS Server**

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48 A database driven web application that acts as a host for the collected information. It also has a
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50 web interface for data manipulation by the facility healthcare worker(s) and reviewer.
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54 The mDSS server application incorporates an application logic component that connects with the
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56 SMS and email gateways. This allows for real-time communication of certain critical indicators
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3 to the respective recipients. For example, where a patient has not shown up at the referred
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5 facility, the CHV will be alerted.
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8 9 **Facility (web access)**

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11 This module is accessible at the facility via the web. The application allows the clinician to treat
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13 the patient and record the treatment. The facility portal is accessible by facility staff to manage
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15 referrals. The “Messages” to alert the CHVs are to be integrated with WhatsApp for effective
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17 message delivery over the same mobile phone.
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20 21 22 **Reviewer (web access)**

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24 This module is also accessible via the web, and provides the reviewer a view to assess both the
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26 CHV referral report and the clinician’s diagnosis. It is based on this analysis that a decision is
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28 measured.
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31 32 33 **Null hypothesis:**

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35 Usage of a CHV decision-support module does not have an effect on utilization of MNH services
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37 or MNH outcomes.
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40 41 **Study Design and Sampling Strategy**

42 43 a. **Study Design**

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45 To answer the question on effect of the decision support system, we will use a quasi-
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47 experimental design with pre and post assessments to determine the impact, if any, on the MNH
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49 services and selected health indicators.
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52 We will work with three community units (CUs) from which a group of 50 CHVs will serve as
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54 the intervention group. Three CUs in Embakasi sub-County, with 50 CHVs will serve as the
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3 control. The CUs in the control group will be geographically distant from the intervention site to
4 limit contamination. The control group will be facilitated within the normal standard of practice
5 which includes paper-based reporting. The idea is to compare access to MNH services, referral
6 practices and MNH outcomes between those with a decision-support tool with those working
7 with traditional paper-based tools.
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17 We will conduct a baseline survey and an end-line at least one year after the full implementation
18 of the intervention. The control group will be assessed at the same time as the surveys are being
19 conducted in the intervention group. To strengthen the case for causal inference we will also do
20 a systematic monitoring and documentation of the intervention based on our theory of change.
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27 The monitoring and documentation will also capture any other contextual factors that may
28 influence the same outcomes as our intervention.
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32 To answer the question on feasibility, we will conduct a mixed methods assessment of the CHVs
33 and CHEWs. Qualitative assessments of their current work experiences with the paper based
34 system as well as after the introduction of the mobile based system will be conducted. We will
35 assess ease of use, challenges experienced and opportunities for improvement. These will be
36 triangulated with their HMIS reports (paper and electronic).
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43 **b. Study Setting**

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

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

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15 ➤ **Quantitative study**

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18 ▪ *Study population*

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20 The project will target households with women of reproductive age (15-49 years) in the informal
21 settlements of Kamukunji. It will also target health care providers in five selected health facilities
22 as well as the sub-County Health Management teams of Kamukunji, Embakasi, Makadara and
23 Nairobi City County.
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29 A quantitative survey will be conducted focussing mainly on maternal and newborn health and
30 family planning services.
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34 ▪ *Sample size estimation*

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36 The key outcome of interest is correct referral practices. Using proportion of neonates with at
37 least one danger sign referred by CHVs as the indicator, since it is representative of the target
38 population, the total sample size for each group has been estimated as 173 (346 in total). Using a
39 difference in proportion 13.3 % for neonates with danger signs referred (rising from 16.7 to
40 30%), at 95% CI for 80% power and sample proportions of 50% in the intervention and 40% in
41 the control groups, respectively, we came up with a sample size of 315. Accounting for a
42 potential non-response rate of 10% based on previous studies in similar study populations, the
43 effective sample size is 346. Using correct decisions made by CHVs (one of the indicators to be
44 measured), the sample size was estimated as 199. 346 is therefore an appropriate sample size.
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3 ▪ *Sampling procedure*
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6 To measure feasibility and acceptability, all the CHVs in the intervention site will be assessed, in
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8 addition to an audit of the functionality of the system. We will measure the percentage time for
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10 which the system is down on a monthly basis (**Numerator:** Number of times (in minutes) when
11
12 the system is down. **Denominator:** Total active time in a month. Down time defined as 30
13
14 minutes of hanging and Active time as time without hitches), proportion of CHVs effectively
15
16 using the decision support system (Within the system, on a quarterly basis we will be able to
17
18 generate reports on decisions, correct or otherwise, made by the CHVs. These will also be
19
20 compared to the control site that will only have a paper based system of data collection), and the
21
22 experiences of the CHVs and the mothers with the mobile based system. These will be compared
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24 to the investment.
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31 To answer the question on effect of the system on utilisation of services, the data above will be
32
33 triangulated with data from the **mPAMANECH application which already has an integrated**
34
35 **data collection module**, the data generated by the CHVs and participating health facilities will
36
37 be retrieved, cleaned and analyzed to derive estimates of the main outcome of interest – correct
38
39 referral practices. In addition, these data will be triangulated with other sources such as the CHV
40
41 monthly reports and health facility HMIS. A system of random numbers generated using STATA
42
43 will be used to select the respondents based on a sampling frame that is going to be informed by
44
45 an updated household register in the selected community units.
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50 ➤ **Qualitative study**
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53 We will use focus group discussions (FGDs) and in-depth interviews among the direct project
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55 beneficiaries and CHVs, and key informant interviews with key actors (sCHMTs, health
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3 providers, CHVs and community leaders). Participants will be purposively selected to represent
4
5 the different stakeholders as well as different health service user categories (users and non-
6
7 users).
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10 Data from the quantitative survey will be used to identify women who have or not used specific
11
12 MNH services and these will be approached to participate in the focus group discussions or in-
13
14 depth interviews. Other respondents will be identified based on their position in the community
15
16 and their role in the project.
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20 21 22 **Data Collection, Management and Analysis**

23
24 Data collection:

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26 We will conduct a baseline survey and an end-line at least one year after the full implementation
27
28 of the intervention. The control group will be assessed at the same time as the surveys are being
29
30 conducted in the intervention group. To strengthen the case for causal inference we will also do
31
32 a systematic monitoring and documentation of the intervention based on our theory of change.
33
34 The monitoring and documentation will also capture any other contextual factors that may
35
36 influence the same outcomes as our intervention. The effects and impact of the project will be
37
38 determined by triangulating data and information from different sources, examining trends where
39
40 possible, and trying to find and support explanations for the observed findings.
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45 Our key data sources will be the following: household surveys, routine HMIS data and
46
47 qualitative assessments (interviews and focus group discussions).
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50 We will conduct simple and multiple logistic regression analyses comparing differences in the
51
52 proportions of women in reproductive age and children under-five at baseline and end line for
53
54 variables like antenatal coverage, vaccination coverage, skilled birth attendance, among others,
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3 (See figure 1 for key indicators). These analyses will control for any differences in the samples
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5 (if any) at the two time points as well as the contribution of contextual factors that may have
6
7 occurred in the course of the implementation.
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12 mPAMANECH data: Descriptive data in terms of referrals by, diagnostic decisions, among
13
14 others, will be summarised using means and standard deviations for the parametric continuous
15
16 data and medians with inter-quartile ranges for the non-parametric data. Categorical data such as
17
18 referrals by age and gender will be summarised using proportions and percentages.
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21
22 Qualitative data: Qualitative data will be transcribed and saved in Word format. Transcribed
23
24 word files will be imported into NVIVO software (QSR International Pty Ltd) for coding and
25
26 further analysis. Analysis across all transcripts will be conducted using a constant comparative
27
28 method to identify themes and their repetitions and variations. The analysis will also aim to
29
30 identify changes (if any) in various indicators that could be attributed to the intervention.
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34 **3. Ethics and Dissemination**

35
36 The study was reviewed internally by APHRC's internal scientific review committee. Ethical
37
38 approval for the project was obtained from the African Medical Research Fund's Ethical and
39
40 Scientific Review Committee (AMREF-ESRC P279/2016). The research team has undergone the
41
42 NIH training on protecting human research participants. We shall seek informed consent from all
43
44 study participants. All survey data will be collected in privacy and will be treated with
45
46 confidentiality. It will be made clear to participants from the onset that participation in the study
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48 is voluntary and that they may choose to withdraw from the study at any time and for whatever
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50 reasons without fear of penalty. The mPAMANECH datasets will be available to users (CHVs,
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52 clinicians, CHEWs, among others) based on assigned, but limited, rights to protect the identity of
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3 study participants. Only the core research team will have access to all of this information. The
4
5 entire dataset will be stored in the APHRC server.
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10 The potential risks for study participants are limited to (i) data breaches ii) time spent on the
11 interview and (iii) discomfort experienced due to particular questions that respondents may
12 perceive as upsetting or personal. These potential risks will be carefully explained to each
13 participant during the process of obtaining informed consent.
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19 For the data collected on the phones and computers, once it is saved the data is relayed in real
20 time to the APHRC server and no information is saved on the phone or the computer. The users
21 will only be able to see summary data, without the participants' details. To further minimise the
22 risk attached to data breaches following the loss of a smartphone, each phone will have a 4-digit
23 pass code to enable the CHVs log into the phone. This code will become active after 3 minutes
24 on non-use. The third level of security is the username and password on each device.
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36 Plan for Communicating Findings of the Study:

37 Results obtained through this study will be made available to those who contributed information;
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39 the communities of Kamukunji and Embakasi. In addition,
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- 43 i. The study team will conduct one major dissemination workshop in Kenya to share
44 research findings with development partners, local NGOs, healthcare providers, activists,
45 media houses, health professional societies, and policymakers.
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- 49 ii. Findings of the study will be shared at local and international conferences with
50 researchers and policy makers.
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- 54 iii. We also expect to publish 3 peer-reviewed articles in Open Access scientific journals.
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3 iv. The Policy Engagement and Communications (PEC) unit at APHRC will also use the
4 findings of this study to produce policy briefs, fact sheets, and working papers, as well as
5 newsletters, which will be shared with a wide range of stakeholders.
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10 v. The findings of the study will also be shared through APHRC's website.
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22 4. Discussion 23 24 25

26 Maternal and neonatal health are both national and global priorities given that maternal and
27 neonatal health indicators have not appreciably improved over the Millennium Development
28 Goals life-span. They remain aspirations in the Sustainable Development agenda. CHVs are a
29 critical component of the health workforce bridging the gap between communities and the formal
30 health system. They not only improve coverage and access to basic health services but are also
31 usually available in locations where and at times when formal health services are unavailable or
32 inadequate. Quality healthcare is largely supported by quality data. Kenya still faces challenges
33 with its Health Management Information System. Inaccurate data as a result of poor
34 documentation impair the country's planning processes. This project accords APHRC and its
35 partners an opportunity to utilize funds that have been identified to respond to Kenya's needs; to
36 improve maternal and newborn health.
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51 The next steps of the project if the experiments under this grant are successful will include
52 sharing the findings with the Nairobi City County and the funder and agreeing on the next phase
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3 of implementation. The Ministry of Health, Nairobi, is keen to roll out the system county-wide
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5 subject to availability of funding. The project team will work with the consortium to generate
6
7 evidence to support decision-making at whatever stage of implementation. These may include
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9 effectiveness in reducing adverse maternal and neonatal outcomes at national level, cost-
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11 effectiveness, process issues such as CHV motivation and efficiency among others.
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15 Potential impediments to the intervention include possible technology failure, loss of equipment
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17 (phones) and CHV turnover; all of which could require revisions and adaptations in the work
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19 plan (e.g., quality assurance, insurance, and training). A potential harmful unintended
20
21 consequence stems from the fact that CHVs are not medically trained and as such could make a
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23 decision to treat at home, rather than refer (even when the system advises otherwise) with
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25 possible negative health consequences for the mothers and their newborns. However, since the
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27 system allows health workers to access this data, they will be in-charge of following up on such
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29 cases to avoid unnecessary delays and such unintended consequences.
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36 **5. Conclusion**

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39 The study outlined in this protocol will assess the added value of using a CHV decision-support
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41 module of mPAMANECH in reducing maternal complications and newborn deaths in the
42
43 informal settlements of Nairobi, Kenya. The study's findings will contribute to the body of
44
45 knowledge on the effectiveness of mHealth innovations in improving maternal, newborn and
46
47 child health services and outcomes in urban informal settlements. Successful execution of the
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49 protocol will generate evidence on the effectiveness, if any, of the system. Based on the positive
50
51 lessons learned, this project will provide a system for adoption by the local and central
52
53 governments, for resource limited communities.

54 **6. Competing interests statement:**

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3 None declared.
4
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6 **7. Authors' contributions:**
7

8 PB, CK, EK, AKZ conceived the project and its design and participated in refining the manuscript. MO
9 contributed to the refining of the design. PB drafted the manuscript. All authors read and approved the
10 final manuscript.
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13 **8. Funding statement:**
14

15 This project is supported by the County Innovation Challenge Fund for Kenya (GR: CICF-INN-R2-088).
16 The funder had no role in the decision to write and publish this protocol.
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20 **9. References:**
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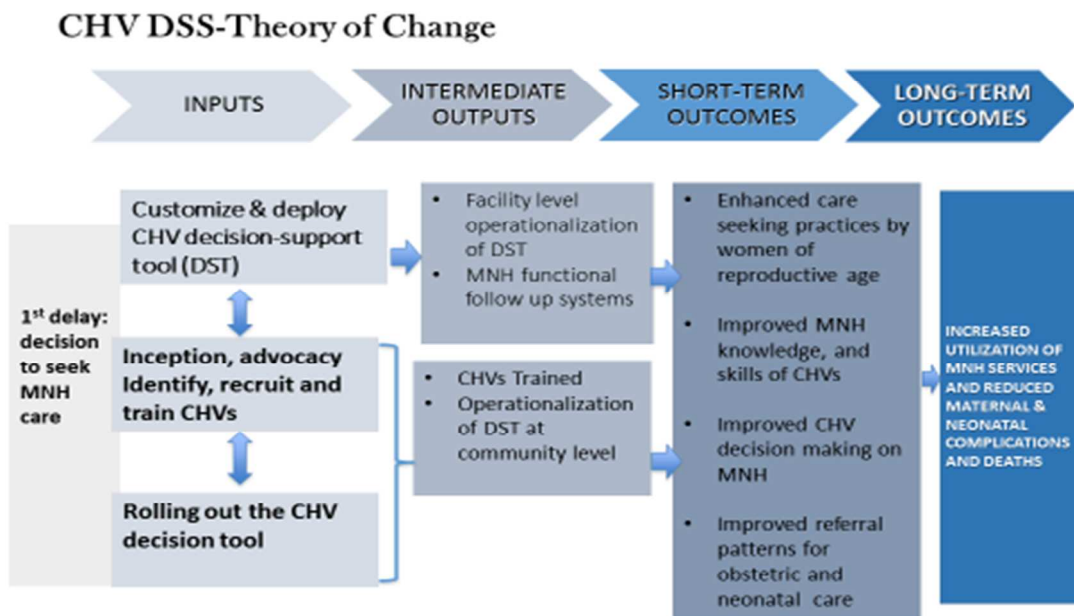
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Figure 1, Key Outcomes:

Domain of Inquiry	Key Outcome Indicators
Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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



view only

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Figure 3, Mobile Data Gathering Platform

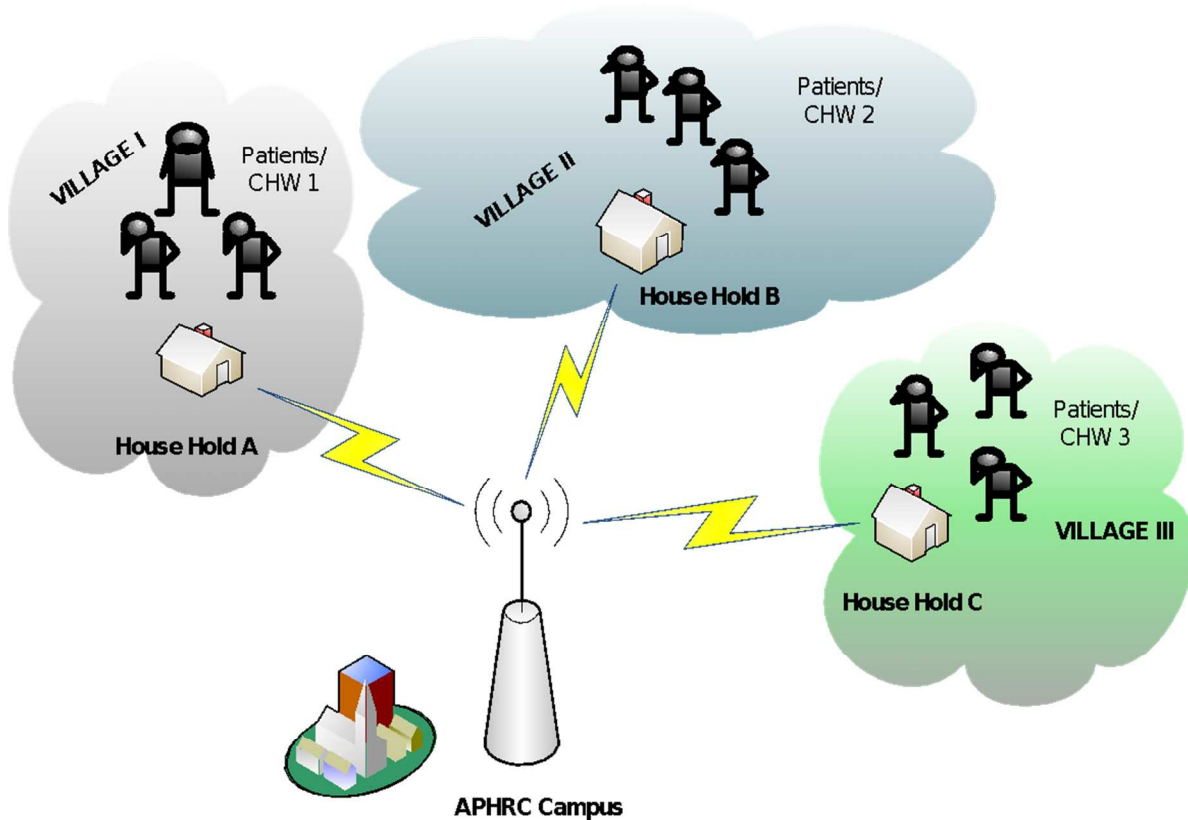
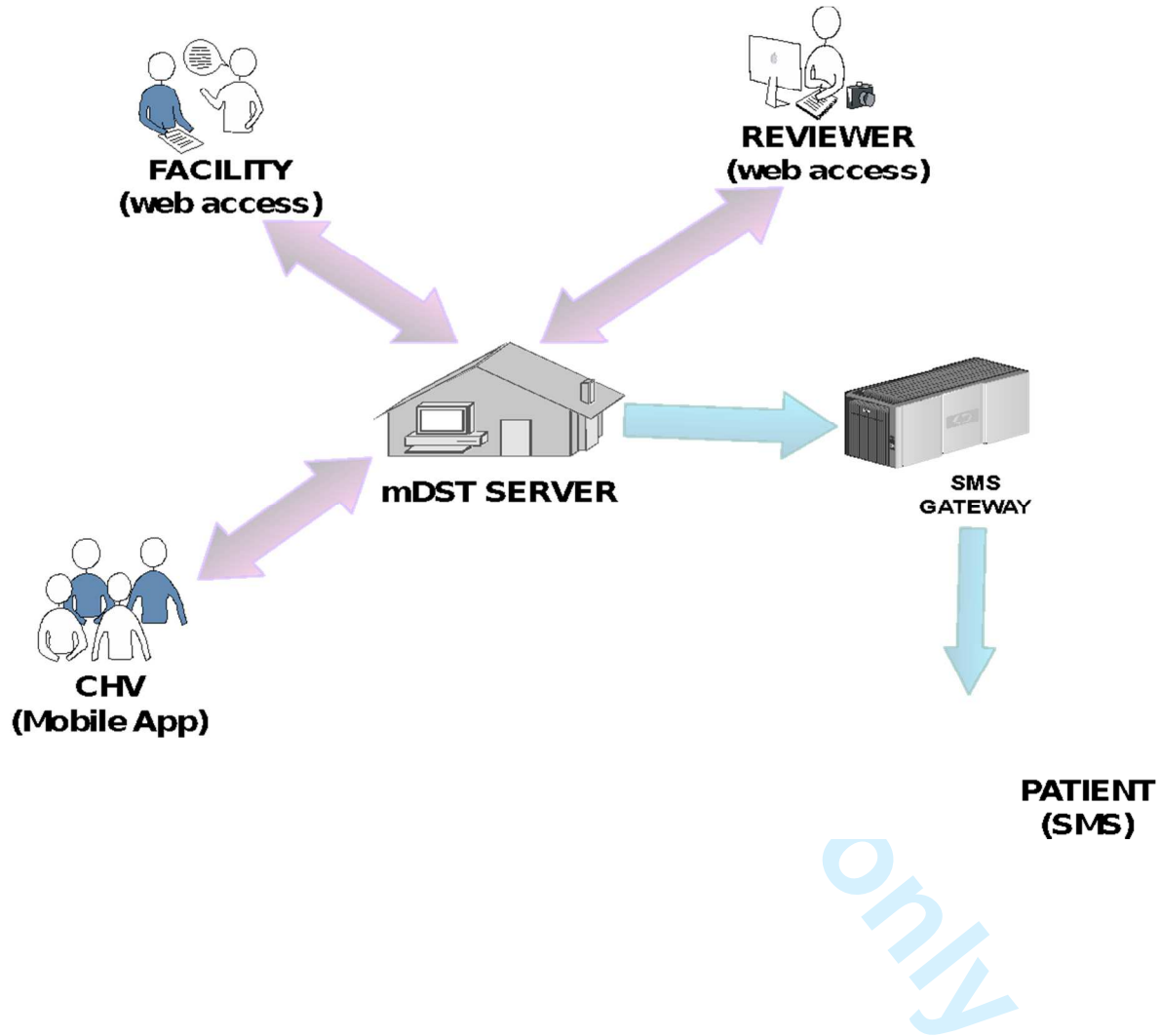


Figure 4: How the system works



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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			■				

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-014896.R1
Article Type:	Protocol
Date Submitted by the Author:	03-Feb-2017
Complete List of Authors:	Bakibinga, Pauline; African Population and Health Research Center, Health Challenges and Systems Program Kamande, Eva; African Population and Health Research Center, Health Challenges and Systems Omuya, Milka; African Population and Health Research Center, Health Challenges and Systems Ziraba, Abdhalah; African Population and Health Research Center, Health Challenges and Systems Kyobutungi, Catherine; African Population and Health Research Center, Health Challenges and Systems
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health, Health informatics
Keywords:	Decision-Support, Maternal and Newborn Health, Community Health Volunteers, Slums, Kenya

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3 **The role of a decision-support smartphone application in enhancing Community Health**
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5 **Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-**
6 **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

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2
3 parts of the world [8-10]. CHVs in Kenya, like in many emerging economies, are responsible for
4
5 the majority of grassroots health care delivery, and as such, continue to play a very critical role
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7 in primary health care delivery.
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10 **Decision-support systems**

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

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33 Mobile technologies have the potential to bridge systemic gaps needed to improve access to and
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35 use of health services, particularly among underserved populations [15]. Worldwide, the use of
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37 mobile and/or electronic devices to support both medical and public health practice and research
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39 (mHealth) is increasingly being appreciated [16-19]. The high and ever growing mobile
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41 penetration coupled with investments from technology companies that provide accessible
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43 platforms onto which innovations can establish and offer value-based products [17]. Innovations
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45 include mobile phone platforms/applications and micro-insurance packages. Given the nature
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47 and tight timeframes of most obstetric and neonatal emergencies, which more often than not
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49 demand quick access to quality care at short notice, mobile phone innovations are a cheap and
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51 fast solution especially in areas with poor healthcare infrastructure which have shown
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3 improvements in maternal and child health outcomes [19, 20]. The majority of innovations on
4 the market are tailored towards promoting reproductive, maternal, and child health [16, 21]. In
5 addition, various projects have been designed and evaluated on CHVs use of mobile technology
6 to deliver interventions [22, 23]. Decision-support systems have been highlighted as a critical
7 factor in reducing errors in evidence-based clinical practice. For clinicians, studies have
8 demonstrated that computerized decision support systems can be used to improve compliance to
9 practice guidelines [12, 13]. Given the limited training obtained and skills that the CHVs
10 possess, coupled with the distances they work from the clinical settings mobile information
11 technologies tools enable them to provide much needed health services.
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27 Over the last decade, more mobile and electronic information tools have been developed, tested
28 and implemented with CHVs to support their work roles. The tools help the CHVs in
29 surmounting challenges such as lack of appropriate work tools and inadequate supportive
30 supervision and training [22, 23]. These tools have been instrumental in improving access to care
31 by marginalized population groups subjected to stigma and those in hard to reach areas by
32 reducing both time and cost of travel. As such, research on CHVs' use of mHealth tools in
33 important. Several pilot projects, utilizing multiple designs and measures have been
34 implemented. The projects have reported improvements in services rendered by CHVs and the
35 related health outcomes for communities. In sub-Saharan Africa, most of the interventions have
36 demonstrated improvements in the CHVs' delivery of maternal, newborn and child health,
37 Tuberculosis and sexual and reproductive health services, among others [20, 22]. The
38 innovations largely use SMS and hotlines enabling mothers to access vital information and
39 timely referrals as a result of better and faster communication and transport. Available evidence
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3 shows the usefulness of mHealth tools in facilitation of compliance with practice guidelines and
4 process improvement [22]. However, many of the interventions have been limited
5 methodologically by their inability to demonstrate effectiveness and or impact related to patient
6 outcomes. In addition a lack of use of nationally accepted guidelines and open source tools limits
7 the scalability of these interventions. In addition, available literature does not provide cost
8 estimates necessary for delivery of program targets. Furthermore, a top to bottom approach that
9 does not incorporate the ideas of the CHVs in the development of the tools is a major
10 impediment as successful projects use the CHVs as experts in the design and management of
11 their interventions [22].
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29 The African Population and Health Research Center (APHRC) has implemented a health systems
30 strengthening project, Partnership for Maternal, Newborn and Child Health (PAMANECH) in
31 Korogocho and Viwandani informal settlements of Nairobi, Kenya [24]. The project sought to
32 strengthen the healthcare delivery system in the urban informal settlements to be more
33 responsive to the health needs of mothers and their children through enhanced service delivery
34 public-private partnerships. In a bid to improve the health management information system, an
35 innovative mHealth application, was developed. The mPAMANECH application was developed
36 as an integrated data capture tool running as a mobile app with selected reporting forms for
37 CHVs in Kenya. It operates in an interconnected network of CHVs and health facilities within a
38 defined local system. It is designed to replace the numerous paper-based forms that do not allow
39 integration of patient data from the community to the health facility and back for better referral
40 and management of patients. This system has been seen to improve the reporting abilities of
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3 CHVs as it is less cumbersome than the paper-based system and enhanced data quality as it has a
4 function that limits saving data until all necessary fields are filled in [25]. In addition, the CHEW
5 can access a CHV's data remotely without having to wait for the end of the month for the CHV
6 summaries. The desire to improve the functionality of the existing system to include a decision
7 support function provides the basis on the new project.
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10 This project attempts to bridge this gap by incorporating CHV views, utilizing the tools approved
11 by the Ministry of Health and allowing for assessment of health outcomes in the design and
12 implementation of the project. The decision support system is developed from open source tools.
13 In addition, a cost effectiveness analysis would be conducted to inform county and national
14 implementation plans regarding the necessary investments for set up and maintenance.
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29 **2. Methods and Analysis**

30 **Research Objectives**

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32 The overall objective of the proposed work is to develop and validate a decision-support
33 algorithm within a mHealth application in improving maternal and newborn health outcomes in
34 urban slums in Kamukunji sub-County in Nairobi, Kenya. The project seeks to assess the added
35 value of using a CHV decision-support module of mPAMANECH in reducing prenatal and
36 postnatal maternal complications and newborn deaths.
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39 Specifically the project will assess (i) the feasibility and acceptability of using a decision-support
40 module of mPAMANECH and (ii) whether decision-support platform contributes to increase in
41 utilization of MNH services. We will measure several outcomes, *figure 1* related to the two
42 specific objectives, above. The outcome measures have been used in different studies assessing
43 CHV abilities to assess and make referrals [26, 27].
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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

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3 will enable on-going supportive supervision in order to improve the quality of the CHVs work.

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5 In addition, more assessment will be made for those referrals that will be seen at health facility
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7 level, comparing danger signs identified by the CHV to those seen by the clinician.
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10 The attributes of the solution include: 1) Use of any android devices - the entire application is
11 operable on phones, tablets or desktops/laptops; 2) Within a linked local system – messaging is
12 delivered internally via the portal and no extra network charges are required for messaging; 3)
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15 The application is bandwidth light and takes about 100 Kenya shillings a month per user, based
16 on local data bundle charges. The application can work offline and auto-synchronize as soon as
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19 network connectivity is re-established; 4) Updates are automated and there is no need for an IT
20 expert to have physical access to the device to execute a software patch or change; 5) The
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23 application has security features that protect users' confidentiality and limit access to a closed
24 but linked local system of health facilities and CHVs with varied access rights; 6) It has the
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27 ability to limit use of other phone functionality to only allow this application to run. This helps
28 prevent abuse of the device and promote saving on bandwidth. We aim to enhance the
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31 functionality and utility of the current mPAMANECH application to include a community
32 decision support tool to be used within a local system comprised of selected CHVs and five
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35 maternity centres serving slum settlements in Nairobi. In the 'Operationalisation' section, we
36 describe more on how the decision support system is expected to work.
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3 From our proposed theory of change, *figure 2*, we anticipate that the decision support module of
4 mPAMANECH will assist the CHVs in the identification of high risk pregnant women, new
5 mothers and newborns with complications, and to make timely and correct decisions on referral
6 for cases that need intervention. With the improved knowledge and skills possessed by the CHVs
7 more women and neonates in need of health care will be identified and referred to the necessary
8 health facilities. As a result, there will be increase utilisation of maternal and neonatal health
9 services and reduced maternal and neonatal complications and deaths.
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23 **Operationalisation of the Decision Support System**

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26 The mobile decision support system (mDSS) mobile application (app) is an Android app that
27 installs from the phone and runs as an application, *figure 3*. The app will be hosted at Google
28 store and is accessible for download via the internet automatically to the user handset.
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34 Once installed, the handset and the application will be configured with the credentials of the
35 CHV including username and password, which are linked with the operating phone number. This
36 setup allows the system to register and associate collected records to the respective CHV; useful
37 for reporting and analysis purposes.
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44 The CHVs will be provided with a mobile phone running the mHealth app for data collection
45 which is then relayed to the head office at APHRC Campus. When visiting households for data
46 collection, by initiating a new record the system automatically picks the geolocation of the
47 household and associates it with the record.
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3 The CHV will complete the respective form and save the information at any stage on the
4 handset. This method allows the CHV to continue collecting more information and only submit
5 the completed form to the server over the internet. Where the handset detects that internet
6 connectivity is not available for one reason or the other, the completed forms will be stored in the
7 phone and only be relayed to the server when the connectivity is established. Because the
8 application is in communication with the server in real-time, any update of the data is
9 immediately available to the CHVs. The application is preconfigured with danger signs for both
10 mothers and newborns as defined by the WHO [30]. When any of the danger signs is picked by
11 the system, the CHV is immediately prompted to refer the patient to a facility within the
12 network.

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

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

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3 Both the CHV and the clinician's information are available to a reviewer in real time from the
4 web. The reviewer's role would be to assess the CHV's reason for referral and the clinician's
5 final diagnosis for correctness. The feedback from the reviewer will be available and shared on a
6 monthly basis during review meetings. Every week, the CHEW, will randomly sample referrals
7 made by each CHV to assess their correctness. This will be compared with the 'reviewers'
8 summary.
9

10 **mDSS Solution- Key Features (figure 4)**

11 **CHV (mobile App)**

12 Through this app, the mDSS data collection tools are accessible on the CHV mobile handset. It
13 allows for completion and submission of the information to the mDSS Server.
14

15 **mDSS Server**

16 A database driven web application that acts as a host for the collected information. It also has a
17 web interface for data manipulation by the facility healthcare worker(s) and reviewer.
18

19 The mDSS server application incorporates an application logic component that connects with the
20 SMS and email gateways. This allows for real-time communication of certain critical indicators
21 to the respective recipients. For example, where a patient has not shown up at the referred
22 facility, the CHV will be alerted.
23

24 **Facility (web access)**

25 This module is accessible at the facility via the web. The application allows the clinician to treat
26 the patient and record the treatment. The facility portal is accessible by facility staff to manage
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3 referrals. The “Messages” to alert the CHVs are to be integrated with WhatsApp for effective
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5 message delivery over the same mobile phone.
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8 9 **Reviewer (web access)**

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11 This module is also accessible via the web, and provides the reviewer a view to assess both the
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13 CHV referral report and the clinician’s diagnosis. It is based on this analysis that a decision is
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15 measured.
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18 19 **Null hypothesis:**

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21 Usage of a CHV decision-support module does not have an effect on utilization of MNH
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23 services.
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26 27 **Study Design and Sampling Strategy**

28 29 **a. Study Design**

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31 To answer the question on effect of the decision support system, we will use a quasi-
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33 experimental design with pre and post assessments to determine the impact, if any, on the MNH
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35 services and selected health indicators.
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39 We will work with three community units (CUs) from which a group of 50 CHVs will serve as
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41 the intervention group. Three CUs in Embakasi sub-County, with 50 CHVs will serve as the
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43 control. The CUs in the control group will be geographically distant from the intervention site to
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45 limit contamination. The control group will be facilitated within the normal standard of practice
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47 which includes paper-based reporting. The idea is to compare access to MNH services, referral
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49 practices and MNH outcomes between those with a decision-support tool with those working
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51 with traditional paper-based tools.
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3 We will conduct a baseline survey and an end-line at least one year after the full implementation
4 of the intervention. The control group will be assessed at the same time as the surveys are being
5 conducted in the intervention group. To strengthen the case for causal inference we will also do
6 a systematic monitoring and documentation of the intervention based on our theory of change.
7
8 The monitoring and documentation will also capture any other contextual factors that may
9 influence the same outcomes as our intervention.
10

11
12 To answer the question on feasibility, we will conduct a mixed methods assessment of the CHVs
13 and CHEWs. Qualitative assessments of their current work experiences with the paper based
14 system as well as after the introduction of the mobile based system will be conducted. We will
15 assess ease of use, challenges experienced and opportunities for improvement. These will be
16 triangulated with their HMIS reports (paper and electronic).
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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:

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3 ➤ **Quantitative study**

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5 ▪ *Study population*

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8 The project will target households with women of reproductive age (15-49 years) in the informal
9 settlements of Kamukunji and Embakasi. It will also target health care providers in five selected
10 health facilities as well as the sub-County Health Management teams of Kamukunji, Embakasi,
11 Makadara and Nairobi City County.
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15 A quantitative survey will be conducted focussing mainly on maternal and newborn health and
16 family planning services.
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20 ▪ *Sample size estimation*

21
22 The key outcome of interest is correct referral practices. Using proportion of neonates with at
23 least one danger sign referred by CHVs as the indicator, since it is representative of the target
24 population, the total sample size for each group has been estimated as 173 (346 in total). Using a
25 difference in proportion 13.3 % for neonates with danger signs referred (rising from 16.7 to
26 30%), at 95% CI for 80% power and sample proportions of 50% in the intervention and 40% in
27 the control groups, respectively, we came up with a sample size of 315. Accounting for a
28 potential non-response rate of 10% based on previous studies in similar study populations, the
29 effective sample size is 346. Using correct decisions made by CHVs (one of the indicators to be
30 measured), the sample size was estimated as 199. 346 is therefore an appropriate sample size.
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46 ▪ *Sampling procedure*

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48 To measure feasibility and acceptability, all the CHVs in the intervention site will be assessed, in
49 addition to an audit of the functionality of the system. We will measure the percentage time for
50 which the system is down on a monthly basis (**Numerator:** Number of times (in minutes) when
51 the system is down. **Denominator:** Total active time in a month. Down time defined as 30
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3 minutes of hanging and Active time as time without hitches), proportion of CHVs effectively
4 using the decision support system (Within the system, on a quarterly basis we will be able to
5 generate reports on decisions, correct or otherwise, made by the CHVs. These will also be
6 compared to the control site that will only have a paper based system of data collection), and the
7 experiences of the CHVs and the mothers with the mobile based system. These will be compared
8 to the investment.
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20 To answer the question on effect of the system on utilisation of services, the data above will be
21 triangulated with data from the **mPAMANECH application which already has an integrated**
22 **data collection module**, the data generated by the CHVs and participating health facilities will
23 be retrieved, cleaned and analyzed to derive estimates of the main outcome of interest – correct
24 referral practices. In addition, these data will be triangulated with other sources such as the CHV
25 monthly reports and health facility HMIS. A system of random numbers generated using STATA
26 will be used to select the respondents based on a sampling frame that is going to be informed by
27 an updated household register in the selected community units.
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38 ➤ **Qualitative study**

39 We will use focus group discussions (FGDs) and in-depth interviews among the direct project
40 beneficiaries and CHVs, and key informant interviews with key actors (sCHMTs, health
41 providers, CHVs and community leaders). Participants will be purposively selected to represent
42 the different stakeholders as well as different health service user categories (users and non-
43 users).
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52 Data from the quantitative survey will be used to identify women who have or not used specific
53 MNH services and these will be approached to participate in the focus group discussions or in-
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3 depth interviews. Other respondents will be identified based on their position in the community
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5 and their role in the project.
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10 **Data Collection, Management and Analysis**

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12 Data collection:

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14 We will conduct a baseline survey and an end-line at least one year after the full implementation
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16 of the intervention. The control group will be assessed at the same time as the surveys are being
17
18 conducted in the intervention group. To strengthen the case for causal inference we will also do
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20 a systematic monitoring and documentation of the intervention based on our theory of change.
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22 The monitoring and documentation will also capture any other contextual factors that may
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24 influence the same outcomes as our intervention. The effects and impact of the project will be
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26 determined by triangulating data and information from different sources, examining trends where
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28 possible, and trying to find and support explanations for the observed findings.
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34 Our key data sources will be the following: household surveys, routine HMIS data and
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36 qualitative assessments (interviews and focus group discussions).
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39 We will conduct simple and multiple logistic regression analyses comparing differences in the
40
41 proportions of women in reproductive age and children under-five at baseline and end line for
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43 variables like antenatal coverage, vaccination coverage, skilled birth attendance, among others,
44
45 (See figure 1 for key indicators). These analyses will control for any differences in the samples
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47 (if any) at the two time points as well as the contribution of contextual factors that may have
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49 occurred in the course of the implementation.
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3 mPAMANECH data: Descriptive data in terms of referrals by, diagnostic decisions, among
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5 others, will be summarised using means and standard deviations for the parametric continuous
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7 data and medians with inter-quartile ranges for the non-parametric data. Categorical data such as
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9 referrals by age and gender will be summarised using proportions and percentages.
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13 Qualitative data: Qualitative data will be transcribed and saved in Word format. Transcribed
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15 word files will be imported into NVIVO software (QSR International Pty Ltd) for coding and
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17 further analysis. Analysis across all transcripts will be conducted using a constant comparative
18
19 method to identify themes and their repetitions and variations. The analysis will also aim to
20
21 identify changes (if any) in various indicators that could be attributed to the intervention.
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24 25 **3. Ethics and Dissemination**

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27 The study was reviewed internally by APHRC's internal scientific review committee. Ethical
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29 approval for the project was obtained from the African Medical Research Fund's Ethical and
30
31 Scientific Review Committee (AMREF-ESRC P279/2016). The research team has undergone the
32
33 NIH training on protecting human research participants. We shall seek informed consent from all
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35 study participants. All survey data will be collected in privacy and will be treated with
36
37 confidentiality. It will be made clear to participants from the onset that participation in the study
38
39 is voluntary and that they may choose to withdraw from the study at any time and for whatever
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41 reasons without fear of penalty. The mPAMANECH datasets will be available to users (CHVs,
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43 clinicians, CHEWs, among others) based on assigned, but limited, rights to protect the identity of
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45 study participants. Only the core research team will have access to all of this information. The
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47 entire dataset will be stored in the APHRC server.
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3 The potential risks for study participants are limited to (i) data breaches ii) time spent on the
4 interview and (iii) discomfort experienced due to particular questions that respondents may
5 perceive as upsetting or personal. These potential risks will be carefully explained to each
6 participant during the process of obtaining informed consent.
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12 For the data collected on the phones and computers, once it is saved the data is relayed in real
13 time to the APHRC server and no information is saved on the phone or the computer. The users
14 will only be able to see summary data, without the participants' details. To further minimise the
15 risk attached to data breaches following the loss of a smartphone, each phone will have a 4-digit
16 pass code to enable the CHVs log into the phone. This code will become active after 3 minutes
17 on non-use. The third level of security is the username and password on each device.
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29 Plan for Communicating Findings of the Study:

30 Results obtained through this study will be made available to those who contributed information;
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32 the communities of Kamukunji and Embakasi. In addition,
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- 35 i. The study team will conduct one major dissemination workshop in Kenya to share
36 research findings with development partners, local NGOs, healthcare providers, activists,
37 media houses, health professional societies, and policymakers.
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- 39 ii. Findings of the study will be shared at local and international conferences with
40 researchers and policy makers.
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- 43 iii. We also expect to publish 3 peer-reviewed articles in Open Access scientific journals.
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- 46 iv. The Policy Engagement and Communications (PEC) unit at APHRC will also use the
47 findings of this study to produce policy briefs, fact sheets, and working papers, as well as
48 newsletters, which will be shared with a wide range of stakeholders.
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3 v. The findings of the study will also be shared through APHRC's website.
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14 **4. Discussion**

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19 Maternal and neonatal health are both national and global priorities given that maternal and
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21 neonatal health indicators have not appreciably improved over the Millennium Development
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23 Goals life-span. They remain aspirations in the Sustainable Development agenda. CHVs are a
24
25 critical component of the health workforce bridging the gap between communities and the formal
26
27 health system. They not only improve coverage and access to basic health services but are also
28
29 usually available in locations where and at times when formal health services are unavailable or
30
31 inadequate. Quality healthcare is largely supported by quality data. Kenya still faces challenges
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33 with its Health Management Information System. Inaccurate data as a result of poor
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35 documentation impair the country's planning processes. This project accords APHRC and its
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37 partners an opportunity to utilize funds that have been identified to respond to Kenya's needs; to
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39 improve maternal and newborn health.
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45 The next steps of the project if the experiments under this grant are successful will include
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47 sharing the findings with the Nairobi City County and the funder and agreeing on the next phase
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49 of implementation. The Ministry of Health, Nairobi, is keen to roll out the system county-wide
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51 subject to availability of funding. The project team will work with the consortium to generate
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53 evidence to support decision-making at whatever stage of implementation. These may include
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3 effectiveness in reducing adverse maternal and neonatal outcomes at national level, cost-
4 effectiveness, process issues such as CHV motivation and efficiency among others.
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8 Potential impediments to the intervention include possible technology failure, loss of equipment
9 (phones) and CHV turnover; all of which could require revisions and adaptations in the work
10 plan (e.g., quality assurance, insurance, and training). A potential harmful unintended
11 consequence stems from the fact that CHVs are not medically trained and as such could make a
12 decision to treat at home, rather than refer (even when the system advises otherwise) with
13 possible negative health consequences for the mothers and their newborns. However, since the
14 system allows health workers to access this data, they will be in-charge of following up on such
15 cases to avoid unnecessary delays and such unintended consequences.
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29 **5. Conclusion**

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

48
49 None declared.
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51 **7. Authors' contributions:**

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3 PB, CK, EK, AKZ conceived the project and its design and participated in refining the manuscript. MO
4 contributed to the refining of the design. PB drafted the manuscript. All authors read and approved the
5 final manuscript.
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8. Funding statement:

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10
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12 The funder had no role in the decision to write and publish this protocol.
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For peer review only

Figure 1, Key Outcomes:

Domain of Inquiry	Key Outcome Indicators
Assess the feasibility and acceptability of using a decision-support module of mPAMANECH	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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)

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Figure 2, Theory of Change

CHV DSS-Theory of Change

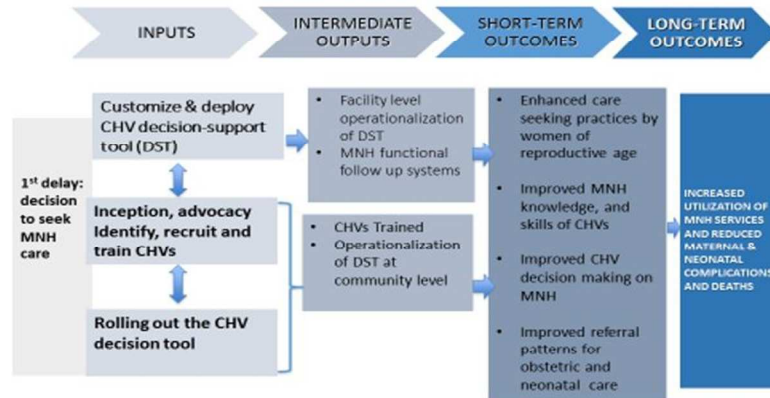


Figure 2: Theory of change

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review only

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Figure 3, Mobile Data Gathering Platform

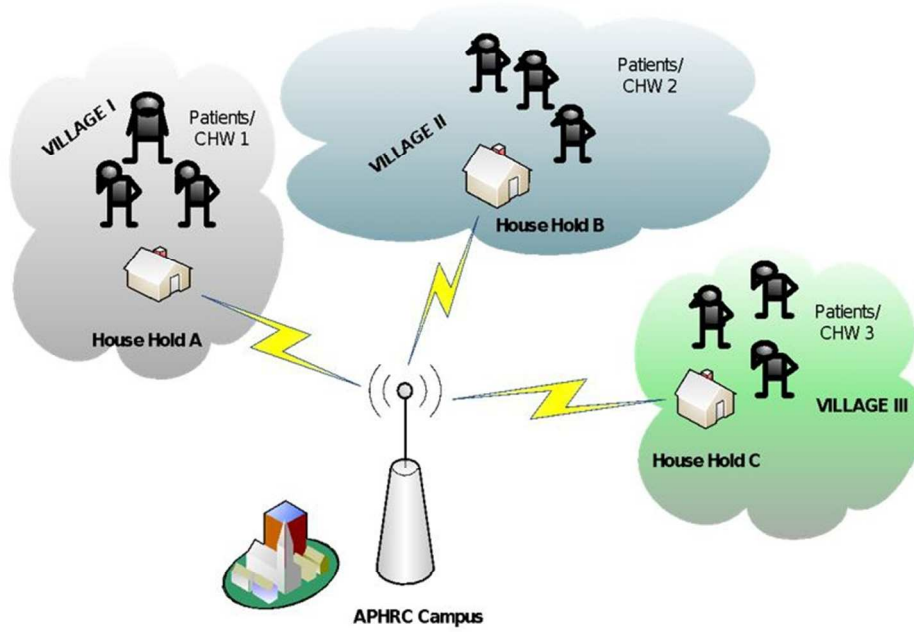


Figure 3: The system

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Figure 4: How the system works

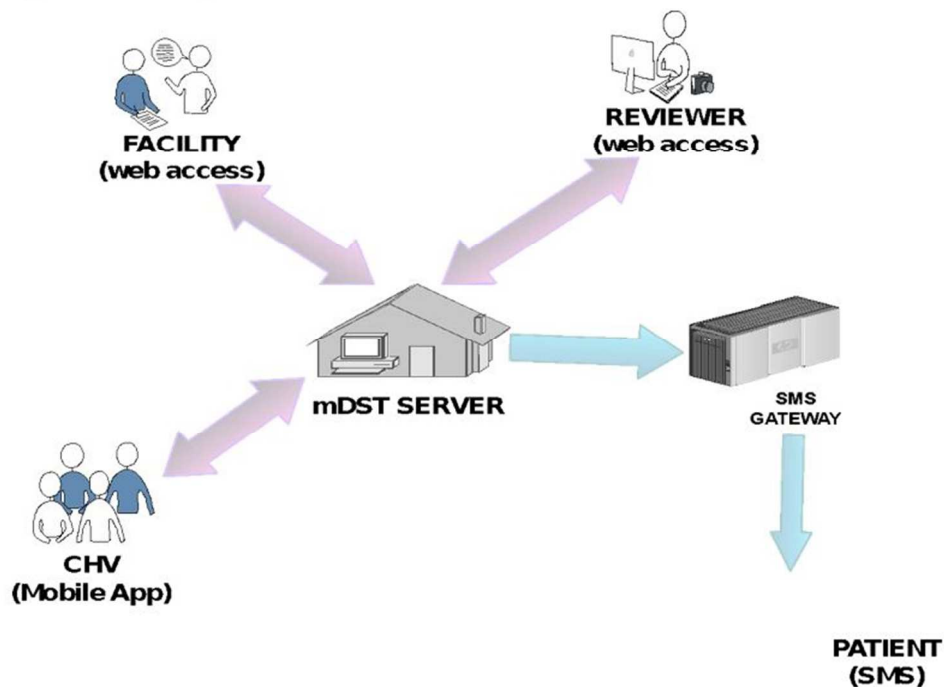


Figure 4: How the system works

70x53mm (300 x 300 DPI)

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Figure 5, Project timeline

CHV Decision Support Application: Pilot study							
Activities	2016			2017			
	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)

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5	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,			
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8		Objectively Verifiable Indicators			
9	Domain of inquiry	Indicators	Method of calculation		
10	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		
11		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		
12			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).	
13			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)	
14			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	
15	2. Determine the decision-support platform's effect on utilization of MNH services	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		
16		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		
17		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		
18		Proportion of women attending at least 4 ANC	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		
19		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.		
20	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			
21		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		
22		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		
23	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).			
24		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		
25		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		
26	Proportion of newborns (aged upto 28 days) who failed to report to selected health facilities	Numerator: Number of newborns (aged upto 28 days) who failed to report to selected health facilities. Denominator: Total number of newborns (aged upto 28 days) referred by CHVs			
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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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Manuscript ID	bmjopen-2016-014896.R2
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health, Health informatics
Keywords:	Decision-Support, Maternal and Newborn Health, Community Health Volunteers, Slums, Kenya

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3 **The role of a decision-support smartphone application in enhancing Community Health**
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5 **Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi, Kenya: a quasi-**
6 **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

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

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

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36 Mobile technologies have the potential to bridge systemic gaps needed to improve access to and
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38 use of health services, particularly among underserved populations [15]. Worldwide, the use of
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40 mobile and/or electronic devices to support both medical and public health practice and research
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42 (mHealth) is increasingly being appreciated [16-19]. The high and ever growing mobile
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44 penetration coupled with investments from technology companies that provide accessible
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46 platforms onto which innovations can establish and offer value-based products [17]. Innovations
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48 include mobile phone platforms/applications and micro-insurance packages. Given the nature
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50 and tight timeframes of most obstetric and neonatal emergencies, which more often than not
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52 demand quick access to quality care at short notice, mobile phone innovations are a cheap and
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3 fast solution especially in areas with poor healthcare infrastructure which have shown
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5 improvements in maternal and child health outcomes [19, 20]. The majority of innovations on
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7 the market are tailored towards promoting reproductive, maternal, and child health [16, 21]. In
8
9 addition, various projects have been designed and evaluated on CHVs use of mobile technology
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11 to deliver interventions [22, 23]. Decision-support systems have been highlighted as a critical
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13 factor in reducing errors in evidence-based clinical practice. For clinicians, studies have
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15 demonstrated that computerized decision support systems can be used to improve compliance to
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17 practice guidelines [12, 13]. Given the limited training obtained and skills that the CHVs
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19 possess, coupled with the distances they work from the clinical settings mobile information
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21 technologies tools enable them to provide much needed health services.
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29 Over the last decade, more mobile and electronic information tools have been developed, tested
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31 and implemented with CHVs to support their work roles. The tools help the CHVs in
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33 surmounting challenges such as lack of appropriate work tools and inadequate supportive
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35 supervision and training [22, 23]. These tools have been instrumental in improving access to care
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37 by marginalized population groups subjected to stigma and those in hard to reach areas by
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39 reducing both time and cost of travel. As such, research on CHVs' use of mHealth tools in
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41 important. Several pilot projects, utilizing multiple designs and measures have been
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43 implemented. The projects have reported improvements in services rendered by CHVs and the
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45 related health outcomes for communities. In sub-Saharan Africa, most of the interventions have
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47 demonstrated improvements in the CHVs' delivery of maternal, newborn and child health,
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49 Tuberculosis and sexual and reproductive health services, among others [20, 22]. The
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51 innovations largely use SMS and hotlines enabling mothers to access vital information and
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3 timely referrals as a result of better and faster communication and transport. Available evidence
4 shows the usefulness of mHealth tools in facilitation of compliance with practice guidelines and
5 process improvement [22]. However, many of the interventions have been limited
6 methodologically by their inability to demonstrate effectiveness and or impact related to patient
7 outcomes. In addition a lack of use of nationally accepted guidelines and open source tools limits
8 the scalability of these interventions. In addition, available literature does not provide cost
9 estimates necessary for delivery of program targets. Furthermore, a top to bottom approach that
10 does not incorporate the ideas of the CHVs in the development of the tools is a major
11 impediment as successful projects use the CHVs as experts in the design and management of
12 their interventions [22].
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32 The African Population and Health Research Center (APHRC) has implemented a health systems
33 strengthening project, Partnership for Maternal, Newborn and Child Health (PAMANECH) in
34 Korogocho and Viwandani informal settlements of Nairobi, Kenya [24]. The project sought to
35 strengthen the healthcare delivery system in the urban informal settlements to be more
36 responsive to the health needs of mothers and their children through enhanced service delivery
37 public-private partnerships. In a bid to improve the health management information system, an
38 innovative mHealth application, was developed. The mPAMANECH application was developed
39 as an integrated data capture tool running as a mobile app with selected reporting forms for
40 CHVs in Kenya. It operates in an interconnected network of CHVs and health facilities within a
41 defined local system. It is designed to replace the numerous paper-based forms that do not allow
42 integration of patient data from the community to the health facility and back for better referral
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3 and management of patients. This system has been seen to improve the reporting abilities of
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5 CHVs as it is less cumbersome than the paper-based system and enhanced data quality as it has a
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7 function that limits saving data until all necessary fields are filled in [25]. In addition, the CHEW
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9 can access a CHV's data remotely without having to wait for the end of the month for the CHV
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11 summaries. The desire to improve the functionality of the existing system to include a decision
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13 support function provides the basis on the new project.
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17 This project attempts to bridge this gap by incorporating CHV views, utilizing the tools approved
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19 by the Ministry of Health and allowing for assessment of health outcomes in the design and
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21 implementation of the project. The decision support system is developed from open source tools.
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23 In addition, a cost effectiveness analysis would be conducted to inform county and national
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25 implementation plans regarding the necessary investments for set up and maintenance.
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32 **2. Methods and Analysis**

33 **Research Objectives**

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35 The overall objective of the proposed work is to develop and validate a decision-support
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37 algorithm within a mHealth application in improving maternal and newborn health outcomes in
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39 urban slums in Kamukunji sub-County in Nairobi, Kenya. The project seeks to assess the added
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41 value of using a CHV decision-support module of mPAMANECH in reducing prenatal and
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43 postnatal maternal complications and newborn deaths.
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48 Specifically the project will assess (i) the feasibility and acceptability of using a decision-support
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50 module of mPAMANECH and (ii) whether decision-support platform contributes to increase in
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52 utilization of MNH services. We will measure several outcomes, *figure 1* related to the two
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54 specific objectives, above. The outcome measures have been used in different studies assessing
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3 CHV abilities to assess and make referrals [26, 27]. Supplementary files 1, 2 and 3 show the
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5 quantitative and qualitative measures under study.
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8 9 10 **Conceptual framework, Theory of Change and Operationalization**

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12 Our innovation centres around enhancing the functionality and utility of the current
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14 mPAMANECH application to include a community decision support tool to be used within a
15
16 local system comprised of CHVs and five maternity centres serving five slum settlements in
17
18 Nairobi. The decision-support module in the mPAMANECH application will supplement the
19
20 existing MNCH data capture modules and help in the identification of high risk facing pregnant
21
22 women, new mothers and newborns with complications, and to make timely and correct
23
24 decisions on referral for cases that need intervention. The main beneficiaries are pregnant women
25
26 (over 24 weeks), mothers in the immediate post-partum period and their newborns (up to 28 days
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28 old).
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34 The use of CHVs in delivering the mobile phone based intervention and follow up by the
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36 SCHMT will ensure sustained support and adherence to the intervention during pregnancy,
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38 immediate postpartum and in the neonatal period. The mPAMANECH has the official 100, 513,
39
40 514 and 515 forms in use by CHVs and CHEWs, who supervise the CHVs [28, 29]. A dedicated
41
42 team of CHEWs will ensure that the intervention is delivered as expected and non-adherence
43
44 captured and documented. CHV adherence will be measured by the CHEWs who will provide
45
46 additional support, correcting CHVs but not forms. They will be used to sample some of the
47
48 CHVs' work. For each woman or newborn with referral symptom, seen at household level, we
49
50 will compare the CHEW's assessment to that of the CHV in regard to the proportion of cases for
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52 whom CHWs identified and indicated correctly on their forms as requiring a referral, and the
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3 proportion for whom a written referral was provided. This is beneficial because the review
4 meetings are at the end of the month. The sampling of the work will enable on-going supportive
5 supervision in order to improve the quality of the CHVs work. In addition, more assessment will
6 be made for those referrals that will be seen at health facility level, comparing danger signs
7 identified by the CHV to those seen by the clinician.
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11 The attributes of the solution include: 1) Use of any android devices - the entire application is
12 operable on phones, tablets or desktops/laptops; 2) Within a linked local system – messaging is
13 delivered internally via the portal and no extra network charges are required for messaging; 3)
14 The application is bandwidth light and takes about 100 Kenya shillings a month per user, based
15 on local data bundle charges. The application can work offline and auto-synchronize as soon as
16 network connectivity is re-established; 4) Updates are automated and there is no need for an IT
17 expert to have physical access to the device to execute a software patch or change; 5) The
18 application has security features that protect users' confidentiality and limit access to a closed
19 but linked local system of health facilities and CHVs with varied access rights; 6) It has the
20 ability to limit use of other phone functionality to only allow this application to run. This helps
21 prevent abuse of the device and promote saving on bandwidth. We aim to enhance the
22 functionality and utility of the current mPAMANECH application to include a community
23 decision support tool to be used within a local system comprised of selected CHVs and five
24 maternity centres serving slum settlements in Nairobi. In the 'Operationalisation' section, we
25 describe more on how the decision support system is expected to work.
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3 From our proposed theory of change, *figure 2*, we anticipate that the decision support module of
4 mPAMANECH will assist the CHVs in the identification of high risk pregnant women, new
5 mothers and newborns with complications, and to make timely and correct decisions on referral
6 for cases that need intervention. With the improved knowledge and skills possessed by the CHVs
7 more women and neonates in need of health care will be identified and referred to the necessary
8 health facilities. As a result, there will be increase utilisation of maternal and neonatal health
9 services and reduced maternal and neonatal complications and deaths.
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23 **Operationalisation of the Decision Support System**

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26 The mobile decision support system (mDSS) mobile application (app) is an Android app that
27 installs from the phone and runs as an application, *figure 3*. The app will be hosted at Google
28 store and is accessible for download via the internet automatically to the user handset.
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33
34 Once installed, the handset and the application will be configured with the credentials of the
35 CHV including username and password, which are linked with the operating phone number. This
36 setup allows the system to register and associate collected records to the respective CHV; useful
37 for reporting and analysis purposes.
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44 The CHVs will be provided with a mobile phone running the mHealth app for data collection
45 which is then relayed to the head office at APHRC Campus. When visiting households for data
46 collection, by initiating a new record the system automatically picks the geolocation of the
47 household and associates it with the record.
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3 The CHV will complete the respective form and save the information at any stage on the
4 handset. This method allows the CHV to continue collecting more information and only submit
5 the completed form to the server over the internet. Where the handset detects that internet
6 connectivity is not available for one reason or the other, the completed forms will be stored in the
7 phone and only be relayed to the server when the connectivity is established. Because the
8 application is in communication with the server in real-time, any update of the data is
9 immediately available to the CHVs. The application is preconfigured with danger signs for both
10 mothers and newborns as defined by the WHO [30]. When any of the danger signs is picked by
11 the system, the CHV is immediately prompted to refer the patient to a facility within the
12 network.

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14
15 The system is to be set up in such a way that the CHV will not be allowed to proceed and
16 complete the forms until the referral is done. The patient's information will be available to all the
17 facilities within the network and he/she will be able to visit any of the networked facilities for
18 treatment. This information is also relayed to the rest of the other facilities and a record of the
19 visit is kept in the server. Within 24 hours if the patient has not been seen in any of the
20 networked facilities, an SMS message is relayed to the respective CHV handset. At this point,
21 the CHV should follow up with the patient to inquire about their condition and whether they
22 chose to honour the referral to a facility outside the network or not.

23
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25 When the patient visits a facility within the network, using the household number and the name
26 he/she will be easily identified and treated. The clinician is able to record the treatment in the
27 patient's information, which is recorded in the server.

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3 Both the CHV and the clinician's information are available to a reviewer in real time from the
4 web. The reviewer's role would be to assess the CHV's reason for referral and the clinician's
5 final diagnosis for correctness. The feedback from the reviewer will be available and shared on a
6 monthly basis during review meetings. Every week, the CHEW, will randomly sample referrals
7 made by each CHV to assess their correctness. This will be compared with the 'reviewers'
8 summary.
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17 **mDSS Solution- Key Features (figure 4)**

18 **CHV (mobile App)**

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

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31
32 A database driven web application that acts as a host for the collected information. It also has a
33 web interface for data manipulation by the facility healthcare worker(s) and reviewer.
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38 The mDSS server application incorporates an application logic component that connects with the
39 SMS and email gateways. This allows for real-time communication of certain critical indicators
40 to the respective recipients. For example, where a patient has not shown up at the referred
41 facility, the CHV will be alerted.
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48 **Facility (web access)**

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51 This module is accessible at the facility via the web. The application allows the clinician to treat
52 the patient and record the treatment. The facility portal is accessible by facility staff to manage
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3 referrals. The “Messages” to alert the CHVs are to be integrated with WhatsApp for effective
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5 message delivery over the same mobile phone.
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8 9 **Reviewer (web access)**

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11 This module is also accessible via the web, and provides the reviewer a view to assess both the
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13 CHV referral report and the clinician’s diagnosis. It is based on this analysis that a decision is
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15 measured.
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18 19 **Null hypothesis:**

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21 Usage of a CHV decision-support module does not have an effect on utilization of MNH
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23 services.
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26 27 **Study Design and Sampling Strategy**

28 29 **a. Study Design**

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31 To answer the question on effect of the decision support system, we will use a quasi-
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33 experimental design with pre and post assessments to determine the impact, if any, on the MNH
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35 services and selected health indicators.
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38
39 We will work with three community units (CUs) from which a group of 50 CHVs will serve as
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41 the intervention group. Three CUs in Embakasi sub-County, with 50 CHVs will serve as the
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43 control. The CUs in the control group will be geographically distant from the intervention site to
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45 limit contamination. The control group will be facilitated within the normal standard of practice
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47 which includes paper-based reporting. The idea is to compare access to MNH services, referral
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49 practices and MNH outcomes between those with a decision-support tool with those working
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51 with traditional paper-based tools.
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3 We will conduct a baseline survey and an end-line at least one year after the full implementation
4 of the intervention. The control group will be assessed at the same time as the surveys are being
5 conducted in the intervention group. To strengthen the case for causal inference we will also do
6 a systematic monitoring and documentation of the intervention based on our theory of change.
7
8 The monitoring and documentation will also capture any other contextual factors that may
9 influence the same outcomes as our intervention.
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11
12 To answer the question on feasibility, we will conduct a mixed methods assessment of the CHVs
13 and CHEWs. Qualitative assessments of their current work experiences with the paper based
14 system as well as after the introduction of the mobile based system will be conducted. We will
15 assess ease of use, challenges experienced and opportunities for improvement. These will be
16 triangulated with their HMIS reports (paper and electronic).
17
18

19 **b. Study Setting**

20 The intervention site covers informal settlements in Kamukunji sub County, which, like other
21 slums, are characterized by poverty, poor coverage of social services and poor health outcomes.
22 We will identify CUs and 5 facilities that serve the CUs. Embakasi sub-County will serve as the
23 control site. We will identify three CUs to serve as controls.
24
25

26 **c. Sampling**

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

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3 ➤ **Quantitative study**

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5 ▪ *Study population*

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8 The project will target households with women of reproductive age (15-49 years) in the informal
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10 settlements of Kamukunji and Embakasi. It will also target health care providers in five selected
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12 health facilities as well as the sub-County Health Management teams of Kamukunji, Embakasi,
13
14 Makadara and Nairobi City County.

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16
17 A quantitative survey will be conducted focussing mainly on maternal and newborn health and
18
19 family planning services.

20
21
22 ▪ *Sample size estimation*

23
24 The key outcome of interest is correct referral practices. Using proportion of neonates with at
25
26 least one danger sign referred by CHVs as the indicator, since it is representative of the target
27
28 population, the total sample size for each group has been estimated as 173 (346 in total). Using a
29
30 difference in proportion 13.3 % for neonates with danger signs referred (rising from 16.7 to
31
32 30%), at 95% CI for 80% power and sample proportions of 50% in the intervention and 40% in
33
34 the control groups, respectively, we came up with a sample size of 315. Accounting for a
35
36 potential non-response rate of 10% based on previous studies in similar study populations, the
37
38 effective sample size is 346. Using correct decisions made by CHVs (one of the indicators to be
39
40 measured), the sample size was estimated as 199. 346 is therefore an appropriate sample size.

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42
43 ▪ *Sampling procedure*

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45
46 To measure feasibility and acceptability, all the CHVs in the intervention site will be assessed, in
47
48 addition to an audit of the functionality of the system. We will measure the percentage time for
49
50 which the system is down on a monthly basis (**Numerator:** Number of times (in minutes) when
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52 the system is down. **Denominator:** Total active time in a month. Down time defined as 30
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3 minutes of hanging and Active time as time without hitches), proportion of CHVs effectively
4 using the decision support system (Within the system, on a quarterly basis we will be able to
5 generate reports on decisions, correct or otherwise, made by the CHVs. These will also be
6 compared to the control site that will only have a paper based system of data collection), and the
7 experiences of the CHVs and the mothers with the mobile based system. These will be compared
8 to the investment.
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20 To answer the question on effect of the system on utilisation of services, the data above will be
21 triangulated with data from the **mPAMANECH application which already has an integrated**
22 **data collection module**, the data generated by the CHVs and participating health facilities will
23 be retrieved, cleaned and analyzed to derive estimates of the main outcome of interest – correct
24 referral practices. In addition, these data will be triangulated with other sources such as the CHV
25 monthly reports and health facility HMIS. A system of random numbers generated using STATA
26 will be used to select the respondents based on a sampling frame that is going to be informed by
27 an updated household register in the selected community units.
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38 ➤ **Qualitative study**

39 We will use focus group discussions (FGDs) and in-depth interviews among the direct project
40 beneficiaries and CHVs, and key informant interviews with key actors (sCHMTs, health
41 providers, CHVs and community leaders). Participants will be purposively selected to represent
42 the different stakeholders as well as different health service user categories (users and non-
43 users).
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52 Data from the quantitative survey will be used to identify women who have or not used specific
53 MNH services and these will be approached to participate in the focus group discussions or in-
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3 depth interviews. Other respondents will be identified based on their position in the community
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5 and their role in the project.
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10 **Data Collection, Management and Analysis**

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12 Data collection:

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14 We will conduct a baseline survey and an end-line at least one year after the full implementation
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16 of the intervention. The control group will be assessed at the same time as the surveys are being
17
18 conducted in the intervention group. To strengthen the case for causal inference we will also do
19
20 a systematic monitoring and documentation of the intervention based on our theory of change.
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22 The monitoring and documentation will also capture any other contextual factors that may
23
24 influence the same outcomes as our intervention. The effects and impact of the project will be
25
26 determined by triangulating data and information from different sources, examining trends where
27
28 possible, and trying to find and support explanations for the observed findings.
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34 Our key data sources will be the following: household surveys, routine HMIS data and
35
36 qualitative assessments (interviews and focus group discussions).
37

38 We will conduct simple and multiple logistic regression analyses comparing differences in the
39
40 proportions of women in reproductive age and children under-five at baseline and end line for
41
42 variables like antenatal coverage, vaccination coverage, skilled birth attendance, among others,
43
44 (See figure 1 for key indicators). These analyses will control for any differences in the samples
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46 (if any) at the two time points as well as the contribution of contextual factors that may have
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48 occurred in the course of the implementation.
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3 mPAMANECH data: Descriptive data in terms of referrals by, diagnostic decisions, among
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5 others, will be summarised using means and standard deviations for the parametric continuous
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7 data and medians with inter-quartile ranges for the non-parametric data. Categorical data such as
8
9 referrals by age and gender will be summarised using proportions and percentages.
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12 Qualitative data: Qualitative data will be transcribed and saved in Word format. Transcribed
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14 word files will be imported into NVIVO software (QSR International Pty Ltd) for coding and
15
16 further analysis. Analysis across all transcripts will be conducted using a constant comparative
17
18 method to identify themes and their repetitions and variations. The analysis will also aim to
19
20 identify changes (if any) in various indicators that could be attributed to the intervention. Figure
21
22 5 shows the study's timeline.
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26 27 **3. Ethics and Dissemination**

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29 The study was reviewed internally by APHRC's internal scientific review committee. Ethical
30
31 approval for the project was obtained from the African Medical Research Fund's Ethical and
32
33 Scientific Review Committee (AMREF-ESRC P279/2016). The research team has undergone the
34
35 NIH training on protecting human research participants. We shall seek informed consent from all
36
37 study participants. All survey data will be collected in privacy and will be treated with
38
39 confidentiality. It will be made clear to participants from the onset that participation in the study
40
41 is voluntary and that they may choose to withdraw from the study at any time and for whatever
42
43 reasons without fear of penalty. The mPAMANECH datasets will be available to users (CHVs,
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45 clinicians, CHEWs, among others) based on assigned, but limited, rights to protect the identity of
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47 study participants. Only the core research team will have access to all of this information. The
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49 entire dataset will be stored in the APHRC server.
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3 The potential risks for study participants are limited to (i) data breaches ii) time spent on the
4 interview and (iii) discomfort experienced due to particular questions that respondents may
5 perceive as upsetting or personal. These potential risks will be carefully explained to each
6 participant during the process of obtaining informed consent.
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12 For the data collected on the phones and computers, once it is saved the data is relayed in real
13 time to the APHRC server and no information is saved on the phone or the computer. The users
14 will only be able to see summary data, without the participants' details. To further minimise the
15 risk attached to data breaches following the loss of a smartphone, each phone will have a 4-digit
16 pass code to enable the CHVs log into the phone. This code will become active after 3 minutes
17 on non-use. The third level of security is the username and password on each device.
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29 **Plan for Communicating Findings of the Study:**

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31 Results obtained through this study will be made available to those who contributed information;
32 the communities of Kamukunji and Embakasi. In addition,
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- 35 i. The study team will conduct one major dissemination workshop in Kenya to share
36 research findings with development partners, local NGOs, healthcare providers, activists,
37 media houses, health professional societies, and policymakers.
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- 39 ii. Findings of the study will be shared at local and international conferences with
40 researchers and policy makers.
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42
- 43 iii. We also expect to publish 3 peer-reviewed articles in Open Access scientific journals.
44
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- 46 iv. The Policy Engagement and Communications (PEC) unit at APHRC will also use the
47 findings of this study to produce policy briefs, fact sheets, and working papers, as well as
48 newsletters, which will be shared with a wide range of stakeholders.
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3 v. The findings of the study will also be shared through APHRC's website.
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10 **4. Discussion**

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14 Maternal and neonatal health are both national and global priorities given that maternal and
15 neonatal health indicators have not appreciably improved over the Millennium Development
16 Goals life-span. They remain aspirations in the Sustainable Development agenda. CHVs are a
17 critical component of the health workforce bridging the gap between communities and the formal
18 health system. They not only improve coverage and access to basic health services but are also
19 usually available in locations where and at times when formal health services are unavailable or
20 inadequate. Quality healthcare is largely supported by quality data. Kenya still faces challenges
21 with its Health Management Information System. Inaccurate data as a result of poor
22 documentation impair the country's planning processes. This project accords APHRC and its
23 partners an opportunity to utilize funds that have been identified to respond to Kenya's needs; to
24 improve maternal and newborn health.
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40 The next steps of the project if the experiments under this grant are successful will include
41 sharing the findings with the Nairobi City County and the funder and agreeing on the next phase
42 of implementation. The Ministry of Health, Nairobi, is keen to roll out the system county-wide
43 subject to availability of funding. The project team will work with the consortium to generate
44 evidence to support decision-making at whatever stage of implementation. These may include
45 effectiveness in reducing adverse maternal and neonatal outcomes at national level, cost-
46 effectiveness, process issues such as CHV motivation and efficiency among others.
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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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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

CHV DSS-Theory of Change

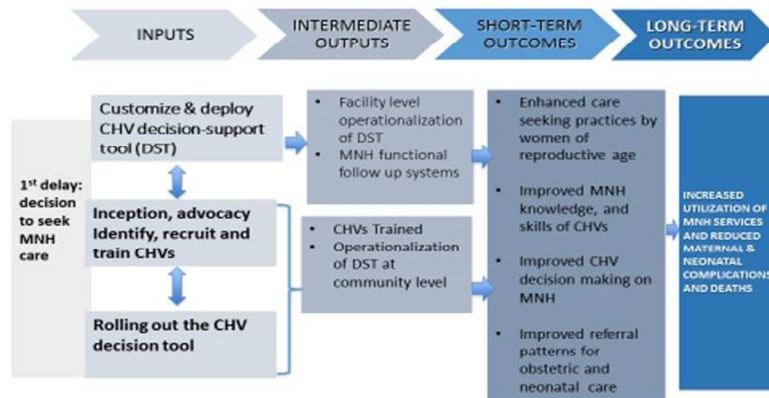


Figure 2: Theory of change

78x40mm (300 x 300 DPI)

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Figure 3, Mobile Data Gathering Platform

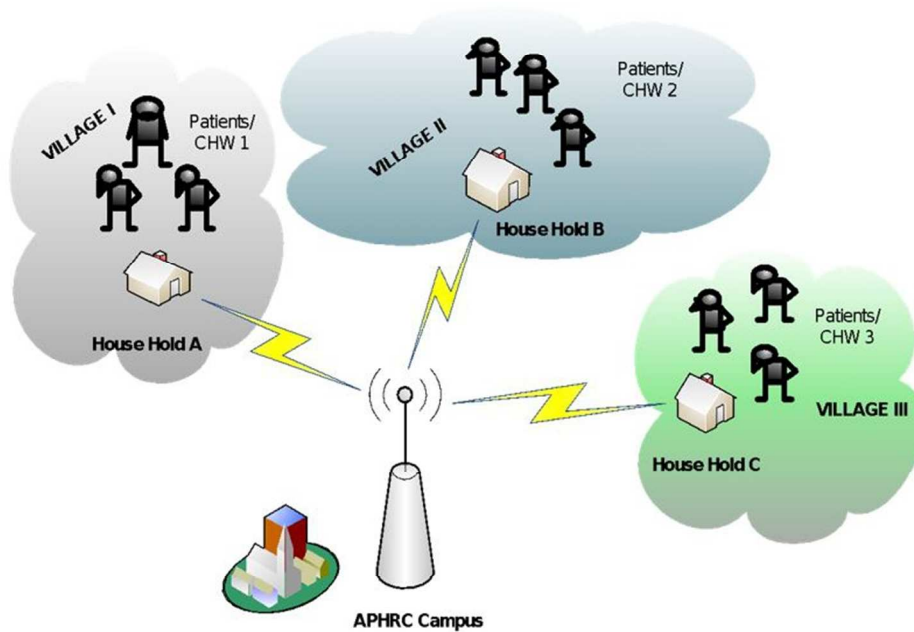


Figure 3: The system

72x53mm (300 x 300 DPI)

Review only

Figure 4: How the system works

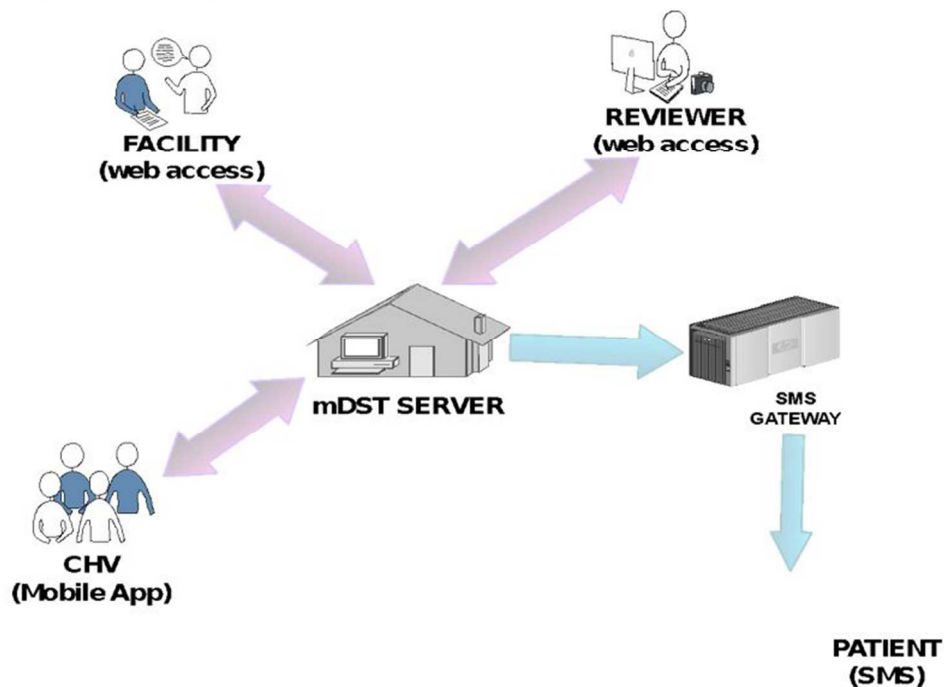


Figure 4: How the system works

70x53mm (300 x 300 DPI)

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Figure 5, Project timeline

CHV Decision Support Application: Pilot study							
Activities	2016			2017			
	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)

only

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
	Proportion of women attending at least 4 ANC	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 to selected health facilities.	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) who failed to report to selected health facilities	Numerator: Number of newborns (aged upto 28days) who failed to report to selected health facilities (aged upto 28 days) referred by CHVs

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3 **Using a Decision-Support Smartphone application to enhance Community Health**
4 **Volunteers' effectiveness in reducing maternal complications and reducing newborn**
5 **Deaths in the informal settlements of Nairobi, Kenya**
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8 **Thematic Interview Guide with suggestions to questions**
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10 **FGD CHVs**
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12 **INTRODUCTION AND WARM UP (2 mins)**
13

- 14 ● The moderator introduces him/herself and explains the purpose of the study
- 15 ● The moderator explains that the discussion is open, not an exam and there is no
16 wrong or right answer. Explain that the information given by each participant is confidential.
- 17 ● Encourage the respondent to give honest opinions.
- 18 ● Talk not just for yourself but also what you know your friends think.
- 19 ● Explain the use of the recorder.
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23 **A. Experience working in the community**
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25 **Probes**

- 26 a) How many households are you allocated and how often do you visit them?
- 27 b) What are some of the activities conducted in the household? (Counselling,
28 Referral)
- 29 c) How do you collect/report information collected from households?
- 30 d) How do you handle maternal, neonates and children complications, deliveries?
- 31 e) Do you have a way of identifying any danger signs in newborns and mothers and
32 how easy it?
- 33 f) At what point do you refer complicated cases?
- 34 g) What do you think should be improved?
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38 **B. Health facilities in the area**
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40 **Probes**
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- 42 a) Which health facilities do you refer your patients?
- 43 b) How do you follow up patients referred to ensure they go to the health facilities?
- 44 c) Do you get feedback on referrals done?
- 45 d) Are the services offered in the facilities affordable and responsive to the needs of
46 the community?
- 47 e) In your opinion are the patients satisfied with the services?
- 48 f) Perceived quality, accessibility and affordability regarding the existing FP and
49 maternal health services, effectiveness of referral system, and barriers to
50 utilization of the health services.
- 51 g) Challenges and Opportunities (how to assist mothers and children to access care),
52 improve their work lives (reporting, knowledge and skills)
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8 C. Data collection/reporting and follow-up tools
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10 **Probes**

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12 a) Generally how do you feel about the data collection/reporting system
13 currently in use
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15 b) On average how much time does it take to collect data from one household
16
17 c) How often is your work reviewed and by who?
18
19 d) What are the advantages and disadvantages/challenges of the current system?
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21 e) How in your opinion do you think it can be improved?
22
23 a) If you have heard of any health related mobile applications used in this
24 community, what is your opinion?
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26 b) What are your views on the use of a decision support tool for CHVs to
27 collect/report information & make referrals/ follow-ups?
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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?

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17 **KII Health Providers**

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19 A. Tell me about your roles as a Clinician in provision of health services to people in this
20 community
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22 **Probes**

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24 a) Health status of the community
25 b) Interaction with the CHVs
26 c) Interaction with DHMTs
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29 B. Now I would like to ask about the services offered by health facilities in this area
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31 **Probes**

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33 a. What services do they utilize mostly?
34 b. Are they able to get quality care from these health facilities
35 c. Are they referred by the CHVs to these facilities
36 d. Overall, what are your views on the referral system by CHVs and health facilities? please
37 tell me more
38 e. How do you think it can be improved?
39

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

- 42 a. What tools are used to collect data in this community? Generally how do you feel about
43 the data collection/reporting system currently in use?
44 b. What are the advantages and disadvantages/challenges of the current system?
45 c. How in your opinion do you think it can be improved?
46 d. In your opinion what would you say about mobile app in data collection and reporting
47 process?
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52 D. What do you understand by the term “dignity”?
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55 Threats to dignity:
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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?

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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

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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?

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AFRICAN POPULATION AND HEALTH RESEARCH CENTER
HEALTH CHALLENGES AND SYSTEMS PROGRAM
Using a Decision-Support Smartphone application to enhance Community Health Volunteers' efforts in
reducing Maternal complications and reducing Newborn Deaths in the informal settlements
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 degree

1.5 What grade/class did you attain?

2.0 COMMUNITY SERVICES
I would like us to discuss about the community services you are involved in. For
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.....

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<p>2.2</p>	<p>As a CHV, what are your roles?</p> <p><i>FW instructions:</i> <i>Circle All that apply</i> <i>Do not Prompt or read the options</i></p>	<p>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).....</p>			
<p>2.3</p>	<p>How many households are allocated /assigned to you?</p>	<table border="1" style="width: 100px; height: 20px; margin: auto;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> </table>			
<p>2.4</p>	<p>In the allocated households in Qn 2.3, how many have?</p> <p><i>FW Instruction:</i> <i>Ask about counts in each category</i></p>	<p>Non pregnant wome Pregnant women How many of the pr categorized as havin Newborns (0-28 day Infants (29 days to 1 Children (12 month:</p>			
	<p>Would you categorize pregnant women with the following conditions as having high risk pregnancies.</p> <p><i>FW Instructions: Read out the options.</i> <i>Multiple response allowed</i></p>	<p>Carrying twins and l multiples Gestestional diabete HIV positive wome High blood pressure Pregnancy in teens < Pregnancy in wome Overweights/ obese History of miscarria</p>			
	<p style="text-align: center;"><i>NOW, I would like us to discuss about services that you have offered in the l</i> <i>Some questions may require you refer to your records/registers</i></p>				

	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 health 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 : 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 <i>FW instructions:</i> <i>Circle All that apply</i> <i>Do not Prompt or read the options</i>	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

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		Very pale palms of hands or nail bed Genital ulcers Other, specify _____
2.9	Kindly identify danger signs in postpartum women <i>FW instructions:</i> <i>Circle All that apply</i> <i>Do not Prompt or read the options</i>	Fever without chills Fever with chills Heavy bleeding after 1 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 feet 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 t more in 1 minute co Chest indrawing Movement only on s

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

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	<p><i>Fill with the correct response</i></p> <p>1=Yes 2=No 98=Do not know</p>	<p>Shorten time in HHs Assist in correct identification of danger signs Increase timely referral Reduce misdiagnosis at community level Others specify _____</p>
<p>3.6</p>	<p>Have you been trained on mobile /electronic data collection</p>	<p>Yes..... No.....</p>
<p>FW INSTRUCTION : THANK THE PARTICIPANT FOR PARTICIPATION AND RECORD ANY GENERAL COMMENTS ABOUT THE INTERVIEW/REVIEW</p>		
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<p>END TIME (24 Hrs Format)</p>		
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n > 35 years	1	2	98
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ask the following question

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END THE INTERVIEW

RESPONDENT

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For peer review only