PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	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
AUTHORS	Bakibinga, Pauline; Kamande, Eva; Omuya, Milka; Ziraba, Abdhalah; Kyobutungi, Catherine

VERSION 1 - REVIEW

REVIEWER	Timothy Abuya Population Council Kenya
REVIEW RETURNED	15-Nov-2016

GENERAL COMMENTS	The article is well written. There are a few issues that can be improved 1. First use of the acronym for the name of the app needs to be defined in the abstract 2. The key messages can be made clearer to include issues to do with the design of the app 3. One conceptual issue is the use of outcome indicators- the authors use correct referrals yet in the outcome of they use maternal deaths. i recommend consistency and clarity on the key primary outcome throughout 4. Similarly use of the two outcomes in the hypothesis is confusing- utilization or MNH outcomes 5. clear definition of adequate referral needed ie defined as (% of neonates with danger signs defined as.?)

REVIEWER	Mary Adam Kijabe Hospital, Kijabe Kenya
REVIEW RETURNED	01-Dec-2016

GENERAL COMMENTS	Thank you for allowing me to review the following manuscript titled, The role of decision-support smart phone applications in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi; a quasi-experimental research design decision-support smart phone applications in enhancing Community Health Volunteers' effectiveness to improve maternal and newborn outcomes in Nairobi; a quasi-experimental research protocol This manuscript is addressing an important question, can a decision support tool used by community health volunteers (CHVs) improve accurate diagnosis and timely referral of patients with danger signs

	(neonates or pregnant woman). The research team is building on previous work with these slum settlements and with CHVs that have been part of a health system strengthening system and who have been using paper based tools for reporting (Bakbinga, 2014). This protocol describes a mobile application known as mPAMANECH designed to digitize information transfer and link household diagnosis of danger signs to facility and health professional management, thus delivering an integration of patient data from the community to the health facility and back again. The manuscript is well written and the overall concept of intervention clearly described. The protocol description and safeguards for the electronic component is appropriate as is the ethics approval, discussions of strengths and limitations. The background is appropriately comprehensive. However Page 9 line 3 states, “This system has been seen to improve the reporting abilities of CHVs….. Please add reference. The manuscript does a good job describing the qualitative components of the study to assess feasibility The mechanics and measurement of the decision support system are well described but the specifics of the decision support tool(DST) to be utilized by the CHVs is not discussed in detail. This omission is important because it is the basis of the grading of the adherence or non adherence of the CHVs to protocol for clinical decision making in the household and this would in turn influence measurement of the main outcome (correct referral or not). Page 10 line 29 references the MOH 503and 504, however these forms are not in an appendix or referenced. These forms are the digitized version of what is currently in use and paper based. It would be useful to see what level of clinical information is required by the referral forms and if that is or is not what is meant intended by the statement that the app is “preconfigured with danger signs for both mothers and newborns as defined by WHO (page 12 line 38). The protocol assumes that CHVs make errors in diagnosis and referral, and that there are delays in referrals due to a paper based system, which is a highly plausible assumption, but no baseline rate is documented in the population they have been working in. The baseline survey done in both control and intervention areas could give information about this the rate of errors, but there is not a clear enough description in the methods section of how adherence or non-adherence of CHVs will be measured at the household level. Additional clarification in the protocol of how the CHEWs measure to determine adherence or non adherence and assess clinical decision making of CHVs would be beneficial. The description of the quantitative study (baseline and endline) targets households with women of reproductive age, (page 17 line 43) but these households may not have had a neonate born in the last year. Even if the household had a neonate born, the neonate or pregnant mother may not have had at least one danger sign. This means there may be an insufficient number of households actually sampled that have had neonates or pregnant women who had at least one danger sign reported so as stated it is uncertain if this outcome variable can be assessed. Please clarify. In addition, the protocol states in line 46 page 15 that the study population will be Kamukunji settlements, but does not include the

	control sites in Embakasi. The control group is also part of the study population. Sampling of the control group is implied in multiple places in the text. Please clarify. Please clarify some issues Figure 1: Key Outcome The proportion of CHVs able to identify 4 danger signs needs to be validated evaluated, separately in some way. Please describe how that was done in the methods. I would request some clarification on the primary outcome (Percentage of correct referral decisions by CHVs for post partum mothers and newborns). Please clarify does this mean correct referral/total referrals OR correct referral/all patients examined. This is important in that if a decision not to refer is made in the household level, but that is a wrong decision I do not see a description of a method for tracking the primary outcome (correct referral) at the household level. Please clarify, Does proportion of mothers/newborns lost during follow up =death or lost to follow up? It is unclear to me at what level of measurement maternal mortality is being assessed? The overall objectives stated, page 9 line 53,reduction of MNH complications and deaths. What denominator are you using? Please reference the MOH manual you are using for training of CHVs in maternal newborn assessment. Where you are using "standard protocols" they should be included in the references. Thank you for the opportunity to review this protocol.

VERSION 1 – AUTHOR RESPONSE

Reviewers' Comments to Author:
Reviewer: 1
1. First use of the acronym for the name of the app needs to be defined in the abstract
Response: This has been done
2. The key messages can be made clearer to include issues to do with the design of the app
Response: We have deleted the key messages as suggested by the editor.
3. One conceptual issue is the use of outcome indicators- the authors use correct referrals yet in the outcome of they use maternal deaths. i recommend consistency and clarity on the key primary outcome throughout
Response: This has been corrected. We have deleted references to maternal deaths.
4. Similarly use of the two outcomes in the hypothesis is confusing- utilization or MNH outcomes
Response: This has been corrected. We refer to utilisation.
5. Clear definition of adequate referral needed ie defined as (% of neonates with danger signs defined as.?)
Response: To limit the size of the limit, only a summary was presented as part of the manuscript. We have added a supplementary excel file with the measures.

Reviewer: 2
6. The manuscript is well written and the overall concept of intervention clearly described. The protocol description and safeguards for the electronic component is appropriate as is the ethics approval, discussions of strengths and limitations. The background is appropriately comprehensive. However Page 9 line 3 states, "This system has been seen to improve the reporting abilities of

CHVs….. Please add reference. The manuscript does a good job describing the qualitative components of the study to assess feasibility
Response: We have added the reference.
7. The mechanics and measurement of the decision support system are well described but the specifics of the decision support tool(DST) to be utilized by the CHVs is not discussed in detail. This omission is important because it is the basis of the grading of the adherence or non adherence of the CHVs to protocol for clinical decision making in the household and this would in turn influence measurement of the main outcome (correct referral or not).
Response: The section under 'operationalisation' we provide information about the system. This is the approved version of the protocol. The understanding from Amref ethical and scientific review committee was that we would obtain input from different users (including CHVs, CHEWs, and clinicians, among others). These discussions are still on-going. The final version of the system that will be used published alongside the additional material that will be generated as part of the project.
8. Page 10 line 29 references the MOH 503and 504, however these forms are not in an appendix or referenced. These forms are the digitized version of what is currently in use and paper based. It would be useful to see what level of clinical information is required by the referral forms and if that is or is not what is meant intended by the statement that the app is "preconfigured with danger signs for both mothers and newborns as defined by WHO (page 12 line 38).
Response: We have added the respective references.

9. The protocol assumes that CHVs make errors in diagnosis and referral, and that there are delays in referrals due to a paper based system, which is a highly plausible assumption, but no baseline rate is documented in the population they have been working in. The baseline survey done in both control and intervention areas could give information about this the rate of errors, but there is not a clear enough description in the methods section of how adherence or non-adherence of CHVs will be measured at the household level. Additional clarification in the protocol of how the CHEWs measure to determine adherence or non adherence and assess clinical decision making of CHVs would be beneficial.
Response: Indeed, the baseline survey asked questions about knowledge of danger signs. The CHEWs will not be assessing CHVs' clinical decision making. This is an additional assessment by a reviewer (senior doctor). The CHVs will receive training on assessing, treating and referring a pregnant woman and a newborn, identification of danger signs appropriately and how to keep basic records. The CHEWs will provide additional support, correcting CHVs but not forms. They will be used to sample some of the CHVs' work (sit in on some of the household visits). This is beneficial because the review meetings are at the end of the month. The sampling of the work will enable on-going supportive supervision in order to improve the quality of the CHVs work. We have added more information on pages 9 & 10.

10. The description of the quantitative study (baseline and endline) targets households with women of reproductive age, (page 17 line 43) but these households may not have had a neonate born in the last year. Even if the household had a neonate born, the neonate or pregnant mother may not have had at least one danger sign. This means there may be an insufficient number of households actually sampled that have had neonates or pregnant women who had at least one danger sign reported so as stated it is uncertain if this outcome variable can be assessed. Please clarify.
Response: We have made provisions to use CHVs working in the area to direct the field workers to households that have had a pregnant woman in the immediate past 6 months. We also have additional outcomes that will be used to assess CHV knowledge (identification of danger signs, referral of LBW infants, among others).
11. In addition, the protocol states in line 46 page 15 that the study population will be Kamukunji settlements, but does not include the control sites in Embakasi. The control group is also part of the study population. Sampling of the control group is implied in multiple places in the text. Please clarify.
Response: This has been clarified. We used similar sample sizes for both the control and intervention sites.
12. Please clarify some issues Figure 1: Key Outcome. The proportion of CHVs able to identify 4 danger signs needs to be validated evaluated, separately in some way. Please describe how that was done in the methods.
Response: We are using at least one danger sign, as from the sample size estimation, as the main reference outcome. We have added a supplementary file with the measures.
13. I would request some clarification on the primary outcome (Percentage of correct referral

decisions by CHVs for post partum mothers and newborns). Please clarify does this mean correct referral/total referrals OR correct referral/all patients examined. This is important in that if a decision not to refer is made in the household level, but that is a wrong decision I do not see a description of a method for tracking the primary outcome (correct referral) at the household level.
Response:
14. Please clarify, Does proportion of mothers/newborns lost during follow up =death or lost to follow up?
Response: Lost during follow up does not include deaths.
15. It is unclear to me at what level of measurement maternal mortality is being assessed? The overall objectives stated, page 9 line 53,reduction of MNH complications and deaths. What denominator are you using?
Response: This has been deleted. The focus is on referrals and utilisation of services. We have added a supplementary file covering the measures used.
16. Please reference the MOH manual you are using for training of CHVs in maternal newborn assessment. Where you are using “standard protocols” they should be included in the references.
Response: This has been done

VERSION 2 – REVIEW

REVIEWER	Timothy Abuya Population Council Kenya Office Nairobi
REVIEW RETURNED	10-Feb-2017

GENERAL COMMENTS	The paper may need a few edits for clarity. For example in page 9, the authors could clarify the role of CHV and CHEWs. Their role towards the end of page 9 may need clarity Second the idea of having a midline given a short period of the project may need revisiting to ensure that there is sufficient time on the implementation process. Finally, i think the authors do not need to publish the time line for the project

REVIEWER	Mary Adam Kijabe Hospital, Kijabe Kenya
REVIEW RETURNED	08-Feb-2017

GENERAL COMMENTS	The requested revisions have adequately addressed. Clarification on when the senior doctor assesses the CHWs decision making about danger signs would be useful.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

The paper may need a few edits for clarity. For example in page 9, the authors could clarify the role of CHV and CHEWs. Their role towards the end of page 9 may need clarity
Response:
Thank you for highlighting this. Under the introduction section ‘Community Health Volunteers’ on page 4 we cover the CHVs’ roles and also mention CHEWs. Page 9 just provides a short recap of what is on page 4. The introduction section is already too long and at th last review we attempted to reduce

the content. We are of the view that adding extra information will make the paper longer.
Second the idea of having a midline given a short period of the project may need revisiting to ensure that there is sufficient time on the implementation process.
Response:
This is noted for implementation purposes, subject to the funder and Ethics Review Committee's reviews. The content in the manuscript is what was approved and any changes must be reported to the concerned bodies.
Finally, i think the authors do not need to publish the time line for the project
Response:
Thank you for highlighting this. Timelines, for protocols, normally help the reader to know when to expect results. That is if they are interested in the outcomes of the study

Reviewer: 2

The requested revisions have adequately addressed. Clarification on when the senior doctor assesses the CHWs decision making about danger signs would be useful.
Response:
Thank you for the comment. This will be conducted weekly. This is noted on page 13.