

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	A protocol for engaging unlicensed private drug shops in Rural Eastern Uganda for Integrated Community Case Management (ICCM) of malaria, pneumonia and diarrhea in children under five years of age
<b>AUTHORS</b>	Buchner, Denise; Awor, Phyllis

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Anthony K Mbonye MBCHB, Dip. C.Sc, MA, MPH, PhD Director Health Services (Clinical & Community)
<b>REVIEW RETURNED</b>	28-Jul-2015

<b>GENERAL COMMENTS</b>	<p>Major comments:</p> <ol style="list-style-type: none"><li>1) Review the objectives and delete number 1 since this is mere activity in the project</li><li>2) Explain how they will measure objective number 4 with the suggested study design. This objective is best measured by a cluster randomized design. How will the before and after design evaluate the impact of the proposed intervention without controlling for confounding? How will data that is not robust influence policy?</li><li>3) The authors should include the primary outcome and secondary outcomes</li><li>4) The authors should show how these out comes will be measured; showing numerators and denominators where applicable</li><li>5) Study inclusion, exclusion criteria and recruitment should be clearly stated.</li></ol> <p>Minor comments</p> <ol style="list-style-type: none"><li>1) The Ugandan context quotes outdated data on under-five and infant mortality rates, they should quote UDHS, 2011 which shows lower rates.</li><li>2) The authors should review the section on FGDS and KIs to delete the numbers they target to conduct since these are known after saturation and are never pre-determined in</li></ol>
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## VERSION 1 – AUTHOR RESPONSE

### MAJOR COMMENTS:

1. Review the objectives and delete number 1 since this is a mere activity of the project.

Response: We have reviewed the objectives and changed objective one to read, “To determine the distribution of drug shops in four sub-districts of Kamuli district.” We agree that mapping drug shops is an activity and so we have changed the objective. It is an important objective of this study to determine the distribution of drug shops (i.e. how many drug shops are there? How far apart are they? How close are they to a health center?)

2. Explain how they will measure objective number 4 with the suggested study design. This objective is best measured by a cluster randomized design. How will the before and after design evaluate the impact of the proposed intervention without controlling for confounding? How will data that is not robust influence policy?

Response. We appreciate this comment and have made several changes to the manuscript to increase clarity.

First, we added an item to the limitations section. This reads: “As we are only able to carry out our intervention with drug shops that become licensed, we are limited to a pre-post cross sectional study design.”

Second, we added clarity to our methods section. We clarified that 25 drug shops will be selected for a baseline study and that we will assist all of these drug shops to become licensed. The drug shops that become licensed will be invited to participate in the intervention.

Third, we changed the sentence that indicated that our study will inform policy to read: “Data from this study will increase knowledge about unlicensed drug shop distribution and practices and provide important information to the National Drug Authority regarding the distribution and practice of rural unlicensed drug shops and how they might be engaged in the public health system.” We feel that this revised sentence clarifies how our information will be used by national authorities.

3. The authors should include the primary outcome and secondary outcomes.

Response: Primary and secondary outcomes are added to the manuscript. These are:

#### Primary Outcome:

Increased quality of care for children under five years of age who are brought to an intervention drug shop for treatment of fever, cough and diarrhea.

#### Secondary Outcomes:

1. Increased use of RDT's to determine malaria status of children under five who are brought to an intervention drug shop with fever.
2. Increased accurate treatment of malaria based on RDT result.
3. Increased ability of drug sellers to diagnose pneumonia using breath rate monitors.

4. Increased accurate treatment of pneumonia by intervention drug sellers
5. Increased accurate treatment of diarrhea by intervention drug sellers.
6. Increased ability of drug sellers to recognize danger signs in young children.
7. Increased referral of children with danger signs to a public health facility for treatment.

4. The authors should show how these outcomes will be measured; showing numerators and denominators where applicable

Response: We have added a sentence to our Study Design section to indicate how we will measure outcomes. This sentence reads: "Outcomes will be measured from baseline and endline exit interview data."

5. Study inclusion, exclusion criteria and recruitment should be clearly stated.

We have clarified our study inclusion and exclusion criteria, and recruitment by creating a new section titled "Inclusion Criteria and Recruitment" and revising the second paragraph that describes inclusion and recruitment of caregivers for exit interviews. The revised paragraph reads:

"Caregivers who seek treatment from a study drug seller for a child under five years of age will be approached by a research assistant after the caregiver has received treatment. At this time the caregiver will be asked to participate in an exit interview survey. Eligible caregivers must be 18 years of age or older and they must have sought treatment for a child under five years of age. The child for whom treatment is sought can be present or not present at the time of the exit interview and this will be recorded on the survey. If the child is present and the caregiver reports that he child has fever, an RDT will be performed by the research assistant. All children who have a positive RED result will be referred to a public health facility for treatment of malaria."

#### MINOR COMMENTS

1. The Ugandan context quotes outdated data on under five and infant mortality rates, they should quote UDHS, 2011 which shows lower rates.

Response: The under-five mortality rate and infant mortality rate for Uganda have been updated using statistics from the Ugandan Demographic Health Survey 2011 and the references are updated accordingly.

2. The authors should review the section on FGDS and KIs to delete the numbers they target to conduct since these are known after saturation and are never pre-determined in advance.

Response: The numbers for FGDs and KIs have been removed from the manuscript. The revised paragraph reads:

"At endline focus group discussions will be conducted with study drug sellers and individual interviews will be conducted with key stakeholders who are involved with the study. Focus group discussions and individual interviews will continue until saturation of study questions is reached."

Numbers of participants in FGDs and KIs were also removed from paragraphs under Data Collection.