

Facilitators and barriers to uptake of the Med Safety Mobile App for adverse drug reaction reporting by health workers in Uganda: a qualitative study

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Running Head: Acceptability, facilitators and barriers to the use of Med Safety for adverse reaction reporting

Supplementary material

Semi-structured interview/focus group discussion guide

A: Start by explaining the study objectives to participants and seek for written informed consent.

B: Record Bio-data:

To record details such as age, gender, qualification (certificate/diploma/degree), cadre of participants.

Open-ended questions

To start off please tell us about yourself (what you do in this job and how long you have been at it).

Which HIV services do you offer here?

How many active ART clients do you have on your books?

Are you aware that you are required to report ADRs or side effects of medicines that patients are taking?

How have you been reporting side effects of ART medicines? (paper-based, web-based, Med Safety)

Have you ever reported side effects?

To whom did you report?

What form did this take? (Oral, written, online, Med Safety App, Regional NPC?).

Have you heard about the Med Safety mobile application for reporting adverse drug reactions or side effects of medicines?

Do you have a smart phone?

Do you have this app downloaded on your phone?

What is your comment on health workers using the Med Safety App to report the side effects of ART medicines?

How easy is it to use the Med Safety App?

How user-friendly is the lay out of the app?

How easy is it to report side effects using the Med Safety App?

What challenges would you encounter in using the Med Safety app?

How can you be helped to use the Med Safety App to report side effects?

Would joining a WhatsApp group of health workers help you in reporting side effects? Peer-support? Champions?

We have read in newspapers about complaints on the new ART drugs, especially dolutegravir. What is your comment? Is it a problem at all here at this facility?

Have patients or their leaders complained to you about dolutegravir? What of Isoniazid Preventive Therapy?

What advice would you give to National Drug Authority about health workers increasing the use of the Med Safety App to report side effects?

Is there something about reporting side effects that we have not talked about?

What is your final comment about the use of the Med Safety App for reporting ADRs or side effects?

Thank you for your attention.

Consent Form for Health Workers

Title: Two-way risk communication mobile application use versus traditional methods of adverse drug reaction reporting in Uganda: a randomized controlled trial

Consent for the study

Welcome to this interview on the use of a mobile app to report adverse drug reactions

Purpose of the study: In this project experts from National Drug Authority, Makerere University, University of Liverpool, UK's Medicines and Healthcare products Regulatory Authority and World Health Organization are working together to improve the recognition and reporting of adverse drug reactions using a mobile phone (smartphone) application (app). Part of this project focuses on adapting the Med Safety App for use by both patients and healthcare professionals to report adverse drug reactions and receive safety information of medicines. Safety information of medicines will contain, for example, warnings about newly detected adverse drug reactions.

Procedures: In this interview we ask you for your opinion on a mobile app with which you can report adverse drug reactions and receive safety information about medicines. The opinion and preferences of app users are very important in adapting the app for use in Uganda. This interview will take no more than 90 minutes of your time. During this interview, a mobile app for reporting adverse drug reactions will be installed on your mobile phone, which you will use to report any adverse drug reactions you encounter, particularly those linked to the use of dolutegravir and isoniazid preventive therapy.

Time Compensation for participation: We greatly appreciate your time and opinion. You will be time compensated UGX 20,000 for the time you will spend in the interview.

Confidentiality: Any information that is obtained in connection with this study and that can identify you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of a code number to let the research team know you and contact you to request for further details regarding an adverse drug reaction you might have reported. We will not use your name in any information we get from this study or in any of the research reports.

Participation and withdrawal: Participation is voluntary and you can withdraw at any time.

Identification of Investigators: If you have any questions or concerns about the research, please feel free to contact: Dr. Ronald Kiguba, Principal Investigator, Department of Pharmacology & Therapeutics, School of Biomedical Sciences, Makerere University College of Health Sciences, Tel: +256712840683 & email: kiguba@yahoo.co.uk

Rights of participants: The School of Biomedical Sciences Research & Ethics Committee and the Uganda National Council for Science & Technology (UNCST) have reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact Dr. Erisa Mwaka Tel: +256 752575050 & email: erisamwaka@gmail.com OR UNCST on +256 414 705500 / +256 312 314800

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Signature of participant: Date:

Signature of research assistant: Date: