Reviewer's report

Title: Feasibility and Validity of On-The-Phone Screening of Adverse Events after Voluntary Medical Male Circumcision in Swaziland

Version: 3 Date: 14 October 2013

Reviewer: Valerian Kiggundu

Reviewer's report:

General overview and comment:
This research article is addressing an important method of data collection that may be applied to future medical research and/or health care delivery. With new and changing technology especially in information technology and telecommunications, the phone will be an important tool in reaching clients and patients for appointments, follow ups, consultations, study interviews, etc. The use of the phone to address these medical related issues will go a long way in reducing the cost of both healthcare and research. This research article therefore, will be a great step in the right direction. The authors however need to understand that given the magnitude of medical male circumcision and its impact on HIV/AIDS, this research article once published will inform and influence policy, and will be an important reference for other related programs. It is thus important that the article is well written. Following below, please find my detailed review.

Minor essential revisions:

1. Study design, author involvement and data format: The study design is not mentioned or described anywhere. It is also not clear if the authors carried out the study on already collected Ministry of health (MoH) service data or if the data collection was done between the authors and the EPR nurses. Whatever the case, this needs to be clearly described in the methods. It is important to know at what level the authors got involved with the data collection, management or analysis. The authors actually talk about data being obtained from the EPR department-was this a data set, data abstraction from registers, or individual client CRFs? Were study subjects’ names (or other identifiers) excluded from the data before it was used?

2. Objective of the study: The aims or objectives of the “Ambitious national VMMC campaign (Soka Uncombe)” from which data was obtained were clear. i.e. “Specifically, the AETMS (Adverse event triage and management system) was created to facilitate transfer of clinical information among medical providers and improve the accuracy and completeness of data collection for monitoring and evaluation (Figure 1). The purpose of this system was to confirm AEs diagnosed by both the AETMS and through clinical consultation” (please see last paragraph of the introduction). What is not clear though is the objective of the authors when they made the decision to analyze the collected data. Were the authors trying to fulfill the aims of the MoH of Swaziland? Which of the objectives did this
manuscript address? It’s not uncommon for medical service data to be collected for one reason, but other researchers use it to answer other questions.

3. Description of the clinical consultations: The Adverse Event Triage and Management System (AETMS) is described in great detail throughout the write up; the default method (clinical consultation) however is only mentioned briefly at the end of the introduction and details of what actually happens is not provided. Both the AETMS and the clinical consultation should be well described under the methods section of the manuscript.

4. Details of Soka Uncombe not available: Details of the Ambitious national campaign (Soka Uncombe) that designed and implemented the Medical triage system conducted in 2011 are not available. This seems to be the guiding document (protocol) for this work and manuscript. It is not part of the 5 year strategic plan for scaling up VMMC in Swaziland cited as number 17 of this write up. This may be important as an additional document. If it is already published or present on the website of the MoH of Swaziland, it may be used as a citation. The detailed description of objectives, study sites, targeted study subjects, etc, should be identified in this kind of document and some of these should be in the methods section.

5. Origin and cost of phone call: A proper description of who initiates the call is not given. In Africa, the phone has reached many but not all the people, and there are also challenges in different settings. Challenges such as ownership, access, electricity are not uncommon. The authors need to mention who initiates the phone call and who bears the cost. Would clients make toll-free calls? Otherwise, what would happen if a client experienced an AE, but has no money to make a call or, he has not been called by the AETMS nurses? Was a phone database maintained by the EPR nurses? This study depends on phone access and coverage and this must be well described.

6. Cost and availability of transport for subjects: It is mentioned that transport was coordinated by the EPR nurses-but it’s not clear whether this was free to the clients, or whether a vehicle was sent out to collect subjects who had made calls. In some cases, transport is assured and just refunded once the client makes it to the health facility.

7. AE definitions: Introduction, 3rd paragraph;
   i. 1st sentence: A definition of adverse events (AEs) relating to the time of surgery is given as either intra-operative (occur during or shortly after surgery) or post-operative (…); the statement “shortly after surgery...” must be qualified by a timeline e.g. 30 minutes, 1 hour, etc. Intra-operative may refer to the time allowed for recovery (in the recovery room) which may be 30 minutes to 1 hour, but this may vary according to other conditions, such as type of surgery, space and personnel.
   ii. “Intra-operative AEs are extremely rare”-this fact needs to be backed up by a citation (2nd sentence).
   iii. “Mild AEs are generally understood to be part of routine surgery and are easily
managed” (4th sentence); Authors may need to give some examples of such mild AEs. This statement too needs a citation.

iv. “Definitions of AE types vary by country”; this needs a citation. (7th sentence)
v. “Exposure of a healthcare provider to a blood borne pathogens is also reported as an AE (Last sentence)”;
   a) The statement may be true but does not seem to be relevant to this paper.
   b) Otherwise, please provide a citation.

Major compulsory revisions:

1. Subjects' baseline demographic and clinical characteristics: The paper does not describe any clients' baseline demographic and clinical characteristics. Although we are dealing with males only, we still need to know their age ranges. Clients who were reached and those who were not reached by phone should have had their baseline characteristics compared to rule out any potential biases. Is it possible that clients who can access a phone are actually the clients who may easily seek for health care, hence a great response among phone users, and a poor response among non phone users? Therefore, baseline characteristics-age, HIV status, phone-ownership/access, occupation, and address (rural/urban)) should be compared using appropriate data analysis methods to rule out bias. Young, HIV +, rural, unemployed males may not have phones but may actually be sexually active and participated in the study.

2. Wrong figures for citation number 9 (Introduction, 4th paragraph, 5th sentence):
   a. the authors quote “.46%”, but the paper quotes something different and this is exactly the same statement from the cited paper “The prevalence of complications (moderate and severe adverse events) was 1.3% (3/240)” in the cited paper

3. Different AE rates quoted and referenced by authors, (4th paragraph, 2nd sentence); the AE rates quoted from the three randomized trials as 1.8%, 3.6% and 7.6% for the Kenyan, South African and Ugandan trials respectively seem to be different. This is what I find in the published papers for moderate and severe AE rates for the same trials;
   a) Kenyan trial AE rate-1.5%
   b) South African AE rate-3.8% (during the trial); this may have changed at the end of the trial.
   c) Ugandan AE rate 3.6%.
   I advise the authors to read published literature very well before they quote anything that is already published. Some of the potential readers are the authors of these papers that are cited.

4. Discussion: The discussion does not cite any related research articles. Discussion of specific findings should be related to the literature. The readers may need to understand how these findings compare with already written
literature.

End of Report

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.