Reviewer’s report

Title: What Counts as Reliable Evidence for Public Health Policy: the Case of Circumcision for Preventing HIV Infection

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Reviewer: Stephen Moses

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This is a well written and cogent analysis of the need to examine and incorporate information from observational studies, not only from randomized controlled trials, in evaluating the utility of public health interventions. Male circumcision (MC) for HIV prevention is used as a case study in this regard. The external validity argument is particularly strong. I have a few suggestions for minor essential revisions:

1) On page 4, second line from bottom, it should be “recognize”.

2) It is noted near the bottom of page 9 that only one of the male circumcision RCTs controlled for STIs, but both the Kenyan and Ugandan RCTs did so.

3) On page 12, it is mentioned that the RCTs did not provide follow-up for more than two years, but the Kenyan study did (Bailey RC, Moses S, Parker CB, et al. The protective effect of male circumcision is sustained for at least 42 months: results from the Kisumu, Kenya Trial [Abstract THAC0501]. XVII International AIDS Conference, Mexico City, Mexico, August 3-8. 2008). I believe that there is long-term follow-up data from the Uganda trial as well.

4) On page 14, third bullet, it should be “high HIV and STD”.

5) On page 14, a number of key issues are noted that require more information, including acceptability, cost-effectiveness, and applicability of the results to real life settings. It is then proposed that it would have been better to have used a “stepped” approach, and to have designed a number of serial RCTs to address these issues. However, I believe that most of these issues could be addressed outside the context of RCTs. Furthermore, given the length of time that it takes to design and conduct an RCT of this kind, such an approach would likely be lengthy, costly and impractical. In addition, the fact there were three trials in very different settings that produced similar results was very powerful in convincing authorities to believe the results.

6) At the top of page 15, the authors note that there are doubts about the cost-effectiveness of MC programs. Most of the studies that I have seen which have examined this issue for heterosexual HIV transmission have concluded that MC is highly cost-effective. The only study that the authors cite in this regard involves MSM.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.