Reviewer's report

Title: Practicing opt-out HIV testing in high prevalence settings: Consent concerns and missed preventive opportunities

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Reviewer: Omotayo Bolu

Reviewer's report:

The paper does bring out important issues about HIV counseling and testing and the way in which PITC is offered. However there are major concerns with the way the paper is written. The paper needs editing, and interpretation of some of the results and conclusions are not always correct.

Major Compulsory Revisions:

1. Interpretation based on results is not clear. Mostly quotes and making the conclusions based on a couple of the quotes which vary somewhat is hard to understand. For example on pg. 14 authors state that "Informants acknowledged that the preventive counselling was practiced when they underwent VCT. “Me, I was tested at the VCT. There, they have really counselled me on HIV and how I can protect my life”. (Male adults, FGD, urban Malindi). BUT this doesn't support what behavior change happened after receiving counseling.

Need to review all the quotes and see if the interpretations are aligned.

2. Data presented are not always clear. For example in the abstract a comparison of 57% vs. 27% is quoted. What were the denominators? What is the N here?

3. Comparison of PITC services with VCT needs to be emphasized in the analysis to show what the differences are in these two approaches. This was mentioned but needs to be emphasized throughout.

Minor Essential Revisions:

1. Page 4: Provider Initiated Testing and Counseling is defined wrongly. Please use the WHO definition of PITC which states that "Provider-initiated HIV testing and counselling involves the health care provider specifically recommending an HIV test to patients attending health facilities. In these circumstances, once specific pre-test information has been provided, the HIV test would ordinarily be performed unless the patient declines (the patient declining is what is referred to as opt-out." Also avoid the use of the terms opt-in and opt-out as these can be confusing. W.H.O, also recommends avoiding those terms.

Page 4, reference 16: routine testing of all where the prevalence is >0.1%. This is a U.S. Quote. Consider using W.H.O 2007 guide on PITC in generalized epidemic as this is more applicable to your study context.

Page 5: End of 1st paragraph; hypothesis statement is not correct, in fact there
are plenty of articles stating the prevention benefits of knowing one's HIV status, particularly for HIV infected individuals and within discordant couples. Sweat et al documented this with their study in Kenya, Tz, and Trinidad some years ago, and Susan Allen's work can also be cited here, among others...

Page 5, 2nd para: Authors state that: "The roll-out of provider initiated testing services has been criticised from an ethical and human rights perspective for paving way for neglect of informed consent [14, 21, 22]." YET this has also not been substantiated with evidence - and where it is the case, this is not in line with international guidance.

Page 7: under study area and population: First sentence states that the districts have similar disease burden--which diseases, HIV?? the prevalence varies greatly between 16% in Malindi and 8% in Mbarili and up to 32% in urban Kapiri. These are widely different so why state that the disease burden is similar, based on what???

Page 7 last sentence: The reported timing of starting practicing opt-out seems to be from 2007 in Malindi, 2008 in Mbarali and 2007 in Kapiri Mposhi, BUT there is no ref. this is based on????

Page 8/9: Huge time difference in terms of when FGDs were conducted 2007 when PITC was announced by WHO and 2009 when it has become well established in many countries. Something needs to be said about if the difference in time affected policy change at these districts and its implication on roll out and practice by Health care workers.

It is not clear to me how the questions were asked for example on page 12 it states that "In Mbarali district, about 9% of the women indicated having been tested in other places, possibly" BUT did you ask questions to find out where / what other methods? this is vague and unclear.

Also some of the first set of responses are just perceptions as the authors stated but its hard to make a definitive conclusion from these.

Result section: Exposure to Testing:

Page 11/12: "Women in Malindi were more likely to have been tested compared to women in Mbarali (54% vs. 27%, p< 0.001) and Kapiri Mposhi (54% vs. 34%, p<0.001." These comparisons across countries seem a little odd to me - why not start with within-country comparisons... seems more appropriate.

What proportion overall were tested? Denominator numbers need to be presented first.

Page 14: Interpretation of results are not always clear. For example on pg. 14 authors state that "Informants acknowledged that the preventive counselling was practiced when they underwent VCT. “Me, I was tested at the VCT. There, they have really counselled me on HIV and how I can protect my life”. (Male adults, FGD, urban Malindi). BUT this doesn't support what behavior change happened after receiving counseling.
Bias outlook on rate of negative consequences with disclosure is presented here. There are several other studies that have shown positive outcomes. I believe a meta analysis by Medley et al. also showed that 70-90% of the time, women received a positive response or outcome after disclosure but need to recognize that there are between 4-28% that may have experienced some negative response. Best to show both sides and consequences of disclosure.

In the analysis: emphasize the comparison between traditional VCT or client initiated approach with PITC. For every result or quote presented under PITC, what was the quote for those who had VCT. I am not convinced this was fully done. Need

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**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