Author's response to reviews

Title: Is 'Opt-Out HIV Testing' a Real Option among Pregnant Women in Rural Districts in Kenya?

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Author's response to reviews: see over
To,  
The Editor,  
BMC Public Health

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Is ‘Opt-Out HIV Testing’ a Real Option among Pregnant Women in Rural Districts in Kenya?

Dear Sir/Madam,

Please find attached our revised article on the perceived ability of pregnant women to make informed choices about HIV testing. The authors have made substantial language revisions to the entire manuscript. Find attached the comprehensive response to the reviewer’s comments.

We request to have an answer as soon as possible to enable us include this manuscript in an application for PhD defense in the next few days.

We hope that you will find the article of interest for the readers of BMC Public Health.

Thank you.

Sincerely,
Oondo Awiti Ujiji
Author’s response to reviewers

Title: Is ‘Opt-Out HIV Testing’ a Real Option among Pregnant Women in Rural Districts in Kenya?

Authors:
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Reviewer's report

Title: Is 'Opt-Out HIV Testing' a Real Option among Pregnant Women in Rural Districts in Kenya?

Version: 1 Date: 8 August 2010

Reviewer: Laura Bogart

Reviewer's report:

This study examined factors associated with feeling able to make informed choices about HIV testing among a sample of 900 pregnant women getting antenatal care in three public hospitals in Kenya. They were surveyed after giving blood for an HIV test but prior to getting their results. The strengths of this study include a unique and large sample, and significant topic of study. A key result is that most people in the sample did not know that testing was optional. However, several weaknesses of the study undermine the strengths.

The manuscript would require the following major compulsory revisions if it were to be acceptable for publication.

1. The introduction is a bit disorganized. It consists mainly of one paragraph and could be broken up. It should be used as a vehicle to foreshadow the factors considered in the regression analysis, with a conceptual framework and hypotheses. For example, reasons for some of the significant factors are unclear (e.g., it is not immediately apparent why not being in a stable relationship with the child’s father would be related to the outcome) – a conceptual framework would link the examined factors together. The introduction needs to be better focused. Moreover, it would be useful for the introduction to include a little about the context of testing in Kenya. For example, most readers may not be familiar with a group approach to pre-test counseling.

The authors have now performed a literature review that had included the debates concerning the ‘opt-out’ and ‘opt-in’ HIV testing approach in the introduction as the reviewer requested as follows.

Introduction

The World Health Organization (WHO) and the joint United Nations program on HIV/AIDS (UNAIDS) revised the guidelines for HIV testing in 2007 [1]. The current guidelines were designed to increase coverage of testing and identify patients in need of antiretroviral therapy (ART). In the former ‘opt in’ HIV strategy, the initiative to be tested was with the individual, not with the health care services, and individual pre-test counseling followed by informed consent was required before testing. In some areas people were even required to sign a separate informed consent form, which detailed the risks and benefits of being tested [2]. With the new ‘opt-out’ strategy, individuals have to actively opt out or decline the HIV test after a pre-test information session, often carried out in a group, while post-test counseling is still carried out on an individual basis for all clients.
The implications of provider-initiated HIV testing greatly affect women in sub-Saharan Africa (SSA) where they account for nearly 60% of those infected with HIV and where 75% of those living with HIV are between 15-24 years [3]. Women have more contact with the health services e.g. during pregnancy [4] and are thus more likely to undergo HIV screening [5], but it has been observed that consent may be compromised in SSA, which negatively affects women’s autonomy and possibly also completion of PMTCT [6, 7].

The shift from ‘opt in’/client-initiated to ‘opt out’/provider-initiated HIV testing has generated a debate on how to best increase the uptake of HIV testing while, at the same time, protect individual rights to voluntary consent for HIV testing [1]. Proponents of “opt out” assert that the provider-initiated consent process is protective of autonomy and crucial to achieve high coverage of HIV testing and prevention of mother-to-child transmissions (PMTCT) [8]. It also helps the ‘streamlining’ of HIV into ‘normal care’ thereby decreasing the stigma [8, 9].

Those who question the ‘streamlined’ consent process express doubt about whether informed consent can be ensured in the context of routinely offered HIV testing under conditions of scarce human resources [10, 11]. Others identify the power differences in the provider-client relationship as a problem, stating that it is uncertain whether clients who normally have a lower social status will feel able to opt out of testing against the recommendation of their providers [6]. Others are concerned about the client’s ability to provide voluntary consent and to what extent any choice will be presented given that providers are encouraged to motivate clients to test and could be coercive [6]. Women in particular are often also unable to make decisions independently due to gender inequality and lack of knowledge [3, 12]. Finally, and most important from a public health perspective, there is concern that pregnant women who fail to make an informed choice about HIV testing are less likely to come back for their test results, an obvious prerequisite for identifying and enrolling HIV-infected women in the PMTCT program, thus undermining the quality and effectiveness of this important intervention [5, 13]. A study from Botswana showed that pregnant women felt compelled to test when it was routinely offered and some instead exerted their decision-making power by not returning to collect their test results [13].

2. The method of recruitment and sampling should be better described. Were there any refusals? Does the sample represent all pregnant women who were tested in the three hospitals within the timeframe?

The authors have given additional information at the bottom line of the study design and participant sampling stating that. “No woman among those approached declined to participate and no participant had been informed of her HIV test results before the interview. The sample included all pregnant women who were tested in the three hospitals within the timeframe.”

3. The researchers observed 12 pre-test counseling sessions. These observations are not reported in the paper and could potentially add a richness to the results, especially if they indicate some deficiencies in pre-test counseling.

The authors have presented findings of the sit in observations of pretest information sessions at the beginning of the findings section as the reviewer requested as follows.

**Observations during pre-test information session at group level**
The setting of the pre-test counseling session: Pre-test counseling sessions were provided to groups of 10-15 pregnant women in a private room. There were between three and four information sessions per day at each facility. The sessions normally took 45-50 minutes and were mainly performed in the national language Kiswahili and translated simultaneously into the local dialect of Luhyia. Female midwives greeted the audience and introduced themselves when starting the session. The pregnant women were told that they could ask questions during the session in case they wanted to know more, but no woman asked any question or sought clarification at any of the sessions observed. The pregnant women nodded unanimously when the midwife sought to stress the benefits of HIV testing as shown below.

_Midwife:_ Do you mothers agree that it is important to test for HIV and protect the unborn child?
_Women:_ (nodding) yes (in a group).

The content of the pre-test counseling session: The information included a description of HIV and AIDS, modes of HIV transmission from a pregnant woman to their child during and after pregnancy, the importance of HIV testing for a diagnosis, secondary prevention of HIV transmission to uninfected male partners and the PMTCT program (single dose nevirapine tablets for the mother and syrup for the infant during a six week period after delivery; skilled hospital delivery; and options of exclusive breastfeeding or formula feeding).

The information about HIV testing: The women were given information about the importance of HIV testing and of learning about their HIV status, and also the status of their partner. Women were not required, but encouraged, to bring their partners in to be HIV tested as well. The importance of having an uninfected baby was emphasized as well as the fact that testing was important in the first trimester of pregnancy. In all the sessions the midwives’ undertone was motivational and the message was that testing and knowing one’s HIV status was the best decision a mother could make for her unborn child. No information was provided stating that it was an individual and voluntary choice of the woman to decline or accept HIV testing. The midwives referred to the women as ‘mothers’ and emphasized that it was their responsibility to take the HIV test to protect the baby and have a healthy and virus-free child. When asked by the main author about reasons for not requiring women to bring their partners for HIV testing, the midwives said that men who really loved their women normally accompanied them to ANC to test of their own free will and did not need to be asked to come. Pregnant women attending ANC were always encouraged to disclose their status to partners and encourage partners to have an HIV test.

4. More details should be given on the measures, in terms of how variables were operationalized (e.g., how a stable relationship was defined). For example, it is not immediately clear the extent to which two of the variables differed in meaning (knowing that testing is optional vs feeling able to make an informed choice to decline HIV testing). Both may tap into a similar or the same underlying construct, that testing is thought to be voluntary/can be declined). The authors have explained their analysis in the data analysis section line eight to twelve and reads as follows. Independent variables that were used to model the outcome variable were the type of union (formal i.e. living together had been discussed and endorsed by the parents of both parties, or informal), duration of the current sexual relationship (not in a relationship, ≤4 years and >4), having a stable relationship with the child’s father (living together and the father providing financially for the woman) and discussing HIV testing with the partner before the ANC visit.
We have also changed the wordings for the outcome variable as requested by the reviewer in the third and fourth line of the data analysis section. It now reads: The outcome variable ‘perceived ability to decline HIV testing’ was defined as the ability to decline HIV testing when realizing that testing was optional. All the 900 surveyed women answered the question.

5. A major weakness is that the wording of the outcome variable is double-barreled and unclear (“feeling able to make an informed choice to decline HIV testing”). It is asking whether they felt their choice was informed, in addition to whether they think they had a choice at all.

We have also changed the wordings for the outcome variable as requested by the reviewer in the third and fourth line of the data analysis section. It now reads: The outcome variable ‘perceived ability to decline HIV testing’ was defined as the ability to decline HIV testing when realizing that testing was optional. All the 900 surveyed women answered the question.

6. The backwards elimination model is data driven rather than hypothesis-driven, and thus the results may not replicate with another sample. The authors may want to outline conceptual reasons for the study and analysis up front and choose a less data-driven analysis type. Backward step elimination model was used to test for actual confounders of the estimates of the outcome. We also used the forward step model and found similar results. This information has been added in the last few sentences of the data analysis section.
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, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests
Reviewer's report

Title: Is ‘Opt-Out HIV Testing’ a Real Option among Pregnant Women in Rural Districts in Kenya?

Version: 1 Date: 30 August 2010

Reviewer: catrin Evans

Reviewer's report:

This paper is on an important topic. I have 3 issues with the paper however which I feel need to be addressed:

First, as it is currently written is that it is not really clear WHICH HIV testing debates the paper wishes to address. The main focus of the paper seems to be on the issue of whether or not antenatal mothers feel able to exercise informed consent during routine opt out HIV testing. The authors’ conclusion is that most mothers do not articulate a strong sense of informed consent and do not particularly feel that they have a choice about HIV testing. As such, the paper needs to bring in and articulate the debates about consent and coercion in HIV testing and review some of the literature that addresses these issues. It needs to situate itself in the context of the existing evidence and policy analysis in this particular area. At the moment, the literature review section merely provides an overview of the development of HIV testing policy and is not really a literature review at all. Likewise, the conclusion/discussion veers off into a discussion on factors associated with women's perceived ability to make an informed decision about HIV testing - these are mainly social factors however and the authors do not then sufficiently connect them back to the nature HIV testing service provision (e.g. the type and quality of counselling/information giving provided) which seems initially to be the main focus of the paper.

Response: Thank you very much for the insightful suggestion. The authors have added adequate literature review regarding ongoing debates about consent and coercion during HIV testing in the background as follows.

Introduction

The World Health Organization (WHO) and the joint United Nations program on HIV/AIDS (UNAIDS) revised the guidelines for HIV testing in 2007 [1]. The current guidelines were designed to increase coverage of testing and identify patients in need of antiretroviral therapy (ART). In the former ‘opt in’ HIV strategy, the initiative to be tested was with the individual, not with the health care services, and individual pre-test counseling followed by informed consent was required before testing. In some areas people were even required to sign a separate informed consent form, which detailed the risks and benefits of being tested [2]. With the new ‘opt-out’ strategy, individuals have to actively opt out or decline the HIV test after a pre-test information session, often carried out in a group, while post-test counseling is still carried out on an individual basis for all clients.
The implications of provider-initiated HIV testing greatly affect women in sub-Saharan Africa (SSA) where they account for nearly 60% of those infected with HIV and where 75% of those living with HIV are between 15-24 years [3]. Women have more contact with the health services e.g. during pregnancy [4] and are thus more likely to undergo HIV screening [5], but it has been observed that consent may be compromised in SSA, which negatively affects women’s autonomy and possibly also completion of PMTCT [6, 7].

The shift from ‘opt in’/client-initiated to ‘opt out’/provider-initiated HIV testing has generated a debate on how to best increase the uptake of HIV testing while, at the same time, protect individual rights to voluntary consent for HIV testing [1]. Proponents of “opt out” assert that the provider-initiated consent process is protective of autonomy and crucial to achieve high coverage of HIV testing and prevention of mother-to-child transmissions (PMTCT) [8]. It also helps the ‘streamlining’ of HIV into ‘normal care’ thereby decreasing the stigma [8, 9].

Those who question the ‘streamlined’ consent process express doubt about whether informed consent can be ensured in the context of routinely offered HIV testing under conditions of scarce human resources [10, 11]. Others identify the power differences in the provider-client relationship as a problem, stating that it is uncertain whether clients who normally have a lower social status will feel able to opt out of testing against the recommendation of their providers [6]. Others are concerned about the client’s ability to provide voluntary consent and to what extent any choice will be presented given that providers are encouraged to motivate clients to test and could be coercive [6]. Women in particular are often also unable to make decisions independently due to gender inequality and lack of knowledge [3, 12]. Finally, and most important from a public health perspective, there is concern that pregnant women who fail to make an informed choice about HIV testing are less likely to come back for their test results, an obvious prerequisite for identifying and enrolling HIV-infected women in the PMTCT program, thus undermining the quality and effectiveness of this important intervention [5, 13]. A study from Botswana showed that pregnant women felt compelled to test when it was routinely offered and some instead exerted their decision-making power by not returning to collect their test results [13].

Second, a major problem with the paper as it is currently written is ambiguity and confusion in some of the analysis.

If I have understood correctly, no-one out of the entire sample of 900 women declined the HIV test – i.e. there was a 100% consent (or compliance rate). There is an explicit assumption somehow that some of these women felt coerced into taking the test, and the paper seems to be determined to make this point, but I am not completely convinced that this is the case – especially when the data is based entirely on questionnaire responses rather than qualitative research. The fact that only 17% ‘knew’ that testing was optional (i.e. 83% did not realise that it was optional) is very interesting. However – I think the authors also need to consider how this figure would compare for any other kind of medical test (i.e. is this ‘normal’ for the Kenyan context? Do patients in other medical settings feel they have great choice or do they always do the tests that the doctor recommends even when they don’t fully understand them?). If the latter – how unique and or worrying really is the HIV testing issue?

In our study we also performed qualitative observations to better explore and understand the
situation of pretest information on HIV/AIDS including delivery of counseling about HIV testing in real life. This information is added at the beginning of the findings section as follows.

Observations during pre-test information session at group level
The setting of the pre-test counseling session: Pre-test counseling sessions were provided to groups of 10-15 pregnant women in a private room. There were between three and four information sessions per day at each facility. The sessions normally took 45-50 minutes and were mainly performed in the national language Kiswahili and translated simultaneously into the local dialect of Luhyia. Female midwives greeted the audience and introduced themselves when starting the session. The pregnant women were told that they could ask questions during the session in case they wanted to know more, but no woman asked any question or sought clarification at any of the sessions observed. The pregnant women nodded unanimously when the midwife sought to stress the benefits of HIV testing as shown below.

Midwife: Do you mothers agree that it is important to test for HIV and protect the unborn child?
Women: (nodding) yes (in a group).

The content of the pre-test counseling session: The information included a description of HIV and AIDS, modes of HIV transmission from a pregnant woman to their child during and after pregnancy, the importance of HIV testing for a diagnosis, secondary prevention of HIV transmission to uninfected male partners and the PMTCT program (single dose nevirapine tablets for the mother and syrup for the infant during a six week period after delivery; skilled hospital delivery; and options of exclusive breastfeeding or formula feeding).

The information about HIV testing: The women were given information about the importance of HIV testing and of learning about their HIV status, and also the status of their partner. Women were not required, but encouraged, to bring their partners in to be HIV tested as well. The importance of having an uninfected baby was emphasized as well as the fact that testing was important in the first trimester of pregnancy. In all the sessions the midwives’ undertone was motivational and the message was that testing and knowing one’s HIV status was the best decision a mother could make for her unborn child. No information was provided stating that it was an individual and voluntary choice of the woman to decline or accept HIV testing. The midwives referred to the women as ‘mothers’ and emphasized that it was their responsibility to take the HIV test to protect the baby and have a healthy and virus-free child. When asked by the main author about reasons for not requiring women to bring their partners for HIV testing, the midwives said that men who really loved their women normally accompanied them to ANC to test of their own free will and did not need to be asked to come. Pregnant women attending ANC were always encouraged to disclose their status to partners and encourage partners to have an HIV test.

I do not fully understand the question: “20% felt they would be able to make an informed choice to decline HIV testing even if they knew it was optional” – does this mean that 20% still would not have felt able to decline even if they knew it was optional (i.e. they would still have had a sense of compulsion to do the test) or does it mean that 20% would have declined the test had they realised that it was optional – this is a very critical distinction that is currently not clear in the paper.

This statement has been changed to mean that 20% would have declined the test had they realised that it was optional and appears after the figure 1 and reads as: Only 20% (N=180) of the women said they thought they would have been able to decline HIV testing if they had realized it was optional.
Please be clear about which question is figure one referring to?

We have described that figure 1 shows reasons for not understanding the information provided during pretest session among 90 pregnant women. It appears in the result section as: *(PLEASE INSERT Figure 1 Reasons for not understanding pre-test counseling among 90 women)*

Likewise, please be clear about which question figure 2 is referring to and what percentage of the sample this sub-analysis applies to.

We have described that figure two shows reasons for not having a perceived ability to decline HIV testing among 720 pregnant women and appears in the result section as *(PLEASE INSERT Figure 2 Reasons for not having a perceived ability to decline HIV testing among 720 women)*

In the section on ‘factors associated with feeling able to make an informed choice to decline HIV testing (p.11), I have the following comments:

• Please be clearer about which sub-sample the analysis presented here applies to (I am assuming it applies to the 20% of women who said they would have felt able to decline if they had realised they had a choice)

The analysis involved all 900 women who responded to this question. We have added this information right below figure 1 stating that only 20% (N=180) of the women said they thought they would have been able to decline HIV testing if they had realized it was optional.
The assumptions behind this analysis need to be clear. As per my understanding, 20% of the sample said they would have ‘felt able to decline if they knew that had a choice’. This is NOT the same as saying that they would have declined the test (just that they would have felt able to). This seems to me to be a crucial linguistic distinction. Yet, the authors seem to assume that it means that 20% of the sample would have declined the test. This is a conflation that seems to be erroneously made throughout the rest of the paper. For example, on p.11, the authors state “number of pregnancies, education levels, age and occupation were not significantly associated with the ability to make an informed choice to decline testing” – this assertion cannot be made on the basis of the findings – only that these factors were not significantly associated with women SAYING that they felt they would be able to decline testing. For example, on p.13 a statement is made that: “many more would have declined testing if information had been properly conveyed” – how do you know this? In another example, on p.13 the authors state that: “women not discussing HIV testing with the partners before visiting ANC declined testing to avoid being in a position where they were expected to convey an unfortunate diagnosis” – this statement does not relate at all to the findings as none of your sample did actually decline testing – so what is being referred to here? Likewise, the authors state that (p.13/14) “our findings show that perceived partner attitudes exert a strong influence on HIV testing” – this is simply not the case – you showed an association between perceived partner attitude and perceived ability to decline testing – no relation to actual testing behavior however. On p.14, the confusion and conflation about the findings is even worse: the authors state that “our findings showed that women who did not discuss HIV testing with a partner declined testing” – but you previously said that non-not actual behaviour. These statements are highly misleading therefore – this misleading statement continue on p.14/15 (last sentence on p.14, 1st sentence on p.15)

- e of the sample declined testing! – you are reporting an association between perceptions

We have changed the wordings of the outcome variable and it is found between the second and fourth line of the data analysis section. It now reads as: For the cross-sectional data analysis, the outcome variable ‘perceived ability to decline HIV testing’ was defined as the ability to decline HIV testing when realizing that testing was optional. All the 900 surveyed women answered the question.

Third and finally, the papers’ conclusion needs to address the ‘so what’ question. Given the public health imperative to increase HIV testing and the human and material resource constraints within the Kenyan health system, the paper needs to clearly articulate what the implications of the findings are? Is further research needed? How should programme managers or policy makers respond to these findings? The authors also need to consider that the antenatal service ‘got it right’ and managed to ensure a very ‘good’ (in public health terms) adoption rate – it might be worth considering how this was achieved.

The authors have followed your suggestion and included the ‘so what’ questions in relation to increasing HIV testing and under-resourced health system in the conclusion and reads as follows.

While provider-initiated HIV testing is necessary to increase the number of women who access PMTCT and ART, caution must be taken to actively involve the woman during the consent process, to respect their autonomy and improve the enrollment and completion of PMTCT. Intensive community campaigns are warranted to raise awareness of the HIV testing being performed at ANC and the reasons why it is being carried out, to sensitize the community and make them better prepared to make informed decisions. Health authorities could collaborate with
NGOs to disseminate information, improve education and increase communication at household level in rural areas to supplement human and material resources shortages.

**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.