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Anticipated changes in sexual risk behaviour following vaccination with a low-efficacy HIV vaccine: survey results from a South African township

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Summary

We assessed the potential for anticipated changes in sexual risk-taking behaviour following hypothetical administration of a low-efficacy preventive HIV vaccine. We developed a survey and collected self-reported data from 158 HIV-negative volunteers in a cohort undergoing prescreening for Phase I/II HIV vaccine trials in Soweto. Overall, 22% reported they might use condoms less frequently; 9% reported that they might increase their frequency of sex with casual/anonymous partners; and 55% reported their sexual partners might want to use condoms less frequently knowing they were vaccinated. Multivariate analyses revealed that anticipated decrease in condom use was predicted by poor comprehension and by young age. Individuals may increase their risk-taking behaviour knowing that a vaccine would provide only incomplete protection against HIV transmission. In HIV vaccine trials and future vaccination programmes, education and risk-reduction counselling will be needed for vaccinated individuals and their partners, and mass media education campaigns may be necessary.

Keywords

HIV risk behaviour; sexual risk behaviour; HIV vaccine trials; vaccination; risk compensation; Africa

INTRODUCTION

Potential HIV vaccine candidates are being tested in clinical trials worldwide and many more are under development.¹ While the first HIV vaccines will likely be only partially effective in preventing transmission, even low-efficacy vaccines will be useful for populations such as those across much of sub-Saharan Africa in which the risk of HIV infection is high.² The individual and population benefits from any HIV vaccine which is not 100% effective in preventing HIV transmission will depend on whether risk compensation – the notion that individuals might change their sexual risk-taking behaviour in response to vaccination – occurs.³

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Little is known about the potential for risk behaviour change associated with mass vaccination campaigns,⁴⁻⁶ although several exploratory studies in North America have shown that participants were likely to increase their HIV risk behaviour if they received a hypothetical HIV vaccine.^{7,8} This is particularly true in the African setting where only one study has asked whether individuals might change their behaviour in response to hypothetical vaccination. In a household survey of adults, a Ugandan study revealed that 18% of respondents did not think (or were not sure) they would need to use a condom for non-spouse sexual partners if they received a 50% effective HIV vaccine.⁹

There have been no risk behaviour studies to date on the potential impact of future HIV vaccination programmes in South Africa. Further, baseline sexual practices, risk behaviour and attitudes towards a partially effective vaccine have not been fully assessed in the populations from which vaccine trial participants will be drawn.¹⁰⁻¹³ Because of South Africa's enormous HIV epidemic, relatively strong health infrastructure, and political support for HIV vaccine development and clinical trials, it is likely to be one of the first countries in sub-Saharan Africa to consider widespread use of a low-efficacy vaccine. Although decreases in risky sexual behaviours would enhance the benefits of programmes using low-efficacy vaccines, increases in risky sexual behaviours would decrease potential programme benefits and merit further investigation. We developed a survey instrument to investigate the potential for increases in sexual risk behaviour in response to a hypothetical, low-efficacy preventive HIV vaccine and administered it to participants in a South African cohort undergoing screening and enrollment into current HIV vaccine trials.

METHODS

Study participants and setting

We collected data on anticipated responses to a hypothetical low-efficacy preventive vaccine from 158 participants undergoing screening for Phase I/II HIV vaccine trials in South Africa. The participants were enrolled in the Pre-Screening Protocol in the HIV/AIDS Vaccine Division of the Perinatal HIV Research Unit and undergoing sexual risk behaviour assessment, which we have described previously.¹⁴ We obtained written informed consent from all participants under the auspices of the Pre-Screening Protocol, and this study was approved by the Committee for Research on Human Subjects at the University of the Witwatersrand in South Africa and the Human Investigations Committee at the Yale University School of Medicine in the USA.

Assessment of anticipated changes in sexual risk behaviour

We designed a survey in which respondents were asked to consider a hypothetical situation of immediate vaccine availability. The scripted survey described a vaccination scenario in which participants were asked to imagine that a low-efficacy vaccine was available now, rather than at some point in the future, and questions were posed regarding how they might change their current behaviours if they were to receive such a vaccine.

We used focus groups and pilot testing to optimize the survey language; we trained multilingual interviewers to administer the survey in private face-to-face encounters; and, we conducted manual and automated reviews of data for accuracy, as previously described.^{14,15} The data presented here were collected from participants scheduled for either initial or follow-up visits in the Pre-Screening Protocol; however, no participants had prior exposure to this survey. We linked the answers from this survey to sociodemographic data collected at the same visit in the Pre-Screening Protocol,¹⁴ including gender, age, education level, alcohol use and recreational drug use.

The specific vaccine concept we used in this study was a 30% effective vaccine which provided 100% protection to those individuals in whom the vaccine worked; thus, the vaccine would provide 100% protection to only 30% of those vaccinated, as opposed to providing 30% protection to 100% of those vaccinated. The survey involved a scripted, structured educational component on what is meant by a 30% effective vaccine, followed by questions to assess comprehension. Similar techniques have been used elsewhere to assess anticipated changes in sexual risk behaviour following hypothetical vaccination with a partially effective HIV vaccine.^{7,9,16} After comprehension was assessed, participants were re-educated if they answered any of the questions incorrectly or had further questions. We then asked participants questions regarding whether they predicted that they might change their condom use and number of sexual partners in response to receiving such a vaccine, as well as whether they predicted that their partners might change their condom use. Our questions differentiated responses on anticipated changes in behaviour between anonymous, casual and steady/stable sexual partners. The script and questions used for vaccine comprehension and anticipated changes in sexual risk behaviour are detailed in the Appendix.

Statistical analyses

We employed standard descriptive statistical methods to report frequencies and used the chi-squared test for statistical comparison of categorical variables. We used logistic regression techniques to estimate odds ratios (OR) and 95% confidence intervals (CI) for bivariate and multivariate analyses, as previously described.¹⁴ Age and gender were retained in all final adjusted models due to their potential roles as confounders. All analyses were conducted with SAS Version 9.1 software (SAS Institute Inc, Cary, NC, USA).

For bivariate and multivariate analyses, we created covariates as follows: (1) male gender (versus female gender); (2) age <25 years (versus age ≥ 25 years); (3) education level of high school or less (versus technical college or university degree); (4) any heavy alcohol use (defined as consumption of >5 alcoholic beverages, with one beverage defined as 6 oz wine, 12 oz beer or 1 oz liquor) in the past six months (versus no heavy alcohol use); (5) any recreational drug use (versus no use); and (6) poor initial comprehension of vaccine concept (versus good comprehension) (poor comprehension of vaccine concept was defined as initially answering any of the three vaccine comprehension questions incorrectly, whereas good comprehension was defined as answering all three questions correctly). We created the following outcome variables to indicate potential increases in sexual risk behaviour predicted by participants following vaccination with a hypothetical low-efficacy vaccine, dichotomized to reflect increased risk behaviour versus unchanged or decreased risk behaviour: (1) anticipated decrease in condom use by participants with either an anonymous, casual or steady/stable sexual partner; (2) anticipated increase in sex with casual or anonymous partners; and (3) anticipated decrease in condom use by sexual partners of participants, including those who thought their partners would or might want to decrease condom use.

RESULTS

Participant characteristics

We collected hypothetical risk behaviour responses from 158 participants (91 men and 67 women) in the Pre-Screening Protocol. The mean age was 27.0 years (median, 25 years; range, 18–53 years) and 26% of the participants reported education beyond high school level. Alcohol use (at least 1 day of heavy drinking in the previous 6 months) was reported by 54% of participants and recreational drug use (any use over the previous 6 months) was reported by 18% of participants. The majority of participants (68%) completed the survey at

their first full clinic visit, while the remainder completed the survey at a follow-up visit. However, results presented here represent the first time a participant was given the survey, thus there was no prior exposure to these questions.

Comprehension of low-efficacy vaccine concept

Following the scripted description of a low-efficacy vaccine, we assessed initial comprehension of this concept (Table 1). Overall, 82% of participants answered the three concept questions correctly. We included the 18% of participants who answered at least one question incorrectly in the 'poor comprehension of vaccine concept' category, used in the regression analyses described below. We counselled all participants to assure full comprehension before completing the remainder of the survey.

Anticipated changes in sexual risk behaviour

Anticipated behaviour changes for specific partner types following administration of a hypothetical low-efficacy vaccine are presented in Table 2. Additionally, when asked if their sexual partners might want to use condoms less frequently if they knew the participant had received a vaccine, 37% of participants responded 'yes' and an additional 18% of participants responded 'maybe'.

Predictors of anticipated increases in sexual risk behaviours

Potential decrease in condom use by participants: a total of 22% of participants reported that they might decrease their condom use with sexual partners if they received a low-efficacy vaccine. Poor vaccine concept comprehension was associated ($P < 0.01$) with an anticipated decrease in condom use by participants in bivariate analyses (OR = 3.3; 95% CI 1.4, 7.7) whereas gender, age, education, alcohol use and drug use showed no association. We included age, gender and vaccine comprehension in the adjusted multivariate model, and poor vaccine concept comprehension was the only factor associated with an anticipated decrease in condom use by participants (OR = 3.6; 95% CI 1.5, 8.8).

Potential increase in sex with casual or anonymous partners: overall, 9% of participants reported that they might have sex with casual or anonymous partners more frequently if they received a low-efficacy vaccine. None of the covariates examined (gender, age, education, alcohol use, drug use and vaccine concept comprehension) were associated with this outcome in bivariate or multivariate analyses.

Potential decrease in condom use by partners of participants: overall, 55% of participants reported that their sexual partners would or might use condoms less frequently if they knew the participant had received a vaccine, with no significant differences between male and female participant responses. Poor vaccine concept comprehension was associated ($P < 0.05$) with an anticipated decrease in condom use by the partners of participants in bivariate analyses (OR = 2.4; 95% CI 1.04, 5.4) while gender, age, education, alcohol use and drug use were not. We included age, gender and vaccine comprehension in the multivariate analysis. In the final adjusted model, both poor vaccine comprehension (OR = 2.7; 95% CI 1.2, 6.4) and young age (OR = 2.0; 95% CI 1.03, 4.0) were associated with an anticipated decrease in condom use by the partners of the participants.

DISCUSSION

Anticipated change in sexual risk behaviours following HIV vaccination has rarely been studied within the African setting. We assessed anticipated changes in sexual risk behaviours in response to vaccination with a hypothetical low-efficacy HIV vaccine in a cohort of volunteers currently undergoing screening and enrollment into multiple Phase I/II

HIV vaccine trials in South Africa. We developed a scripted, educational survey tool for this purpose, adapted for local use and pilot-tested in the same population. Overall, we found evidence of the potential for sexual risk behaviour to change following vaccination, even among individuals who understand the concept that a vaccine may only provide incomplete protection against HIV transmission.

We found that almost all of the participants (99%) comprehended the idea that they would not get infected with HIV from the vaccine itself, although this survey was given to participants already enrolled in a cohort for HIV vaccine trial screening and enrollment, which involved general education on HIV vaccines, prior to participation in this study. Comprehension of the new concept of a low-efficacy vaccine, however, was still excellent: 82% of participants overall understood that they would not know whether a low-efficacy vaccine would work at an individual level and that protection from HIV infection would depend on this factor. While these concepts were newly introduced in the survey, caution must be taken in extrapolating the ease of comprehension to the general population. However, with adequate education, introducing the concept of partially effective vaccines should be very feasible in the general population beyond those participating in HIV vaccine trials.

After education to ensure that all participants understood the concept of a low-efficacy vaccine, we assessed anticipated changes in sexual risk behaviours following hypothetical vaccination within a variety of sexual partnership scenarios. We found that 9% of participants reported that they might have sex with casual or anonymous partners more frequently if they were to receive such a vaccine, and that this behaviour was not predicted by age, gender, education, alcohol use, recreational drug use or comprehension of the vaccine concept. Poor comprehension of the low-efficacy vaccine concept was, however, significantly associated with reporting an anticipated decrease in condom use with sexual partners, both for participants reporting their own anticipated condom use as well as for participants reporting anticipated condom use by their sex partners. Specifically, 22% of participants reported that they would probably decrease their condom use in sexual partnerships as a result of vaccination. For these participants reporting their own anticipated behaviour change, the majority of the decrease in condom use was expected to occur with steady or stable partners, which would not be a significant factor in HIV transmission in populations with low HIV prevalence. However, in populations where HIV prevalence is high and a generalized epidemic exists, such as Soweto and many communities in South Africa and beyond, even a decrease in condom use with stable partners will likely result in a general increase in HIV transmission. In addition, 55% of participants reported that their sexual partners might want to use condoms less frequently than at present if they knew that the participant had received the vaccine. In our sample, there were no significant gender differences in this statistic, despite a body of the literature suggesting that women are less likely to successfully negotiate condom use in South Africa.^{17–20}

The major limitation of this study is the use of a hypothetical scenario to approximate real-life behavioural changes, and therefore our results may either underestimate or overestimate risk behaviour change in an eventual mass vaccination campaign. While the exploratory nature of this study will not allow us to predict exactly how people would change their risk behaviour after receiving an actual vaccine, our results show that a substantial number of these participants predicted that they or their partners *might* increase their risk behaviour and this should be an area for further research and monitoring. Additionally, we conducted our survey in a face-to-face interview format and within the context of screening for HIV vaccine trial participation, in which participants had received prior education and risk-reduction counselling; therefore, the data we collected on anticipated changes in sexual risk behaviours are susceptible to social desirability bias. Our results may therefore

underestimate the actual potential for risk-taking behaviour to increase, at least among participants reporting their own anticipated changes in behaviours. Because there was such a difference in the number of participants reporting that their partners might want to use condoms less frequently, as opposed to their own reported proposed decrease in condom use, it is possible that this line of questioning reduces such bias. More than half of the participants reported that their partners might want to use condoms less frequently, thus the true number of participants who might decrease their own condom use behaviours could be much higher. However, it is also possible that social desirability bias causes an overestimation of anticipated changes in behaviours reported for sex partners. Future studies should address this issue, and audio computer-assisted self-interviewing technology may assist in reducing potential desirability bias as well as standardizing the survey encounter.²¹

Another limitation of our study is that it may be difficult to generalize the results to the greater population of Soweto. Participants in this prescreening cohort were recruited through community outreach methods, which included the provision of free HIV voluntary counselling and testing (VCT), thus possibly selecting individuals who engaged in higher or lower risk behaviours than the general population. Higher levels of risky behaviour have been demonstrated in a vaccine trial preparedness cohort in a similar South African community.¹³ However, this potential sample bias may have been tempered for the purposes of this survey by the risk reduction counselling and vaccine education that participants in our study had previously received.

Because an HIV vaccine has not yet been licensed or used in a vaccination campaign outside of clinical trials, no data exist on the actual changes that might occur in risk behaviour after widespread vaccination. Limited inferences can be made from risk behaviour studies and survey techniques in HIV vaccine trial participants, as clinical trials are operated under different conditions than mass vaccination campaigns and may underestimate the true changes that might occur,⁶ but they represent the only alternative source of information available at present. Increases in risk behaviour associated with small HIV vaccine trials have already been observed,²² as well as in other clinical trials such as large hepatitis B vaccine efficacy trials,²³ treatment of HIV-infected individuals with antiretroviral therapy²⁴ and male circumcision for HIV prevention.²⁵ Although several large HIV vaccine efficacy trials have been conducted worldwide and showed no increase in risk behaviour,^{26–29} 46% of participants gave joining to ‘get protection from HIV’ as one of the reasons for participating in the trial.^{27,30}

Only limited African data exist, from two cohort studies in Kenya, on changes or anticipated changes in risk behaviour concerning HIV vaccine trial participation. First, a survey of a high-risk heterosexual cohort of male truck drivers and female commercial sex workers (CSWs) on anticipated participation in a Phase III HIV vaccine trial revealed that 17% of men and 9% of women thought that they would increase their risk behaviour as a result of participation in the trial.³¹ This occurred despite intensive individual HIV counselling during the study, and despite being educated that half of the participants would receive a placebo. Second, in a cohort of CSWs prospectively maintained in readiness for future HIV vaccine trials, there was a significant decline in risk behaviour during the study period, which included VCT and follow-up.³²

In summary, the potential for sexual risk behaviour to change following vaccination is a valid concern. In particular, we have shown that individuals predict that they may increase their risk-taking behaviour even after successfully understanding the concept that a vaccine may provide only incomplete protection against HIV transmission. Our research also underscores the need for risk reduction counselling and education surrounding the implementation of future vaccination campaigns with partially effective vaccines. It may not

be sufficient to provide education regarding risk behaviour only to individuals who are vaccinated; their sex partners may also need risk reduction counselling and mass media education campaigns may be necessary.

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APPENDIX

The scripted survey developed for assessing hypothetical risk behaviour response to vaccination with a low-efficacy preventive HIV vaccine is detailed below.

In this questionnaire, we would like to ask some *hypothetical* questions. ‘Hypothetical’ means that we must imagine a situation that does not actually exist. These questions will be about what we call a partially effective HIV vaccine.

To help explain what ‘partially effective’ means, let us first discuss the polio vaccine, which you have probably already received when you were younger. The effectiveness of the polio vaccine, which is a very good vaccine, is 90–100%. This means that if you line up 10 people and give each of them the vaccine, it will work in nine of them or all 10 of them. This means that they will be protected from getting polio even when they are exposed to the disease. But, it is possible that one of them is not protected from getting polio because the vaccine did not work in that person. This is because our bodies are not the same and some medicines work differently in different people, for example, drinking panados for a headache might help some people but not other people.

Before we continue, we want to make it *very* clear that there is no effective HIV vaccine available anywhere in the world, either commercially or through a research facility. But we would like to ask you some questions about what you might do if there were a vaccine. This means imagining a vaccine that has already been tested in clinical trials and approved for use – which may in reality take 10 more years to accomplish.

Suppose you were to receive an HIV vaccine that is known (after many tests and clinical trials in humans) to be 30% effective. This means that if you line up 10 people and give each of them the vaccine, the vaccine will only work in three of them. It will not work in seven of them. This means that only three of them will be protected from getting HIV if they have sex without protection with a person who has HIV. It also means that if you get the vaccine yourself, you do not know if you are one of the three people who would be protected. You could also be one of the seven people who are not protected because the vaccine did not work in them.

Do you have any questions about this? To make sure that I have explained this to you well, I will now ask you three questions. Do not worry if you get a question wrong, it just means that I need to explain this better.

Q1. Please answer yes or no. If you get an HIV vaccine that is 30% effective, will you get HIV from the vaccine itself?

1 Yes

0 No

If answer is 1, more discussion is needed.

Q2. Please answer yes or no. If you get an HIV vaccine that is 30% effective, will you know whether the vaccine worked on you?

1 Yes

0 No

If answer is 1, more discussion is needed.

Q3. I will now read a statement and then give you four choices to complete the statement. If you get an HIV vaccine that is 30% effective, you will be protected from getting HIV?

(Choose one)

- 1 Never
- 2 Every time you have sex without protection
- 3 3 out of 10 times you have sex without protection
- 4 It depends on whether you are one of the 3 out of 10 people who the vaccine worked on

If answer is 1, 2 or 3, more discussion is needed. Please explain to all participants why answer 4 is right and answers 1,2 and 3 are wrong before continuing.

We would now like to ask you some questions about what you *might* do if you were to get this vaccine. Remember, there is no vaccine available for HIV and there is no right or wrong answer. We are just interested in what you *might think* you would do. Again, these questions are confidential so we will not tell anyone what you have told us.

In the following questions, we refer to three types of sexual partners: steady/stable, casual and anonymous. A steady/stable partner is someone who is special to you, like a husband/wife/boyfriend/girlfriend or lover. A casual sexual partner is a person you know but who is not your main sexual partner, whether you had sex only once or many times. An anonymous sexual partner is someone whose name you did not know the day before you had sex. For the following questions, if you do not currently have one of these partner types, you can answer hypothetically – what you imagine you would do.

Q4. If you received this vaccine, do you think that any of your sexual partners might want to use condoms *less* frequently with you if they knew you had received a vaccine? (*Make sure the participant is talking about their partner's behaviour, not their own behaviour.*)

- 1 Yes
- 0 No
- 8 Maybe
- 9 Refuse to answer

For the next three questions, if you received this vaccine, how frequently would you use condoms compared with presently? (*Make sure that each answer reflects how the person would CHANGE their behaviour from the way they act at present.*)

Q5. With an anonymous sexual partner?

- 1 I would probably use condoms less frequently than I do at present
- 2 I would probably use condoms about the same as I do at present
- 3 I would probably use condoms more frequently than I do at present
- 9 Refuse to answer

Q6. With a casual sexual partner?

- 1 I would probably use condoms less frequently than I do at present
- 2 I would probably use condoms about the same as I do at present

3 I would probably use condoms more frequently than I do at present

9 Refuse to answer

Q7. With a steady/stable sexual partner?

1 I would probably use condoms less frequently than I do at present

2 I would probably use condoms about the same as I do at present

3 I would probably use condoms more frequently than I do at present

9 Refuse to answer

For the next two questions, if you received this vaccine, how many partners would you have sex with compared with presently? (*Make sure that each answer reflects how the person would CHANGE their behaviour from the way they act at present.*)

Q8. If they were anonymous sexual partners?

1 I would probably have sex with anonymous partners less frequently than I do at present

2 I would probably have sex with anonymous partners about the same as I do at present

3 I would probably have sex with anonymous partners more frequently than I do at present

9 Refuse to answer

Q9. If they were casual sexual partners?

1 I would probably have sex with casual partners less frequently than I do at present

2 I would probably have sex with casual partners about the same as I do at present

3 I would probably have sex with casual partners more frequently than I do at present

9 Refuse to answer

Thank you very much for participating in this survey. Do you have any questions for us or anything you would like to discuss?

Table 1Comprehension of low-efficacy vaccine concept ($n = 158$)

Concept evaluated	<i>n</i> (%) incorrect*
One can get HIV from a low-efficacy HIV vaccine	2 (1)
One will know whether a low-efficacy HIV vaccine worked on one's body and is providing full protection	10 (6)
A 30% effective vaccine will only work on three of every 10 people vaccinated (any incorrect answer)	17 (11)
At least one of the above concepts incorrect	29 (18)

* Sample sizes within 2% of total $n = 158$

Table 2Anticipated changes in sexual risk behaviour ($n = 158$)^{*}

Specific risk behaviour [†]	Less frequently (%)	About the same (%)	More frequently (%)
Condom use with anonymous sexual partners	2.5	57.0	40.5
Condom use with casual sexual partners	2.6	63.7	33.8
Condom use with steady/stable sexual partners	20.4	65.6	14.0
Sex with anonymous partners	37.8	57.1	5.1
Sex with casual partners	40.7	52.9	6.5

^{*} Sample sizes within 2% of total $n = 158$

[†] All questions assess anticipated risk behaviour changes as compared with current levels of behaviour for individual participants, following hypothetical vaccination with a 30% effective vaccine