Randomised controlled trial on whether advance knowledge of prostate-specific antigen testing improves participant reporting of unprotected sex

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Sex Transm Infect 2007;**83**:419–420. doi: 10.1136/sti.2006.022772

Objectives: To determine whether the process of informing research participants that they would be tested for the presence of a biological marker of semen exposure would reduce bias in their reports of unprotected sex.

Methods: A randomised trial of 210 female sex workers from Mombasa, Kenya, was conducted, where half the group had advance knowledge (via the request for informed consent) that they would be tested for prostate-specific antigen (PSA) in their vaginal fluid before they reported on sex and condom use for the past 48 h. The other half were invited to participate (via additional informed consent) in the test for PSA after they had already consented to be questioned and reported on these sexual behaviours. A trained nurse instructed participants to self-swab to collect vaginal fluid specimens, which were tested for PSA using ELISA.

Results: Reporting of unprotected sex did not differ between those with advance knowledge of the test for PSA and those without this knowledge (14.3% *v* 11.4%, respectively; p = 0.27). Surprisingly, more women with advance knowledge (15.8%) had discrepant self reports and PSA results than women without advance knowledge (9.1%); however, the difference was not statistically significant (OR 1.9; 95% CI 0.8 to 4.5).

Conclusions: Knowing that one's answers to a questionnaire could be verified with a biological marker of semen exposure did not make respondents more likely to report unprotected sex.

Evaluations of behavioural interventions designed to prevent transmission of HIV/sexually transmitted infections frequently rely on self-reported condom use data to measure success, yet such data are often acknowledged to be potentially inaccurate, either owing to faulty recall or social desirability bias.[1 2] Although research techniques to improve the validity of self-reported data on sexual behaviour have been recommended,[3] their ability to reduce information bias has not been shown. Until recently, the objective assessment of research methods designed to improve the validity of self-reports of sex and condom use has not been possible. However, verifying recent unprotected sex is now feasible by testing women for prostate-specific antigen (PSA), a protein found in high concentrations in semen and detectable in vaginal secretions from women up to 48 h after unprotected sex.[4–8]

We conducted a randomised controlled trial to determine whether the process of informing participants about PSA testing would reduce reporting bias. We compared women who knew that their vaginal specimens were to be tested for PSA before they completed the questionnaire on sex and condom use with women who did not have this knowledge in advance. We hypothesised that those with advance knowledge of the PSA testing would report more unprotected sex and would have better agreement between the PSA test results and their self-reported data than those without advance test knowledge.

METHODS

The population consisted of 210 female sex workers associated with a peer education programme designed to reduce transmission of HIV/sexually transmitted infections in Mombasa, Kenya. The trial took place during the baseline measurement of a larger study examining the effects of introducing the female condom in a peer education programme with sex workers.[9] The institutional review boards of the sponsoring institution and Kenyatta National Hospital, Nairobi, Kenya, approved the study.

Sex workers who fulfilled the eligibility criteria were randomised into two groups of equal sizes using a previously created randomisation list. Both the randomisation process and the group assignments were unblinded. The first group provided written informed consent for both the questionnaire and the PSA test before we administered the sex and condom use questionnaire and took vaginal specimens for PSA testing. By contrast, the second group was first asked for informed consent for the questionnaire and were told that they would be asked to participate in a second study only after they had completed the questionnaire. At that point, we requested informed consent for the PSA test. The informed consent for the PSA testing advised participants that if they had sex without a male or female condom or if they used the condom incorrectly, semen could be detected for 1–2 days afterwards. Although we informed participants that we would test for this, we did not assess the participants' comprehension of the study procedures or objectives. For both groups, a trained nurse used pictures to instruct participants on sample collection and then left the women to self-swab in private. Specimens were air dried and sent by air to a laboratory in the US for analysis. We identified PSA using a microparticle enzyme immunoassay (IMx, Abbott Laboratories, Abbott Park, Illinois, USA).

We examined two hypotheses: (1) whether the group with advance knowledge of the PSA test would report more unprotected sex for the past 48 h than the group without advance knowledge and (2) whether the group with advance knowledge would have less disagreement between their PSA results and self-reports of unprotected sex. We measured only one type of disagreement: reporting no sex or protected sex for the past 48 h, yet testing positive for PSA. We did not assess disagreement resulting from reporting exposure yet testing negative for PSA because other factors could explain the absence of PSA, such as the effect of practices such as douching

Abbreviations: PSA, prostate-specific antigen

Key Messages

- Women who knew that their questionnaire answers could be verified with a biological marker of semen exposure were not more likely to report unprotected sex or have better agreement between self-reports and prostate-specific antigen (PSA) test results than women without this advance knowledge.
- Future studies should use PSA to evaluate the effect of research methods designed to improve the accuracy of self-reported sex and condom use data.

or the marker's short clearance time. Although PSA can be detected with high sensitivity (98–100%) immediately after semen exposure, the antigen clears rapidly from the vagina.[4 5] Macaluso *et al*[4] found PSA in only 29% of specimens collected from women 24 h after clinical insemination with 1 ml of their partner's semen and in 3% of specimens at 48 h. We tested the hypotheses with one-sided χ^2 tests.

RESULTS

All of the 210 eligible women who were recruited to the study agreed to participate. Two participants in the group without the advance knowledge of PSA testing declined to self-swab at baseline; however, both contributed a swab for PSA testing at the follow-up visit. Owing to missing test results, we have PSA data for 194 participants.

We found no difference between the advance knowledge (n = 105) and no advance knowledge groups (n = 105) in the proportion of women who reported exposure to unprotected sex for the past 48 h (14.3% and 11.4%, respectively; p = 0.27). A greater proportion of those who knew about the PSA test in advance (15.8%; n = 15) reported no exposure for the past 48 h and yet tested positive for PSA than those without the advance knowledge (9.1%; n = 9). However, the odds of having this type of discordant self-reported and PSA data did not differ by randomisation group (p = 0.08; OR 1.9; 95% CI 0.8 to 4.5).

DISCUSSION

Women who knew about the PSA test in advance did not report more exposure than those without advance knowledge. Surprisingly, more women with the advance test knowledge had discordant self-report and PSA results than the comparison group; however, this difference was not statistically significant. Whether respondents who know that their responses can be verified would be less likely to misrepresent their sex and condom use to researchers is unknown. However, these results do not support the assumption that such information necessarily would motivate individuals to provide more accurate responses. Other psychosocial and cultural factors—besides the desire to present oneself in a positive light—could motivate a person to respond inaccurately. For example, participants could become confused while answering questionnaires about what they are ''supposed to do'',[10] or they could lie on purpose to ''test'' the system. Owing to the small sample size, we recommend that similar studies using PSA be conducted to determine the directionality of the effects (if any) on accuracy of self-report of sex and condom use derived from using research methods (eg, advance knowledge of biological testing or audio computer-assisted self-interviewing) that are believed to reduce social desirability bias.

ACKNOWLEDGEMENTS

We thank Jane Parker and Kimberly Rich for performing the assays for PSA. This study was funded by the United States Agency for International Development (cooperative agreement #AID/CCP-3079-A-00-5022-00) and supported by the Microbiology Core Laboratory of the North Carolina Sexually Transmitted Infections and Topical Microbicide Cooperative Research Center (NIH grant #U19-AI031496). The views expressed in this document, however, do not necessarily reflect those of the funding agencies.

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Competing interests: None.

Contributors: The idea for the study came from BJ, who also reviewed analyses and the text. SCT designed and oversaw the conduct of the study and, along with, MFG, who coordinated the PSA portion of the study, wrote the bulk of the text. MH was the principal investigator and WO was the research coordinator. ZO conducted training and monitored the study. ELW designed and approved all statistical analyses, which were carried out by HT. MMH oversaw all laboratory procedures. All authors contributed to the writing of the manuscript and have reviewed and approved its content.

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Accepted 16 November 2006
Published Online First 29 November 2006

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