



Published in final edited form as:

Sex Transm Dis. 2015 March ; 42(3): 160–161. doi:10.1097/OLQ.0000000000000243.

Differences in misreporting of sexual behavior over time: implications for HIV trials

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Abstract

We used data from a prospective study of 300 women attending a sexually transmitted infection clinic in Kingston, Jamaica, to compare participant self-report of recent semen exposure to actual semen exposure measured by prostate-specific antigen in vaginal swabs. Underreporting of semen exposure was significantly more frequent at follow-up than baseline, suggesting the accuracy of reports of sexual behavior may vary over time.

Study participants may misreport sexual behaviors (intentionally or not). Efforts to quantify misreporting have ranged widely from measuring self-reported virginal status among pregnant women¹ or sexually transmitted infections (STIs) among young adults reporting sexual abstinence² to detecting biological markers such as semen among women reporting no recent sexual exposure³ and drug levels in hair as evidence of pre-exposure prophylaxis use.⁴ Despite the increasing recognition of the need for improved measures, HIV prevention studies continue to depend on participant reports of sensitive behaviors. This practice is problematic. For example, the association detected in observational studies between injectable contraception and HIV acquisition⁵ could be explained by differential condom use between study arms. Hormonal contraception users might have more unprotected sex with HIV-infected partners than nonusers, yet participant reports of sexual activity and condom use may be inadequate for controlling for this difference in risk.⁶

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Conflicts of Interest

The authors have no conflicts of interests.

One argument supporting continued use of self-reported measures could be that any misreporting is assumed to be nondifferential between arms in comparison trials or in a population over time, which would tend to conservatively bias results toward the null.⁷ To examine this question, we assessed the consistency of misreporting over time by comparing self-reports to a semen biomarker at baseline and follow-up among females participating in a trial on the effectiveness of counseling messages conducted during 2010–2011.⁸

Participants consisted of nonpregnant, HIV-negative women 18 years of age attending a public STI clinic in Kingston, Jamaica who were prescribed syndromic treatment for cervicitis or vaginal discharge according to standard care.⁸ Women were randomized to receive a counseling message promoting either abstinence alone or abstinence backed up by promotion and provision of condoms for the treatment period of 7 days. At enrollment and the 6-day follow-up visit, a study clinician collected vaginal swabs to test for prostate-specific antigen (PSA), and study staff administered a questionnaire. Women had to give written consent for screening, enrollment and PSA testing to be part of this analysis. Ethical review committees at the Jamaican Ministry of Health and the US Centers for Disease Control and Prevention approved the research.

PSA detected in vaginal fluid is a marker of semen exposure occurring within the past 48 hours.⁹ On-site laboratory staff used previously described methods¹⁰ to test for PSA with ABACard p30 (Abacus Diagnostics, West Hills, CA), which produces results that can be interpreted semi-quantitatively (negative, low positive, or high positive). We dichotomized the results (negative versus low or high positive). We used a chi-squared test to evaluate differences between enrollment and follow-up visits in the proportion of women who self-reported no recent semen exposure (i.e., either no sex without a condom or no sex in the past 2 days) among those with PSA positivity.

Of 300 women enrolled in the trial, 7 failed to return for follow up, 7 declined to consent to PSA testing, and 1 had missing PSA data at enrollment. Thus, the current analysis is based on 286 women (95% of randomized women) who completed 571 visits (285 enrollment and 286 follow-up visits). Altogether, 16.8% of participants (48/286) had PSA detected at 1 study visit. Similar proportions of women had PSA detected at enrollment (8.4%) and follow up (10.1%) (Figure). Fifteen percent of women reported having sex without a condom in the past 2 days, with similar percentages at enrollment (15.3%) and follow up (14.7%). Among visits where PSA was detected, however, in nearly two-thirds (64%) of visits, the participant denied having unprotected sex in the preceding 2 days. Notably, the proportion of women with biological evidence of semen exposure who reported no unprotected sex increased significantly between enrollment (50%) and follow up (75.9%) ($P=0.05$).

Women may have perceived more pressure not to disclose unprotected sex at follow up because of the counseling at enrollment, which instructed them to be abstinent while on syndromic treatment. As previously revealed in a qualitative study conducted among a subset of the participants informed about their PSA positivity (following rapid testing at follow up), this social desirability bias may have prevented women from reporting failure to adhere to clinic staff's instructions.¹¹ In contrast, at enrollment, women were asked to report on their behaviors, including unprotected sex, before any counseling messages were

provided. Whether misreporting would have regressed to baseline levels (from participants becoming desensitized to counseling messages) or would have increased (from effect of cumulative messages) had our trial been longer is unknown. A previous study of female sex workers in Kenya, which compared participant reports and PSA outcomes at both enrollment and 12-month follow-up visits, did not find differences in discordancy between the two study visits.¹² Collectively, these findings suggest that the changes in accuracy could differ by study population, research question, or trial procedures.

A recent analysis found no evidence of differential misclassification of semen exposure between hormonal contraception users and nonusers.¹³ Previous studies, though, have found that having discordant biological and self-reported measures of semen exposure was associated with a range of characteristics and behaviors: study site, race/ethnicity, age, education, use of amphetamine-type stimulants, self-reported injection drug use, number of partners, self-perceived risk of HIV infection, or infection with HIV, human papillomavirus, bacterial vaginosis, or chlamydia.^{14–17} This further evidence that misclassification does not occur at random suggests that attempts to adjust for self-reported condom use could actually introduce bias, occurring in any direction.

Identifying those women at risk of HIV/STIs from engaging in unprotected sex could be useful in many settings. Public health interventions to prevent these diseases could improve their efficiency by targeting sexually-active people who are not consistent condom users. Also, research on interventions to prevent HIV/STIs could benefit from collection of objective biologic measures of semen exposure. The interpretation of data from HIV prevention trials involving only self-reports from participants is more complicated than previously suspected given the present results indicating that participant underreports of semen exposure may change over time.

Acknowledgments

Source of Funding: The trial was funded by the Division of Reproductive Health, CDC through a cooperative agreement maintained by USAID with FHI 360 (Contraceptive and Reproductive Health Technology Research and Utilization Project (CRTU), Agreement no.GPO-A-00-05-00022). Laboratory activities for the study were supported in part by the Southeastern Sexually Transmitted Infections Cooperative Research Center of the NIAID (U19-AI031496). The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC.

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Summary

Participant underreporting of exposure to semen increased over time. Misclassification of participant reports of sensitive behaviors cannot be assumed to occur at random.

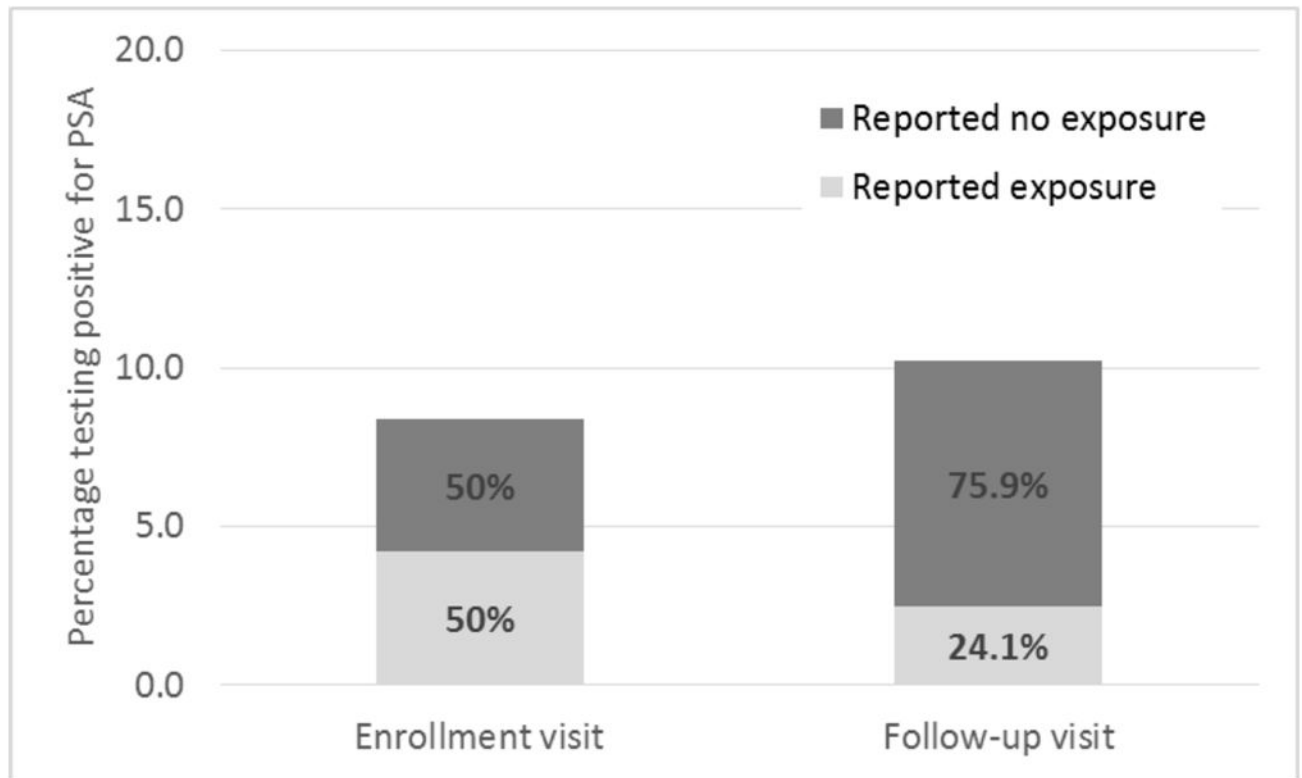


Figure.
Reported versus actual semen exposure^a among women attending a sexually transmitted infection clinic (n=300), Kingston, Jamaica, 2010–2011
^aAs determined by vaginal fluid swabs testing positive for prostate-specific antigen, a marker of semen exposure.