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Predictors of Unprotected Sex Among Female Sex Workers in Madagascar: Comparing Semen Biomarkers and Self-Reported Data

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Abstract

Research on the determinants of condom use and condom non-use generally has relied on self-reported data with questionable validity. We identified predictors of recent, unprotected sex among 331 female sex workers in Madagascar using two outcome measures: self-reports of unprotected sex within the past 48 h and detection of prostate-specific antigen (PSA), a biological marker of recent semen exposure. Multivariable logistic regression revealed that self-reported unprotected sex was associated with three factors: younger age, having a *sipa* (emotional partner) in the prior seven days, and no current use of hormonal contraception. The sole factor related to having PSA detected was prevalent chlamydial infection (adjusted odds ratio, 4.5; 95% confidence interval, 2.0–10.1). Differences in predictors identified suggest that determinants of unprotected sex, based on self-reported behaviors, might not correlate well with risk of semen exposure. Caution must be taken when interpreting self-reported sexual behavior measures or when adjusting for them in analyses evaluating interventions for the prevention of HIV/STIs.

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Disclaimer The findings and conclusions in this report are those of the authors and do not necessarily represent official views of the Centers for Disease Control and Prevention.

Keywords

Female sex workers; Condoms; Biological markers; Prostate-specific antigen; Africa

Introduction

Promoting the use of condoms among high-risk groups, including female sex workers (FSWs), is considered a cornerstone of controlling the HIV pandemic [1–3]. Accordingly, a vast body of research has been conducted on the determinants of condom use and non-use among FSWs. Condom use, among FSWs in Africa, has been associated with age, partner type, duration of sex work, number of clients, partner violence, prior HIV testing, and access to condoms [4–9]. Engaging in unprotected sex has been linked to binge drinking, charging more for the act, pregnancy intentions, knowing other women who have unprotected sex, older age of the partner, and sex at home [10–14].

Studies generally have identified determinants of condom use and condom non-use with self-reported data, which have questionable validity [15–19]. The detection of prostate-specific antigen (PSA) in vaginal fluid is a marker of exposure to semen within the previous 48 h [20–23]. Research suggests that almost all vaginal-swab specimens (97%) will be negative for PSA (defined as ≤1 ng of PSA/ml eluate) by 48 h after exposure to semen [23]. Thus, the detection of PSA can serve as a measure of recent sex unprotected by a condom or sex in which a condom either failed or was used incorrectly. We identified predictors of recent, unprotected sex (measured by both self-reports and PSA detection) and evaluated whether the associations between factors and the two measures of unprotected sex differed.

Methods

Study Procedures

The study was conducted among FSWs in two sites in Madagascar participating in an 18-month, randomized controlled trial of the effect of supplementing community-based promotion of male and female condoms with clinic-based counseling [24, 25]. Participants attending their last (18-month) study visit between December 2002 and May 2003 were asked to participate in this additional research, which consisted of answering eight questions about sex and condom use and having two vaginal swabs collected to test for PSA. Specifically, we asked participants about any sex acts (yes or no) with any clients, partners, or boyfriends during four timeframes: the previous 24 h, 48 h, 7 days and 14 days. For each timeframe, women also were asked to report whether any of the acts were unprotected (yes or no). As part of the main study visit on that same day, the participants also were administered a questionnaire, which included questions on potential correlates of unprotected sex (see below). Both questionnaires were administered by female study clinicians in a private setting within the clinic.

The same female clinician inserted a cotton-tipped swab into the posterior fornix and rotated it four times to collect the specimens for testing for PSA. After several hours of air-drying, staff sealed the swabs in individual transport tubes and froze them until data collection ended. Specimens were shipped on dry ice to the research laboratory at the University of North Carolina for processing. Only participants who gave verbal consent for the additional research were included. The consent process included an explanation that the purpose of the additional research was to improve ways of measuring when women have unprotected sex. Ethical review boards at Family Health International and the Madagascar Ministry of Health approved the additional research. All names and personal identifiers were removed before researchers at the Centers for Disease Control and Prevention (CDC) received the data, and

the CDC institutional review board determined that the present analysis of anonymous data was exempt from review.

Laboratory Methods

We used Abbot IMx microparticle enzyme immunoassay (Abbott Laboratories, Abbott Park, IL) for detecting PSA in the vaginal swab eluates. After each vaginal swab was inserted into a 1.5 ml microcentrifuge tube, with 1 ml of phosphate-buffered saline, the contents were allowed to elute at room temperature for 5–15 min. We vigorously rotated individual specimens and pressed the swabs against the side of the tube to maximize the recovery of the sample. Capped tubes then were centrifuged at 13,000×*g* for 5 min before 250 μl of the resulting supernatant was dispensed into an IMx reaction cell. We did not perform the dilution and retesting necessary for quantifying concentrations above 100 ng PSA/ml. To have a threshold consistent with that of Macaluso and colleagues (who used three times the volume for eluting vaginal swab specimens), we defined a positive result as >3 ng PSA/ml vaginal swab eluate [23].

Methods for diagnosing sexually transmitted infections in this study have been reported elsewhere [24, 25]. Gonorrhea and chlamydial infections were diagnosed with ligase chain reaction testing (Abbott LCx Probe System, Abbott Laboratories, Abbott Park, IL, USA), and trichomoniasis was diagnosed by culture using InPouch (Bio-Med, White City, OR, USA).

Statistical Analysis

We assessed predictors of engaging in recent unprotected sex, using two outcome measures: self-reports of having had unprotected sex within the previous 48 h and the detection of PSA in vaginal fluid. Potential correlates included randomization group (peer-only counseling vs. peer and clinic counseling); study site (Tamatave vs. Antananarivo); age (highest quartile [≥35 years] vs. younger age); location from which clients were typically recruited (street only vs. bar, market, other); single without a steady partner (yes vs. no); current hormonal contraception use (yes vs. no); prevalent chlamydial infection (yes vs. no); prevalent gonorrhea infection (yes vs. no); prevalent trichomoniasis infection (yes vs. no); number of sexual partners in previous seven days (0–3 vs. ≥4 [median, 4]); *sipas* (emotional, non-client partner) in previous seven days (0 vs. ≥1); number of clients in previous seven days (0, 1–4 vs. ≥5 [median among those with any clients in previous seven days, 5]); when using condoms with clients, FSW usually suggests their use (yes vs. no); when using condoms with clients, FSW usually decides between male and female condoms (yes vs. no); symptoms of STI since last study visit (yes vs. no); told partner to get STI treatment since last study visit (yes vs. no); reported talking about male and female condoms with clinic provider (yes vs. no); and reported talking about male and female condoms with peer educator (yes vs. no).

We simultaneously fit models for the two outcome measures using bivariate logistic regression [26]. The dataset was augmented to have two records for each FSW (i.e., one for each outcome measure). Generalized estimating equations (using a logit link function and unstructured working correlation matrix) were applied to control for the correlation between outcome measures from the same woman. We chose this approach because assessing whether two models differ requires a direct comparison of the models; it is generally insufficient to declare that a difference exists simply because certain factors are significant in one model but not in the other. We first performed bivariable analyses by fitting individual models with the outcome type (self-report or PSA test results), the potential predictor, and the two-way interaction between the outcome type and the potential predictor. We then constructed a full initial model, which included parameters for outcome type, all

potential predictors, and the two-way interactions between outcome type and each potential predictor. We reduced the full model using manual backwards elimination, in which variables that were not significant at the 0.05 level were removed; variables were only removed if they were non-significant for both outcomes. We report the *P*-values for contrasts, testing the differences in the associations between each potential predictor and the two outcomes. All analyses were performed by using SAS, version 9.1 (SAS Institute, Cary, NC).

Results

Of the 347 women who were recruited to participate in this additional research at their last study visit, all consented to participate. The analysis is restricted to the 331 women who provided both outcome measures (i.e., self-report and PSA data). The mean age of FSWs was 29 years (range, 17–52). Most FSWs (81%) solicited their clients on the streets, and few used oral contraception (6%) or injectable contraception (13%) for pregnancy prevention (Table 1). At least one breakage or slippage of the male or female condom during sex in the previous 30 days was reported by 8.5% of FSWs. Condom malfunctions generally were reported for the use of male condoms rather than female condoms (data not shown). Overall, 29.0% ($n = 96$) of FSWs reported unprotected sex in the previous 48 h and 38.1% ($n = 126$) had PSA detected in their specimens.

In the bivariable analysis, we found two predictors of both self-reported unprotected sex and having PSA detected in vaginal fluid: (1) having more clients in the previous seven days and (2) when using condoms with clients, FSW usually decides between male and female condoms (Table 2). Self-reported unprotected sex also was associated with seven factors that were not related to having PSA detected: study site, age, having more sexual partners in the previous seven days, having more than one *sipa* in the previous seven days, when using condoms with clients, FSW usually suggests their use, being other than single without a steady partner, and not having talked about male and female condoms with a provider at the clinic. The only factor that was associated with PSA, but not associated with self-reported data, was prevalent chlamydial infection.

In the multivariable analysis, three factors were associated with self-reported unprotected sex (Table 3). Younger women had a greater odds of self-reported unprotected sex compared to women 35 years of age or older (adjusted OR [aOR], 2.1; 95% CI 1.1–4.0). Current hormonal contraception use was protective against unprotected sex (aOR, 0.4; 95% CI 0.2–0.9). Finally, women who reported having one or more *sipas* in the previous seven days, had an odds of reporting unprotected sex 4.8 times (95% CI 2.9–8.1) that of women without a *sipa*. The sole predictor of having PSA detected was having a prevalent chlamydial infection (aOR, 4.5; 95% CI 2.0–10.1). Only the association with having one or more *sipas* in the previous seven days was significantly different between the models for the two outcomes (*P*-value <0.01).

As a sensitivity analysis, we repeated the analysis after defining a positive PSA result as 15 ng/ml vaginal swab eluate. The use of this higher threshold had a negligible effect on the effect estimates and did not change any of the conclusions from the multivariable analysis.

Discussion

We found different predictors of unprotected sex in the multivariable analysis, depending on the outcome measure used. Self-reports of recent, unprotected sex were associated with younger age, no hormonal contraception use, and having a *sipa* in the previous seven days. In contrast, recent, unprotected sex, measured with PSA detection, was associated only with

having a prevalent chlamydial infection. Prior research conducted among FSWs and non-FSWs in four West African countries demonstrated an association between PSA detection and prevalent gonorrhea and chlamydial infections and *Mycoplasma genitalium* [27].

With a few exceptions, we measured predictors using self-reported data, for which the validity could not be assessed. Interestingly, the sole predictor of having PSA detected, chlamydial infection, was based on an objective, laboratory test. The association between self-reported condom use and a reduction in STI risk has not been consistently demonstrated [28]. However, the present findings suggest that the fallibility of self-reported data could have been responsible for the lack of correlation in prior studies.

The main strength of this research involves the use of PSA to measure recent unprotected sex. To our knowledge, this is the first study to evaluate factors associated with unprotected sex among FSWs by using both self-reports and a biological measure of semen exposure. Previous research has highlighted potential problems of relying on self-reported data when measuring coitus and condom use [29–31]. For example, in a substudy conducted among 135 women participating in a trial evaluating a candidate microbicide, 78% admitted in follow-up audio computer-assisted self-interviews (ACASI) that they had previously misreported behaviors at least once during face-to-face interviews for the larger study [19]. Notably, more women described past over-reporting than under-reporting of unprotected sex. If the data from the ACASI are valid, these findings suggest that we cannot even assume that bias will always be in the direction of *under*-reporting of risky behaviors.

Studies have detected apparent under-reporting of unprotected sex by comparing self-reports to the detection of PSA. A previous report, based on the present study, demonstrated that 29% of the FSWs who reported not engaging in unprotected sex within the previous 48 h, had PSA detected [16]. Similar studies have found PSA in specimens of 36% of FSWs in Guinea, 11% of FSWs in Kenya, and 15% of women in Zimbabwe, who denied recent unprotected sex [17, 18, 32]. Because PSA immediately begins to clear from the vagina following exposure (with 71% of women testing negative for PSA at 24 h after semen exposure) [23], these estimates should be interpreted as measuring the lower bound of under-reporting of unprotected sex. On the other hand, because of the decay period for PSA, the use of the biomarker likely underestimates the occurrence of unprotected sex in the previous 48 h. Thus, differences in the predictors of the two methods of measuring unprotected sex might be explained, at least in part, by this clearance time.

Although the variables that were significantly associated with the two outcomes differed, the only variable with a significant difference in predictive value was having a sipa in the previous seven days. With a larger sample size, additional variables might have emerged in the multivariable analysis as significant predictors for each of the individual outcomes. Thus, we cannot rule out the possibility that the predictors of the two outcomes might have shown more agreement—had the study been larger. Another study limitation is that if the level of condom use was very low, and if most FSWs were engaging in unprotected sex, our findings might demonstrate predictors of the frequency of sex rather than predictors of unprotected sex per se. Finally, because the questionnaires did not collect data on condom breakage or slippage in the previous 48 h, we cannot assess whether PSA detection was the result of a condom malfunction. However, given the relatively small proportion of women who reported malfunctions in the prior 30 days, the occurrence of these events within the previous 48 h might have been rare. Furthermore, the results of the sensitivity analysis suggest that the differences in the two outcomes are not explained by low levels of semen exposure.

The current study was conducted among FSWs in Madagascar who had participated in an 18-month study of condom promotion. Furthermore, the validity of participant responses could be dependent on a range of factors (e.g., rapport with the interviewers, comprehension of the questionnaire, order of questions or order of visit procedures). Thus, these results might not be generalizable to other populations or even to the same population when studied in other contexts.

The differences in predictors of the two outcomes identified in the present study, suggest that determinants of unprotected sex or condom use on the basis of self-reported data might not correlate well with the risk of semen exposure. The variables significantly associated with self-reported unprotected sex might be more appropriately interpreted as predictors of the reporting behavior, rather than the behavior of interest (i.e., unprotected sex). Thus, we cannot rule out that prior studies purporting to identify determinants of condom use or non-use, instead, might have identified correlates of the reporting of these behaviors. Given the substantial apparent misreporting in measures of unprotected sex, the use of more objective outcomes is crucial for understanding behaviors and other factors related to HIV/STI risk. In the meantime, we must take caution when interpreting self-reported sexual behavior measures or when adjusting for them in multivariable analyses evaluating interventions for the prevention of HIV/STIs.

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Table 1

Characteristics of female sex workers in Madagascar ($N = 331$)

Characteristics	*N* (%)
Randomization group	
Peer-only counseling	165 (49.9)
Peer counseling and clinic counseling	166 (50.2)
Study site	
Antananarivo	166 (50.2)
Tamatave	165 (49.9)
Age	
17–34 years	246 (74.3)
≥35 years	85 (25.7)
Location where recruit clients	
Street only	268 (81.0)
Bar, market or other	63 (19.0)
Single without steady partner	
Yes	117 (35.4)
No	214 (64.7)
Current hormonal contraception use	
Yes	61 (18.4)
No	270 (81.6)
Prevalent chlamydial infection	
Yes	31 (9.4)
No	300 (90.6)
Prevalent gonorrhea	
Yes	40 (12.1)
No	291 (87.9)
Prevalent trichomoniasis	
Yes	35 (10.6)
No	296 (89.4)
Sexual partners in previous 7 days	
0–3	149 (45.0)
≥4	182 (55.0)
Sipas[a] in previous 7 days	
0	189 (57.6)
≥1	139 (42.4)
Clients in previous 7 days	
0	48 (16.3)
1–4	111 (37.8)
≥5	135 (45.9)
When using condoms with clients, FSW usually suggests their use	
Yes	119 (36.2)

Characteristics	*N* (%)
No	210 (63.8)
When using condoms with clients, FSW usually decides between male and female condoms	
Yes	83 (25.3)
No	245 (74.7)
Symptoms of STI since last study visit	
Yes	63 (19.0)
No	268 (81.0)
Told partner to get STI treatment since last study visit	
Yes	235 (71.0)
No	96 (29.0)
Reported talking about male and female condoms with clinic provider	
Yes	212 (64.1)
No	119 (36.0)
Reported talking about male and female condoms with peer educator	
Yes	310 (93.7)
No	21 (6.3)

STI sexually transmitted infections

[a] *Sipas* are emotional, non-client partners

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Table 2

Bivariable analysis of factors associated with recent, unprotected sex among female sex workers in Madagascar

Predictors	Self-reports		Detection of PSA		*P*-value[a]
	OR	95% CI	OR	95% CI	
Randomization group					
Peer-only counseling	1.3	0.8–2.1	0.8	0.5– 1.3	0.12
Peer counseling and clinic counseling	Referent		Referent		
Study site					
Antananarivo	1.9[b]	1.2–3.2	1.4	0.9– 2.2	0.24
Tamatave	Referent		Referent		
Age					
17–34 years	1.9[b]	1.0–3.5	1.2	0.7–2.0	0.15
≥35 years	Referent		Referent		
Location where recruit clients					
Street only	1.5	0.8–2.9	1.3	0.7–2.3	0.26
Bar–market or other	Referent		Referent		
Single without steady partner					
Yes	0.5[b]	0.3–0.8	1.0	0.6–1.5	0.02
No	Referent		Referent		
Current hormonal contraception use					
Yes	0.7	0.4–1.3	0.8	0.4–1.4	0.78
No	Referent		Referent		
Prevalent chlamydial infection					
Yes	1.4	0.6–3.0	3.9[b]	1.8–8.6	0.04
No	Referent		Referent		
Prevalent gonorrhea					
Yes	0.9	0.4–1.9	1.6	0.8–3.0	0.27
No	Referent		Referent		
Prevalent trichomoniasis					
Yes	0.7	0.3–1.6	0.6	0.3–1.3	0.79
No	Referent		Referent		

Predictors	Self-reports		Detection of PSA		*P*-value[a]
	OR	95% CI	OR	95% CI	
Sexual partners in previous 7 days					
0–3	Referent		Referent		0.26
≥4	2.1[b]	1.3–3.5	1.5	1.0–2.4	
Sipas[c] in previous 7 days					
0	Referent		Referent		<0.01
≥1	4.5[b]	2.7–7.5	1.5	1.0–2.4	
Clients in previous 7 days					
0	Referent		Referent		
1–4	2.3	1.0–5.4	2.3[b]	1.1–4.8	0.97
≥5	2.5[b]	1.1–5.8	2.1	1.0–4.3	0.70
When use condoms with clients, FSW usually suggests their use					
Yes	1.8[b]	1.1–2.9	1.4	0.9–2.3	0.54
No	Referent		Referent		
When use condoms with clients, FSW usually decides between male and female condoms					
Yes	2.1[b]	1.2–3.5	1.6[b]	1.0–2.7	0.52
No	Referent		Referent		
Symptoms of STI since last study visit					
Yes	1.7	0.9–3.0	1.1	0.6–1.9	0.26
No	Referent		Referent		
Told partner to get STI treatment since last study visit					
Yes	1.7	1.0–2.9	1.0	0.6–1.7	0.11
No	Referent		Referent		
Reported talking about male and female condoms with clinic provider					
Yes	0.6[b]	0.4–1.0	1.0	0.6–1.6	0.06
No	Referent		Referent		
Reported talking about male and female condoms with peer educator					
Yes	0.5	0.2–1.3	1.0	0.4–2.5	0.08
No	Referent		Referent		

CI confidence interval, *FSW* female sex worker, *OR* odds ratio, *PSA* prostate-specific antigen, *STI* sexually transmitted infection

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Recent, unprotected sex measured by self-reports of unprotected sex within the previous 48 h or by detection of PSA in vaginal fluid

[a] *P*-value for difference in the associations between the factor and the two outcomes for recent unprotected sex

[b] *P*-value < 0.05

[c] *Sipas* are emotional, non-client partners

Table 3

Multivariable analysis of factors associated with recent unprotected sex among female sex workers in Madagascar

Predictors	Self-reports		Detection of PSA		*P*-value[a]
	aOR	95% CI	aOR	95% CI	
Age in years					
17–34	2.1[b]	1.1–4.0	1.2	0.7–2.0	0.11
≥35	Referent		Referent		
Current hormonal contraception use					
Yes	0.4[b]	0.2–0.9	0.6	0.3–1.1	0.54
No	Referent		Referent		
Prevalent chlamydial infection					
Yes	1.7	0.8–3.9	4.5[b]	2.0–10.1	0.07
No	Referent		Referent		
Sipas[c] in previous 7 days					
≥1	4.8[b]	2.9–8.1	1.6	1.0–2.5	<0.01
None	Referent		Referent		

OR adjusted odds ratio, *CI* confidence interval, *PSA* prostate-specific antigen

Recent, unprotected sex measured by self-reports of unprotected sex within the previous 48 h or by detection of PSA in vaginal fluid

[a] *P*-value for difference in the associations between the factor and the two outcomes for recent unprotected sex

[b] *P*-value < 0.05

[c] *Sipas* are emotional, non-client partners