Can We Trust Self-reported Condom Use? Association between Reporting Bias and Occurrence of Syphilis

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ABSTRACT

Background: The objective of this study was to assess information bias in self-reported condom use verified by prostate specific antigen (PSA) as a gold standard biomarker.
Methods: A multisite cross-sectional study with respondent-driven sampling (RDS) was conducted among1245 older female sex workers (FSWs) in three cities in China. The positivity of PSA indicates unprotected sex. Respondents' over-reported condom use was defined as reporting no unprotected sex for the past 24 hours but testing positive for PSA.
Results: The prevalence and incidence of syphilitic infection was 23% and 10% respectively among older FSWs. The RDS-adjusted proportion of over-reported condom use with all sex partners (clients, husbands, or boyfriends) was between 26% and 46.4% in the three cities. Over-reported condom use associated with prevalent syphilitic infection [Prevalence Ratio (PR) = 1.60; 95% CI: 1.17-2.21)], incident syphilitic infection (PR = 1.91; 95%CI: 1.27-2.88), and favorable attitudes toward condom use (PR =1.08; 95% CI: 1.02-1.15).
Conclusions: Self-reported condom use generates strong bias and may not be used as an outcome measure to evaluate intervention efficacy because the bias is also associated with the intervention outcome, i.e., syphilitic infection. PSA test provides a valid bio-marker approach for assessing actual condom use.

INTRODUCTION

Self-reported condom use has been recommended as a useful approach to measure protected sex (1). Because of this consensus, almost all behavioral studies and intervention trials have used it as a major assessment variable. However, research has documented that a higher level of self-reported condom does not always lead to lower incidence of sexually transmitted infections (STIs) including HIV among high risk groups (2). Therefore, there is a need for validation studies of self-reported measures with biologic tests as the reference standard..

In recent years, biologic measures of condom use have been available and provide a gold standard in sexual behavior research. Testing of prostate specific antigen (PSA) is one of them. The presence of PSA is detectable in vaginal discharge for 48 hours after acts of unprotected vaginal intercourse. The PSA test is 100% sensitivity and 96% specificity for testing PSA within 48 hours after vaginal intercourse (3). Results from recent studies comparing detection of PSA in vaginal swabs with self-reported condom use suggest that substantial respondents over reported condom use (4). However, gaps exist regarding the association between the over-report of condom use and occurrence of STIs and the direction of information bias in self-reported condom use.

In order to fill these research gaps, we conducted a multisite study among older female sex workers (FSWs) in China. The objectives of this study were to investigate the association between over-reported condom use verified by PSA tests and syphilitic infection and to assess the direction of information bias in assessment of behavioral intervention efficacy for HIV/STIs.

METHODS

Study sites and study samples

This cross-sectional study was conducted in three cities in 2014: Qingdao, Hefei, and Nanning. The inclusion criteria for older FSW who (1) were women living in one of the cities for at least 3 months; (2) were at least 35 years old, and (3) had commercial sex at least once a week in the past month prior to interview. RDS (RDS) was used to recruit participants.

Interviews

Interviewers used CAPI to interview subjects in a private room. . Interview sites were located in the local Centers for Disease Control and Prevention, general clinics, and hotels.

Biological tests

Specimens collected from each consenting participant included (1) venipuncture blood for syphilitic infection and (2) a vaginal secretion for prostate-specific antigen (PSA) test. Syphilitic infection was first screened using the Alere Determine^{TM} TP test and confirmed by the TPPA test. Confirmed TPPA positive sample were tested by the TRUST test. Presence of PSA was tested using ABAcard p30 test).

Prevalent and incident cases of syphilitic infection

Older FSWs who were sero-tested positive for TPPA were classified as prevalent cases of syphilitic infection. Those who were sero-tested positive for both TPPA and TRUST were classified as incident cases of syphilitic infection.

Self-reported condom use in the past 24 hours

Self-reported protected sex was defined as having used condoms for every intercourse with all types of partners (including clients, husbands, or boyfriends).

Over-reported condom use verified by PSA test

If an older FSW reported protected sex for every sex act but tested positive for PSA in her vaginal sample, she was classified as having over-reported condom use. If an older FSW reported protected sex for every sex act and PSA was absent, she was classified as having not over-reported condom use.

Statistical analysis

Bivariate and multiple log-binominal regression analyses were performed to estimate the crude prevalence ratio (cPR) and adjusted one (aPR) and their 95% confidence intervals (95%CI) of factors that were possibly associated with over-report of condom use, using SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Characteristics of study samples

In total, 1245 older FSWs were recruited and interviewed in the three study sites: 417 from Nanning, 407 from Hefei, and 420 from Qingdao. The RDS-adjusted prevalence of syphilitic infection was 34% in Hefei, 32% in Qingdao, and 7% in Nanning. The RDS-adjusted incidence of active syphilitic infection was between 5% and 17% (Table 1). The median age of respondents was between 37 and 42 years old. Older FSWs in Qingdao has longest mean duration of commercial sex work (6.2 years), compared to 1.3 years in Hefei and 3 years in Nanning. The rural-to-urban migrants counted for more than half of the subjects (between 59% and 73%).

Table 1. Social demographic characteristics, sexual behaviors, and syphilitic infection among older FSWs in three study sites

	Nanning		Hefei		Qingdao		All sites	
	N	%	N	%	N	%	Yes	%
Education								
Primary or less	151	34.5	202	47.9	193	43.0	546	43.8
Middle school	213	52.3	171	42.2	193	46.5	577	46.4
high school or above	54	13.3	34	9.9	34	10.4	122	9.8
Marital status								
Unmarred	52	13.3	47	13.1	17	2.5	116	9.3
Married	237	57.6	226	54.5	147	38.6	610	49.0
Divorced or widowed	129	29.2	134	32.4	256	58.9	519	41.7
Residency								
Urban	103	27.2	162	41.1	115	33.6	380	30.5
Rural	315	73.8	245	58.9	305	66.4	865	69.5
Had diagnosed STD	28	4.9	19	4.6	145	29.2	192	15.4
Prevalent syphilitic infection	30	6.8	134	33.6	125	32.0	289	23.2
Incident syphilitic infection	24	5.4	68	17.3	36	9.9	128	10.3
Continuous variables	Median 25th-75th percentile							
Age (years)	37	36-40	38	35-43	42	36-48	38	35-43
Duration of sex work (years)	3	1.8-5.0	1.3	0.5-3.0	6.2	4.0-9.9	4.2	4.0-4.4
HIV knowledge	9	8-10	7	4-9	8	6-9	8	7-8
Attitude to condom use	13	12-15	12	10-15	13	12-15	13	11-15

Proportions of over-reported condom use

In Qingdao, 200 older FSWs who reported having had sex only with clients in the past 24 hours and reported having used condoms for every sex act (protected sex), among which 84 were tested PSA positive. The RDS-adjusted proportion of over-reported condom use with clients only was 45.1% in Qingdao, 44.5% in Hefei and 26.5 in Nanning (Table 2). In Hefei, 32 of 73 older FSWs who reported having protected sex with all partners (clients, boyfriends, and/or husband) were tested PSA positive, resulting in the RDS-adjusted proportion of over-reported condom use was 45.9%. This RDS-adjusted proportion with all partners was 26% in Nanning and 46.4% in Qingdao).

Table 2. Proportions of over-reported condom use among older FSWs

	Nanning			Hefei			Qingdao			Total		
	No.	PSA+*	%	No.	PSA+	%	No.	PSA+	%	No.	PSA+	%
Protected sex with												
clients only	143	40	26.5	49	22	44.5	200	84	45.1	392	146	37.2
boyfriend only	7	3	39.6	14	5	49.5	1	1	-	22	9	40.9
husband only	3	0	0	7	4	42.1	0	0	-	10	4	40.0
all partners	169	47	26.0	73	32	45.9	203	87	46.4	445	166	37.3

*positivity of prostate specific-antigen test

Factors associated with over-report of condom use

In binary analysis, over-reported condom use was significantly associated with prevalent syphilitic infection (cPR =1.35; 95%CI: 1.02-1.80) and attitudes toward condom use (cPR =1.07; 95% CI: 1.02-1.12). Although the association did not reach the statistically significant level, incident cases of syphilitic infection were more likely to over report condom use than those who were not incident cases (cPR = 1.36; 95%CI: 0.94-1.96).

After adjustment of social demographic variables (SDVs), history of STDs, and duration of sex work (model 2), older FSWs who were prevalent cases or incident cases were more likely to over report condom than older FSWs who were not prevalent cases use (aPR = 1.60; 95%CI: 1.17-2.21) or not incident cases (aPR = 1.91; 95%CI: 1.27-2.88) (Table 3). Model 1 in which only SDVs were adjusted generated similar associations.

older FSWs who had favorable attitudes toward condom use were more likely to over report condom use (aPR = 1.08; 95% CI: 1.02-1.15). In contract, older FSWs who had ever had diagnosed STDs were less likely to over report condom use (aPR = 0.45; 95%CI: 0.26-0.82). HIV/STI knowledge, length of sex work and study site were not significantly associated with the over-report.

KEY MESSAGES

Table 3. Multivariate analysis of over-reported condom use among older female sex workers

	Model 1		Model 2		Model 1		Model 2	
	aPR*	95% CI	aPR	95% CI	aPR	95 CI	aPR	95 % CI
Prevalent syphilitic infection								
Positive vs. negative	**1.43**	**1.06-1.94**	**1.60**	**1.17-2.21**	-	-	-	-
Incident syphilitic infection								
Positive vs negative	-	-	-	-	**1.57**	**1.05-2.36**	**1.91**	**1.27-2.88**
Age	1.00	0.97-1.02	1.01	0.98-1.04	1.00	0.97-11.03	1.01	0.98-1.04
Education								
Primary or less	1		1.00		1.00		1.00	
Middle school	**1.38**	**1.04-1.85**	1.30	0.97-1.73	**1.39**	**1.01-1.92**	1.27	0.93-1.75
high school or above	**1.73**	**1.10-2.72**	1.54	0.98-2.43	**1.94**	**1.14-3.27**	1.59	0.95-2.68
Marital status								
Married	1		1.00		1.00		1.00	
Unmarred	0.60	0.29-1.24	0.56	0.29-1.20	0.66	0.32-1.35	0.60	0.29-1.23
Divorced or widowed	1.04	0.78-1.38	1.03	0.78-1.36	1.04	0.76-1.42	1.02	0.75-1.38
Residency								
Rural vs. urban	1.25	0.91-1.73	1.19	0.86-1.65	1.35	0.92-1.97	1.26	0.87-1.74
Study Sites								
Hefei	1.00		1.00		1.00		1.00	
Nanning	1.10	0.72-1.69	1.14	0.73-1.80	0.93	0.60-1.45	0.91	0.58-1.44
Qingdao	1.24	0.85-1.80	1.49	0.97-2.30	1.08	0.71-1.64	1.36	0.84-2.20
HIV knowledge			1.03	0.97-1.10			1.07	0.99-1.15
Attitude Condom use			**1.08**	**1.02-1.13**			**1.08**	**1.02-1.15**
Had diagnosed STD								
Yes vs. no			0.71	0.49-1.04			**0.45**	**0.26-0.82**
Duration of sex work (years)			0.99	0.99-1.00			0.99	0.99-1.01

Key Messages:

Despite frequently-reported bias in self-reported condom use, almost all behavioral studies and behavioral intervention trials have used it as a major outcome assessment variable.

Using prostate specific antigen (PSA) as a gold standard biomarker to assess the validity of self-reported condom use, this study documents a large proportion of older female sex workers over reported condom use.

Self-reported condom use is not a valid subjective approach to measure the level of protected sex in behavioral intervention trials because differential misclassification bias was strongly associated with outcome evaluation measures, i.e., syphilis.

The PSA test provides a valid bio-marker approach for assessing actual condom use and can be used in behavioral studies and behavioral intervention trials.

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