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Author manuscript *AIDS Behav.* Author manuscript; available in PMC 2017 June 01.

Published in final edited form as:

AIDS Behav. 2016 June ; 20(6): 1343–1352. doi:10.1007/s10461-015-1269-6.

### Bias in Self-Reported Condom Use: Association Between Over-Reported Condom Use and Syphilis in a Three-Site Study in China

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#### Abstract

This study examined over-reporting bias in self-reported condom use and assessed its association with syphilis. A survey was conducted among 1245 female sex workers (FSWs) in three cities in China. Respondent's over-reported condom use was defined as reporting no unprotected sex for the past 24 h but testing positive for prostate specific antigen. The proportion of prevalent syphilis and active syphilis was 23 and 10 % respectively among FSWs. The proportion of over-reported condom use with sex clients only was 27–45 % among the three study sites. The proportion of over-reported condom use with all sex partners (clients, husbands, or boyfriends) was 26–46 %. FSWs who had active or prevalent syphilis were more likely to over report condom use. Self-reported condom use may not be a valid tool to measure the efficacy of HIV/STI intervention because the bias is associated with the outcome measure, i.e., syphilis.

#### Keywords

Over-reporting bias; Misclassification; Condom use; Syphilis; Female sex workers

Conflict of interest The authors declare that they have no conflict of interest.

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**Compliance with Ethical Standards** 

#### Introduction

Self-reported condom use has been recommended as a useful approach to measure protected sex [1]. Because of this consensus, the majority of behavioral studies and behavioral intervention trials have used it as a major assessment variable. However, research has documented that a higher level of self-reported condom use does not always lead to a lower incidence of sexually transmitted infections (STIs) including HIV among high-risk groups [2–4]. Individuals who reported consistent condom use but were subsequently diagnosed with an STI may have over-reported condom use [5–7]. As reported by Cohen and colleagues in their milestone HPTN052 project [7, 8], the findings of acquisition of STIs and the frequency of pregnancy in their study suggest that self-reported condom use was misleading as almost all (95 %) of the study participants reported 100 % condom use during the study period. Therefore, there is a clear need for assessment of potential information bias and validation studies of self-reported measures with biologic tests as the reference standard [9, 10].

Information bias refers to a measurement error that arises from the imperfect procedures used for measurement or classification of the exposure, the disease, or other relevant variables [11]. Consequences of information bias include misclassification of exposure and/or outcome status for a significant proportion of study participants, which leads to invalid studies. For example, the occurrence of over-reported condom use caused by the self-report measure misclassifies sex workers who have high sexual risk for STIs into a group with low or no sexual risk. Information bias can occur because respondents misunderstand the questions, have problems with recall, use inaccurate estimation and judgment strategies, round their answers, try to perceive the researcher's expectations, or feel social desirability [5, 12, 13]. However, in addition to the above sources of reporting errors, answers to sensitive questions involve an additional problem—respondents simply do not want to tell the truth or try to reduce the degree of stigmatizing behavior that they have engaged [13]. Several interview modes and scales (audio computer-assisted self-interviewing, tape-recorded interviewing, and interviewing scales) have been designed to solve the problem and tested with mixed result [10, 14–16].

Factors that influence over-reported condom use may be multiple and complicated. Although there are no consistent findings or consensus, previous empirical studies have found over-reporting of condom use was associated with drug use, young age, ethnicity, HIV infection, bacterial vaginosis, and STI diagnosis [17–19]. Having STIs may influence overreporting of condom use. When FSWs know that there are strong norms and expectation regarding condom-protected sex and they are infected with STIs due to un-protected sex, they may be more likely to over report condom use. It may be especially true for FSWs as the decision for condom use is usually made by their clients. The hypothetical association between having STIs including HIV and over-reported condom use may explain the failure of behavioral interventions that used self-report approach to measure condom use.

However, this hypothesis has not been well tested in large scale studies among FSWs. The over-reporting of condom use may also be determined by attitudes toward condom use. Attitudes toward condoms use are likely to depend, in part, on personal beliefs or

expectations about the social acceptability of condom use that individuals update through social interactions [20, 21]. Individuals who perceive promotion of condoms among the people with whom they usually interact may be more likely to over report condom use due to peer norms or social desirability [5]. More research is needed to investigate to what degree condom use is over-reported and factors that potentially influence over-reported condom use.

In recent years, biologic measures of condom use have been available and provide a gold standard in sexual behavior research. Prostate-specific antigen (PSA, also known as p30), a protein produced by the prostate gland and secreted into the urethra during ejaculation, can be detected in vaginal fluid samples. It has been validated as a reliable marker of semen exposure in studies of vaginal specimens obtained after unprotected intercourse [22, 23]. High PSA concentrations (100–10000 ng PSA/mL vaginal swab eluate) are detectable immediately after exposure, and levels return to baseline (<1.0 ng/mL) within 24–48 h [23]. The PSA test is 100 % sensitive [95 % confidence interval (CI), 98–100 %] and 96 % specific (95 % CI, 93–97 %) for detection of >1.0 ng PSA/mL of vaginal swab eluate [22]. Results from recent studies comparing detection of PSA in vaginal swabs with self-reported condom use suggest that a large number of respondents over reported condom use [18, 24]. However, gaps exist regarding the association between the over-reporting of condom use and the outcome measure, i.e., STIs and the direction of information bias in self-reported condom use [25].

In HIV/AIDS research, older people living with HIV have been defined as adults who are 50 years and older [26, 27]. Epidemiologic data from both developed and developing countries suggest that STIs, including HIV, have spread rapidly among older adults over 50 years old [26]. Paralleling the new face of the global epidemic, the number of older cases of HIV/STIs in China has quickly increased in the past years [28, 29]. Previous studies have documented that a majority of older HIV/STI cases in China reported a history of commercial sex with mid-age female sex workers (FSWs) who were over 35 years [30, 31]. Research in China and other developing countries have examined the epidemic of syphilis and its potential determinants among predominantly young FSWs who are younger than 35 years [32–34]. However, findings from these studies may not apply to mid-age FSWs as they may have different behavioral risk factors for HIV/STIs. Therefore, behavioral research needs to be conducted among this vulnerable group. However, as the first step, studies among mid-age FSWs need to assess the validity of behavioral measures, especially the measures of condom use as previous research has documented over-reporting of condom use was strongly associated with age [17].

In order to fill these research gaps, we conducted a three-site study among mid-age FSWs in China. In this study, we assessed the validity of self-reported condom use in a three-site survey of mid-age FSWs, using PSA as a biological marker. The objectives were to (1) investigate the degree of over-reporting of condom use verified by PSA tests among this high-risk population, (2) examine the association between over-reported condom use and syphilis and other variables, and (3) assess the direction of information bias in the assessment of behavioral intervention efficacy for HIV/STIs.

#### Methods

The study protocol was approved by the Institutional Review Boards of University of Maryland, Shandong University School of Public Health, Hefei and Guangxi Centres for Disease Control and Prevention. Written informed consent was obtained from all participants.

#### **Study Sites and Study Samples**

This cross-sectional study was conducted in three cities in China between March and July 2014: Qingdao (Shandong Province, east China), Hefei (Anhui Province, central China), and Nanning (Guangxi Province, southwest China). The selection of the three cities located in different geographic regions provides variation at the level of the HIV/STI epidemics. According to the China HIV/AIDS Surveillance data [35], Nanning is located in the area with the highest HIV prevalence (8618 HIV cases and 36,404 notifiable STI cases reported from 2010 to 2013), Hefei at the mid-level (1105 HIV cases and 21,344 STI cases), and Qingdao at the lower level (733 HIV cases and 8748 STI cases).

The inclusion criteria for mid-age FSW who (1) were women living in one of the three cities for at least three 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. The selection of 35 years to define mid-age FSWs was based on the findings from our qualitative studies conducted in the three sites [31] and from other reports [30, 36].

#### **Recruitment of Study Participants**

Respondent-driven sampling (RDS) was used to recruit participants [37, 38]. Four or five sample seeds were selected in each site. These seeds were diversified in the duration of sex work and location of client solicitation (street-based, massage parlours and karaoke bars). The seeds received an explanation of the study purpose and three coupons to recruit up to three eligible subjects from their social networks. All new recruits in the subsequent recruitment waves participated in an anonymous interview in a private room and were offered three coupons similar to the seeds. Study participants received compensation for participating in a face-to-face interview and for referring up to three peers into the study. The number of recruitment waves was 8 in Qingdao, 9 in Hefei, and 11 in Nanning. Applications of RDS have demonstrated that the RDS sample is expected to include a broad cross-section of the hidden population and be a representative sample of it after the RDS recruitment process penetrates deeply into the hidden population, usually after 5–6 recruitment waves [37].

Convergence plots and bottleneck plots were used to determine whether the final RDS estimates were biased by the initial convenience sample of seeds [39]. Five variables were used in the convergence analysis, including age, education, marital status, migration status, and location of client solicitation. In each site, after 100–300 participants were recruited, the proportions of the five variables reached convergence (or equilibrium) and there was no evidence of unstable estimates from convergence plots. Bottleneck plots that show the changes of the estimates from each seed individually also indicated no unstable estimates in

each accumulated sample recruited by each seed. Therefore, our evaluation of this RDS sample at each study site indicated its success in reaching the convergence of RDS compositions and including a broad cross-section of the hidden population.

In this study, we estimated a sample size of 400 participants in each study site, which ensured that recruitment went through a sufficient number of recruitment waves (at least 5 waves required by RDS). In addition, a sample size of 400 produced a two-sided 96 % confidence interval with a width equal to 0.10 when the sample proportion was 0.35 [40]. According to previous reports [18, 19], about 35 % participants over reported condom use. In total, 1245 mid-age FSWs were recruited and interviewed in the three study sites; 418 from Nanning, 407 from Hefei, and 420 from Qingdao.

#### Interviews

All participants provided verbal inform consent after all their questions and concerns regarding their participation were answered by trained research staff. Eligible participants recruited by the seeds and new recruits in subsequent recruitment waves participated in a face-to-face anonymous interview in a private room. Interviewers used computer-assisted personal interviewing to interview participants because the education level among mid-age FSW was low as documented in our qualitative study [31]. Interviewers at each site received training in interviewing techniques, developing rapport, ensuring confidentiality, and answering questions raised by participants. Interview sites were located in the local Centres for Disease Control and Prevention, general clinics, and hotels. The selection of these sites was based on two conditions: easy access (less than 1 h-travel time) and protection of participants' confidentiality.

#### **Biological Tests**

Before interviewing consenting participants, trained lab technicians collected and tested the following specimens: (1) venepuncture blood specimen for syphilis and (2) a vaginal secretion specimen for prostate-specific antigen (PSA) test. Syphilis was first screened using a qualitative immunoassay to detect antibodies to *Treponema pallidum* (Alere Determine<sup>TM</sup> TP test; Alere Medical Co., Ltd, Chiba Prefecture, Japan) and confirmed by a *Treponema pallidum* (TPPA; Fujirebio Inc., Tokyo, Japan or ABON Biopharm Co., Ltd., Hangzhou, China). Confirmed TPPA positive sample were tested for non-treponemal antilipoidal antibodies, using Toluidine Red Unheated Serum Test (TRUST; Wantai Biological Pharmacy Enterprise Co., Ltd., Beijing, China). The positivity of TPPA indicates previous syphilis (cured syphilis) and/or active (or recent) syphilis because the existing antibodies to Treponema pallidum is lifelong. In order to detect a recent or active syphilitic infection, a third test (TRUST) was used because the existing non-treponemal antilipoidal antibodies indicate active syphilitic only. Presence of PSA was tested using ABAcard p30 test (Abacus Diagnostics, West Hill, CA).

#### Measurements

**Prevalent Syphilis Cases and Active Syphilis Cases**—FSWs who sero-tested positive for TPPA were classified as *prevalent* syphilis cases (including both previous and

or recent treponemal infection).

Self-Reported Condom Use in the Past 24 h—FSWs were first asked if they had sex during the past 24 h prior to the interview (the computerized questionnaire automatically generated the 24-h window based on the starting time of the interview). If they had sex in the past 24 h, they were then asked with whom they had sex (types of sex partners including: clients, husbands, or boyfriends) and the frequency of condom use with each type. The frequency of condom use was measured by 'used condoms for every sexual intercourse', 'used them, but not for every sexual intercourse', and 'did not use condoms'. Self-reported protected sex was defined as having used condoms for every sexual intercourse with all types of sexual partners. That is, a FSW was not categorized as engaging in protected sex if she reported having used condoms with some partners, but not with all partners in the 24-h period. Similarly, a FSW was not considered to engage in protected sex if she reported having not used condoms for every act of sexual intercourse when she had multiple acts of sex intercourse with the same partner. The use of a short window of 24 h might reduce recall bias in condom use. The use of this window is also dictated by the PSA as vaginal fluids are cleared of PSA between 24 and 48 h after unprotected sexual intercourse. The same information about condom use in the period between the past 24 and 48 h was also collected. The frequency of condom use was similar between the two windows.

**Over-Reported Condom Use Verified by PSA Test**—If a FSW self-reported protected sex for every sex intercourse in the 24-h window but tested positive for PSA in her vaginal sample, she was defined as having over-reported condom use. If a FSW reported protected sex for every sex act and PSA was absent, she was classified as having not over-reported condom use. The proportion of over-reported condom use was calculated by number of FSWs who were tested positive for PSA divided by number of FSWs with self-reported protected sex in the 24-h window.

**HIV Knowledge**—Knowledge regarding transmission and prevention of HIV/STIs was measured by 11 true or false questions (e.g., If clients' penis is washed clean, I do not need to use condoms to prevent HIV/STIs). One point was given for each correct answer, with a possible composite index ranging from 0 to 11 points.

**Attitudes Towards Condom Use**—It was measured by an 8-item scale that was validated in our previous study (e.g., "It is not necessary to use condoms if you trust your partner") [41]. Response categories ranged from (0) 'strongly disagree' to (3) 'strongly agree'. The reversed composite score ranged from 0 to 24. Higher scores indicated greater favorable attitudes. The Cronbach's reliability alpha was 0.64 in Nanning, 0.80 in Hefei, and 0.70 in Qingdao.

**Self-Reported STIs**—FSWs were asked if you had an STI that was diagnosed by a physician in the past 12 month.

#### **Statistical Analysis**

Bivariate and multiple log-binominal regression analyses were performed to estimate the crude prevalence ratio (cPR) and adjusted ratio (aPR) and their 95 % confidence intervals (95 % CI) of factors that were possibly associated with over-reporting of condom use, using SAS 9.4 (SAS Institute, Cary, NC) [42]. In order to assess the separate associations between over-reported condom use and prevalent syphilis and active syphilis, two multivariate models were performed, model one including prevalent syphilis as a predictor, and model two including active syphilis along with other variables (socio-demographic characteristics, HIV knowledge, attitude to condom use, history of STIs, and duration of sex work). In order to adjust for potential cluster effects incurred from different study sites, the variable of study sites was entered into these models [43].

Data were weighted to account for potential sampling bias in the RDS [37]. The weight for the outcome variable was calculated using the RDS Analyst (RDS-A, version 0.42, Statistics-UCLA, Los Angeles, CA) [44]. Because modelling techniques for analysing RDS data are unavailable [45], unweighted regression analysis is commonly used [46–48]. Unweighted log-binomial regression was performed in this multivariate analysis.

#### Results

#### **Characteristics of Study Samples**

In total, 1245 mid-age FSWs were recruited and interviewed in the three study sites; 418 from Nanning, 407 from Hefei, and 420 from Qingdao. The RDS-adjusted proportion of prevalent syphilis was 34 % in Hefei, 32 % in Qingdao, and 7 % in Nanning. The RDS-adjusted proportion of active syphilis was between 5 and 17 % (Table 1). The median age of respondents was between 37 and 42 years old. FSWs in Qingdao had the longest mean duration of commercial sex work (6.2 years), compared to 1.3 years in Hefei and 3.0 years in Nanning. The majority of FSWs attained middle school education or lower, and only about 10 % had high school education or above. In Qingdao, more than half (59 %) of FSWs were divorced or widowed, 29 % in Nanning, and 32 % in Hefei. The rural-to-urban migrants counted for more than half of the participants (between 59 and 74 %).

The score of HIV knowledge was highest among FSWs in Nanning (9), compared to the other two study sites (7 in Hefei and 8 in Qingdao). The level of attitudes towards condom use was similar at the three sites. The RDS-adjusted prevalence of physician-diagnosed STIs was 5 % in Nanning and Hefei, but 29 % in Qingdao (Table 1).

Among 1245 mid-age FSWs, 742 had sex in the 24-h window. Among these 742 FSWs, 629 (85 %) FSWs had sex with clients, 81 (11 %) with their husband, and 159 (21 %) with boyfriends (Table 1).

#### Self-Reported Condom-Protected Sex and PSA Negativity

Among the 742 mid-age FSWs who had sex in the past 24 h, 511 (69 %) had sex only with clients, 81(11 %) with boyfriends only, and 46 (6 %) with husband only. The proportion of self-reported protected sex was 77 % with clients, 27 % with boyfriends, and 22 % with

husbands. The proportion of PSA-verified condom use (PSA negative) was 52 % with clients, 41 % with boyfriends, and 39 % with husbands (Table 2).

#### **Proportions of Over-Reported Condom Use**

In Qingdao, 84 out of 200 FSWs who reported having had sex only with clients in the past 24 h and reported having used condoms for every sex act (protected sex) tested PSA positive. The RDS-adjusted proportion of over-reported condom use with clients only was 45 % (84/200) in Qingdao, 45 % (22/49) in Hefei, and 27 % (40/143) in Nanning (Table 3). In Hefei, 32 of 73 mid-age 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 of 46 % (32/73). This RDS-adjusted proportion with all partners was 26 % (47/169) in Nanning and 46 % in Qingdao (87/203). The overall proportion of over-reported condom use with all sexual partners was 37 % and 37 % for sex with clients only across the study sites.

#### Factors Associated with Over-Reporting of Condom Use

As depicted in the binary analysis (Table 4), over-reported condom use was significantly associated with prevalent syphilis (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 statistical significance, active syphilis cases were more likely to over report condom use than those who were not active cases (cPR 1.36; 95 % CI, 0.94–1.96).

After adjustment of social demographic variables, history of STIs, duration of sex work, and study sites, FSWs who were prevalent cases or active cases were more likely to over report condom use than FSWs who were not prevalent cases (aPR 1.60; 95 % CI, 1.17–2.21) or not active cases (aPR 1.91; 95 % CI, 1.27–2.88) (Table 4).

In addition, 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 contrast, FSWs who had ever had diagnosed STIs 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-reporting.

#### Discussion

This multisite study documents a large proportion of mid-age FSWs over reported condom use, which was associated with both prevalent and active syphilis. The findings suggest that self-reported condom use may not be a valid subjective approach to measure the level of protected sex in behavioral studies including intervention trials because over-reported condom use was significantly associated with the outcome evaluation measure, i.e., syphilis. This is the first study, to our knowledge, to document the potential influence of prevalent and incident syphilis on self-reported condom use.

Among FSWs who reported condom use during *every* vaginal sex act, more than one-third (between 26 and 46 %) tested for semen PSA, indicating over-reporting of condom use. The level of over-reporting in condom-protected sex was similar to other studies conducted

among FSWs in other countries, for example, 33 % in Cambodia [18], 36 % in Guinea [19], and 39 % in Madagascar [49]. The high level of over-reported condom use may result from social desirability, distrust to interviewers, breakage of condoms, and recall bias. We conducted qualitative studies among mid-age FSWs in the three study sites before this quantitative study [50], in which few mid-age FSWs reported having experienced breakage of condoms. We undertook several approaches to increase rapport relations between interviewers and interviewees, including carefully selecting interviewers and training them in interviewing techniques, developing rapport, ensuring confidentiality, and answering questions raised by participants. The distrust to interviewers may have been reduced although it could not be fully eliminated. As condom use was asked in the past 24 h, recall bias may also have been reduced. It is possible that drug use may increase recall bias. We did a qualitative study among 20 mid-age FSWs in each of the three cities and found that drug use was low in this special population as commercial sex was their survival job [50]. In this survey, drug use was low and only 7.6 % (95/1245) of mid-age FSWs had ever used illicit drugs (e.g., heroin, opium, methamphetamine, or ketamine). Therefore, we believe that it was social desirability that influenced mid-age FSWs' self-report on condom use. Condom use to prevent HIV/STIs had been frequently propagated in the media and the promotion of it was a routine education activity performed by the local CDCs. In order to avoid embarrassment or repercussions from disclosing sensitive information, respondents may deliberately edit their answers before they report them [13]. Consequently, the errors introduced by editing tend to be in the same direction, that is, to over report socially desirable behaviour and to underreport socially undesirable ones [51]. While mid-age FSWs over reported protected sex with clients, a small proportion of them, however, under reported protected sex with boyfriends and husbands. Further research, especially qualitative studies, need to explore the reasons for the under-report with non-clients partners. The over and under reporting of condom use with different types of sexual partners complicates the use of self-reported approach to assess engagement in safer sex and largely reduces the validity of self-reported condom use.

As there is a large discordance between self-reported condom use and actual condom use, the legitimate question is 'Can we use self-reported condom use to assess the efficacy of behavioral interventions?' As documented in this study, both prevalent and active syphilis was associated with over-reported condom use. The association between syphilis and over-reporting of condom use indicates the existences of differential misclassification bias that may lead to over-reporting of intervention efficacy or non-differential misclassification bias that may result in under-report of intervention efficacy [11]. According to the theory of planned behavior [52], the more favourable the attitude towards a behaviour (condom use), the stronger an individuals' intention to perform the behaviour will be. Findings of this study indicates that favorable attitude to condom use was positively associated with over-reported condom use. HIV/STI interventions targeting unprotected sex among FSWs often note increased attitudes toward condom use in the intervention group with little change in the control group [53–55]. The over-reporting of condom use in the intervention group could be disproportionally higher than in the control group, leading to an over-estimate of intervention efficacy.

In addition, it is usually not feasible to use a blinding technique to make participants and researchers unaware of which group participants are assigned (intervention vs. control) in randomised trials, the knowledge of assignment in an intervention group may cause over-reporting of condom use, which is particularly true when outcomes are subjectively measured. Several well-designed randomized controlled trials reported inconsistent results in which increased condom use was not associated with HIV/STI incidence [3, 56, 57]. While there are many possible reasons to explain this inconsistency, differential misclassification bias caused by self-reported condom may have led this inconsistency. These findings highlight the importance of using biological outcomes as a primary outcome for intervention trials.

It was previously believed that the over-reporting of condom use masked the intervention efficacy if the information bias was non-differential, that is, the degree of inaccurate measures (over-reported condom use) in the intervention group and control group was similar [1]. In this belief, the bias was equally present in both group and its bias impact could be cancelled, leading to reduced estimate of intervention efficacy. However, over-reporting of condom use does not follow a random process [12]. It is determined by factors that are unevenly distributed in the intervention group and control group. Over-reporting of condom use has been reported to be associated with study site, young age, ethnicity, sex work venues, use of illicit drugs, and having more sexual partners [12, 18]. In our study, over-reporting of condom use was significantly associated with attitude toward condom use and having diagnosed STIs. If the distributions of these variables are different in the intervention group and control group and control use will differ between the two groups.

Strengths of our study include first, the use of RDS to recruit large numbers of mid-age FSWs from three cites that covered different levels of the HIV/STI epidemics, and second, the use of biomarkers to measure major variables in this study. However, several limitations should be noted. First, awareness of PSA tests may have influenced participants' answers to condom use. A randomized controlled trial on whether advance knowledge of PSA testing improves participant reporting of unprotected sex documents that reporting of unprotected sex did not differ between those with advance knowledge of the PSA test and those without this knowledge (14.3 vs. 11.4 % respectively; p = 0.27) [58]. If that influence occurred in our study, the proportions of over-reporting of condom use would be underreported. Second, the study may have limited generalizability as it was conducted among mid-age FSWs. Third, some potentially important factors for condom use were missing (e.g., norms regarding condom use or low social power to negotiate with clients to use condoms). Future research is needed to examine the associations between over-reported condom use and these factors. Fourth, temporal ambiguity bias may occur due to the nature of the cross-sectional study. Thus, causality cannot be assessed. Fifth, the measurement scale of attitudes towards condom use was less reliable (Cronbach's alpha = 0.64) in Nanning compared to other cities. The low reliability of the measurement scale may affect our analysis.

Self-reported condom use has been used for more than 30 years in behavioral research and inconsistency of condom use and HIV/STI infections has been commonly reported. It is now the time to start using bio-subjective measurement to measure actual condom use (the PSA

test) and incident STI/HIV infections (bio-tests) in intervention trials. The PSA test is simple, rapid, and inexpensive (\$5.04 per test) to implement and improve the validity of condom use measures. Field workers can successfully perform the tests at interview sites after receive short training. One important limitation of the PSA test is that it can only be used to assess condom use with a short period (in the past 24 or 48 h). However, it is still useful in measuring condom use for high risk groups, i.e., sex workers, as they have frequent sex intercourses in the past one or two days. Despite of this limitation, this study suggest that the rapid PSA biomarker assay can be an effective and valid strategy in monitoring condom use and evaluating efficacy of HIV and STI prevention interventions.

#### Acknowledgments

This work was supported by a research Grant (R01HD068305) from National Institutes of Health, awarded to Hongjie Liu. We are grateful to the staff from Shandong University School of Public Health, Nanning Centre for Disease Control and Prevention, Hefei Centre for Diseases Control and Prevention, and Qingdao Centre for Disease Control and Prevention for their participation in the study, and to all the participants who willingly gave their time to provide the study data.

#### References

- Pequegnat W, Fishbein M, Celentano D, Ehrhardt A, Garnett G, Holtgrave D, et al. NIMH/APPC workgroup on behavioral and biological outcomes in HIV/STD prevention studies: a position statement. Sex Transm Dis. 2000; 27(3):127–32. [PubMed: 10726643]
- Peterman TA, Lin LS, Newman DR, Kamb ML, Bolan G, Zenilman J, et al. Does measured behavior reflect STD risk? An analysis of data from a randomized controlled behavioral intervention study. Project RESPECT Study Group. Sex Transm Dis. 2000; 27(8):446–51. [PubMed: 10987449]
- Imrie J, Stephenson JM, Cowan FM, Wanigaratne S, Billington AJ, Copas AJ, et al. A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial. BMJ. 2001; 322(7300):1451–6. [PubMed: 11408300]
- Scott-Sheldon LA, Huedo-Medina TB, Warren MR, Johnson BT, Carey MP. Efficacy of behavioral interventions to increase condom use and reduce sexually transmitted infections: a meta-analysis, 1991 to 2010. J Acquir Immune Defic Syndr. 2011; 58(5):489–98. [PubMed: 22083038]
- Zenilman JM, Weisman CS, Rompalo AM, Ellish N, Upchurch DM, Hook EW 3rd, et al. Condom use to prevent incident STDs: the validity of self-reported condom use. Sex Transm Dis. 1995; 22(1):15–21. [PubMed: 7709320]
- Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011; 365(6):493–505. [PubMed: 21767103]
- 7. Rodger A, Phillips A, Lundgren J. Prevention of HIV-1 infection with antiretroviral therapy. N Engl J Med. 2011; 365(20):1934. author reply 5. [PubMed: 22087688]
- Cohen MS, McCauley M, Gamble TR. HIV treatment as prevention and HPTN 052. Curr Opin HIV AIDS. 2012; 7(2):99–105. [PubMed: 22227585]
- Phillips AE, Gomez GB, Boily MC, Garnett GP. A systematic review and meta-analysis of quantitative interviewing tools to investigate self-reported HIV and STI associated behaviours in low- and middle-income countries. Int J Epidemiol. 2010; 39(6):1541–55. [PubMed: 20630991]
- Zimmerman RS, Morisky DE, Harrison L, Mark HD. Validity of behavioral measures as proxies for HIV-related outcomes. J Acquir Immune Defic Syndr. 2014; 66(Suppl 3):S285–92. [PubMed: 25007198]
- Rothman, KJ.; Greenland, S.; Lash, TL. Modern Epidemiology. Philadelphia: Lippincott Williams & Wilkins; 2008.

- Gallo MF, Steiner MJ, Hobbs MM, Warner L, Jamieson DJ, Macaluso M. Biological markers of sexual activity: tools for improving measurement in HIV/sexually transmitted infection prevention research. Sex Transm Dis. 2013; 40(6):447–52. [PubMed: 23677018]
- Tourangeau R, Yan T. Sensitive questions in surveys. Psychol Bull. 2007; 133(5):859–83. [PubMed: 17723033]
- Minnis AM, Steiner MJ, Gallo MF, Warner L, Hobbs MM, van der Straten A, et al. Biomarker validation of reports of recent sexual activity: results of a randomized controlled study in Zimbabwe. Am J Epidemiol. 2009; 170(7):918–24. [PubMed: 19741042]
- Chen X, Wang Y, Li F, Gong J, Yan Y. Development and evaluation of the brief sexual openness scale-a construal level theory based approach. PLoS One. 2015; 10(8):e0136683. [PubMed: 26308336]
- 16. Liu H, Detels R. An approach to improve validity of responses in a sexual behavior study in a rural area of China. AIDS Behav. 1999; 3:243–9.
- Gallo MF, Sobel JD, Rompalo AM, Cu-Uvin S, Schoenbaum E, Jamieson DJ. Discordance between spermatozoa detection and self-reported semen exposure. Sex Transm Dis. 2011; 38(10): 909–12. [PubMed: 21934562]
- Evans JL, Couture MC, Stein ES, Sansothy N, Maher L, Page K. Biomarker validation of recent unprotected sexual intercourse in a prospective study of young women engaged in sex work in Phnom Penh. Cambodia. Sex Transm Dis. 2013; 40(6):462–8. [PubMed: 23680902]
- Aho J, Koushik A, Diakite SL, Loua KM, Nguyen VK, Rashed S. Biological validation of selfreported condom use among sex workers in Guinea. AIDS Behav. 2010; 14(6):1287–93. [PubMed: 19680799]
- 20. Cordero-Coma J, Breen R. HIV prevention and social desirability: husband-wife discrepancies in reports of condom use. J Marriage Fam. 2012; 74(3):601–13.
- Morisky DE, Ang A, Sneed CD. Validating the effects of social desirability on self-reported condom use behavior among commercial sex workers. AIDS Educ Prev. 2002; 14(5):351–60. [PubMed: 12413181]
- Hobbs MM, Steiner MJ, Rich KD, Gallo MF, Alam A, Rahman M, et al. Good performance of rapid prostate-specific antigen test for detection of semen exposure in women: implications for qualitative research. Sex Transm Dis. 2009; 36(8):501–6. [PubMed: 19455082]
- Macaluso M, Lawson L, Akers R, Valappil T, Hammond K, Blackwell R, et al. Prostate-specific antigen in vaginal fluid as a biologic marker of condom failure. Contraception. 1999; 59(3):195– 201. [PubMed: 10382083]
- Gallo MF, Behets FM, Steiner MJ, Thomsen SC, Ombidi W, Luchters S, et al. Validity of selfreported 'safe sex' among female sex workers in Mombasa, Kenya–PSA analysis. Int J STD AIDS. 2007; 18(1):33–8. [PubMed: 17326860]
- 25. Siegfried N, Mathews C. Commentary: All is not what it seems: a systematic review and metaanalysis of quantitative interviewing tools to investigate self-reported HIV and STI-associated behaviours in low- and middle-income countries. Int J Epidemiol. 2010; 39(6):1556–7. [PubMed: 20959353]
- 26. High KP, Brennan-Ing M, Clifford DB, Cohen MH, Currier J, Deeks SG, et al. HIV and aging: state of knowledge and areas of critical need for research. A report to the NIH Office of AIDS Research by the HIV and Aging Working Group. J Acquir Immune Defic Syndr. 2012; 60(Suppl 1):S1–18. [PubMed: 22688010]
- Emlet CA, Brennan DJ, Brennenstuhl S, Rueda S, Hart TA, Rourke SB. The impact of HIV-related stigma on older and younger adults living with HIV disease: does age matter? AIDS Care. 2015; 27(4):520–8. [PubMed: 25397643]
- Xing J, Li YG, Tang W, Guo W, Ding Z, Ding G, et al. HIV/AIDS epidemic among older adults in china during 2005–2012: results from trend and spatial analysis. Clin Infect Dis. 2014; 59(2):e53– 60. [PubMed: 24700658]
- 29. Liu H, Lin X, Xu Y, Chen S, Shi J, Morisky D. Emerging HIV epidemic among older adults in Nanning, China. AIDS Patient Care STDS. 2012; 26(10):565–7. [PubMed: 22984779]

- 30. Zhou C, Rou K, Dong WM, Wang Y, Dong W, Zhou Y, et al. High prevalence of HIV and syphilis and associated factors among low-fee female sex workers in mainland China: a cross-sectional study. BMC Infect Dis. 2014; 14:225. [PubMed: 24767104]
- Hao C, Liu H, Sherman S, Jian B, Li X, Xu Y, et al. Typology of older female sex workers and sexual risks for HIV infection in China: a qualitative study. Cult Health Sex. 2014; 16(1):47–60. [PubMed: 23998493]
- Remis RS, Kang L, Calzavara L, Pan Q, Liu J, Myers T, et al. Prevalence and correlates of HIV infection and sexually transmitted infections in female sex workers (FSWs) in Shanghai, China. Epidemiol Infect. 2015; 143(2):258–66. [PubMed: 24759515]
- 33. Yang Z, Su J, Peng X, Wu N. A decline in HIV and syphilis epidemics in Chinese female sex workers (2000–2011): a systematic review and meta-analysis. PLoS One. 2013; 8(12):e82451. [PubMed: 24349288]
- 34. Weir SS, Li J, Edwards JK, Gandhi AD, Huang Y, Suchindran CM, et al. Exploring venueassociated risk: a comparison of multiple partnerships and syphilis infection among women working at entertainment and service venues. AIDS Behav. 2014; 18(Suppl 2):S153–60. [PubMed: 23851672]
- 35. Ministry of Health of the People's Republic of China. 2012 China AIDS response progress report. Beijing: China Ministry of Health; Mar 31. 2012 [updated November 8, 2015]. Available from: http://www.unaids.org/sites/default/files/en/dataanalysis/knowyourresponse/ countryprogressreports/2012countries/ce\_CN\_Narrative\_Report[1].pdf
- 36. Huang ZJ, Hu D, Chang R, Zaccaro H, Iguchi M, Zheng H, et al. Female streetwalkers' perspectives on migration and HIV/STI risks in a changing economic and social environment: a qualitative study in Shanghai, China. Cult Health Sex. 2015; 17(6):763–76. [PubMed: 25587711]
- 37. Heckathorn DD. Extensions of respondent-driven sampling: analyzing continuous variables and controlling for differential recruitment. Sociol Methodol. 2007; 37(1):151–208.
- Liu H, Li J, Ha T, Li J. Assessment of random recruitment assumption in respondent-driven sampling in egocentric network data. Soc Netw. 2012; 1(2):13–21. [PubMed: 23641317]
- 39. Gile KJ, Johnston LG, Salganik MJ. Diagnostics for respondent-driven sampling. J R Stat Soc Ser A Stat Soc. 2015; 178(1):241–69.
- Fleiss, JL.; Levin, B.; Paik, MC. Statistical methods for rates and proportions. 3. New York: Wiley; 2003.
- Liu H, Kennedy M, Liu H, Hong F, Ha T, Ning Z. Mediation effect of perceived behavioural control on intended condom use: applicability of the theory of planned behaviour to money boys in China. Sex Health. 2013; 10(6):487–94. [PubMed: 24119302]
- 42. Spiegelman D, Hertzmark E. Easy SAS calculations for risk or prevalence ratios and differences. Am J Epidemiol. 2005; 162(3):199–200. [PubMed: 15987728]
- 43. Twisk, JWR. Applied multilevel analysis. New York: Cambridge Unicersity Press; 2006.
- 44. Handcock, MS.; Fellows, IE.; Gile, KJ. RDS Analyst: software for the analysis of respondentdriven sampling data, Version 0.42. 2014. URL http://hpmrg.org
- 45. Johnston LG, Malekinejad M, Kendall C, Iuppa IM, Rutherford GW. Implementation challenges to using respondent-driven sampling methodology for HIV biological and behavioral surveillance: field experiences in international settings. AIDS Behav. 2008; 12(4 Suppl):S131–41. [PubMed: 18535901]
- 46. Strathdee SA, Lozada R, Pollini RA, Brouwer KC, Mantsios A, Abramovitz DA, et al. Individual, social, and environmental influences associated with HIV infection among injection drug users in Tijuana, Mexico. J Acquir Immune Defic Syndr. 2008; 47(3):369–76. [PubMed: 18176320]
- Jenness SM, Begier EM, Neaigus A, Murrill CS, Wendel T, Hagan H. Unprotected anal intercourse and sexually transmitted diseases in high-risk heterosexual women. Am J Public Health. 2011; 101(4):745–50. [PubMed: 20558790]
- Koram N, Liu H, Li J, Luo J, Nield J. Role of social network dimensions in the transition to injection drug use: actions speak louder than words. AIDS Behav. 2011; 15(7):1579–88. [PubMed: 21431412]

- Gallo MF, Behets FM, Steiner MJ, Hobbs MM, Hoke TH, Van Damme K, et al. Prostate-specific antigen to ascertain reliability of self-reported coital exposure to semen. Sex Transm Dis. 2006; 33(8):476–9. [PubMed: 16865047]
- Hao C, Guida J, Morisky D, Liu H. Family network, workplace network, and their influence on condom use: a qualitative study among older female sex workers in China. J Sex Res. 2015; 52(8): 924–35. [PubMed: 25411685]
- 51. Tourangeau, R.; Rips, LJ.; Rasinski, K. The psychology of survey response. Cambridge: Cambridge University Press; 2000.
- 52. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process. 1991; 50:179–211.
- 53. Montanaro EA, Bryan AD. Comparing theory-based condom interventions: health belief model versus theory of planned behavior. Health Psychol. 2014; 33(10):1251–60. [PubMed: 23977877]
- 54. Noar SM. Behavioral interventions to reduce HIV-related sexual risk behavior: review and synthesis of meta-analytic evidence. AIDS Behav. 2008; 12(3):335–53. [PubMed: 17896176]
- Kyrychenko P, Kohler C, Sathiakumar N. Evaluation of a school-based HIV/AIDS educational intervention in Ukraine. J Adolesc Health. 2006; 39(6):900–7. [PubMed: 17116522]
- 56. Metsch LR, Feaster DJ, Gooden L, Schackman BR, Matheson T, Das M, et al. Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. JAMA. 2013; 310(16):1701–10. [PubMed: 24150466]
- 57. Lu H, Liu Y, Dahiya K, Qian HZ, Fan W, Zhang L, et al. Effectiveness of HIV risk reduction interventions among men who have sex with men in China: a systematic review and meta-analysis. PLoS One. 2013; 8(8):e72747. [PubMed: 24137497]
- Thomsen SC, Gallo MF, Ombidi W, Omungo Z, Janowitz B, Hawken M, et al. Randomised controlled trial on whether advance knowledge of prostate-specific antigen testing improves participant reporting of unprotected sex. Sex Transm Infect. 2007; 83(5):419–20. [PubMed: 17135328]

## Table 1

Social demographic characteristics, sexual behavior, and syphilis among mid-age FSWs at three study sites

	Nanning	ing	Hefei		Qingdao	dao	<u>All sites</u>	tes
	Z	%	z	%	z	%	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 syphilis	30	6.8	134	33.6	125	32.0	289	23.2
Active syphilis	24	5.4	68	17.3	36	6.6	128	10.3
Had sex in the past 24 h	220	52.8	167	42.0	355	84.5	742	60.1
Had sex with clients	186	84.5	102	61.1	341	96.1	629	84.8
Had sex with husband	22	10.0	26	15.6	33	9.3	81	10.9
Had sex with boyfriends	52	23.6	43	25.7	64	18.0	159	21.4
Continuous variables	Media	Median 25th-75th percentile	th perc	entile				
Age (years)	37	36-40	38	35-43	42	36-48	38	35-43
Duration of sex work (years)	3.0	1.8 - 5.0	1.3	0.5 - 3.0	6.2	4.0-9.9	3.2	1.3-5.8
HIV knowledge	6	8 - 10	٢	49	×	69	×	7-8
Attitude to condom use	5	5 		1 	ç		, ,	

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#### Table 2

Proportions of self-reported protected sex and PSA negativity among mid-age FSWs

	Had sex in the past 24 h	Self-reported protected sex	PSA negativity	p value
Clients only	511	392 (76.7 %)	265 (51.9 %) <sup>a</sup>	< 0.01
Boyfriend only	81	22 (27.2 %)	33 (40.7 %)	0.03
Husband only	46	10 (21.7 %)	18 (39.1 %)	0.13
All partners	742	445 (60.1 %)	354 (47.7 %)	< 0.01

<sup>a</sup>265/511 = 51.9 %

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Proportions of over-reported condom use among mid-age FSWs at three study sites

Self-reported protected sex with Nanning	Nanr	ing		Hefei	ei		Qingdao	dao		Total		
	N	PSA+a % $N$ $PSA+$ % $N$ $PSA+$ % $N$ $PSA+$ % $N$ $PSA+$ %	%	N	PSA+	%	N	PSA+	%	N	PSA+	%
Clients only	143	143 40	26.5 49 22	49	22	44.5	44.5 200 84		45.1 392 146	392	146	37.2 <sup>b</sup>
Boyfriend only	7	3	39.6 14	14	5	49.5 1	1	1	I	22	6	40.9
Husband only	ю	0	0	٢	4	42.1 0	0	0	T	10	4	40.0
All partners	169 47	47	26.0 73 32	73	32	45.9	203	45.9 203 87	46.4	46.4 445 166	166	37.3
<sup>a</sup> Positivity of prostate specific-antigen test	n test											
$b_{146/392} = 37.2 \%$												

# Table 4

Binary and multivariate analysis of over-reported condom use among mid-age female sex workers

	<b>Binary analysis</b>	is		Model 1 <sup>a</sup>	$1^d$	Model 2 <sup>e</sup>	2 <sup>e</sup>
	Yes (n/%)	CPR <sup>a</sup>	95 % CI <sup>b</sup>	APR <sup>c</sup>	95 % CI	APR	95 % CI
Prevalent syphilis							
Negative	114/20.5	1		1			
Positive	52/27.8	$1.35^{f}$	1.02 - 1.80	1.60	1.17–2.21		
Active syphilis							
Negative	142/21.5	1				-	
Positive	24/29.3	1.36	0.94 - 1.96			1.91	1.27-2.88
Age (years)	40.4 vs 40.0	1.01	0.99 - 1.34	1.01	0.98 - 1.04	1.01	0.98 - 1.04
Education							
Primary or less	64/18.8	1		1		-	
Middle school	85/24.8	1.32	0.99 - 1.76	1.3	0.97 - 1.73	1.27	0.93 - 1.75
High school or above	17/29.3	1.56	0.99–2.46	1.54	0.98-2.43	1.59	0.95-2.68
Marital status							
Married	79/22.3	1		1		1	
Unmarred	7/14.0	0.63	0.31 - 1.28	0.56	0.29 - 1.20	0.6	0.29 - 1.23
Divorced or widowed	80/23.7	1.07	0.81 - 1.40	1.03	0.78 - 1.36	1.02	0.75 - 1.38
Residency							
Urban	39/19.9	1		1		1	
Rural	127/23.3	1.17	0.85 - 1.61	1.19	0.86 - 1.65	1.26	0.87 - 1.74
HIV knowledge	7.9 vs. 7.6	1.04	0.98 - 1.11	1.03	0.97 - 1.10	1.07	0.99 - 1.15
Attitude to condom use	13.4 vs. 12.7	1.07	1.02 - 1.12	1.08	1.02 - 1.13	1.08	1.02 - 1.15
Had diagnosed STD							
No	133/22.9	-		1		1	
Yes	33/20.6	06.0	0.64 - 1.27	0.71	0.49 - 1.04	0.45	0.26 - 0.82
Duration of sex work (years)							
	4.4 vs. 4.8	1.00	0.99 - 1.01	0.99	0.99 - 1.00	0.99	0.99 - 1.01
Study sites							
Hafai	37/10.7	-		-			

	<b>Binary analysis</b>	s		Model 1 <sup>d</sup>	p	Model 2 <sup>e</sup>	2 <sup>e</sup>	
	$\operatorname{Yes}\left(n/^{0}\right)$	CPR <sup>d</sup>	CPR <sup>a</sup> 95 % CI <sup>b</sup> APR <sup>c</sup> 95 % CI	APR <sup>c</sup>	95 % CI	APR	APR 95 % CI	
Nanning	47/21.4	1.11	0.75-1.67 1.14	1.14	0.73-1.80 0.91 0.58-1.44	0.91	0.58 - 1.44	
Qingdao	87/24.5	1.28	0.89 - 1.84	1.49	0.89–1.84 1.49 0.97–2.30 1.36 0.84–2.20	1.36	0.84 - 2.20	
<sup>a</sup> Crude prevalence ratio								
$b_{95}$ % confidence interval								
$^{\mathcal{C}}$ Adjusted prevalence ratio								
$d_{M}$ odel includes prevalent syphilis as predictor	philis as predicto	٥٢						
$^{e}$ Model includes active syphilis as predictor	is as predictor							
$f_{ m Bold}$ indicates $p$ < 0.05								