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Original article

Biomarker validation of self-reported sex among middle-aged female sex workers in China

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ABSTRACT

Purpose: The objective of this study was to examine information bias arising from self-reported sexual activity and its association with syphilitic infections among female sex workers (FSWs) aged 35 years and older in China.

Methods: A questionnaire was administered to 1245 middle-aged FSWs. Respondents self-reported sexual intercourse in the past 48 hours. The prostate-specific antigen test was used to verify self-reported sexual activity. FSWs were considered discordant if they indicated no sexual intercourse in the past 48 hours on the questionnaire and had a positive prostate-specific antigen test. Logistic regression was used to assess the associations between discordance and syphilis.

Results: Three hundred twenty FSWs self-reported no engagement in sexual intercourse in the past 48 hours. One-fourth of respondents (25%) were discordant. Twenty-two percent and 35.8% of discordant FSWs tested positive for active and prevalent syphilis, respectively. After adjusting for confounders, discordant FSWs had 3.8 times the odds of active syphilis (95% confidence interval: 1.52–9.30) and 2.6 times the odds of prevalent syphilis (95% confidence interval: 1.37–5.02), compared with concordant FSWs.

Conclusions: FSWs who had active or prevalent syphilis were more likely to be discordant. Data collected via self-reported questionnaire may not be a valid tool to assess sexual behavior.

Introduction

Self-reported questionnaires are a central component of public health data collection. In the field of sexually transmitted infections (STIs) including HIV/AIDS, self-reporting sexual behavior is commonly practiced. However, the responses generated from questionnaire data may not always be accurate [1]. Such inaccuracies may lead to misclassification of the outcome and/or exposure status of subjects (information bias) [2]. Misreporting may arise from inaccurate recall, misinterpretation or incomprehension of survey items, or in response to "*sensitive*" questions. Participants may perceive a question to be "*sensitive*" if they feel it is inappropriate, stigmatizing, threatening, invasive, socially undesirable, or inconsistent with the researcher's expectations [3]. Therefore, validation of self-reported sexual behavior is paramount.

Self-reported sexual activity can be validated by biomarkers, such as prostate-specific antigen (PSA). PSA is transmitted through ejaculation and can be subsequently detected in vaginal fluid for up to 48 hours after unprotected sex [4]. The PSA test is 100% sensitive and 95% to 96% specific to detect 1.0 ng PSA/mL of vaginal swab ejaculate immediately after semen exposure [5–7], and declines thereafter [4,7].

Earlier studies revealed that self-reported condom use was associated with lower STI rates [8]. However, with the advent of biological measures, such as the PSA test, several studies in different populations of sex workers have revealed that condom use may be inaccurately reported [9–12] and that bias exists regardless of the interview mode (e.g., face-to-face interviews, audio computer-assisted self-interviewing, and computer-assisted self-interviewing) [13]. In addition, our previous study demonstrated that a substantial proportion of FSWs over-reported their condom use, and that this over-reporting was associated with syphilitic infection [14].

High-risk individuals may be more inclined to misreport socially undesirable behaviors. However, previous studies linking misreported sexual activity to STIs are mixed [9,11,14]. These inconsistencies may stem from different definitions of discordance, including using self-reported condom use instead of sexual activity. It is possible that less bias may be associated with reporting sexual activity in general, rather than specific sex practices (e.g., condom

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use) because FSWs are selected into studies based on occupation (e.g., engaging in sexual activity with clients). However, it remains unknown if misreporting sexual activity occurs, what the magnitude and direction of the bias is, and what factors contribute to misreporting.

The objective of this study was twofold: (1) to validate self-reported data with a biomarker (PSA) to determine if middle-aged FSWs accurately reported their sexual activity in the past 48 hours and (2) to determine if discordance between self-reported sexual intercourse and biomarker data was associated with active and prevalent syphilitic infection.

Materials and methods

Study population and location

Detailed information regarding sampling has been previous reported elsewhere [14]. Briefly, a multisite cross-sectional study was carried out in 2014 in Hefei, Nanning, and Qingdao, China. The three different cities were chosen based on their heterogeneity in prevalence estimates of HIV/STIs. From 2010 to 2013, Nanning had the highest HIV/STI prevalence of notifiable STIs (e.g., notifiable STIs include HIV/AIDS, syphilis, and gonorrhea [15]) followed by Hefei, and Qingdao [14].

Women who were middle-aged FSWs and resided in one of the three cities for at least 3 months were included in the study. Middle-age was defined as 35 years and older and was based on the findings from a qualitative study [16]. Women were considered FSWs if they had commercial sex at least once a week in the 30 days before the interview.

Recruitment of study participants

FSWs were recruited using Respondent Driven Sampling (RDS), a peer recruitment strategy used to target hidden populations [17,18]. RDS methods for the sample have been previously described [14]. Briefly, seeds with different durations of sex work and client solicitation location (e.g., street based, massage parlors, and karaoke bars) were purposefully selected to recruit a diverse sample of middle-aged FSWs at each site (~400 participants at each site). Applications of RDS suggest that after 5 to 6 recruitment waves, the RDS sample provides a broad cross-section of the hidden population [17]. We successfully completed more than six waves of recruitment at each site (e.g., eight waves of recruitment in Qingdao, nine in Hefei, and 11 in Nanning). Convergence plots and bottleneck plots were used to determine whether the final RDS estimates were biased by the convenience sample of seeds [19] based on five variables: age, education, marital status, migration status, and client solicitation site. After 100 to 300 participants were recruited at each study location, the five variables reached equilibrium, indicating that the RDS sample included a broad cross-section of the middle-aged FSW population. Our final sample size was 418 in Nanning, 407 in Hefei, and 420 in Qingdao.

Interviews

All eligible subjects participated in a face-to-face anonymous interview in a private room conducted by trained interviewers. Interviewers were either local public health staff who provided free STI counseling and testing or were well-trained graduate students. All interviewers completed training on interviewing techniques, establishing and maintaining rapport with participants and ensuring participant confidentiality. To aide subject's comprehension, interviewers used computer-assisted personal interviewing.

Ethical considerations

Because sex work in China is illegal and stigmatized, we used three approaches to ensure participant confidentiality. First, interviewers received training on confidentiality. Second, interview sites were chosen for their capability to maintain confidentiality and included clinics, hotels, and the local Centers for Disease Control and Prevention. Third, FSWs were recruited using RDS, a peer referral method that serves to build rapport between researchers and potential participants and address fears related to study participation. Trained research team members explained the study protocol and procedures and answered questions before obtaining informed consent. This study was approved by the Institutional Review Boards of the University of Maryland, Shandong University School of Public Health, and the Centers for Disease Control and Prevention in Hefei and Guangxi.

Measurement

PSA test

PSA is detectable in vaginal discharge for up to 48 hours after acts of unprotected vaginal intercourse and therefore can be used as a biological indicator of unprotected sex [5,20,21]. Before interviewing consenting participants, trained laboratory technicians collected vaginal secretions and administered rapid PSA tests at the interview sites. Presence of PSA was tested using the rapid ABAcard p30 test (Abacus Diagnostics, West Hill, CA), which has been shown to be reliable, sensitive, specific [20,21], and comparable to the quantitative PSA assay [5]. Extraction of specimens from fresh vaginal swabs was performed in the extraction buffer provided with the testing kit, and swabs were soaked for at least 5 minutes. ABAcard p30 was tested using 200 μL of swab extraction and was loaded directly into the well of the immunochromatographic test strip according to the manufacturer's instructions.

Discordance

FSWs were asked to report their sexual activity in the past 48 hours. The computer-assisted personal interviewing questionnaire automatically generated the 48-hour window based on the starting time of the interview. Those who indicated no sexual intercourse in the past 48 hours on the questionnaire, but tested positive for the PSA test, were considered discordant. Those who indicated no sexual intercourse in the past 48 hours and tested negative on the PSA test were considered concordant (Fig. 1). FSWs who reported having intercourse in the past 48 hours were not included in the study because negative PSA results may be due to reasons other than misreporting. For example, a well-controlled clinical trial demonstrated that almost all women (98%) tested positive immediately after being inseminated with their partner's semen, but that the proportion testing PSA positive dropped to 29% by 24 hours and declined to only 3% 48 hours after insemination [4]. Women self-reporting semen exposure within 48 hours or less may test negative because of PSA clearance, and therefore would not be considered a true misreport.

Prevalent and active syphilitic infection

Trained laboratory technicians collected venipuncture blood specimens to test for syphilis. Syphilitic infection was first assessed with a qualitative immunoassay to detect antibodies to *Treponema pallidum* (Alere Determine TP test; Alere Medical Co., Ltd, Chiba Prefecture, Japan) and was confirmed by a *T. pallidum* particle agglutination test (TPPA; Fujirebio Inc., Tokyo, Japan or ABON Biopharm Co., Ltd., Hangzhou, China). Confirmed TPPA positive samples were tested for non-*Treponemal antilipoidal* antibodies, using Toluidine Red Unheated Serum Test (TRUST; Wantai Biological