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# Symptom-based versus laboratory-based diagnosis of five sexually transmitted infections in female sex workers in Iran

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## INTRODUCTION

Sexually transmitted infections (STIs) are a major public health concern worldwide. Youth and high-risk populations have usually been considered to be at an elevated risk for getting an STI.(1) An estimated 357 million new, curable STIs (eg, syphilis, gonorrhea, chlamydia) occurred around the world in 2012.(2) This is of particular concern, as untreated STI may result in infertility, ectopic pregnancy, preterm labor, fetal and neonatal death, cancer, and increased risk for HIV acquisition and transmission.(3) Screening, diagnosis, and treatment of infected individuals have been reported to be the most effective strategies in controlling STIs.(4)

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**Conflict of Interest:** All authors declare that they have no conflict of interest.

**Ethical approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent:** Informed consent was obtained from all individual participants included in the study. The study was anonymous, and no identifying information was collected during recruitment, informed consent, interview, or STIs testing. A unique identification code was provided to participants to help link survey responses to their test results. Participants were able to receive their STIs test results, post-test counseling, and referrals from the local testing and counseling center by providing their unique identification code. FSWs were given 70,000 Rials (equal to ~2.5 USD) as an incentive for participating in the study and 30,000 Rials (equal to ~1 USD) if they returned to receive their test results. The study protocol was reviewed and approved by the Ethics Committee of Kerman University of Medical Sciences (Ethical Code: K/93/209).

STIs are usually diagnosed through 2 main approaches: laboratory-based and symptom-based. Laboratory-based STI tests are the gold standard for diagnosis; however, they are often expensive, require training and infrastructure, and may not be available in resource-limited settings.(5) Symptom-based diagnosis relies on self-reported symptoms and medical history and can be done with limited training; however, it is less specific and can lead to under- or over-diagnosis of STIs.(6)

Most laboratory-based STI tests are time-consuming and often delay treatment initiation, given that results are often unavailable at the same visit as the test. Relying on laboratory-based diagnosis for STI management in female sex workers (FSW) is even more challenging, as they are a hard-to-reach population.(7, 8) Indeed, the requirement that an FSW return to an STI clinic to collect her laboratory-based test results and start treatment, if necessary, has been shown to create barriers to STI testing uptake among FSW.(5) Given the higher prevalence of STI among FSW, compared with the general population,(9, 10) some health care providers may fear losing an FSW patient in follow-up visits and therefore may initiate STI treatment based merely on STI-associated symptoms.

In Iran, where the prevalence of STIs ranges widely, from 1.4% for gonorrhea to 20% for chlamydia,(11–13) the diagnosis and management of STIs rely on the symptom-based approach. However, our understanding of the validity of this approach in Iran remains limited. Moreover, the findings of studies on the validity of self-reported STI symptoms in developing settings are mixed and not entirely applicable to Iran. This is due in part to the dissimilar prevalence of STI symptoms among FSW across different settings; for example, STI prevalence is 75.1% in El Salvador(14) and 56% in India,(15) which leads to different positive predictive values (from 25% to 83%) and negative predictive values (from 56% to 98%).(15) Furthermore, the sociocultural context of Iran differs greatly from other developing settings, and the stigma around reporting STI symptoms is more pronounced. For example, in our study of FSW in 3 cities in 2012, we found that only 63.9% of those who had STI symptoms had reported them.(16) Therefore, we used data from the second round of Iran's national biobehavioral surveillance survey (2015) among FSW to evaluate the diagnostic characteristics of 4 main STI symptoms to diagnose 5 common laboratory-confirmed STIs. The results of our study have significant implications for future STI research among FSW, as well as for evaluation of the STI surveillance system in Iran.

## METHODS

### Study sample

Between January and August 2015, a facility-based and outreach-based (recruitment at street venues by an outreach team) sample of 1337 FSW was recruited at 20 sites in 13 cities in Iran. Facilities were selected among nongovernmental organizations and sexually transmitted disease clinics serving vulnerable women. Eligible participants were Iranian women aged ≥18 years who resided or worked in the city where the study was implemented, and who self-reported having vaginal, anal, or oral sex with more than 1 male client in exchange for money, goods, drugs, or a favor during the previous year.

### Data collection

Data were collected through face-to-face interviews using a structured risk assessment questionnaire. Information was gathered regarding sociodemographic characteristics of FSW, their sexual risk behaviors, and their current STI-associated symptoms. To evaluate the validity of symptom-based management of STIs among this population, we asked participants to report whether they had any symptom of vaginal discharge, genital pain or burning, genital ulcers, or genital warts at the time of the study. A list of STI symptoms was read to the participants, and the interviewer marked any they mentioned from the list. We also asked for other nonspecific symptoms in an open question. For the diagnosis of syphilis, rapid diagnostic tests (SD BIOLINE HIV/Syphilis Duo rapid test, Standard Diagnostics Inc., Gyeonggi-do, South Korea) were used, and participants who had a reactive result in the first rapid test underwent a second rapid test (Alere Syphilis RPR). If both tests were reactive, the patient was considered to be a positive case. In the case of a reactive result for the first test and a nonreactive result for the second test, diagnosis was confirmed by running an enzyme-linked immunosorbent assay. Diagnosis of gonorrhea, chlamydia, trichomoniasis, and human papillomavirus (HPV, types 16 and 18, which are the most prevalent in Iran)(17) was based on a polymerase chain reaction test using self-administered vaginal swabs.

### Data analysis

Descriptive statistics (eg, mean, median, frequencies, percentages) were used to summarize the data. We defined the diagnostic characteristics of STI-associated symptoms by 4 indicators:

- Sensitivity (ie, true positive rate): the probability of having an STI-associated symptom among participants who had a laboratory-confirmed STI.
- Specificity (ie, true negative rate): the probability of having no STI-associated symptom among participants who had no laboratory-confirmed STI.
- Positive predictive value: the probability of having an STI among participants who reported an STI-associated symptom.
- Negative predictive value: the probability of having no STI among participants who reported no STI-associated symptom.

The 95% confidence intervals for STI prevalence and the 4 indicators above were estimated using the exact binomial method.(18) STATA v.13.1 (StataCorp, College Station, Texas, USA) was used to analyze the data.

## RESULTS

### Characteristics of the sample

A total of 1337 FSW were recruited for this study. The response rate to the questions about STI symptoms was very high (1334/1337 = 99%). Moreover, 99% of the study participants also agreed to be tested for STI. The mean (standard deviation) age of participants was 35.6 (9.3) years, 10.1% of participants were illiterate, around half (52.6%) were divorced at the time of the study, and 8.1% reported having a temporary marriage. (A man and an unmarried

woman can enter into a temporary marriage contract [*sigheh*] in which both parties agree on the period of the relationship and the amount of compensation to be paid to the woman. This arrangement requires no witnesses and no registration.) Median (first quartile [Q1], third quartile [Q3]) ages at first vaginal sex and at sex-work debut were 17.0 (15.0, 22.0) and 25.0 (20.0, 30.0) years, respectively. Median (Q1, Q3) number of clients in the past month was 3 (1, 7), and only 32.9% of participants reported consistent condom use in the previous month (Table 1).

### STI-associated symptoms and STI prevalence

Overall, 49% of the FSW had at least 1 STI. Excessive vaginal discharge was the most prevalent symptom (37.7%). Other symptoms were pain or burning (25.9%), genital ulcers (3.0%), and genital warts (1.4%). About 47% of participants reported at least 1 of the 4 STI-associated symptoms (Table 2).

The prevalence of HIV was 2.0% (95% confidence interval [CI], 0.9–4.6). The prevalence of laboratory-based syphilis, gonorrhea, chlamydia, trichomoniasis, and HPV was 0.4%, 1.3%, 6.0%, 11.9%, and 41.9%, respectively.

### Sensitivity of STI-associated symptoms

Overall, individual STI-associated symptoms had a low sensitivity for detecting STI (ranging from 0% to 40%). While around 25% of FSW diagnosed with trichomoniasis or HPV reported having genital pain or burning, these symptoms were reported in less than 17% of cases for the other 3 STIs (Table 3). Moreover, genital ulcers was reported by only 4% of FSW diagnosed with HPV, while none of the FSW who had syphilis reported this symptom. Excessive vaginal discharge was the symptom most frequently reported by FSW who had been diagnosed with any of the 5 STIs; it was around 40% for FSW with gonorrhea, chlamydia, trichomoniasis or HPV. Genital warts was reported by only 2.2% of FSW who had HPV. Less than 50% of FSW diagnosed with any of 5 STIs reported having at least 1 STI symptom. The minimum sensitivity observed was for syphilis (33.3%), and the maximum sensitivity was for gonorrhea (50.0%).

### Specificity of STI-associated symptoms

The specificity of STI-associated symptoms was highest for genital warts (from 98.5% to 99.1%) and genital ulcers (from 96.9% to 97.7%). For excessive vaginal discharge, the specificity was around 62% for all diagnosed STIs, and for pain or burning it was around 74%. The specificity of combined STI-associated symptoms was about 53% for all diagnosed STIs.

### Positive predictive value (PPV)

PPV of genital warts was 64.7% for HPV. The probability of having gonorrhea, chlamydia, or trichomoniasis among FSW who had reported excessive vaginal discharge was 1.4%, 6.1%, and 12.7%, respectively. None of the individuals who reported genital ulcers or genital warts had syphilis. PPV of pain or burning ranged from 0.3% for syphilis to 40.9% for HPV. Considering any of the 4 symptoms, the PPV range was from 0.4% for syphilis to 41.9% for HPV.

### Negative predictive value (NPV)

Overall, 99.4% of FSW who had none of the four STI symptoms were not infected with syphilis. NPV of all symptoms was also high for gonorrhea (from 98.4% to 98.7%), chlamydia (from 92.9% to 93.9%), and trichomoniasis (from 88.0% to 88.7%), but was lower for HPV (from 57.4% to 58.4%).

### STI symptoms among FSW who tested negative for the 5 STIs

Among the 669 FSW who tested negative for all 5 STIs assessed in this study, 222 (33.2%) had vaginal discharge, 154 (23.0%) reported pain or burning, 13 (1.9%) had genital ulcers, and 5 (0.7%) had genital warts.

## DISCUSSION

To the best of our knowledge, the current study is the first of its kind to assess the accuracy of symptom-based management of STIs among a large number of FSW in Iran. We found that around half of the FSW tested positive for at least 1 STI or reported at least 1 STI-associated symptom at the time of the study. The most prevalent STI was HPV, and the most common STI-associated symptom was excessive vaginal discharge. None of the 4 symptoms or combined STI-associated symptoms was sensitive enough for diagnosing the 5 STIs in this study. Therefore, symptom-based management of STIs among FSW resulted in missing the majority of infections. In contrast, as expected, specificity and NPV of the 4 symptoms were fairly high for ruling out any of the 5 STIs.

Among all of the symptoms, excessive vaginal discharge had the highest sensitivity but was reported by only one-third of the FSW who were diagnosed with an STI. Because vaginal discharge is uncommon in patients infected with syphilis or HPV,(19) low sensitivity is reasonable for these infections. On the other hand, while vaginal discharge is often considered a key criterion for the symptom-based detection of gonorrhea, chlamydia, and trichomoniasis,(19, 20) its sensitivity remained low for the diagnosis of these STIs in our study. This finding is in line with a meta-analysis that reported the pooled sensitivity of vaginal discharge for diagnosing gonorrhea to be as low as 30%.(20) Although the most common causes of genital ulcers are syphilis and herpes simplex virus (19) less than 10% of FSW who were infected with these STIs reported having genital ulcers. Moreover, the combination of all 4 symptoms did not significantly improve the diagnostic characteristics of the syndromic approach. The low sensitivity of symptoms is compatible with the existing body of evidence that suggests a high proportion of asymptomatic STI cases.(21–24)

The high proportion of asymptomatic cases may be the result of both underreporting of symptoms among FSW and the asymptomatic nature of STIs. In a previous study on the accuracy of self-reported STI symptoms among Iranian FSW, underreporting of STI symptoms was estimated to be around 36%.(25) Moreover, studies suggest that 60% to 70% of gonococcal and chlamydial infections are asymptomatic.(26, 27)

In our study, the prevalence of STI among asymptomatic individuals (NPV) ranged from 0.4% for syphilis to 41.9% for HPV, highlighting the potential for missing a high proportion of asymptomatic cases when symptomatic management is the dominant approach. These

asymptomatic cases are important because the women usually continue sex work without seeking appropriate treatments(21, 22) and consequently bridge the infection to the general population through their sexual networks.(10, 28)

PPV of symptoms for all STIs in our study was very low. The highest PPV was for HPV (64.7%), which is likely due to the higher prevalence of HPV, compared with other STIs. Furthermore, we found that a considerable number of FSW reported STI symptoms while testing negative for the 5 assessed STIs. Other STIs such as genital herpes, which is relatively common among FSW (ranging from 82% prevalence in El Salvador(14) to 61% in Peru(29)), can partially explain this. Low PPV could also be attributed to the imperfect accuracy of self-reported STI symptoms and the laboratory processes and tests used for the 5 STIs. Therefore, some of the false positives for STI symptoms that we observed may not actually be false positives. Such false-positive cases for the 5 assessed STIs might be treated erroneously when symptom-based management is relied upon; as a consequence, overtreatment could result in side effects and antibiotic resistance (30).

We should acknowledge the limitations of this study. Although we recruited FSW at facilities and outreach locations, the generalizability of results is limited to FSW who had some access to care, either through the facilities or the outreach efforts. We collected our data as part of a nationwide biobehavioral surveillance survey of HIV/STI among FSW, which was not specifically designed to access symptom-based management as a part of STI control strategy. To measure STI symptoms, we asked participants to report whether they had any symptoms of vaginal discharge, genital pain or burning, genital ulcers, or genital warts at the time of the study, which is just a point in time and might lead to misclassification bias. Moreover, we did not clinically examine for the presence of related signs of infection. Only women who agreed to be tested for STI were included in the analysis, vaginal swabs were self-administered, and some of the reported symptoms could have been caused by infections not measured in the study. We also did not verify our RPR positive results with participants' medical history. Our findings are also limited due to underreporting of STI symptoms and to social desirability bias.

Because the recommended approach is to use a sensitive test in the initial screening for an infection, followed by a more specific confirmatory test,(31) symptom-based STI management does not seem to be a good candidate for the screening of STIs among FSW. Our findings highlight the importance of using laboratory-based diagnosis for STIs, rather than relying on self-reported symptoms. However, while most STIs can be tested with rapid tests at clinical and nonclinical sites, future studies would benefit from examining the acceptability of these tests among FSW, as well as the cost-effectiveness of upgrading the surveillance system and its staff to be compatible with such testing. Indeed, the feasibility of such tests is questionable because of their high cost (each rapid test costs approximately $70, and repeated testing is needed among this population). Therefore, primary prevention of STI seems to be the most practical approach in this setting. A meta-analysis on behavioral interventions among FSW in low- and middle-income countries reported that condom promotion and peer education are effective in reducing STI transmission among this subpopulation and their clients,(32) which calls for further scale-up of safer-sex promotion in our study setting.

## CONCLUSIONS

Our study revealed low sensitivity and PPV of symptom-based management of STI among FSW in Iran. Although, historically, syndromic management has been considered an effective approach in resource-constrained settings where access to etiologic diagnosis is restricted, the utilization of this approach could be targeted to more-specific populations and settings. Future research should focus on the efficacy of clinical evaluation combined with symptom-based management. Given that many STI tests are now available as rapid point-of-care testing kits, a more feasible and accurate STI test-and-treat strategy could use these rapid tests instead of a symptom-based approach. Affordability and acceptability of such tests among FSW in developing settings, like Iran, need to be investigated in future studies. Given the cosiderable number of FSW population in Iran (33), harm reduction efforts need to focus on primary prevention of STI among FSW by scaling up free condom distribution, safer-sex promotion, and self-efficacy interventions for this marginalized population and their clients.

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**Table 1.**

Sociodemographic characteristics of 1337 female sex workers in Iran, 2015.

| Variables[a] | Frequency | % |
|---|---|---|
| **Age (years)** | | |
| 18–44 | 1117 | 83.7 |
| >45 | 218 | 16.3 |
| **Age, N/mean (standard deviation)** | 1335 | 35.6 (9.3) |
| **Highest education level** | | |
| Illiterate | 135 | 10.1 |
| Can read and write | 115 | 8.6 |
| Primary school (grades 1–5) | 258 | 19.3 |
| Middle school (grades 6–8) | 343 | 25.6 |
| High school (grades 9–12) | 128 | 9.6 |
| Acquired diploma | 274 | 20.5 |
| University | 84 | 6.3 |
| **Ever married** | | |
| Yes | 1252 | 93.6 |
| No | 85 | 6.4 |
| **Current marital status** | | |
| Single | 85 | 6.4 |
| Married | 440 | 33.0 |
| Divorced | 702 | 52.6 |
| Temporarily married (ie, *sigheh*) | 108 | 8.1 |
| **Age at first vaginal sex, median** | 1323 | 17.0 |
| **Age at first commercial sex, median** | 1323 | 25.0 |
| **Number of clients in last month, N/median** | 1307 | 3.0 |
| **Frequency of condom use in last month** | | |
| Always | 341 | 32.9 |
| Often | 281 | 27.1 |
| Sometimes | 225 | 21.7 |
| Never | 191 | 18.4 |

[a]Data is n (%) unless specified.

**Table 2.**

Point prevalence of laboratory-confirmed STIs and self-reported symptoms among female sex workers in Iran, 2015.

| Symptom/STI | N | % | 95% confidence interval |
|---|---|---|---|
| **Self-reported symptoms (n=1195)** | | | |
| Pain or burning | 309 | 25.9 | 17.8–36.0 |
| Genital ulcers | 36 | 3.0 | 1.9–4.8 |
| Excessive vaginal discharge | 450 | 37.7 | 29.2–47.0 |
| Genital warts | 17 | 1.4 | 0.6–3.3 |
| Other nonspecific symptoms | 240 | 20.1 | 14.4–27.3 |
| Any of the 4 specific symptoms | 561 | 46.9 | 36.7–57.4 |
| **Types of STI (n=1318)** | | | |
| Syphilis | 6 | 0.4 | 0.1–1.4 |
| Gonorrhea | 17 | 1.3 | 0.7–2.5 |
| Chlamydia | 79 | 6.0 | 3.9–9.1 |
| Trichomoniasis | 157 | 11.9 | 8.5–16.5 |
| Human papilloma virus (HPV) | 552 | 41.9 | 38.3–45.5 |

**Table 3.**

Accuracy of 4 symptoms in diagnosing 5 sexually transmitted infections among 1337 female sex workers in Iran, 2015.

| STI lab results | Pain or burning % (95% CI) | Genital ulcers % (95% CI) | Excessive vaginal discharge % (95% CI) | Genital warts % (95% CI) | Any of the 4 symptoms % (95% CI) |
|---|---|---|---|---|---|
| **Syphilis** | | | | | |
| Sensitivity | 16.7 (0.4–64.1) | 0.0 (0.0–45.9) | 33.3 (4.3–77.7) | 0.0 (0.0–45.9) | 33.3 (4.3–77.7) |
| Specificity | 74.1 (71.5–76.6) | 97.0 (95.8–97.9) | 62.3 (59.5–65.1) | 98.6 (97.7–99.2) | 53.0 (50.1–55.9) |
| PPV[a] | 0.3 (0.0–1.8) | 0.0 (0.0–9.7) | 0.4 (0.05–1.6) | 0.0 (0.0–19.5) | 0.4 (0.04–1.30) |
| NPV[b] | 99.4 (98.7– 99.8) | 99.5 (98.9–99.8) | 99.5 (98.6–99.9) | 99.5 (98.9–99.8) | 99.4 (98.4–99.8) |
| **Gonorrhea** | | | | | |
| Sensitivity | 12.5 (1.5–38.3) | 6.25 (0.1–30.2) | 37.5 (15.2–64.6) | 0.0 (0.0–20.6) | 50.0 (24.7–76.3) |
| Specificity | 74.2 (71.6–76.7) | 97.0 (95.8–97.9) | 62.4 (59.6–65.2) | 98.5 (97.7–99.1) | 53.2 (50.3–56.1) |
| PPV | 0.7 (0.0–2.38) | 2.8 (0.0–14.5) | 1.4 (0.5–2.9) | 0.0 (0.0–19.5) | 1.5 (0.6–2.8) |
| NPV | 98.4 (97.3–99.1) | 98.7 (97.8–99.3) | 98.6 (97.5–99.3) | 98.6 (97.8–99.2) | 98.7 (97.5–99.4) |
| **Chlamydia** | | | | | |
| Sensitivity | 13.9 (6.9–24.1) | 4.2 (0.9–11.7) | 37.5 (26.4–49.7) | 0.0 (0.0–4.9) | 38.9 (27.6–51.1) |
| Specificity | 73.6 (70.9–76.2) | 97.0 (95.8–97.9) | 62.4 (59.5–65.3) | 98.5 (97.5–99.1) | 52.6 (49.6–55.6) |
| PPV | 3.3 (1.6–6.02) | 8.3 (1.7–22.5) | 6.1 (4.0–8.8) | 0.0 (0.0–19.5) | 5.1 (3.4–7.3) |
| NPV | 92.9 (91.0–94.5) | 93.9 (92.4–95.3) | 93.9 (91.9–95.5) | 93.8 (92.2–95.1) | 93.0 (90.7–94.8) |
| **Trichomoniasis** | | | | | |
| Sensitivity | 25.2 (18.2–33.2) | 2.9 (0.8–7.2) | 40.3 (32.1–48.9) | 0.71 (0.0–3.9) | 46.0 (37.6–54.7) |
| Specificity | 74.3 (71.6–77.0) | 96.9 (95.7–97.9) | 62.8 (59.8–65.7) | 98.5 (97.5–99.1) | 53.0 (49.9–56.1) |
| PPV | 11.6 (8.2–15.8) | 11.1 (3.1–26.1) | 12.7 (9.7–16.1) | 5.9 (0.1–28.7) | 11.6 (9.0–14.6) |
| NPV | 88.1 (85.8–90.2) | 88.2 (86.1–90.0) | 88.7 (86.2–90.9) | 88.1 (86.1–89.9) | 88.0 (85.2–90.4) |
| **Human papilloma-virus (HPV)** | | | | | |
| Sensitivity | 24.8 (21.1–28.9) | 4.0 (2.5–6.1) | 36.8 (32.5–41.2) | 2.2 (1.1–3.9) | 46.7 (42.2–51.2) |
| Specificity | 73.9 (70.4–77.2) | 97.7 (96.2–98.7) | 61.9 (58.1–65.5) | 99.1 (98.1–99.7) | 53.1 (49.3–56.9) |
| PPV | 40.9 (35.3–46.7) | 55.6 (38.1–72.1) | 41.2 (36.5–45.9) | 64.7 (38.3–85.8) | 41.9 (37.8–46.2) |
| NPV | 57.5 (54.2– 60.8) | 58.4 (55.4– 61.2) | 57.4 (53.7–61.0) | 58.3 (55.4–61.1) | 57.8 (53.8–61.7) |

[a]PPV: positive predictive value.

[b]NPV: negative predictive value.