

EPIDEMIOLOGY

Sexually transmitted and reproductive tract infections in symptomatic clients of pharmacies in Lima, Peru

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Objective: To determine prevalences and predictors of sexually transmitted and reproductive tract infections among men and women seeking care at pharmacies.

Methods: Men and women with urethral discharge or dysuria and vaginal discharge were enrolled at 12 central and 52 smaller pharmacies in Lima, Peru. All participants answered a questionnaire. Men provided urine for polymerase chain reaction (PCR) testing for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, and for leucocyte esterase testing. Women provided self-obtained vaginal swabs for PCR testing for *N gonorrhoeae* and *C trachomatis*, *Trichomonas vaginalis* culture and bacterial vaginosis and *Candida*.

Results: Among 106 symptomatic men, *N gonorrhoeae* and *C trachomatis* were detected in 34% and were associated with urethral discharge compared with dysuria only (odds ratio (OR) 4.3, $p=0.003$), positive urine leucocyte esterase testing (OR 7.4, $p=0.009$), less education (OR 5.5, $p=0.03$), and with symptoms for <5 days (OR 2.5, $p=0.03$). Among 121 symptomatic women, 39% had bacterial vaginosis or *T vaginalis*, and 7.7% had candidiasis. *N gonorrhoeae* and *C trachomatis* were detected in 12.4% of the women. Overall, 48.8% had one or more of these infections. No factors were associated with vaginal infection, and only symptoms of vaginal discharge for <5 days were associated with *N gonorrhoeae* and *C trachomatis* (OR 4.0, $p=0.02$). The main reason reported for seeking advice at pharmacies by both men and women was trust in pharmacy workers.

Conclusions: Among men and women presenting to pharmacies with urethral and vaginal symptoms, rates of urethral and vaginal infections were comparable to those found in other clinical settings. Pharmacies can contribute to the care and prevention of sexually transmitted infection in developing countries.

Syndromic treatment for sexually transmitted infections (STIs) in primary healthcare settings requires knowledge of local aetiologies, syndromes and the efficacy of treatments used.¹ In developing countries, patients with STIs often bypass formal healthcare services and seek care in the informal sector, including pharmacies. In some countries, pharmacies are the predominant providers of STI care.^{2–4} Several groups have undertaken training of pharmacy workers in management of STIs.^{5–7} In a recent randomised controlled trial of a training programme, we observed marked improvement in all aspects of management of STI syndromes in pharmacies,⁸ and showed the cost effectiveness of the intervention.⁹ However, these studies did not assess the actual microbial aetiologies of STI syndromes seen at pharmacies, or characterise the clients of the pharmacies in terms of socio-economic factors or sexual and health-seeking behaviours, which could help to improve the interventions.¹⁰

This study aimed to determine the actual prevalences and predictors of STIs and reproductive tract infections (RTIs) among men and women presenting to pharmacies with STI syndromes in Lima, Peru.

METHODS

Study design

We conducted this study between 2002 and 2003 in Lima. We undertook rapid-assessment visits to evaluate the pharmacies' willingness to participate, the presence within each pharmacy of the facilities required for the study procedures, and to update estimated numbers of clients seen with symptoms of urethral discharge. Of the 468 pharmacies visited, 355 (76%) were willing to participate, and 290 (62%) had a toilet and washbasin required for the study. Twelve pharmacies with the highest estimated numbers of urethral discharge cases were

selected and invited to participate as "central" pharmacies. To increase recruitment, 2–7 additional pharmacies located within 600 m of each central pharmacy were included as "satellite pharmacies", for a total of 52 satellites. The study staff (12 midwives and 12 pharmacists) was stationed with a telephone and supplies in each of the central pharmacies for 8-h daily shifts. The hours of operation for each pharmacy were divided into segments. A random sample of these segments was selected for observation. Overall, 30% of the hours of operation were observed.

Team members were not permanently stationed at the satellite pharmacies. Instead, the team member assigned to the central pharmacy was called by a satellite pharmacy worker when a client was seen with symptoms suggesting an STI or seeking drugs used to treat STIs. The study staff approached and assessed the eligibility of all men with urethral discharge or dysuria, or purchasing spectinomycin, and of all women with vaginal discharge, or purchasing topical intravaginal drugs. Eligible women were 18–55 years old, sexually active, not menstruating, not pregnant and not having taken any antibiotic during the past week, and complaining of <30 days of abnormal vaginal discharge (defined as increased amount of discharge or colour different from usual). Eligible men were 18–55 years old, sexually active and not having taken any antibiotics in the past week, with symptoms of urethral discharge or burning sensation when urinating. From all consenting participants, the staff collected urine from men and four self-obtained vaginal swabs from women. A brief questionnaire including sociodemographic and behavioural questions, as well as reasons for seeking care in pharmacies,

Abbreviations: FSW, female sex worker; PCR, polymerase chain reaction; RTI, respiratory tract infection; STI, sexually transmitted infection

was administered to each participant. Men were also asked questions regarding willingness to refer female partners for treatment. Syndromic treatment, counselling and condoms were also provided. Participants were given a telephone number to obtain laboratory test results. The procedures were performed similarly by the study staff at the central and satellite pharmacies.

Our results were compared with data from residents of Lima, aged 15–49 years, who participated in the 1996 Peruvian National Demographic and Health Survey.

Sample collection and laboratory procedures

Men were instructed to collect 10 ml of urine, which was tested with a dipstick test (Combur 10 Test M; Roche Diagnostics, Mannheim, Germany) and examined after 2 min for the presence of leucocyte esterase. All participants with urethral symptoms were treated with ciprofloxacin 500 mg and azithromycin 1 g (both single oral doses), regardless of the results of the leucocyte esterase test. The urine cup was sealed, stored at -4°C and sent within 4 h to the study laboratory where polymerase chain reaction (PCR) tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were processed using the Roche COBAS AMPLICOR Analyzer (Roche Diagnostics).

Women were instructed on how to collect self-administered vaginal swabs. The first vaginal swab was used to inoculate the culture medium for *Trichomonas vaginalis* (InPouch TV; BioMed Diagnostics, Singapore). Inoculated pouches were kept at room temperature before transportation within 2 h to the laboratory where they were incubated at 37°C and examined daily for 5 days. The second swab was placed in PCR medium and stored at -4°C , then sent to the laboratory within 4 h for PCR tests for *N. gonorrhoeae* and *C. trachomatis*. The third swab was used for the FemExam pH and Amines TestCard (Litmus Concepts, Santa Clara, California, USA). The same swab was then used to prepare a smear for Gram staining. Dry smears were sent daily to the laboratory where they were fixed and later sent to the University of Washington, Seattle, USA, for scoring using the Nugent system and for detection of fungi.¹¹ The fourth swab was used to perform the FemExam *Gardnerella vaginalis* Proline Imino-Peptidase Activity TestCard (Litmus Concepts). Results of these tests are not reported here. All women with symptoms of abnormal vaginal discharge were treated with metronidazole 2 g single oral dose regardless of the test results.

Statistical analysis

Data were analysed using SPSS V.10.0. To test for bivariate associations, odds ratios (ORs) and corresponding 95% confidence intervals (CIs) were calculated by logistic regression. Effect modification was examined by stratified analyses.

Ethical considerations

Protocols were reviewed and approved by the institutional review boards at the University of Washington, Seattle, USA, and Universidad Peruana Cayetano Heredia, Lima, Peru. Written informed consent for participation was obtained from all pharmacy owners and participants included in the study.

RESULTS

During 5 months, 187 men with urethral symptoms and 475 women with vaginal discharge symptoms were approached at the study pharmacies. Of these, 113 (60%) men were eligible, of whom 106 (94%) agreed to participate; and 148 (31%) women were eligible, of whom 121 (82%) agreed to participate.

Characteristics of participants

Male and female participants had similar age distributions, and most reported some high school education. Men were more

often single ($p = 0.003$). Median monthly income was equivalent to USD\$130 for men (range US\$17–571) and US\$114 for women (range US\$14–342). Nearly all participants reported having a regular partner, but more than twice as many men as women reported sex with casual partners. Men more often than women reported use of condoms with regular and casual partners, but even for men during the last intercourse, such use was uncommon. In all, 63% of men reported ever having had sex with a female sex worker (FSW), 22% within the past 2 weeks; 40% of the men reported always using condoms with FSWs and 43% reported condom use during their last sex with an FSW (table 1).

Comparison of pharmacy clients with participants of the Peruvian Demographics and Health Survey

The sociodemographic profile and information on sexual partners of the pharmacy clients were compared with data from the 1996 Peruvian Demographic and Health Survey, which included data from 4979 women and 534 men aged 15–49 years (table 2). Clearly, for both men and women, those seen at pharmacies more often reported regular sexual partners and more often reported casual partners.

Prevalence of STIs or RTIs in pharmacy clients

Symptoms in men included urethral discharge, with or without dysuria in 60%, and dysuria alone in 40%. Symptoms in women

Table 1 Demographic and behavioural characteristics and symptom history for male and female pharmacy clients

Characteristics	Men (n = 106)	Women (n = 121)
Age (years)		
18–23	29 (27.4)	30 (24.8)
24–29	22 (20.8)	32 (26.4)
30–35	29 (27.4)	30 (24.8)
>35	26 (24.5)	29 (24.0)
Marital status		
Single	54 (51.0)	34 (28.0)
Married	22 (21.0)	34 (28.0)
Living together	27 (25.0)	48 (40.0)
Widow/separated	3 (3.0)	5 (4.0)
Education		
Primary school	11 (10.4)	11 (9.1)
Some high school	76 (71.7)	79 (65.3)
Technical school/university	19 (17.9)	31 (25.6)
Has a regular current sex partner	100 (94.0)	118 (97.5)
Always uses condoms with regular partner	12 (12.0)	3 (2.4)
Casual sexual partners ever	95 (89.0)	45 (37.2)
Always uses condoms with casual partners	19 (20.0)	5 (11.0)
Condom use during last intercourse	22 (20.8)	16 (13.2)
Ever had sex with FSW	67 (63.0)	NA
Sex with FSW in past 2 weeks	23 (22.0)	NA
Condom use with FSWs, lifetime		
Never	17 (26.0)	NA
<50%	14 (21.0)	NA
>50%	9 (13.0)	NA
Always	27 (40.0)	NA
Used condom last time had sex with a prostitute	29 (43.0)	NA
Current symptoms		
Urethral discharge only	18 (17.0)	NA
Dysuria only	42 (40.0)	NA
Urethral discharge and dysuria	46 (43.0)	NA
Symptoms of abnormal vaginal discharge	NA	121 (100.0)
Vaginal malodour	NA	52 (43.0)
Had similar symptoms previously	42 (39.6)	86 (71)

Values are numbers (%).

FSW, female sex worker; NA, not applicable.

Table 2 Comparison of demographic characteristics and sexual behaviour of participants in this study with people of the same age from the 1996 Peruvian Demographic and Health Survey

	Men			Women		
	DHS-Lima 1996 (n=534) (%)	Current study (n=106) (%)	p Value	DHS-Lima 1996 (n=4979) (%)	Current study (n=121) (%)	p Value
Single	44.6	51	0.27	39.3	31	0.08
At least high school education	89.5	90	0.98	82.7	91	0.03
Report regular sexual partner	62.5	94	<0.001	57.8	98	<0.001
Report casual sexual partners	18.5	89	<0.001	1.3	37	<0.001

DHS, Demographic and Health Survey.

included abnormal vaginal discharge in 100%, vaginal malodour in 43% and vulvar pruritis in 25%. The median (range) duration of symptoms in men was 7 (1–180) days, and in women, 15 (2–30) days. Similar symptoms had been experienced in the past by 42 (39.6%) men and 86 (71%) women.

Among men, the leucocyte esterase test was positive in 82 (77%), including 83% of those with symptoms of discharge versus 69% of those with dysuria only ($p=0.007$). *N gonorrhoeae*, *C trachomatis*, or both, were detected in 36 (34%), including *C trachomatis* in 18, *N gonorrhoeae* in 22 and both infections in four.

Among women, 41 of 115 (35.7%) had bacterial vaginosis by Nugent score, 5.9% had trichomoniasis, 7.7% had vulvo-vaginal candidiasis, and 44.9% had bacterial vaginosis, candidiasis or trichomoniasis. *N gonorrhoeae*, *C trachomatis*, or both, were detected in 15 (12.4%), including *C trachomatis* in 11 (9.1%) and *N gonorrhoeae* in 4 (3.3%), there were no coinfections (table 3).

Factors associated with detection of STIs or RTIs

In univariate analyses for men, detection of *N gonorrhoeae* and *C trachomatis* were associated with lower education (OR 5.5, 95% CI 1.2 to 25), positive urine leucocyte esterase test (OR 7.4, 95% CI 1.6 to 33.8), and a complaint of urethral discharge compared with dysuria only (OR 4.3, 95% CI 1.6 to 11.0), and having had symptoms of urethritis for <5 days (OR 2.5, 95% CI 1.1 to 5.6). Among men reporting casual partners and commercial sex partners ever, frequency of condom use with both types of partners was associated with lower prevalences of *N gonorrhoeae*,

C trachomatis, or both (table 4). Stratified analyses show that among men with symptomatic urethral discharge for ≤ 5 days, *N gonorrhoeae* and *C trachomatis* were found more often (OR 12.1, 95% CI 2.3 to 63.4).

Among women, only symptoms of abnormal vaginal discharge for <5 days were associated with *C trachomatis*, *N gonorrhoeae* or both (OR 3.95, 95% CI 1.2 to 12.6; $p<0.02$). No factors were associated with vaginal infections. Specifically, candidiasis was not associated with the symptom of itching, and reported vaginal malodour was not associated with bacterial vaginosis diagnosed by the Nugent score.

Reasons to seek care at a pharmacy

When the participants were asked why they were seeking advice for their symptoms at a pharmacy, 39% of them said that they trusted the pharmacy workers, 14% mentioned location was convenient, near their residence, 8.4% did not want to pay a consultation fee, 7.5% said that there was no need to wait, 6% said a friend recommended that they see a pharmacist, 2% reported they could get the drugs easily and 20% did not answer. When asked specifically why they were not going to a doctor, 20% of men and 16% of women reported they did not trust doctors, 21% of men and 29% of women said doctors were too expensive, 11% of men and 5% of women said they thought the problem was too simple to warrant going to a doctor, and 6% of men and 7% of women reported they were too ashamed to go to a doctor.

Attitudes of men with urethral symptoms towards notifying the partner

When men were told the importance of telling their partners about the need for presumptive treatment, and asked how difficult it could be for them, 77% expressed a willingness and a positive attitude towards notifying partners, 12% reported it would be difficult as the last partner was casual, and 11% said that, although the last partner was a regular partner, it would be difficult to discuss this issue with this partner. When asked where they would like their partner to receive treatment, 47% preferred a ministry of health centre, 34% a pharmacy, 11% a private doctor and 8% said they would prefer to buy the drug now and give it to their partner.

DISCUSSION

Of the pharmacy clients in Lima, 45.3% of men with symptoms of urethral discharge had *N gonorrhoeae* or *C trachomatis* infections, and 39% of women with symptoms of abnormal vaginal discharge had BV, or trichomoniasis and 12.4% had *N gonorrhoeae* or *C trachomatis* infection.

Most men with urethral symptoms reported casual partners, and many reported recent sex with an FSW, but few had used condoms with casual partners, and less than half used a condom during their last sex with an FSW. This contrasts with the evaluation of 407 clients of FSWs enrolled at brothels and hostels in Lima, of whom 96% reported condom use during

Table 3 Prevalence of sexually transmitted and reproductive tract infections in male and female pharmacy clients

Men with symptoms of urethral discharge or dysuria or both (n=106)		
	n	%
Leucocyte esterase positive	82	77.3
CT positive	18	17.0
GC positive	22	20.8
GC or CT positive	36	34.0
Women with symptoms of abnormal vaginal discharge (n=121)		
	n	%
BV by Nugent score	41/115	35.7
TV	7/118	5.9
Candidiasis	9/117	7.7
BV or TV	46/118	39.0
Any vaginal infection (BV, TV or candidiasis)	53/118	44.9
CT positive	11/121	9.1
GC positive	4/121	3.3
GC or CT positive	15/121	12.4
Any BV, TV, candidiasis, GC or CT	59/121	48.8

BV, bacterial vaginosis; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*; TV, *Trichomoniasis vaginalis*.

Table 4 Factors associated with detection of *Neisseria gonorrhoeae* (GC), *Chlamydia trachomatis* (CT) or both in men

	GC, CT or both positive n/total (%)	OR	95% CI	p Value
Education				
Elementary or secondary education only	34/87 (39.0)	5.5	1.2 to 25	0.03
Technical or university education	2/19 (10.5)	1.0		
Leucocyte esterase test in urine				
Positive	34/82 (41.5)	7.4	1.6 to 33.8	0.009
Negative	2/24 (8.3)	1.0		
Urethral symptoms				
Urethral discharge with or without dysuria	29/64 (45.3)	4.3	1.6 to 11.0	0.003
Dysuria only	7/42 (16.7)	1.0		
Duration of urethral symptoms				
Symptoms for ≤5 days	21/46 (45.7)	2.5	1.1 to 5.6	0.03
Symptoms for >5 days	15/59 (25.4)	1.0		
Condom use with casual partners and female sex workers				
Never or <50%	11/27 (40.7)	3.8	1.02 to 14	0.047
>50% or always	4/26 (15.4)	1.0		

their last sex with an FSW, and only 2% had chlamydial infection and none had gonorrhoea.¹² It is therefore plausible that those seen with STI symptoms at pharmacies include the subset of clients of FSWs who were least likely to have used condoms.

Most women with symptoms of abnormal vaginal discharge were in stable partnerships (married or cohabiting), unlike most men with urethral symptoms. Fewer women than men reported consistent condom use with regular and with casual partners.

In this study, men with symptoms of urethral discharge had higher prevalence of *N gonorrhoeae* and *C trachomatis* than men 18–29 years old from a general population survey in 24 Peruvian cities during 2002–3 (0.3% and 4.0%, respectively). Women with symptoms of abnormal vaginal discharge had higher prevalence of *N gonorrhoeae* and *C trachomatis* than those from the general population survey (0.8% and 6.8%, respectively).¹³ A 1996 cross-sectional study of 219 women with yellow vaginal discharge for <6 months seen in gynaecology and family planning clinics in Lima, found 27 (11.8%) with *N gonorrhoeae* or *C trachomatis* and 105 (47.9%) with bacterial vaginosis diagnosed by the Nugent score or with trichomoniasis.¹⁴ Compared with that study, ours included women with any symptoms of abnormal vaginal discharge irrespective of colour, and was limited to those with a more recent onset of symptoms.

Most men with urethral discharge reported a willingness to talk to a partner about presumptive treatment. This suggests the importance of raising the issue of treatment of partners with symptomatic male clients seen in pharmacies.

Limitations of this study include the method of pharmacy sampling, which was not random, but rather based on rapid assessment. These findings in a large capital city in Latin America are not necessarily generalisable to other settings. We did not test men with symptoms of urethral discharge or dysuria for *T vaginalis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*, or herpes simplex virus, which are all possible causes of urethritis in men.^{15,16} It was not possible to examine participants for physical signs of urethral discharge or abnormal vaginal discharge.

The strengths of the study include the assignment of staff to each pharmacy to interview and test people seeking care for urethral symptoms or vaginal discharge, the use of state-of-the-art diagnostic testing, collection of demographic and behavioural information directly from participants and the novelty of the data collected from symptomatic clients. We have previously reported that a high proportion of people with

symptoms of STIs in Peru seek care in pharmacies,⁷ but we are not aware of studies on the aetiology of STI syndromes among pharmacy clients in Peru or elsewhere.

The implications of these results are that symptomatic men and women seeking care in pharmacies seem to have specific STIs as often as those seeking care from clinicians. These patients provided clear reasons as to why they chose to seek care in a pharmacy. In conclusion, pharmacies are important sources for treatment and intervention for control of sexually transmitted diseases in developing countries, and the data collected here will help us to model the effect of improving STI care in pharmacies.

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