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REVIEW

Pharmacist-led screening in sexually transmitted infections: current perspectives

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Introduction: Sexually transmitted infection (STI) screening is a crucial initiative that aims to reduce the increasing global prevalence of many common STIs such as chlamydia, gonorrhea, and herpes simplex virus (HSV). Many STIs are either asymptomatic or show mild symptoms that are often attributed to other infections; hence, screening is the only way to identify – and by extension, treat – them. In this way, the spread of STIs can be reduced, and the health implications of an untreated STI are minimized. Community pharmacies could provide an avenue to convenient, confidential STI screening by using noninvasive or minimally invasive sample collection techniques that are used by the consumer or pharmacist. We identified the most common STIs found globally and investigated the current and potential role of pharmacists in provision of STI screening interventions.

Discussion: There is sufficient evidence for pharmacy-based chlamydia screening, with many consumers and pharmacists finding it an acceptable and highly valued service. Some evidence was found for pharmacy-based gonorrhea, hepatitis B virus (HBV), and human immunodeficiency virus (HIV) screening. Appropriate sample collection for gonorrhea screening needs to be further examined in a pharmacy setting. HBV screening presented an increased risk of personal injury to pharmacists through the collection of whole blood specimens, which could be reduced through consumer self-sampling. Pharmacist-collected specimens for HIV is less risky as an oral swab can be used, nullifying the risk of transmission; but pre- and post-screen consultations can be time-intensive; hence, pharmacists would require remuneration to provide an ongoing HIV screening service. Not enough evidence was found for syphilis screening through community pharmacies; more studies are required that consider sampling methods other than pharmacist-collected whole blood specimens. There is no evidence to date for pharmacist-led trichomoniasis or HSV screening.

Conclusion: Pharmacists are well-positioned to provide STI screening services, but further investigations are needed to overcome financial, safety, and confidentiality barriers.

Keywords: pharmacist, screening, sexually transmitted infection, testing, chlamydia, gonorrhea

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Introduction

The prevalence of sexually transmitted infections (STIs) is a global health concern, with more than 1 million curable STIs acquired worldwide every day.[1] There are currently >30 microorganisms including bacteria, viruses, and parasites that are transmissible through vaginal, anal, or oral sex or genital skin to skin contact.[1,2] In addition, some STIs can be transmitted through blood or blood products, or passed from mother to child during pregnancy, childbirth, or through breastmilk.[1,3]

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Although most bacterial STIs are frequently asymptomatic, common symptoms include vaginal or rectal discharge, urethral discharge or burning in men, abdominal pain, or genital ulceration.[4] Early symptoms of viral STIs include small fluid-filled blisters or flesh-colored bumps around the genitals, anus, or oral cavity, systemic flu-like symptoms, or abdominal pain; while protozoal STIs could cause itching due to the presence of egg sacs or lice in pubic hair, unpleasant vaginal discharge or pain during intercourse.

There are eight pathogens that contribute to a significant portion of the worldwide prevalence of STIs. Four of these – chlamydia, gonorrhea, syphilis, and trichomoniasis – are curable. Four viral infections – human papillomavirus (HPV), hepatitis B virus (HBV), herpes simplex virus (HSV), and human immunodeficiency virus (HIV) – are incurable, but the symptoms can be managed with treatment. The symptoms and sequelae of these eight STIs are detailed in Table 1.

STIs are often more prevalent in developing countries where easy access to asymptomatic "screening" and symptomatic "testing" are unavailable, prohibitively expensive, or inaccessible. Particularly, the impact of incurable viral STIs such as HIV has been devastating to residents' health and well-being.[1,13] Furthermore, the World Health Organization (WHO) estimates that up to 90% of all curable bacterial and parasitic infections are found in the residents of developing countries.[1] Detection of STIs in this setting often relies on diagnosis by symptomatic identification; as such, many asymptomatic infections go undetected and therefore untreated.[1] Conversely, coordinated and well-funded health services in developed countries generally provide easy access to accurate diagnostic testing, which helps for prompt diagnosis and treatment of asymptomatic infections.[1]

A basic but well-accepted epidemiology formula could be used to explain the three parameters that affect the rate of spread of STIs (R_0) in a population,[14] namely probability of transmission, contact rate, and duration of infection. The relationship between these parameters can be illustrated by the following formula:

$$R_0 = ß \times k \times D$$

Table 1 Symptoms and sequelae of the most significant STIs

Infection *Causative organism*	Symptoms	Possible sequelae
Chlamydia[5] *Chlamydia trachomatis* bacterium	⚥ Genital or rectal pain, discharge ⚥ Burning sensation on urination ♀ Painful sexual intercourse ♀ Lower abdominal pain	⚥ Reactive arthritis ⚥ Infertility or reduced fertility ♂ Epididymo-orchitis ♀ Pelvic inflammatory disease ♀ Ectopic pregnancy
Gonorrhea[6] *Neisseria gonorrhoeae* bacterium	⚥ Genital or rectal pain, discharge ⚥ Burning sensation on urination ♀ Painful sexual intercourse	⚥ Disseminated infection, affecting joints, skin, heart ⚥ Infertility or reduced fertility ♂ Epididymo-orchitis ♀ Pelvic inflammatory disease
Syphilis[7] *Treponema pallidum* bacterium	⚥ Oral, anal, or genital ulceration ⚥ Generalized rash ⚥ Fever, malaise	⚥ Skin lesions ⚥ Cardiovascular, neurological disease
Trichomoniasis[8] *Trichomonas vaginalis* protozoan	⚥ Genital discharge ♂ Burning sensation on urination ♀ Vulval itching ♀ Cervicitis	♂ Prostatitis ♀ Risk of preterm delivery in pregnant women ♀ Risk of postpartum sepsis
Herpes simplex virus[9]	⚥ Itchy, painful genital or anal blisters or ulcers ⚥ Genital or rectal itching ♂ Urethritis or proctitis ♀ Cervicitis	⚥ Urinary bladder malfunction ⚥ Psychosexual morbidity ♀ Transmission to fetus
Hepatitis B virus[10]	⚥ Flu-like symptoms and general malaise ⚥ Jaundice ⚥ Pale stools and dark urine	⚥ Cirrhosis ⚥ Hepatocellular carcinoma
Human papillomavirus[11]	⚥ Genital or anal warts, usually painless ⚥ Perianal itching ⚥ Perirectal bleeding	♂ Penile, anal, oropharyngeal malignancy ♀ Vulvar, vaginal, cervical, anal, oropharyngeal malignancy
Human immunodeficiency virus (HIV)[12]	⚥ Flu-like symptoms ⚥ Generalized rash	⚥ Opportunistic infections such as pneumonia, esophageal candidiasis ⚥ Kaposi's sarcoma

Notes: ⚥, affects both males and females; ♂, affects males only; ♀, affects females only.

R_0 is the rate of spread of STI in the population; ß is the probability of transmission: how easily the pathogen can be transferred from an infected to a susceptible individual; k is the contact rate: the rate of contact between infected and susceptible individuals; D is the duration of infection: how long the infection persists in the individual.

If $R_0<1$, the infection will eventually disappear, if $R_0=1$, the infection will become endemic (disease found regularly in the population), and if $R_0>1$, there will be an epidemic (disease very common in the population). Even though there are some objections to the generality of this formula, it has been mathematically proven that these three factors equally influence the rate in which STIs spread in society.[14] A 20% decrease in one of these factors will have the same effect as a 20% decrease in any of these factors.

Promoting safe sex and condom use could reduce ß, while promoting educational interventions – resulting in fewer sexual partners and concurrent partnerships – could reduce k. However, the particular challenge is reducing D – the mean duration of infection. Since many STI-positive individuals are asymptomatic, they have no reason to seek health care. Unless they present for a check-up or are notified by a partner who has developed symptoms, they may remain infectious for a long period. This is where the health care system can directly intervene by implementing STI screening interventions that target potentially infected people from an apparently asymptomatic population.

STI screening requirements are determined by an individual's sexual history, personal risk factors for infection, and local clinical guidelines.[15,16] It involves collecting at least one biological sample (urine, blood, cells, or fluid) for analysis and diagnosis.[15] If necessary, treatment is guided by the results, and STI-positive people are encouraged to notify their recent sexual partners of their potential exposure.

Screening interventions can identify many recently acquired or persistent STIs. When STI status is known, treatment or management strategies can be accessed to avoid or reduce long-term complications and lower the chances of the infection spreading to others.[17] In addition, recent sexual partners can be notified to prompt them to seek STI screening, when they otherwise may not have.[17] When utilized, the benefits of STI screening interventions can be seen on an individual, national, and global scale. Individuals who are diagnosed – and by extension, treated – because of screening can receive the health and/or financial benefits associated with early intervention.[18] National benefits can be attributed to reduced morbidity and mortality associated with STIs, and there are resultant economic benefits such as reduced expenditure for health services or reduced loss of productivity.[18] As STIs are a global epidemic, coordinated national screening programs can result in fewer STI-positive individuals traveling internationally and propagating the spread of infection.[18,19]

Community pharmacies could be an appropriate setting for some STI screening.[20] Their convenient location and opening hours improve accessibility, and pharmacists are seen as trusted health professionals in a highly regulated industry.[21] In addition, pharmacists can offer private consultations in a health care setting that is already involved in sexual health through sales of condoms and the provision of emergency hormonal contraceptive (EHC) and oral contraceptives.[20,22]

In this review, we have collated the current and potential role of community pharmacists in screening interventions for STIs.

Methodology

Three databases (EMBASE, Medline, and Global Health) were searched for relevant articles reporting on original research up to August 31, 2017. The following search terms were used:

- "Sexually transmi*" OR chlamydia OR gonorrhea OR gonorrhoea OR syphilis OR "Hepatitis B" OR HIV OR "Human Immunodeficiency Virus" OR trichomoniasis OR HSV OR "Herpes Simplex Virus"; AND
- Pharmac*; AND
- Testing OR screening.

Following full-text screening, 15 relevant articles were selected. A further three articles were included from the authors' own reference libraries.

Chlamydia

Background

WHO estimates that every year there are around 131 million new chlamydial infections globally; latest global estimates of annual new infections by region are shown in Figure 1.[1] Recent data indicate that females have a higher incidence rate over males in every global geographic region for a total of 4.2% versus 2.7% positivity rates, respectively.[23] Those at greatest risk of infection are sexually active people aged 15–29 years, individuals with two or more sexual partners in the preceding year, individuals with a new sexual partner, and men who have sex with men.[24,25]

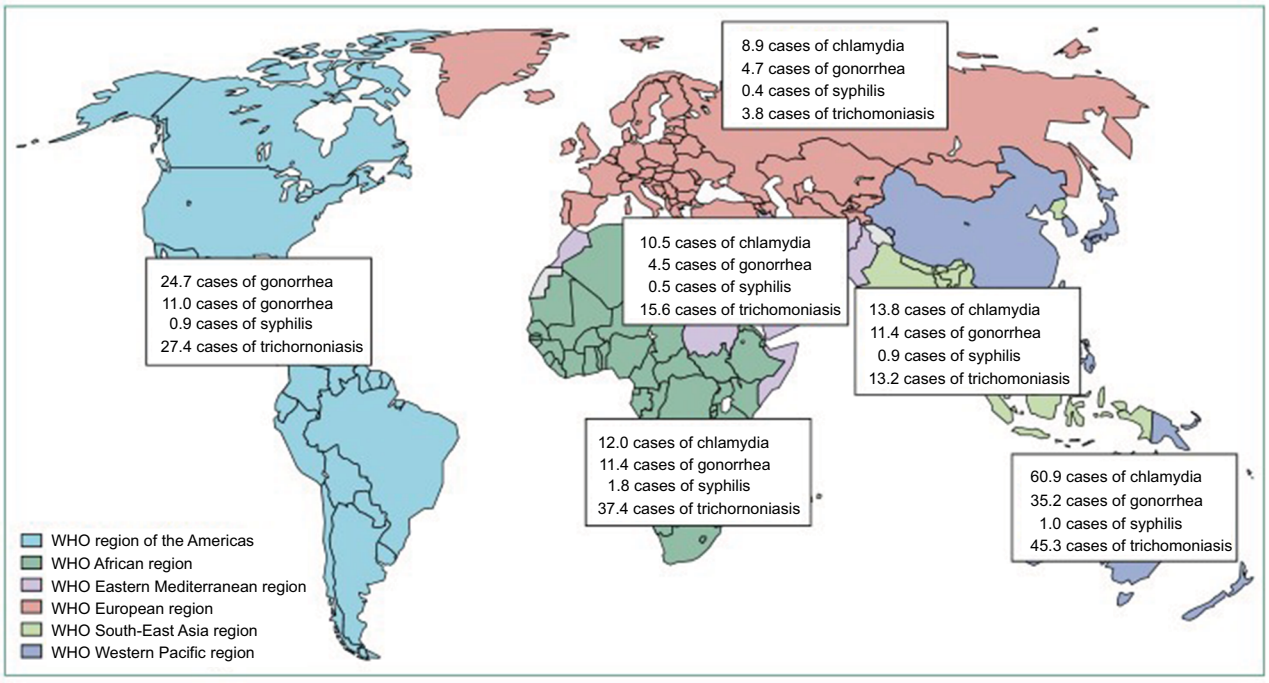

Figure 1 2012 WHO estimate of number in millions of new cases of the four curable STIs, by world region.
Note: Reprinted from *Lancet Infect Dis*, 17(8), Unemo M, Bradshaw CS, Hocking JS, et al, Sexually transmitted infections: challenges ahead, e235–e279, Copyright (2017), with permission from Elsevier.[16]
Abbreviations: WHO, World Health Organization; STI, sexually transmitted infection.

Control of chlamydia is extremely challenging because 70%–90% of infected women and over 50% of infected men are asymptomatic and can remain this way for years.[26,27] If the infection is not detected and treated, chlamydia-positive individuals would spread the infection to subsequent sexual partners – even in the absence of symptoms. Left untreated, persistent chlamydia lead to serious and potentially permanent sequelae such as pelvic inflammatory disease and tubal factor infertility in women, or epididymitis and epididymo-orchitis in men.[27] Screening is therefore essential to detect chlamydia in asymptomatic individuals to prevent the spread of infection and minimize the potential for complications arising from untreated chlamydia.

Current practice

Screening for chlamydia typically involves testing a specimen by using Nucleic Acid Amplification Testing (NAAT).[5,28,29] NAAT is the preferred test recommended by WHO as it is highly sensitive and specific and can be used for a wide range of samples.[29] The type of specimen collection varies depending on gender and risk factors (Table 2). To access chlamydia screening from a traditional setting, the consumers usually needs to make and attend an appointment with their general practitioner (GP), or present to a family planning clinic or sexual health clinic. The health provider or consumer collects the relevant specimens as shown in Table 2 for screening and waits for the pathology result before commencing treatment if positive.

Once diagnosed, chlamydia is easily treated with readily available antibiotics. The management guidelines in the USA, England, and Australia recommend the use of azithromycin (1 g orally, single dose) or doxycycline (100 mg orally, twice daily for 7 days) as first-line treatment for uncomplicated chlamydial infections.[5,31,32]

Well-documented barriers to the existing screening pathways include embarrassment, inconvenience, fear of invasive sample collection, and low motivation to self-refer for screening.[33–36] Consequently, screening rates in general practice remain low; and therefore, alternative sources of chlamydia screening may be warranted.[37,38] Community pharmacists have been identified as a possible provider of chlamydia screening because the convenience and accessibility offered by pharmacies overcome some of the common barriers faced in chlamydia screening in a traditional setting.[39]

Role of the pharmacist

Currently, chlamydia screening kits can be purchased from some pharmacies in the USA and the UK, with some UK

pharmacies also providing free screening kits over the counter.[40–43] Chlamydia screening kits come with everything needed to self-collect a urine or vaginal swab sample and a prepaid postage bag to return the sample for analysis and diagnosis.[40] Results are relayed to the consumer via telephone, text messaging, email, or a website with a secure log-in, and the consumer is directed to an appropriate service for treatment if necessary.[40]

To date, the National Chlamydia Screening Programme in the UK is the only coordinated screening initiative that involves community pharmacists.[44] UK pharmacists are able to provide asymptomatic consumers with a chlamydia screening kit.[44] The consumers collect their own urine or vaginal swab samples and post them to a designated testing facility.[44] If a consumer is chlamydia-positive, the pharmacist can arrange treatment and discuss partner notification – another crucial component of chlamydia management.[44]

Gudka previously identified five core requirements that should be considered when designing future pharmacy-based chlamydia screening interventions.[45] We have reviewed the evidence for the uptake, acceptability, and barriers of key STI screening initiatives conducted from community pharmacies with these five core requirements in mind (Table 4).

In summary, our literature review shows that pharmacist-led chlamydia screening studies have been conducted in the USA, the Netherlands, England, and Australia (Table 4). The timescale of interventions ranged from 2 weeks to 24 months, and the numbers of completed screenings spanned from 18 to 900. Despite the broad range, the key finding is that the concept of pharmacy-accessed chlamydia screening is feasible and acceptable to pharmacists and consumers. Consumers highly valued the convenience of self-collected samples, particularly when they could immediately collect the sample and hand it to pharmacy staff, as opposed to returning samples by post or delivering to pathology drop-off points. Pharmacists were keen to continue providing chlamydia screening beyond the scope of the research and found that opportunistically offering screening to at-risk consumers did not considerably increase their workload or time spent per consultation – particularly when discussed during a sexual health consultation.

Summary

There is sufficient evidence that community pharmacists can have a role in community-based chlamydia screening. The core requirements identified by Gudka et al could be used in developing future interventions, because they set a framework

Table 2 Specimens collected for chlamydia screening

Specimen	When collected
First void urine	♂ All
	♀ Only if endocervical swab or vaginal swab cannot be taken, but not as sensitive as vaginal swab
Anorectal swab	♂ All men who have sex with men
	♀ If patient has had anal sex
Pharyngeal swab	♂ All men who have sex with men
	♀ If patient has had oral sex
Endocervical swab[a]	♀ Collected upon examination
Vaginal swab	♀ Collected when no examination

Notes: ♂, males; ♀, females; [a]cannot be self-collected. Data from Australasian Sexual Health Alliance[5] and Government of Western Australia Department of Health.[30]

Table 3 Core requirements for consideration when designing a pharmacy-based chlamydia screening intervention

Core requirement	
Consumer recruitment approach	Population-based screening – anyone can obtain a chlamydia test from a pharmacist
	Opportunistic screening – pharmacists approach consumers who fit certain criteria, eg, women purchasing emergency hormonal contraception
Consumer eligibility criteria	Restricted by age
	Restricted by gender
Specimen testing/handling procedure	Specimen – noninvasive such as first void urine or vaginal swab sample
	Collected samples – posted directly to pathology laboratory or consumer-delivered to a designated collection point
Arrangement for notifying test results	Usually done by a dedicated chlamydia screening officer
Management of chlamydia-positive patients and partners	Antibiotic therapy can be obtained from general practitioner, sexual health clinic, or community pharmacist (following specific protocol if no prescription)

Note: Data from Gudka.[45]

Table 4 Summary of characteristics, core requirements, and results of pharmacist-led sexually transmitted infection screening studies

Chlamydia screening studies							
Quantitative		**Core requirements**					
Author, year country	**Time frame**	**Recruitment approach**	**Consumer eligibility**	**Type of specimen; method of sample return**	**Result notification**	**Treating health professional**	**Uptake**
Bloomfield et al, 2002[46] USA	2 weeks	Population	NR	FVU; Postal return	Telephone	Pharmacist, GP or sexual health clinician	Distributed: 209 Returned: 80 (38%)
van Bergen et al, 2004[47] The Netherlands	24 months	Opportunistic (contraceptive prescription)	Female 15–29 years	FVU; Postal return	Telephone	GP or sexual health clinician	Eligible: 614 Offered: 446 (73%) Returned: 121 (27%)
Baraitser et al, 2007[48] England	3 months	Population and opportunistic (EHC consultation)	NR	NR	NR	Pharmacist, GP, or sexual health clinician	Returned: 83
Gudka et al, 2009[49] Australia	6 months	Opportunistic (EHC consultation)	Female ≥18 years	Vaginal swab; Pathology laboratory or issuing pharmacy	Telephone	GP or sexual health clinician	Distributed: 166 Returned: 46 (28%)
Brabin et al, 2009[22] England	12 months	Opportunistic (EHC consultation)	Female <25 years	FVU; Postal return	Telephone	GP or sexual health clinician	Offered: 2904 Accepted: 1348 (46.4%) Returned: 236 (17.6%)
Emmerton et al, 2011[50] Australia	4 months	Opportunistic (sexual health consultation)	Female ≥16 years	FVU; Postal return	Telephone, text message, or letter	GP or sexual health clinician	Distributed: 156 Returned: 18 (12%)
Currie et al, 2012[51] Australia	4 weeks	Opportunistic (sexual health consultation)	16–30 years	FVU; Returned to issuing pharmacy	Telephone	GP or sexual health clinician	Distributed: 979 Returned: 900 (91.9%)
Habel et al, 2015[52] USA	17 months	Opportunistic (EHC consultation)	≥18 years	FVU; Left with pharmacy-based clinic	NR	NR	Distributed: 38 Returned: 38 (100%)
Debattista et al, 2016[53] Australia	9 months	Population	NR	FVU; Postal return	Telephone, text message, or letter	Contact tracing support officer	Distributed: 109 Returned: 43 (39.4%)
Qualitative							
Author, year country	**Participants**	**Interview style**		**Acceptability or barriers in pharmacy-based screening**			
Taylor et al, 2007[54] Australia	Pharmacists (n=25) Women aged 18–29 years (n=50)	Written questionnaire		Pharmacists: 84% would support pharmacy-based chlamydia screening as it would enhance their role. Training and incentives should be provided Women: 76% would accept chlamydia screening from pharmacy due to accessibility, anonymity, and affordability. The majority had concerns about the level of privacy in a pharmacy setting			
Thomas et al, 2009[55] England	Pharmacists (n=26)	Written questionnaire (n=26) Verbal in-depth interview (n=12)		Pharmacists were keen to provide new services but made risk assessments on who should be offered tests based on consumers' background (ethnicity, age, education) and type of relationship they perceived them to be in			
Dabrera et al, 2011[20] England	Pharmacists (n=10)	Semi-structured interview		Pharmacists were supportive of chlamydia testing from pharmacies. Many said they only offered a chlamydia test to women who requested EHC			

(*Continued*)

Table 4 (*Continued*)

Author, year country	Time frame	Recruitment approach	Consumer eligibility	Type of specimen; method of sample return	Result notification	Treating health professional	Uptake
Gonorrhea screening studies							
Bloomfield et al, 2002[46] USA	2 weeks	Population	NR	FVU; Postal return	Telephone	Pharmacist, GP, or sexual health clinician	Distributed: 209 Returned: 80 (38%)
Habel et al, 2015[52] USA	17 months	Opportunistic (EHC consultation)	≥18 years	FVU: Left with pharmacy-based clinic	NR	NR	Distributed: 38 Returned: 38 (100%)
Syphilis screening studies							
Buchanan et al, 2014–2015[56] England	9 months	Population and opportunistic (needle exchange and opiate substitution therapy)	NR	Dry blood spot; Left with pharmacist to send to Manchester Royal Infirmary for testing	Automated email	Local sexual health service	Completed: 88
Hepatitis B virus screening studies							
The Hepatitis C Trust, 2009[57] England	3 months	Population and opportunistic (conversation and educational material to identified at-risk consumers)	≥18 years	Dry blood spot; NR	In person, pharmacist-led	GP	Completed: 234
Buchanan et al, 2014–2015[56] England	9 months	Population and opportunistic (needle exchange and opiate substitution therapy)	NR	Dry blood spot; Left with pharmacist to send to Manchester Royal Infirmary for testing	Automated email	Hepatology team	Completed: 88
HIV screening studies Quantitative							
Calderon et al, 2009–2011[58] USA	9 months	Population	≥13 years English- or Spanish-speaking	Oral fluid specimen; N/A as diagnosis performed on-site	In person, by a public health advocate	HIV specialist	Offered: 2805 Accepted: 2030 (72.4%)
Weidle et al, 2011–2013[59] USA	2 years	Population	NR	Oral fluid specimen; N/A as diagnosis performed on-site	In person, by pharmacist, retail clinic staff, or on-site representative of local health department	NR	Completed: 1540

(*Continued*)

Table 4 (*Continued*)

Qualitative			
Author, year country	**Participants**	**Interview style**	**Acceptability or barriers in pharmacy-based screening**
Gorostiza et al, 2009–2010[60] Spain	Consumers of pharmacy-accessed rapid HIV antibody screening tests (n=806)	Survey	Convenience, speed of testing, and accessibility of community pharmacies were identified as the main motivators for consumers to accept the test
Darin et al, 2010–2011[61] USA	Adult consumers presenting to a community pharmacy prescription counter (n=380)	Written survey	Among those who were undecided (n=36; 9.5%) or uninterested (n=209; 55%) in pharmacy-based HIV screening, the main deterrents were the lack of perceived risk or already understanding their HIV status. Main facilitators were confidentiality, screening time of <20 minutes, use of a private counseling room, and free screening

Abbreviations: NR, not reported; FVU, first void urine; GP, general practitioner; EHC, emergency hormonal contraception; N/A, not applicable; HIV, human immunodeficiency virus.

that addresses necessary criteria for consideration when conceptualizing a targeted approach to chlamydia screening. For effective implementation, issues around confidentiality in a community pharmacy setting, pharmacy reimbursement, and the cost of chlamydia screening must be considered for individual countries and unique health settings.

Gonorrhea

Background

WHO estimates that there are ~78 million new cases of gonorrhea every year worldwide, with the greatest incidence seen in the Western Pacific, South-East Asian and African regions (Figure 1).[1] Recent global prevalence is estimated to be 0.6% of men and 0.8% of women.[23] Those at increased risk for gonorrheal infection include sexually active females and males aged 15–29 years, those with multiple recent sexual partners or new sexual partners, men who have sex with men, and presence of other STIs such as chlamydia.[62]

Gonorrhea is an issue of global public health concern; as well as being asymptomatic in most infected consumers, antibiotic-resistant strains of *Neisseria gonorrhoeae* are emerging in recent years, reducing the effectiveness of some antibiotic treatment. The Centers for Disease Control and Prevention (CDC) estimate that, of the 820,000 new gonorrhea infections that occur each year in the USA, ~246,000 show resistance to at least one antibiotic.[63] While efforts are being made to identify and develop new antibiotics that can treat gonorrhea, the CDC has compiled a set of guidelines as part of their Solutions Initiative to reduce drug-resistant gonorrhea.[63] The guidelines recommend expanding the availability of resistance testing, reducing the time taken for health providers to receive test results to ensure timely treatment, and identify and manage sexual partners promptly to minimize the spread of resistance.[63]

Current practice

Screening for gonorrhea involves testing by using NAAT for all specimens except urethral swabs, which rely on cultures for diagnosis (Table 5).[6] Culture samples can be collected from all specimens except first void urine (FVU).[6] Although not as sensitive as NAAT, they can be used to determine the antibiotic sensitivity of the organism to guide treatment.[6]

WHO guidelines for gonorrheal treatment recommend that local resistance data should guide treatment choice; In general, first-line choice when antibiotic susceptibility information is unknown should involve a combination therapy with two antibacterial medications of differing mechanisms of action.[64] This strategy improves treatment effectiveness and can slow down the occurrence of antibiotic resistance in *N. gonorrhoeae*.[65] Recommended dual therapy is either ceftriaxone (250 mg intramuscular single dose) plus azithromycin (1 g oral single dose), or cefixime (400 mg oral single dose) plus azithromycin (1 g oral single dose).[64] As azithromycin treats chlamydial infections in this dose and delivery, there is an additional benefit of simultaneously treating a chlamydial coinfection.[64] Coinfection with chlamydia has been demonstrated to be as high as almost 50% in gonorrhea-positive consumers.[66,67] When specific antibiotic susceptibility is known, this should be used to determine appropriate treatment.[64]

Table 5 Specimens collected for gonorrhea screening

Specimen Testing protocol	When collected
First void urine	♂ MSM
NAAT	♀ Only if endocervical swab or vaginal swab cannot be taken, but not as sensitive as vaginal swab
Anorectal swab	♂ All MSM
NAAT ± culture	♀ If patient has had anal sex or has anorectal symptoms
Pharyngeal swab	♂ All MSM
NAAT ± culture	♀ If patient has had oral sex
Endocervical swab[a]	♀ Collected upon examination if discharge or dysuria is present
NAAT ± culture	
Vaginal swab	♀ Collected when no examination
NAAT ± culture	
Urethral swab	♂ When discharge present
Culture	

Notes: ♂, males; ♀, females; [a]cannot be self-collected. Data from Australasian Sexual Health Alliance[5] and Government of Western Australia Department of Health.[30]
Abbreviations: NAAT, Nucleic Acid Amplification Test; MSM, men who have sex with men.

Role of the pharmacist

Gonorrhea screening kits can be purchased from selected pharmacies in the USA, UK, and Australia, with some UK pharmacies also providing free urine-based screening kits over the counter.[40–43]

Two relevant studies were identified that assessed the feasibility of pharmacy-based gonorrhea screening; both were conducted in the US (Table 4). The timescales of interventions ranged from 2 weeks to 17 months, and the number of completed screenings varied from 38 to 80. Both the studies concluded that gonorrhea screening from community pharmacies is feasible, particularly when offered in conjunction with chlamydia screening. Almost all opportunistically targeted consumers felt that pharmacists should be involved in STI screening, with most reporting satisfaction with their experience. When population-based screening was studied, pharmacists felt that consumers chose to collect screening kits because pharmacies could provide convenient access to a relatively anonymous service.

Bloomfield et al[46] trialed a population-based screening approach that additionally targeted advertising toward the local men who have sex with men (MSM) subgroup. Ninety-five percent of returned specimens belonged to MSM, suggesting that advertising aimed toward at-risk groups could be successful, but trialing over a longer time frame is needed before any conclusions can be made. Habel et al trialed opportunistic targeting of at-risk people; they provided a voucher for gonorrhea screening to anyone who purchased EHC during the study period.[52] Screening uptake was low, which authors suggested could be due to the lack of both advertising and pharmacist-driven discussion about screening.

Both the studies only offered self-collection of urine as a specimen, regardless of gender. A systematic review and meta-analysis by Lunny et al found that, when comparing self-sampled specimens with the equivalent clinician-collected samples, sensitivity of screening urine specimens from asymptomatic women was low. This finding supports CDC guideline recommendations that urine specimens should not be collected to screen asymptomatic women for gonorrhea due to relatively low sensitivity, with preference given to self-collected vaginal swabs.[65,68] To date, no trials have been performed to evaluate the effectiveness of using vaginal swabs to screen women for gonorrhea through a community pharmacy. In the studies that collected urine samples, neither Bloomfield et al nor Habel et al retested self-collected samples or gathered clinician-collected samples to verify the accuracy of results; hence, it is possible that similarly low sensitivity was observed, and by extension some gonorrhea-positive consumers may not have been diagnosed during the study period. Consequently, the infection would remain untreated and undiagnosed for an indeterminate amount of time, or any future symptoms may be dismissed due to an incorrect belief that they are gonorrhea-negative.

As well as potential sensitivity issues, urine-based sampling can introduce further issues with storage and handling. While urine samples can maintain accuracy when stored at room temperature for up to 7 days, locations with higher ambient temperatures would need to assess whether stricter storage requirements are necessary to maintain stability.[46] In addition, Bloomfield et al noted that almost 4% of returned urine samples were lost due to improper sealing of the collection cup.[46] Vaginal swabs offer further advantages as they do not have the leakage problems associated with transporting urine samples.[69] If vaginal swab sampling is used, there is potential for gonorrhea and chlamydia screening initiatives to merge. Because NAAT testing (the preferred diagnostic

test for both infections) has high sensitivity and specificity when performed on urine samples from men and vaginal swab specimens from women – and there is an elevated risk of chlamydia coinfection in gonorrhea-positive consumers – this could prove to be both beneficial and cost-effective.

Summary

There is some evidence that pharmacists can contribute to gonorrhea screening, when performed in conjunction with chlamydia screening. Current WHO recommendations suggest that collected samples should be restricted to urine specimens for men and vaginal swabs for women for optimal sensitivity, but use of vaginal swabs require further exploration in a pharmacy setting.

Syphilis

Background

According to WHO, ~5.6 million new syphilis infections occur globally every year and 18 million established infections at any one time.[1,70] The most recent estimated global prevalence indicated that 0.48% of men and 0.5% of women aged 15–49 years have a syphilis infection.[23] The highest prevalence for both men and women is noted in developing countries, particularly in African nations (Figure 1).[23] Syphilis most commonly affects MSM, men aged 15–54 years, and women aged 15–30 years.[70,71]

When first infected with syphilis, the bacteria enters the body and usually leaves behind at least one small, painless lesion called a chancre that heals on its own within weeks; this is known as primary syphilis.[72] A few weeks later, secondary syphilis may be seen; typically a rash that can cover the entire body.[72] It can be accompanied by wart-like oral or genital lesions and flu-like symptoms.[72] This stage can last anywhere from a few weeks to a year; during which the infection becomes latent; with no obvious signs and/or symptoms.[72] The infection can thus remain latent permanently or could progress to tertiary syphilis that leads to a range of neurological or cardiovascular problems.[72] Pregnant women can pass syphilis to their baby through the placenta or during childbirth, greatly increasing the risk of miscarriage, stillbirth, or neonatal death.[72] Most newborns will not display symptoms but untreated syphilis can lead to deafness, tooth deformities, and a collapsed nasal bridge.[72] In 2012, ~350,000 adverse pregnancy outcomes (infection, low birth weight, stillbirth, and neonatal death) were attributed to syphilis.[70] It is the consequences of tertiary and congenital syphilis that contribute to the public health concern associated with syphilis.[72] In addition, chancres bleed easily so can increase the risk of contracting HIV by an estimated two to five times.[72]

Current practice

When screening for syphilis, a whole blood specimen is taken and usually screened with an enzyme immunoassay, although agglutination assays and hemagglutination assays can be used.[7] If reactive, or if the consumer has previously had a treated syphilis infection, rapid plasma reagin is used to confirm.[7] Screening between one and four times per year is recommended for MSM; HIV-positive MSM should be screened up to four times per year or at every viral load monitor.[7] Pregnant women should be tested at least once during antenatal appointments, with a repeat screen performed in late pregnancy if she is at risk of infection or reinfection.[7] First-line treatment is benzathine penicillin (1.8 g intramuscular single dose) in all populations, with doxycycline (100 mg orally twice a day for 14 days) used when penicillin allergy exists.[7]

Role of the pharmacist

Syphilis screening kits can be purchased from selected community pharmacies in the USA and the UK.[41,73] In these kits, the consumers self-collect the sample by using a thin lancet on their fingertip to draw blood, and the results will be available on the test cassette within 15 minutes. Syphilis screening kits have a high level of accuracy; they report the sensitivity and specificity at over 99% and come with a control line to demonstrate validity.[74,75] These screening kits have not been trialed for accuracy or consumer satisfaction.

Our literature search identified one study that trialed pharmacy-based syphilis screening, in England (Table 4). Recruitment was both opportunistic and population-based; pharmacists and pharmacy staff targeted anyone participating in the needle exchange program or opiate substitution therapy, while local advertising informed the general population of the screening initiative.[56] Pharmacists were trained in conducting a dry blood spot sampling method, counseling consumers, and collecting samples, which were then sent to Manchester Royal Infirmary for testing.[56] Out of 88 participants who were screened for syphilis, 72 were recruited opportunistically by pharmacists; most participants identified themselves as intravenous drug users.[56]

Buchanan et al[56] concluded that dry blood spot syphilis screening from a community pharmacy is both accessible and acceptable to consumers.[56] However, it involved a high level of commitment and training from pharmacists, which can pose problems. Logistically, it would require every

pharmacist in participating pharmacies to complete the necessary training, so that screening is readily available during all opening hours. Locums working in participating pharmacies would need to be trained to continue the service when the usual pharmacist is away. Dry blood spot sampling also involves a high level of risk as it requires the pharmacist to handle whole blood from consumers who potentially carry blood-borne infections.

Summary

There is not enough evidence to date that pharmacist-led syphilis screening is feasible. While there may be potential for an initiative to be successful, more information is needed in a wider variety of settings with targeted recruitment of at-risk populations. If syphilis screening through community pharmacies is justified, consideration should be given to alternative methods of screening that reduce the risks to the pharmacist, such as over-the-counter screening kits.

HBV

Background

Globally, there are ~257 million people infected with HBV, with the highest prevalence observed in adult populations in the Western Pacific (6.2%) and African (6.1%) regions.[76] Although sexual transmission is not the most common route of infection, it can occur through exchange of or mucosal exposure to infected bodily fluid.[76]

HBV is potentially life-threatening, causing chronic infection and leading to a high risk of death from cirrhosis or liver cancer; in 2015, 887,000 people were affected from HBV-related complications.[76] Chronic liver infections are common in infants and children who became infected in utero.[76]

Current practice

HBV can only be differentiated from other types of viral hepatitis by laboratory confirmation.[76] A blood sample is tested for the presence of the HBV surface antigen HBsAg, by using enzyme immunoassay techniques.[76,77] Screening is recommended in pregnant women, adults at increased risk of transmission, and people who are hepatitis C-positive or HIV-positive due to the increased risk of coinfection.[77]

There is no cure for HBV; treatment in acute infections is aimed at relieving symptoms and replacing fluids lost through vomiting and diarrhoea.[76] Medication can be used to manage chronic infection, but treatment is complex and case-specific, depending on the duration of infection, presence of symptoms, and complications arising from chronic infection.[78] Life-long antiviral medication such as tenofovir can be used to slow down the ability of the virus to multiply in chronic HBV infections.[76,78]

Role of the pharmacist

Rapid screening kits to test for HBsAg are available, allowing consumers to self-collect their own blood samples directly into a test cassette.[79] Results are visually seen on the test cassette within 15 minutes, and the screening kit offers a sensitivity and specificity of 99%.[79] High accuracy, self-collection, and privacy of testing make it an attractive screening option to some high-risk consumers.

Our literature review shows that pharmacist-led HBV screening studies have been trialed in England (Table 4). Length of interventions varied from 3 to 9 months, and 234 and 80 screenings were completed, respectively. Both the studies concluded that HBV screening is feasible in a community pharmacy setting, and combining it with hepatitis C screening adds cost-effectiveness. Pharmacists in The Hepatitis C Trust initiative found their whole-day training session to be comprehensive and helpful, with several displaying enthusiasm for the "exciting initiative."[57] Likewise, post-participation consumer feedback was very positive; out of the 19 consumers who completed the survey, 18 indicated that they preferred screening from a pharmacy setting as opposed to a GP surgery.[57] All surveyed consumers found the service convenient and would recommend it to at-risk friends.[57] Neither pharmacist nor consumer satisfaction was reported by Buchanan et al.[56]

The same concerns with respect to dry blood spot syphilis screening apply in this context; HBV screening using dry blood spot sampling requires a high level of pharmacist involvement, and the exposure to potentially infected blood samples poses a risk. The protocol trialed by The Hepatitis C Trust placed even further responsibilities onto the pharmacist. In addition to involvement in pre- and posttest counseling, sample collection, and handling, pharmacists were required to discourage the "worried well" with no risk factors from being screened, follow up with each screened consumer to ensure they returned to the pharmacy for their results, and provide tailored education to HBV-negative or HBV-positive consumers. The report did not indicate how much time pharmacists spent following up with consumers, the number of consumers who failed to return in the required 2–3 weeks for their results, or pharmacists' perspectives of the time taken to comprehensively manage consumers, but these factors must be considered when assessing the feasibility of this initiative in daily practice.

However, The Hepatitis C Trust was more stringent on minimizing the pharmacists' risk of personal injury. The pharmacist training session was twice as long as the equivalent in the study conducted by Buchanan et al,[56] and all participating pharmacists were required to complete a super accelerated course of HBV vaccinations if unvaccinated and provide proof that adequate antibody levels had been achieved prior to participation. These two requirements reduced the level of personal risks that participating pharmacists would be exposed to.

Summary

There is some evidence that pharmacists can have an important role in assisting at-risk consumers to understand their risk factors, provide a relatively anonymous route for HBV screening, and assist in specimen collection, diagnosis, and treatment coordination. However, pharmacists may not have time to perform thorough HBV screening, and dry blood spot sampling still poses a significant health risk. Future trials should investigate a less time-intensive and risky pharmacist-led protocol, such as provision of over-the-counter screening kits.

HIV

Background

Latest WHO estimates indicate that 37 million people are infected with HIV globally; of these, nearly half are unaware of their HIV status.[80] While the recent HIV response to reduce global incidence has been effective in some countries, incidence continues to rise in areas such as sub-Saharan Africa (Figure 2) where ~1 in 25 adults are infected.[80,81] MSM, transgender women, and residents of (or travelers to) countries with high incidence of HIV are in particular at risk of sexually transmitted HIV.[82]

HIV infection causes a chronic immune deficiency that usually first presents as a flu-like illness 2 weeks after exposure.[12] While currently incurable, if detected early, then life-long combination antiretroviral therapy (ART) can be used to lower the viral load, prevent HIV transmission, and prevent progression from HIV to acquired immunodeficiency syndrome (AIDS).[12] Approximately 1 million people died of HIV-related illnesses in 2016; the high mortality associated with opportunistic infections in HIV-positive people makes HIV a serious global public health threat.[80]

Current practice

Testing for HIV is a two-step process. The first step is to test for HIV-specific proteins (antibodies or antigens) in the plasma, serum, whole blood, or oral fluid. The two main types of HIV self-screening kits available from pharmacies and/or online involve either a finger stick/venous whole blood (~5 μL) sample, or oral saliva test conducted by swabbing

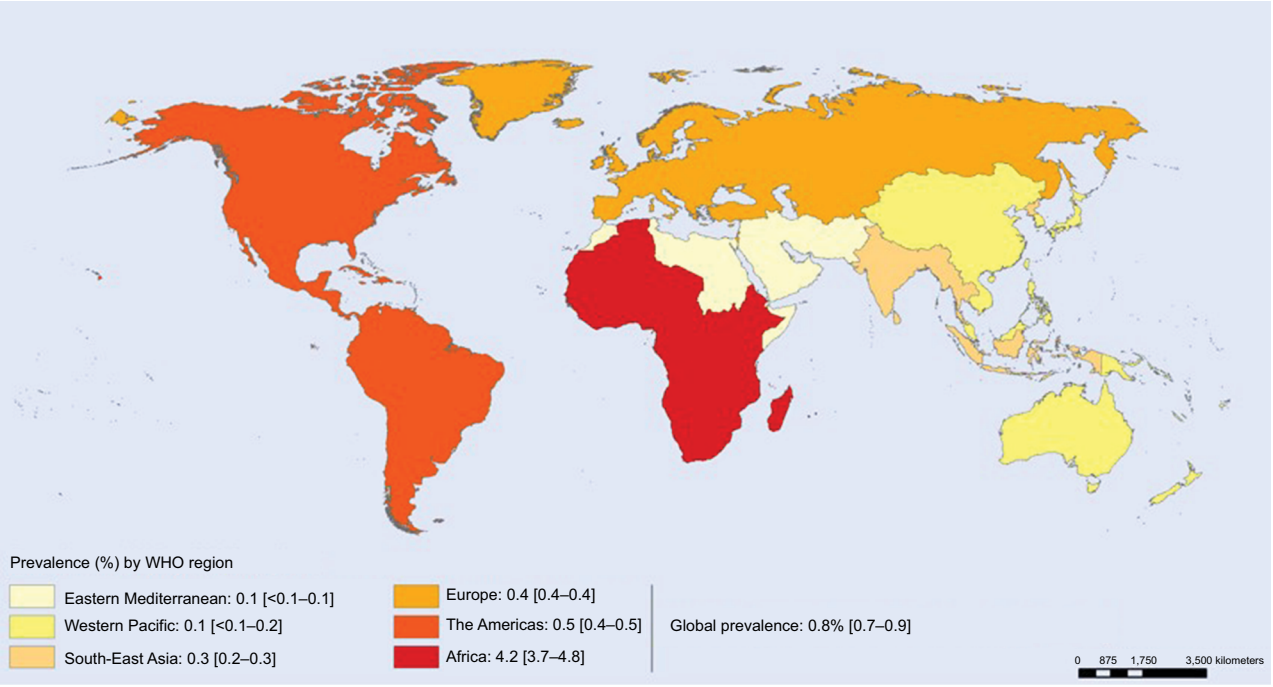

Figure 2 Prevalence of HIV in 15–49 year olds, by WHO region.
Note: Reprinted from World Health Organization [webpage on the Internet]. HIV/AIDS. Available from: http://www.who.int/gho/hiv/en/.[81]
Abbreviations: HIV, human immunodeficiency virus; WHO, World Health Organization.

the upper and lower gum line. The results of both these tests take about 20–40 minutes. If the HIV self-screen results in a positive test, then the individual needs to undergo a second test called a Western blot, which involves skilled staff and equipment. Only when both the tests are positive, it is almost 99% certain that the patient is infected with HIV. The CDC advises HIV screening for sexually active MSM every 3–6 months, annual screening for anyone who has unprotected sexual intercourse or shares injection drug equipment, and one-off screening for all pregnant women.[83] In addition, they recommend that all adolescents and adults aged between 13 and 64 years should be tested at least once for HIV.[83]

Although there is no cure for HIV, lifelong ART medication tailored to the individual can be used effectively to control the virus. There are five main groups of ART medications, which target different stages of the virus lifecycle; combination ART uses multiple medications from at least two of these groups and is taken orally once or twice a day.[84] AIDS-related illnesses, transmission rates, hospital admissions, and mortality rates can all be reduced with early ART intervention.[84] Depending on location and available health services, high-risk HIV-negative consumers may be able to access pre-exposure prophylaxis (PrEP), a combination ART that, when taken daily, can help prevent HIV infection.[85]

Role of the pharmacist

As ART and PrEP are essential components of management and prevention, respectively, pharmacists can provide support with medication management and education. They are in an ideal position to identify and discuss any medication side effects and offer relief or refer to the treating health specialist. They can also identify the use of complementary medicines and ensure they are being used safely with no interaction. Most importantly, pharmacists are able to send prescription refill reminders and emphasize that ART and PrEP must be taken daily to be effective.[84,85] Missed ART doses can lead to treatment resistance and missed PrEP can reduce effectiveness and potentially expose the consumer to infection, so medication compliance is crucial for success.[84,85]

We identified several pilot programs that assessed the feasibility of pharmacy-based HIV screening (Table 4). Two quantitative studies were conducted in the USA; timescales ranged from 9 months to 2 years, with 2030 and 1540 screenings performed, respectively. Calderon et al[58] and Weidle et al[59] concluded that HIV screening through a community pharmacy could be successfully implemented.

Both the studies screened oral fluid specimen rather than whole blood or blood products. Screening oral fluid greatly reduces the personal risk to the pharmacist; brief contact with saliva from an HIV-positive individual has been shown to be "insignificant" in HIV transmission, while contact with blood and semen greatly increases the risk of transmission.[86]

There are financial and logistical barriers that need to be overcome for successful implementation. The biggest barrier relates to remuneration for services, particularly considering that HIV screening is time-intensive; Weidle et al found that pharmacists spent an average of 10 and 21 minutes on non-reactive and reactive screens, respectively, for pre- and posttest consultations.[59] HIV screening and counseling is a skilled, highly involved, and time-consuming initiative for community pharmacists, so reimbursement for this service must be appropriate and sustainable. In addition, in countries where private counseling rooms are not mandatory, improving infrastructure to assure confidentiality can be expensive and may not be financially viable if remuneration is low.

Summary

There is some evidence that pharmacist-led HIV screening is possible, particularly through use of oral fluid specimens. However, a larger number of studies from a wider variety of settings is required before any conclusions can be reached. Consideration must be given to pharmacist reimbursement and infrastructure upgrades with respect to the unique healthcare system and pharmacy infrastructure of each country.

Trichomoniasis and HSV

There have been no studies to date that have examined the possibility of pharmacist-led screening for trichomoniasis or HSV.

Trichomoniasis can be detected in urine sample; hence, there is a potential for a pharmacy-based screening initiative, provided the sensitivity and specificity of the diagnostic test are high.[8] However, pharmacist-led trichomoniasis screening would need to be assessed for feasibility before any conclusions can be made.

The CDC does not recommend screening for HSV; the most accurate diagnosis can be made by testing a swab sample taken from a symptomatic lesion or blister.[87] Absence of symptoms is a key requirement of screening appropriateness; hence, we do not foresee any potential role for pharmacists in this scenario.

Conclusion

STI screening is a critical component of sexual health, ensuring that infections are detected as early as possible for prompt treatment and optimal health outcomes. Avenues for safe, accurate STI screening must be identified and supported, to increase detection in at-risk populations. Pharmacist-led

screening has many benefits: sample collection is either non- or minimally invasive, some samples can be self-collected in the privacy of the consumers' home, and is more convenient than clinician-led testing. To be effective, pharmacist-led screening must also have demonstrated high sensitivity and specificity and must be acceptable to consumers. The role of pharmacists in providing sexual health screening can be as simple as providing an over-the-counter screening kit, or they can bear more responsibility with tasks such as recommending STI screening to at-risk consumers, collecting samples, educating consumers, referring to appropriate health services, and managing medications. Although some STIs have no or some evidence that pharmacists are well-placed to provide screening services, there is sufficient evidence that pharmacists can assume a more prominent role in screening for STIs such as chlamydia. However, further investigations are needed – particularly with respect to remuneration, infrastructure, screening accuracy, and pharmacist safety – before global recommendations can be made.

Disclosure

The authors report no conflicts of interest in this work.

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