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Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis

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ABSTRACT

Background Self-collection of samples for diagnostic testing offers the advantages of patient autonomy, confidentiality and convenience. Despite data showing their feasibility and accuracy, there is a need to better understand how to implement such interventions for sexually transmitted infections (STIs). To support WHO guidelines on self-care interventions, we conducted a systematic review to investigate whether self-collection of samples should be made available as an additional approach to deliver STI testing services.

Methods Peer-reviewed studies were included if they compared individuals who self-collected samples for chlamydia, gonorrhoea, syphilis and/or trichomonas testing to individuals who had samples collected by clinicians on the following outcomes: uptake/frequency of STI testing, social harms/adverse events, positive yield (case finding), linkage to clinical assessment/treatment and reported sexual risk behaviour. We searched PubMed, CINAHL, LILACS and EMBASE for articles published through July 2018. Risk of bias was assessed using the Cochrane tool for randomised controlled trials (RCTs) and the Evidence Project tool for non-RCTs. Meta-analysis was conducted using random effects models to generate pooled estimates of relative risk (RR).

Results Eleven studies, including five RCTs and six observational studies with a total of 202 745 participants, met inclusion criteria. Studies were conducted in Australia, Denmark and the USA. Meta-analysis found that programmes offering self-collection of samples increased overall uptake of STI testing services (RR: 2.941, 95% CI 1.188 to 7.281) and case finding (RR: 2.166, 95% CI 1.043 to 4.498). No studies reported measuring STI testing frequency, social harms/adverse events, linkage to care or sexual risk behaviour.

Discussion While greater diversity in study designs, outcomes and settings would strengthen the evidence base, findings from this review suggest that self-collection of STI samples could be an effective additional strategy to increase STI testing uptake.

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Key questions

What is already known?

- Self-collected samples for sexually transmitted infection (STI) testing are as accurate as clinician-collected methods and are feasible and acceptable in a variety of populations.

What are the new findings?

- A systematic review identified 11 studies from three high-income countries (Australia, Denmark and the USA), conducted in a variety of populations.
- Meta-analysis showed that, compared with clinician-collection, self-collection of samples increased uptake of STI testing services.
- In meta-analysis, the intervention group (people who were offered STI services with self-collection of samples) had a higher yield of positive diagnoses (ie, case finding) compared with the group offered only clinician-collected STI tests; however, when analyses were limited to those who accepted STI testing services (rather than all offered services), self-collection was associated with lower positive yield.

What do the new findings imply?

- Self-collection methods can offer an alternative approach for STI testing, with implications for universal health coverage and the achievement of the UN Sustainable Development Goals.

INTRODUCTION

Worldwide each year, there are an estimated 357 million new infections of one of the four curable sexually transmitted infections (STIs): chlamydia, gonorrhoea, syphilis and trichomoniasis.[1 2] Aetiological diagnosis via STI testing is the best way to ascertain infection status and promote appropriate treatment.[3 4] While STI diagnostic tests are available and used in many high-income countries, diagnostic tests in low-income and middle-income

country (LMIC) settings are largely unavailable.[3 5–7] Syndromic management has been the primary approach for STI treatment in LMICs,[5 8] which has significant limitations despite its practicality; experts doubt it will impact STI disease burden.[5 9 10] Globally, social stigma and a lack of effective policies also affect STI testing uptake and treatment-seeking behaviour. Low STI testing coverage and high transmission rates are common among at-risk vulnerable adolescents and key populations including men who have sex with men (MSM), migrants, sex workers, Indigenous and minority populations and those affected by humanitarian emergencies.[9] Left undiagnosed and untreated, curable STIs can cause acute and chronic illness, infertility, ectopic pregnancy, long-term disability, neurological and cardiovascular disease and death.[11] Serious diseases in their own right, STIs also increase the risk of contracting or transmitting HIV infection.[11] Consequently, greater efforts are needed to expand STI testing globally to reduce this heavy burden of disease.

Self-collection of samples is one way to facilitate the expansion of STI testing services. Self-collection of samples occurs when individuals take a specimen themselves, either at the clinic or elsewhere, and send it to a laboratory for testing.[12] Follow-up in the case of positive test results requires a linkage with the health system. Research in high-income countries, where organised lab facilities and healthcare are available, shows that self-collected STI samples are as diagnostically accurate as clinician-collected samples[13] and that self-collection interventions are feasible and acceptable in a variety of populations.[14–23] Self-collection approaches also have the potential to address some common barriers to clinician-dependent and/or clinic-based diagnosis, such as concerns around autonomy, inconvenience, stigma and lack of privacy.[5 24 25] Systematic reviews have been conducted to compare STI testing programmes (some including self-collection methods) in home or non-clinic settings to those in clinic settings.[19 26–31] However, no review to date has systematically compared self-collection of samples to clinician-collected methods for STI testing on programmatic outcomes. In order to develop WHO guidance on self-care interventions for sexual and reproductive health and rights, we conducted a systematic review to investigate whether STI self-sampling should be made available as an additional approach to deliver STI testing services, whether incorporated into routine STI services or as an alternative model with linkage to care.

METHODS

Definition

We assessed self-collection of samples for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* (TV). This is in line with ongoing multicountry evaluations of promising point-of-care testing (POCT) interventions to detect these four curable STIs as well as the goal of the WHO STI POCT initiative to achieve universal access to reliable and affordable STI testing.[32] There are numerous types of self-collected samples for different STIs, including: urine (mainly among men, but also women and youth) for NG, CT and TV; vulvovaginal swabs for NG, CT and TV; and pharyngeal and anorectal swabs for NG and CT.[33–35] Rapid dual tests for HIV/syphilis have been developed and evaluated, but only one so far has been prequalified by the WHO, though others are in the process.[36 37]

Research question and inclusion criteria

The review addressed the following research question: should self-collection of samples be offered as an additional approach to deliver STI testing services?

Population

Individuals using STI testing services.

Intervention

STI testing services that incorporate self-collection of samples.

Comparison

STI testing services that do not incorporate self-collection of samples (ie, clinician-collection) or no STI testing services (ie, syndromic management alone or no lab-based intervention).

Outcomes

Primary:

1. Uptake of STI testing services (eg, the proportion who accepted and completed the test).
2. Frequency of STI testing.
3. Social harms or adverse events (eg, device-related issues, coercion, violence, psychosocial harm, self-harm, suicide, stigma, discrimination and frequency of HIV testing) and whether these harms were corrected or had redress available.

Secondary:

1. Proportion of people who tested positive for an STI (case finding).
2. Linkage to clinical assessment or STI treatment following a positive test result.
3. Reported sexual risk behaviour (eg, condom use, condomless sex, unprotected sex, number of sexual partners).

To be included in the review, an article had to meet the following criteria:

1. Study design comparing people who self-collected samples to people who had samples collected by a clinician for STI testing or to those who received no STI testing services.
2. Evaluated one or more of the outcomes listed above.
3. Published in a peer-reviewed journal.

Because this study was designed to inform WHO guidelines on the viability of self-sampling as an additional means to increase testing, articles that compared self-collection of samples by the location of intervention delivery (ie, self-collection at home vs self-collection at the clinic)

were not included. These articles have been reviewed elsewhere.[19 26–31]

A full review protocol is available on PROSPERO (CRD42018114871).

Search strategy and screening process

We searched PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Latin American and Caribbean Health Sciences Literature (LILACS) and Embase through the search date of 18 July 2018, with no limits on publication year, study location or language. We also conducted secondary reference searching on all studies included in the review and three relevant systematic reviews.[19 28 31] Selected experts in the field were contacted to identify additional articles not identified through other search methods. We searched for ongoing randomised controlled trials (RCTs) on clinicaltrials.gov, the WHO International Clinical Trials Registry Platform, Pan African Clinical Trial Registry and the Australian New Zealand Clinical Trials Registry. Search terms were developed for STIs and self-sampling; the full search strategy for is available in online supplementary file 1.

After initial screening of titles, abstracts, citation information and descriptor terms, records were screened independently and in duplicate by two reviewers, with differences resolved through consensus. Full-text articles were obtained of all selected records. Three reviewers independently assessed all full-text articles for eligibility to determine final study selection. Differences were resolved through consensus.

Data extraction and management

For each study, the following information was compiled via independent double-data extraction: study citation, objectives, location, population characteristics, description of the type of STI sampling, description of any additional intervention components, sample size, follow-up periods and loss to follow-up, analytic approach, reported numerical outcomes, results and limitations.

Methodological components of the studies were assessed and classified as high or low risk of bias. For RCTs, risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias.[38] For comparative studies that were not RCTs, study rigour was assessed using the Evidence Project risk of bias tool for intervention evaluations.[39]

Data analysis

Data were analysed according to coding categories and outcomes. Where multiple studies reported the same outcome, we conducted meta-analysis using random effects models to generate pooled estimates of relative risk (RR) using the programme Comprehensive Meta-Analysis.[40] Heterogeneity was assessed using both Q and I-squared statistics. Data from RCTs and observational studies were analysed separately. For the case finding outcome for the RCTs, we ran sensitivity analyses to explore differential effects between self-collection and clinician-collection by using as a denominator (1) all study participants enrolled and randomised to study arms regardless of testing uptake (true intention-to-treat) and (2) only participants who collected samples for STI testing services (subgroup of respondents only).

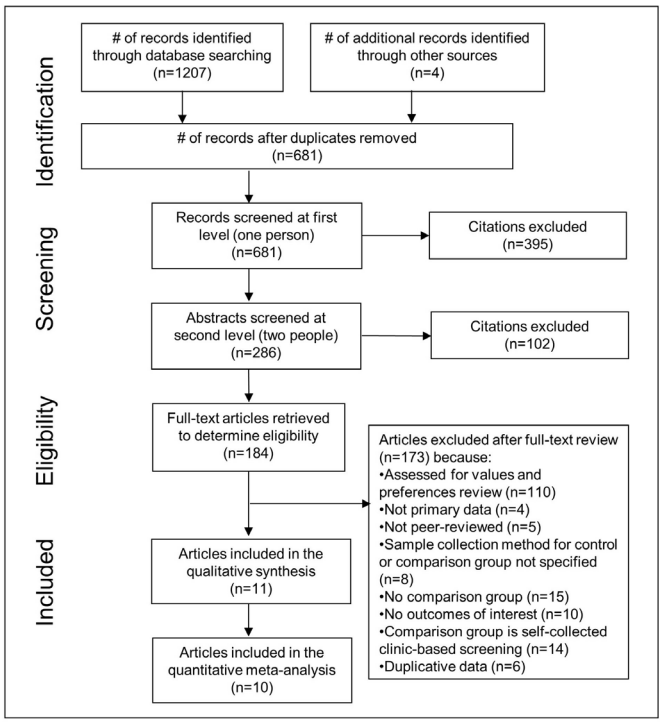

Figure 1 PRISMA flowchart of the study selection process.

Patient and public involvement

Patients and the public are currently involved in a global survey of values and preferences and in focus group discussions with vulnerable communities conducted to inform the WHO self-care guidelines and thus play a significant role in the overall recommendation outcome from this review.

RESULTS

Online database searching retrieved 1207 records and secondary searching 4 records; there were 681 unique citations after removing duplicates (figure 1). After initial screening of titles and abstracts, 286 citations remained for double-screening and 184 underwent full-text review. Total 173 articles were excluded after full-text review, 14 of which were excluded because they compared self-sampling delivery approaches (ie, self-sampling at home vs self-sampling in the clinic) rather than self-sampling vs a non-self-collected sampling approach. A total of 11 studies reported in 11 articles met the criteria for inclusion in the review,[41–51] 10 of which were included in meta-analyses.[41–46 48–51]

Study characteristics

All included studies—with 202 745 participants total—were conducted in high-income countries, with six in the USA,[41 43–46 51] three in Denmark[48–50] and two in Australia.[42 47] Years of publication ranged from 1998[48 50]

to 2018.[45] Three studies focused on NG and CT,[41 43 45] two studies on NG, CT and TV[42 46] and five studies on CT exclusively.[44 48–51] One study did not report which specific bacterial STIs were covered.[47] No studies compared findings for syphilis. Studies varied in location of self-collection (ie, clinic-based[41 45 47] vs home-based[42–44 46 48–51]) as well as target population (ie, general population,[44 51] MSM,[41 47] people living with HIV,[41 47] adolescents and young people,[43–47 50 51] detainees,[46] people who inject drugs,[42 47] sex workers[47] and partners of CT-positive patients[48 49]). Sample self-collection methods included first-void urine,[42 45 48–50] vaginal flush using saline[49 50] and pharyngeal,[41] rectal,[41 47] urethral[41] and vaginal[42–47 51] swabs. Table 1 presents descriptions of the included studies, and table 2 details their reported outcomes.

Five included studies were RCTs,[43 48–51] and the remaining six were observational studies (four serial cross-sectional[41 42 45 47] and two cross-sectional[44 46]). Risk of bias was deemed moderate in the RCTs. Regarding selection bias, one RCT randomly assigned participants 'according to date of birth'[48] and two did not specify the method of random sequence generation.[49 50] Due to the nature of the intervention, blinding was impossible and may have biased performance; four RCTs did not report whether the laboratory personnel conducting the STI testing were blinded.[48–51] The observational studies were judged to have high risk of bias. Four studies used serial cross-sectional surveys to compare before and after implementation of an intervention package which included self-collection of samples for STI testing.[41 42 45 47] None of the observational studies clearly controlled for confounders, though some stratified analyses by gender[45] or by clinic type.[47] Table 3 presents an assessment of study rigour.

For each of the main outcomes, results are presented below and summarised in table 4.

Uptake of STI testing services

All five RCTs[43 48–51] and three observational studies[41 45 47] reported some measure of uptake of STI testing services. Substantial heterogeneity was present in all meta-analyses of STI testing uptake.

Meta-analysis of the five RCTs found that participants were three times as likely to get tested for any STI when using self-collection of samples compared with clinician-collection (RR: 2.941, 95% CI 1.188 to 7.281, I-squared: 98.942) (figure 2).[43 48–51] Three of these RCTs took place in Denmark[48–50] and two in the USA;[43 51] two focused on partner screening,[48 49] two on young people[43 50] and one on rescreening.[51] Self-collected sampling methods evaluated by these RCTs included urine,[48–50] vaginal flush[49 50] and vaginal swab;[43 51] participants returned the self-collected specimen(s) for laboratory testing by mail, using a postage-paid, preaddressed envelope or carton.

When stratifying to RCTs testing solely for CT, meta-analysis of four studies found an even greater impact on STI testing uptake (RR: 3.567, 95% CI 1.096 to 11.608, I-squared: 98.982).[48–51] When stratifying to RCTs testing for multiple STIs, only one was identified: this RCT among young women in the USA found increased uptake with self-collection of samples for CT and NG testing (RR: 1.370, 95% CI 1.190 to 1.580).[43]

We also conducted meta-analysis stratified by gender (figure 3). Among male participants, we found a strong association between self-collection of samples and STI testing uptake (RR: 6.900, 95% CI 1.721 to 27.656, I-squared: 96.784).[48–50] Among female participants, the RR was lower but still strong (RR: 3.292, 95% CI 1.072 to 10.115, I-squared: 98.946).[43 49–51]

The observational studies showed similar findings. Meta-analysis of two observational studies testing for multiple STIs (CT and NG,[41] and NG and TV[42]) found a RR of 2.990, but this was not statistically significant (95% CI 0.426 to 20.978, I-squared: 95.333). When examining the uptake of CT testing specifically, one study found a positive association with self-collection (RR: 2.351, 95% CI 1.597 to 3.462).[42] A third observational study could not be combined in meta-analysis but found that after implementing an express clinic with self-collection of genital and rectal samples within a large sexual health clinic, 5335 patients were seen (combining both the express and main clinics) compared with 4804 patients seen through the prior routine STI triage and testing services.[47]

Case finding

Four RCTs[48–51] and five observational studies[41 42 44–46] reported comparisons of STI test positivity rate comparing participants who self-collected samples to those whose samples were collected by a clinician.

Meta-analysis of RCTs for case finding found effects in opposite directions, depending on which sensitivity analysis was used (figure 4). When the denominator was all study participants who were enrolled and randomly allocated to self-collection or clinician-collection (intention-to-treat), meta-analysis of the four RCTs measuring the proportion of people who tested positive for any STI found double the likelihood of receiving a positive test result among those who self-collected samples for STI testing, with significant heterogeneity (RR: 2.166, 95% CI 1.043 to 4.498, I-squared: 84.387).[48–51] However, when comparing self-collection to clinician-collection among only those who ultimately provided samples for STI testing, the association between proportion of positive tests and self-collection went in the opposite direction (RR: 0.718, 95% CI 0.585 to 0.882, I-squared: 0.000).[48–51] These four RCTs measured CT only.

The observational studies generally showed no difference in case finding between self-collection and clinician-collection groups, whether meta-analyses were performed using a denominator of the entire study population or a subgroup of only those who took up STI testing services, and regardless of which specific STI or combination of STIs were getting tested.[41 42 44–46]

Table 1 Description of included studies

Study	Location, population and STI(s) tested	Intervention	Study methods
Anderson *et al*, 1998[48]	Location: Aarhus, Denmark Population: Index patient CT-positive women attending general practice clinic; their male sexual partners received the intervention STI(s) tested: CT	*Intervention*: Index patients completed a questionnaire about numbers of sexual partners and contacted their partners to collect a first-void urine sample at home for CT testing. Then they returned the sample to laboratory in a prepaid envelope. *Control*: Index patients were given an envelope containing a contact slip and a request for their partner to visit his doctor for a urethral swab sample for CT testing (not reported if index patients completed the questionnaire about number of sexual partners). The doctor returned the sample to study laboratory in a prepaid envelope.	*Study design*: Randomised controlled trial *Sample size*: Total n=133 Intervention n=65 Control n=68
Barbee *et al*, 2016[41]	*Location*: Seattle, Washington, USA *Population*: MSM attending HIV care clinic who were asymptomatic for STIs *STI(s) tested*: CT, NG	*Intervention*: A new programme included clinic-based, unsupervised, self-initiated self-collection of pharyngeal, rectal and urethral samples by swab for CT and NG testing. *Comparison*: Provider or triage nurse would ensure patient was asymptomatic for STIs (and thus eligible for screening); clinician-collected pharyngeal and rectal swabs for CT and NG testing	*Study design*: Serial cross-sectional *Sample size*: Total n=3030 Intervention n=1520 Comparison n=1510
Bradshaw *et al*, 2005[42]	*Location*: Melbourne central business district, Australia *Population*: People who inject drugs, ages 17–45 years, attending a weekly outreach service of The Melbourne Sexual Health Centre who had not been recently screened for STIs *STI(s) tested*: CT, NG, TV	*Intervention*: Participants were approached on foot by research staff in known injecting and dealing locations and encouraged to accompany staff back to nearby clinic for STI testing. Participants self-collected vaginal swab (tampon) samples for CT, NG and TV (for women) or urine samples for CT and NG (for men or women who declined the swab method). *Comparison*: In the pilot programme, participants provided clinician-collected endocervical and vaginal samples for CT, NG and TV for women and clinician-collected urethral samples for CT and NG for men.	*Study design*: Serial cross-sectional *Sample size*: Total n=314 Intervention n=258 Comparison n=56
Cook *et al*, 2007[43] *Study name:* Detection Acceptability Intervention for STDs in Youth (DAISY) study	*Location*: Western Pennsylvania, USA *Population*: Sexually active young women, ages 15–24 years, including: (1) women recently diagnosed with CT, NG or TV, recruited from clinic and (2) women from same communities as clinics with less frequent use of health services, meeting at least three of the following five criteria: young age, black race, monthly douching,>1 sexual partner in the past year or living in a high-risk neighbourhood *STI(s) tested*: CT, NG	*Intervention*: Participants received a vaginal swab self-collection kit for CT and NG testing at home at 6, 12 and 18 months after enrolment (either mailed to address or picked up at clinic), which included a cover letter, instruction sheet, questionnaire, Dacron-tipped swab, prelabelled swab container and postage-paid mailing carton. *Control*: Participants received an invitation to attend an assigned clinic for a free, routine test for CT and NG via clinician-collected vaginal and cervical swabs.	*Study design*: Randomised controlled trial *Sample size*: Total n=420 Intervention n=211 Control n=209

Continued

Table 1 Continued

Study	Location, population and STI(s) tested	Intervention	Study methods
Gaydos *et al*, 2011[44]	*Location*: Baltimore City and the State of Maryland, USA *Population*: Females, ages 14+ years, median age: 23 (range: 14–63) *STI(s) tested*: CT	*Intervention*: An internet-based website (advertised on radio and free community magazines) was designed to promote CT home self-sampling (vaginal swab) among young women. For the first 2 years of the programme, participants were able to obtain self-sampling kits via community pickup locations as well as by mail; in the last 3 years of the programme, kits were mailed only. *Comparison*: Participants underwent CT screening in National Infertility Prevention Project family planning clinic, with clinician-collected cervical swab specimens.	*Study design*: Cross-sectional *Sample size*: Total n=169 531 Intervention n=1171 Comparison n=168 360
Habel *et al*, 2018[45]	*Location*: Pennsylvania State University, University Park campus (State College), Pennsylvania, USA *Population*: Males and female students, ages 18+years, attending Pennsylvania State University and using University Health Services *STI(s) tested*: CT, NG	*Intervention*: Participants used a CT and NG self-testing walk-in clinic service with self-collected vaginal swabs (for women) or urine samples (for men), which eliminated scheduling barriers and allowed for STI testing without seeing a clinician (but could consult a clinician if the student wanted). *Comparison*: Participants scheduled an STI testing appointment with a clinician. Clinician collected cervical specimens during the examination (for women); men were examined by a clinician and provided urine specimens for lab testing (urethral swabs not offered).	*Study design*: Serial cross-sectional *Sample size*: Total n=8110 Intervention n=4385 Comparison n=3725
Holland-Hall *et al*, 2002[46]	*Location*: Juvenile correctional facility, Allegheny County, Pennsylvania, USA *Population*: New female detainees, ages 12–17 years *STI(s) tested*: CT, NG, TV (TV-related outcome data not reported)	*Intervention*: Newly admitted girls to the juvenile detention centre were invited to self-collect samples and were provided with a self-sampling kit (containing a Dacron-tipped swab, PCR transport tube, cotton-tipped swab, empty sterile test tube and instructions for vaginal swab collection) to test for CT, NG and TV. *Comparison*: As standard of care for new detainees, physicians performed a pelvic examination and endocervical swab sampling for CT and NG testing and vaginal swab sampling for TV testing. (These participants also provided self-collected samples for the intervention group.)	*Study design*: Cross-sectional *Sample size*: Total n=133 Intervention n=133 Comparison n=25
Knight *et al*, 2013[47] *Study name:* Xpress	*Location*: Sydney, Australia *Population*: Patients attending Sydney Sexual Health who were asymptomatic for STIs and from a priority population (MSM, Aboriginal people, sex workers, people who use drugs, HIV-positive people and youth younger than 25 years). *STI(s) tested*: not specified, but bacterial STIs (likely CT, NG, TV)	*Intervention*: A fast-track STI testing service (Xpress) for drop-in clients was implemented in a large sexual health clinic, which included a computer-assisted self-interview for sexual history and risk assessment followed by a 15 min consultation with an enrolled nurse and self-collected genital and rectal swabs for STI testing (STIs not specified). *Comparison*: Participants underwent the routine triage system by an experienced sexual health registered nurse at the sexual health clinic and, if they met inclusion criteria, were allocated a 30 min consultation with a registered nurse which included a pen-and-paper sexual history and risk assessment, genital examination and clinician-collected genital and rectal specimens for STI testing.	*Study design*: Serial cross-sectional *Sample size*: Total n=10 139 Intervention n=5335 Comparison n=4804

Continued

Table 1 Continued

Study	Location, population and STI(s) tested	Intervention	Study methods
Ostergaard *et al*, 1998[50]	*Location*: Aarhus, Denmark *Population*: Male and female high school students, mean age: 18 (female), 18.2 (male) *STI(s) tested*: CT	*Intervention*: Students completed a questionnaire and received information regarding CT infection. Female students were asked to collect two urine samples and one vaginal flush sample using saline and males were asked to collect one first-void urine sample. Participants mailed samples from home to the laboratory. *Control*: Students completed a questionnaire and received information regarding CT infection; they were offered free STI testing from their doctor or at the local clinic.	*Study design*: Randomised controlled trial *Sample size*: Total n=8909 Intervention n=4336 Control n=4573
Ostergaard *et al*, 2003[49]	*Location*: Four counties in Denmark *Population*: Male and female index patients identified as CT-positive in routine lab testing at General Practitioner offices; sexual partners received intervention, mean age: 23.7 (control, female), 22.7 (intervention, female); 25.1 (control, male), 25.6 (intervention, male) *STI(s) tested*: CT	*Intervention*: Index patients gave or mailed a package of five specimen collection kits to their partners to be used over the next 12 months. The partners mailed the self-collected samples (first-void urine for male partners; vaginal pipette flush for female partners) to the laboratory for CT testing in postage-paid, preaddressed envelopes. *Control*: Partners of index patients needed to go to a medical office to obtain a sample for CT testing, using the provided specimen collection kit.	*Study design*: Randomised controlled trial *Sample size*: Total N=734 Intervention n=398 Control n=336
Xu *et al*, 2011[51]	*Location*: New Orleans, Louisiana; St Louis, Missouri and Jackson, Mississippi, USA *Population*: CT-positive women at STI or family planning clinics, ages 16+years, mean age: 22.4 (STI clinic, control), 22.5 (STI clinic, intervention), 21.8 (family planning clinic, control): 21.4 (family planning clinic, intervention) *STI(s) tested*: CT	*Intervention*: Participants were mailed (or could pick up from the clinic) a self-collection vaginal swab kit for CT testing; after self-collecting at home, they returned the sample in postage-paid, preaddressed envelopes. *Control*: Participants were given an appointment to return to STI or family planning clinics for rescreening for CT infection.	*Study design*: Randomised controlled trial *Sample size*: Total n=1292 Intervention n=639 Control n=653

CT, *Chlamydia trachomatis*; MSM, men who have sex with men; NG, *Neisseria gonorrhoeae*; STI, sexually transmitted infection; TV, *Trichomonas vaginalis*.

Table 2 Reported outcomes

Study	Outcome: Uptake of STI testing services	Outcome: Case finding
Anderson *et al*, 1998[48]	► The proportion of males who accepted and completed the at-home test was 68% (44/65), a higher proportion compared with males who visited their doctor with a proportion of 28% (19/68), (RR: 2.42, 95% CI 1.60 to 3.68).	► The proportion of males diagnosed positive for CT was 27% (12/44) for those who self-tested and 37% (7/19) for those who physician-tested (RR: 0.740).
Barbee *et al*, 2016[41]	► Any site NG/CT: 670/1520 at baseline, 770/1510 during intervention; 15.0% increase (p<0.001). ► Pharyngeal NG/CT: 444/1520 at baseline, 586/1510 during intervention; 32.0% increase (p<0.001). ► Rectal NG/CT: 390/1520 at baseline, 520/1510 during intervention; 33.3% increase (p<0.001). ► Urethral NG/CT: 510/1520 at baseline, 697/1510 during intervention; 36.7% increase (p<0.001). ► All three sites (pharyngeal, rectal, urethral) NG/CT: 243/1520 at baseline, 466/1510 during intervention; 91.8% increase (p<0.001). ► Absolute testing coverage: 39% tested at the pharynx, 34% at the rectum and 46% at the urethra. ► Complete testing (testing at all three sites) completed by 31% of participants	► Detected NG infections overall: 98/1794 at baseline, 147/2706 during intervention; 50% increase. ► Detected CT infections overall: 96/1794 at baseline, 141/2706 during intervention; 47% increase. ► Test positivity for pharyngeal NG increased by 22% from 6.4% to 7.8% (p=0.292) and for pharyngeal CT by 21% from 1.4% to 1.7% (p=0.639). ► Test positivity for rectal infections declined by 4% (p=0.836) for NG and 16% (p=0.239) for CT. ► Urethral chlamydia test positivity increased by 33% (p=0.076).
Bradshaw *et al*, 2005[42]	► Acceptance of genital examination and practitioner-collected sampling for NG/TV in the pilot study was low (5/56, 9%, 95% CI 3 to 19). If these individuals were then offered screening for CT only by urine collection, substantially more accepted testing (18/56, 32%; 95% CI 21 to 45; p<0.01). ► STI screening by self-collected sampling had a substantially greater level of acceptance among participants (195/258, 76%; 95% CI 70 to 81; p<0.001) compared with practitioner sampling.	► The overall prevalence of STIs in those who consented to screening for CT, NG and TV was 8% (95% CI 5 to 13). ► All STIs detected were from self-collected samples. – CT prevalence: self: 12/195 (6%); practitioner: 0/18. – TV prevalence: self: 3/195 (2%); practitioner: 0.5. – NG prevalence: self: 1/195 (1%); practitioner: 0/5.

Continued

Table 2 Continued

Study	Outcome: Uptake of STI testing services	Outcome: Case finding
Cook *et al*, 2007[43]	► The proportion of women who completed at least one asymptomatic (screening) STI test during the 2 years of follow-up was significantly greater among women in the intervention group (162/197 (82.2%) vs 117/191 (61.3%), p<0.001). ► The proportion of women who completed >2 asymptomatic STI tests was significantly greater among women in the intervention group (55.9% vs 37.2%, p<0.001). ► The number of CT and NG tests completed per year was significantly greater in women in the intervention group for all tests (1.94 vs 1.41 tests per woman-year, p<0.001; RR: 1.38 (95% CI 1.23 to 1.55)) and for asymptomatic tests (1.18 vs 0.75 tests per woman-year, p<0.001; RR: 1.57 (95% CI 1.34 to 1.83)). ► Women in the intervention group were over two times as likely to complete an STI test when asymptomatic or otherwise (RR: 2.12 (95% CI 1.70 to 2.66) vs RR: 1.18 (95% CI 1.03 to 1.35).	► No significant difference in the rate of incidence of STIs detected during follow-up in the intervention group compared with the control group (20.4 vs 24.1 infections per 100 woman-years, p=0.28). The results were similar when restricted to chlamydia only (17.6 vs 18.9 infections per 100 woman-years) or when restricted to gonorrhoea only (4.9 vs 7.9 infections per 100 woman-years).
Gaydos *et al*, 2011[44]	Not reported	► CT positivity was 10.3% (121/1156) for females mailing swabs obtained online; prevalence ranged from 3.3% to 5.5% (total 6947/168308) in testing performed at family planning clinics. ► CT positivity for internet age groups was much higher than those for family planning age groups: CT positivity for internet participants ranged from a low of 4.4% in Baltimore in 2005 to a high of 15.2% Baltimore in 2007. CT positivity in family planning clinics in Baltimore and Maryland ranged from a low of 3.3% in Baltimore in 2006 to a high of 5.5% in Baltimore in 2008. Compared with age-specific positivity proportions obtained for women attending family planning clinics for the City of Baltimore and the State of Maryland for 2004–2008, CT positivity was higher among internet female participants for all age categories; statistically significant differences between programmes for age groups younger than 25 years for Baltimore and <30 years for Maryland. ► Although trends were similar for earlier years, in 2007, differences in prevalence in Baltimore for internet-recruited samples for age 20–24 years, was 23.5%, compared with 5.4% in family planning, (p<0.001).

Continued

Table 2 Continued

Study	Outcome: Uptake of STI testing services	Outcome: Case finding
Habel *et al*, 2018[45]	► In 2013 55 male and 2711 female students used clinician testing for CT and NG. In 2015, after adding a self-testing option (and retaining clinician testing), 1303 male (28.5% increase) and 3082 female (13.7% increase) students tested for CT and NG. 18.9% of testers in 2015 opted for self-testing. ► 18.9% of testers opted for self-testing in 2015: 31.0% of male students and 13.6% of female students. ► Clinician testing from 2013 to 2015 declined by 11.3% for male students and declined by 1.8% for female students, despite overall increases in NG/CT testing.	► In 2013, 9.7% (98/1007) of male students and 5.0% (135/2700) of female students tested positive for CT/NG via clinician testing. Combined positive diagnoses over total tested before intervention: 103/823. ► In 2015, 1% (111/895) of male students and 4.8% (129/2656) of female students tested positive for CT/NG via clinician testing and 12.9% (52/402) of male students and 12.4% (51/412) of female students tested positive via self-testing. Combined positive diagnoses over total tested after intervention: 240/3562 ► In 2015, female students were more likely to test positive when electing to test via self-test vs a clinician test (χ^2(1, N=3068)=36.54, p<0.01). No such significant difference in testing type was observed for male students ($\chi^2 = \chi^2$(1, N=1297)=0.072, p=0.79).
Holland-Hall *et al*, 2002[46]	Not reported	► The prevalence of any STI (NG, CT, TV) was not significantly higher among those who had pelvic exams (5/25) than among those who underwent self-testing only (21/133) (p=0.173). – NG: self: 8/94; clinician: 2/25 – CT: self: 15/133; clinician: 4/25 – TV (culture): self: 12/133; clinician: 2/25 – TV (PCR): self: 11/94; clinician: 2/25 ► Only 30% of subjects with infections had pelvic examinations; therefore, 70% of girls with infections would have been missed in the absence of the self-testing option.
Knight *et al*, 2013[47]	► After implementing Xpress clinic (with self-collection of samples for STI testing), 5335 patients were seen (705 in Xpress clinic) compared with 4804 before. ► The ratio of total patients seen to clinical staff hours rostered after implementing Xpress was 1.49 (1.7 in the Xpress clinic and 1.4 in other clinics) compared with 1.52 before. (OR: 1.02; 95% CI 0.96 to 1.09; p<0.44) ► Total clinic capacity with Xpress was 8007 patients, compared with 6301 before. ► Utilisation rates were lower after implementing Xpress (67%), compared with 76% before (p<0.01).	Not reported.

Continued

Table 2 Continued

Study	Outcome: Uptake of STI testing services	Outcome: Case finding
Ostergaard *et al*, 1998[50]	► The proportion of females who completed the at home sampling was 67.9% (1254/2603), compared with females in the control group with a proportion of 19.1% (1097/2884) (RR: 3.54). ► The proportion of males who completed the at home sampling was 57.0% (590/1733), compared with males in the control group with a proportion of 30.4% (316/1689) (RR: 1.87).	► The proportion of females diagnosed positive for CT was 4.6% (43/1254) for those who did home sampling and 0.456% (5/1097) for those in the control group (RR: 7.52). ► The proportion of males diagnosed positive for CT was 1.86% (11/590) for those who did home sampling and 0.316% (1/316) for those in the control group (RR: 5.89). ► The proportion of eligible (sexually experienced) females diagnosed positive for CT was 4.63% (43/928) for those who did home sampling and 0.600% (5/833) for those in the control group (RR: 7.72). ► The proportion of eligible (sexually experienced) males diagnosed positive for CT was 2.49% (11/442) for those who did home sampling and 0.407% (1/246) for those in the control group (RR: 6.12).
Ostergaard *et al*, 2003[49]	► The proportion of females who were contacted and completed the at home sampling was 67.9% (38/56), compared with females who completed office testing with a proportion of 19.1% (9/47) (RR: 3.54). ► The proportion of males who were contacted and completed the at home sampling was 57.0% (195/342), compared with males who completed office testing with a proportion of 30.4% (88/289) (RR: 1.87).	► The proportion of females diagnosed positive for CT was 44.7% (17/38) for those who did home sampling and 55.6% (5/9) for those who did office testing (RR: 0.805). ► The proportion of males diagnosed positive for CT was 37.9% (74/195) for those who did home sampling and 51.1% (45/88) for those who office testing (RR: 0.742).
Xu *et al*, 2011[51]	► The proportion of women recruited from the STI clinic who were tested for CT was 26.7% (109/408) after 7 weeks and 31.4% (128/408) after 3 months for self-testing and 19.1% (77/403) after 7 weeks (RR: 1.40) and 25.1% (101/403) after 3 months for clinic testing (RR: 1.251). ► The proportion of women recruited from the family planning clinic who were tested for CT was 40.8% (80/196) after 7 weeks and 49% (96/196) after 3 months for self-testing and 20.7% (43/208) after 7 weeks (RR: 1.97) and 27.9% (58/208) after 3 months for clinic testing (RR: 1.756).	► The proportion of women recruited from the STI clinic who were diagnosed positive for CT was 13.9% (17/122) for self-testing and 19.4% (19/98) for clinic testing (RR: 0.719). ► The proportion of women recruited from the family planning clinic who were diagnosed positive for CT was 12.9% (12/93) for self-testing and 14.5% (8/55) for clinic testing (RR: 0.887).

CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*; RR, risk ratio; STI, sexually transmitted infection; TV, *Trichomonas vaginalis*.

Other outcomes

No studies compared the impact of self-collection of samples to clinician-collection of samples on the following outcomes: frequency of STI testing, social harms or adverse events, linkage to clinical assessment or STI treatment following a positive test result and reported sexual behaviour.

DISCUSSION

Despite a limited evidence base and considerable heterogeneity in meta-analyses, the existing literature suggests that using self-collection of samples for STI testing increases uptake of STI testing services, whether for testing of any STI, a combination of multiple STIs or CT alone. Meta-analysis also showed that self-collection

Table 3 Quality assessment of included studies

Cochrane Risk of Bias Tool (for randomised controlled trials (RCTs))

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data addressed (attrition bias)	Selective reporting (reporting bias)	Other bias
Andersen *et al*, 1998[48]	High*	Unclear†	High‡	Unclear§	High¶	Unclear**	High††
Cook *et al*, 2007[43]	Low	Low	High‡	Low	Unclear‡‡	Low	Unclear***
Ostergaard *et al*, 1998[50]	Unclear§§	Unclear†	High‡	Unclear§	High¶	Unclear**	Low
Ostergaard *et al*, 2003[49]	Unclear§§	Low	High‡	Unclear§	High¶	Unclear**	High††
Xu *et al*, 2011[51]	Low	Low	High‡	Unclear§	High¶	Low	Unclear¶¶

Evidence Project Risk of Bias Tool (for non-RCTs)

Study	Study design includes preintervention and postintervention data	Study design includes control or comparison group	Study design includes cohort	Comparison groups equivalent at baseline on sociodemographics	Comparison groups equivalent at baseline on outcome measures	Random assignment (group or Individual level) to the intervention	Participants randomly selected for assessment	Control for potential confounders	Follow-up rate >80%
Barbee *et al*, 2016[41]	Yes	No	No	Not applicable	Not applicable	Not applicable	No	Unclear***	Not applicable
Bradshaw *et al*, 2005[42]	Yes	No	No	Not applicable	Not applicable	Not applicable	No	Unclear***	Not applicable
Gaydos *et al*, 2011[44]	No	Yes	No	No	Unclear†††	No	No	Unclear***	Not applicable
Habel *et al*, 2018[45]	Yes	No	No	Not applicable	Not applicable	Not applicable	No	Unclear‡‡‡	Not applicable
Holland-Hall *et al*, 2002[46]	No	Yes	No	Not reported	Unclear†††	No	No	Unclear§§§	Not applicable
Knight *et al*, 2013[47]	Yes	No	No	Not applicable	Not applicable	Not applicable	No	Unclear¶¶¶	Not applicable

*Participants randomly divided into intervention and control 'according to date of birth'.
†No details on allocation concealment reported.
‡No blinding, and the outcomes are likely to be influenced by lack of blinding.
§No blinding, but no subjective outcomes were reported, and unknown if laboratory personnel or testing assessors were blinded.
¶Over 20% of participants were not tested, and the missing data were not balanced in the intervention and control groups.
**Study protocol not available from trial registries.
††Participants were sexual partners of CT-positive patients.
‡‡Number of completed tests at 6, 12 and 18 months not clearly reported; 58% and 56% missing data from the intervention and control group, respectively.
§§Details on random sequence generation method not reported.
¶¶STI management strategy included reminders; study aim was to evaluate retesting of CT-positive patients.
***Confounders not mentioned.
†††STI testing uptake history at baseline (at preintervention time point or in comparison group) not reported.
‡‡‡Stratified analysis by gender only; other confounders not mentioned.
§§§Sexual experience mentioned but not controlled for; other confounders not mentioned.
¶¶¶Stratified analysis by clinic type only; other confounders not mentioned.
****Both intervention and the control groups had access to usual care if symptomatic.

Table 4 Summary of effect sizes and meta-analyses

Outcome	Study type	Number of effect sizes	RR[1]	95% CI	P value for RR	Q value	P value for Q statistic	I^2
Uptake of STI testing services								
Any STI	RCT	5	2.941	1.188 to 7.281	0.020	378.005	0.000	98.942
Multiple STIs (CT and NG)	RCT	1	1.370	1.190 to 1.580	–	–	–	–
CT only	RCT	4	3.567	1.096 to 11.608	0.035	294.647	0.000	98.982
Any STI—females only	RCT	4	3.292	1.072 to 10.115	0.037	284.542	0.000	98.946
Any STI—males only	RCT	3	6.900	1.721 to 27.656	0.006	62.182	0.000	96.784
CT only—males only	RCT	3	6.900	1.721 to 27.656	0.006	62.182	0.000	96.784
Multiple STIs (CT and NG; NG and TV)	Obs	2	2.990	0.426 to 20.978	0.271	21.427	0.000	95.333
CT only	Obs	1	2.351	1.597 to 3.462	–	–	–	–
Case finding (proportion of positive test results)								
Sensitivity analysis: denominator: those randomised/enrolled (intention to-treat)								
CT only	RCT	4	2.166	1.043 to 4.498	0.038	19.214	0.000	84.387
Any STIs (CT, NG and TV)	Obs	1	1.122	0.449 to 2.802	–	–	–	–
CT only	Obs	2	1.396	0.372 to 5.237	0.621	1.237	0.266	19.168
NG only	Obs	2	0.978	0.249 to 3.835	0.974	0.071	0.789	0.000
TV (PCR) only	Obs	2	1.590	0.43 to 5.878	0.487	0.001	0.981	0.000
TV (culture) only	Obs	1	1.469	0.338 to 6.38	–	–	–	–
Sensitivity analysis: denominator: those who collected samples for STI testing (subgroup)								
CT only	RCT	4	0.718	0.585 to 0.882	0.002	1.343	0.719	0.000
Multiple STIs (CT and NG; NG and TV)	Obs	2	1.378	0.582 to 3.264	0.466	3.886	0.049	74.269
CT only	Obs	4	1.354	0.622 to 2.947	0.445	41.531	0.000	92.776
NG only	Obs	3	0.939	0.558 to 1.577	0.811	2.272	0.321	11.956
TV (PCR) only	Obs	2	0.791	0.208 to 3.004	0.730	1.041	0.308	3.926
TV (culture) only	Obs	1	1.463	0.346 to 6.178	–	–	–	–

CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*; RR, risk ratio (pooled risk ratio if number of effect sizes>1); STI, sexually transmitted infection; TV, *Trichomonas vaginalis*.

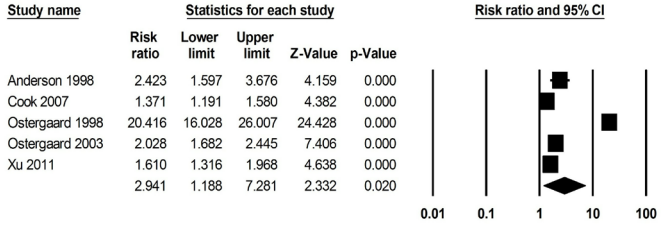

Figure 2 Meta-analysis of RCTs: uptake of STI testing services for any STI. RCTs, randomised controlled trials; STI, sexually transmitted infection.

of samples had a greater impact on uptake among men than women, though it was positively associated with uptake among both. Meta-analysis also found increased case finding with self-collection of samples when examined among all participants, though it decreased among those who self-collected samples if analysing only those who accepted STI testing services. The evidence base generally supports self-collection of samples as an additional approach to deliver STI testing services.

We identified only a small number of articles that met the inclusion criteria, limiting the evidence base from

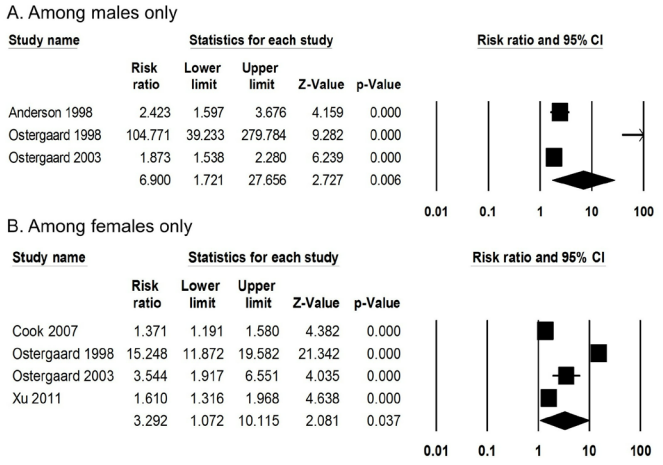

Figure 3 Meta-analysis of RCTs: uptake of STI testing services for any STI, stratified by gender. RCTs, randomised controlled trials; STI, sexually transmitted infection.

which we could draw conclusions. Included studies presented comparative data for CT, NG and TV, but not for syphilis. This is not surprising, given the early stage of developing rapid tests for syphilis and the difficulty of collecting whole blood. The number and type of outcomes were also limited; no studies compared the effect of self-collection of samples to clinician-collection on frequency of STI testing, adverse events, linkage to care or sexual risk behaviour. The included studies varied in their target populations, delivery strategies and STIs of interest, making cross-study comparisons difficult. Finally, no studies were conducted in LMICs. STIs are a global epidemic, and more data are needed on self-collection of samples for STI testing in resource-limited settings.

Strengths of this review include the inclusion of both randomised and non-randomised studies and inclusion of studies in any location or language. While we searched multiple online databases and used several additional approaches to identify relevant articles, it is always possible that our search strategy missed some articles. We also relied on peer-reviewed journal articles, which while ensuring a minimal level of quality, may also be subject to publication bias.

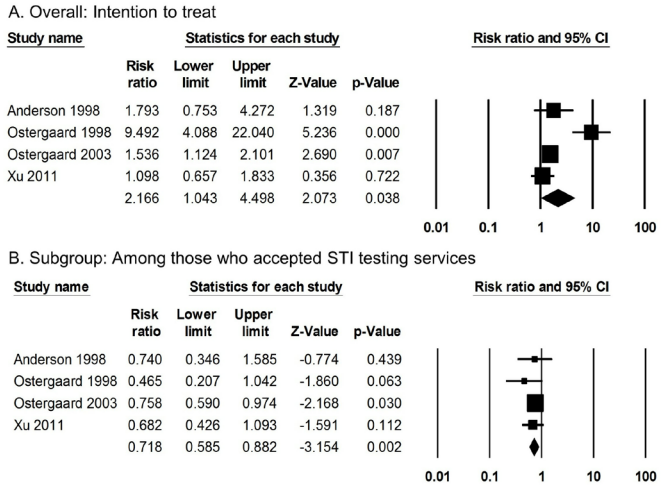

Figure 4 Meta-analysis of RCTs: case finding for any STI. RCTs, randomised controlled trials; STI, sexually transmitted infection.

This review expands on previous reviews, which have assessed accuracy, feasibility and acceptability of self-collection of samples for STI testing and have compared sample (self-) collection in clinical and non-clinical settings.[19 28 31] Our findings that self-collection of samples is associated with increased uptake of testing are comparable with other reviews, which found that home-based sampling is associated with greater uptake compared with clinic-based sampling.[19 28 31] Together, these reviews and ours generally support the idea of self-collection as an approach to facilitate STI testing uptake among diverse populations.

Similar to a Cochrane review of home-based versus clinic-based sample collection for chlamydia and gonorrhoea testing,[28] we found that, among participants who collected samples for STI testing, self-collection of samples was associated with a lower proportion of positive results, though when we expanded the denominator to all enrolled and randomised study participants, case finding increased among self-collectors. It is possible that people who perceived themselves as having lower risk of STIs were more willing to test for STIs when given the option to self-collect samples than if they were asked to come to a clinic for a provider to collect samples for STI testing. Conversely, individuals experiencing symptoms or who believed themselves at higher risk of STIs might have had additional motivation to use clinic-based STI testing services, possibly due to the care and support offered by a conventional STI clinic or the perceived accuracy and trust of a clinician-performed exam. A systematic review of patients' values and preferences around sample self-collection suggests that accuracy and trust in test results is a concern in some populations.[21] Thus, for programmatic purposes, self-collection of samples may both increase STI testing uptake and the number of positive diagnoses, though the proportion of case finding among those who actually self-collected samples for STI testing may be comparatively less than those who had samples collected by a clinician.

The STI burden in many countries has not been adequately addressed, particularly in the face of institutional and funding capacities focused on prevention and treatment of HIV.[52 53] Self-collection of samples for STI testing—already the standard in most high-income settings and well-accepted by a variety of end-users and providers—has the potential to increase uptake of testing services, thus reaching individuals at higher risk of STIs, in particular, those who may be unwilling to provide samples in the traditional manner by healthcare providers.[18] If both uptake and case finding increase, expansion of STI services through sample self-collection may be cost-effective, though more research on this is warranted. Several studies have suggested that

internet-based screening or other models using self-collection of samples for STI testing may be cost-effective compared with clinician-collected samples.[27 54] Self-collection as an additional approach to STI testing and diagnosis supports the WHO global health sector strategy on STIs, which emphasises the need for identifying targeted accessible interventions, which ensure that people use the quality health services they need without suffering financial hardship or stigmatisation.[53] Promoting self-collection of samples as an additional approach for STI testing service delivery could contribute to the achievement of the United Nations Sustainable Development Goals, including universal health coverage and integrated services for sexual and reproductive health, which requires achieving early diagnosis of STIs and linkage to effective treatment.[55]

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Competing interests All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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