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Self-sampling strategies (with/without digital innovations) in populations at risk of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: a systematic review and meta-analyses

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ABSTRACT

Background *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) resulted in over 200 million new sexually transmitted infections last year. Self-sampling strategies alone or combined with digital innovations (ie, online, mobile or computing technologies supporting self-sampling) could improve screening methods. Evidence on all outcomes has not yet been synthesised, so we conducted a systematic review and meta-analysis to address this limitation.

Methods We searched three databases (period: 1 January 2000–6 January 2023) for reports on self-sampling for CT/GC testing. Outcomes considered for inclusion were: accuracy, feasibility, patient-centred and impact (ie, changes in linkage to care, first-time testers, uptake, turnaround time or referrals attributable to self-sampling).

We used bivariate regression models to meta-analyse accuracy measures from self-sampled CT/GC tests and obtain pooled sensitivity/specificity estimates. We assessed quality with Cochrane Risk of Bias Tool-2, Newcastle–Ottawa Scale and Quality Assessment of Diagnostic Accuracy Studies-2 tool.

Results We summarised results from 45 studies reporting self-sampling alone (73.3%; 33 of 45) or combined with digital innovations (26.7%; 12 of 45) conducted in 10 high-income (HICs; n=34) and 8 low/middle-income countries (LMICs; n=11). 95.6% (43 of 45) were observational, while 4.4% (2 of 45) were randomised clinical trials.

We noted that pooled sensitivity (n=13) for CT/GC was higher in extragenital self-sampling (>91.6% (86.0%–95.1%)) than in vaginal self-sampling (79.6% (62.1%–90.3%)), while pooled specificity remained high (>99.0% (98.2%–99.5%)).

Participants found self-sampling highly acceptable (80.0%–100.0%; n=24), but preference varied (23.1%–83.0%; n=16).

Self-sampling reached 51.0%–70.0% (n=3) of first-time testers and resulted in 89.0%–100.0% (n=3) linkages to care. Digital innovations led to 65.0%–92% engagement and 43.8%–57.1% kit return rates (n=3).

Quality of studies varied.

Discussion Self-sampling had mixed sensitivity, reached first-time testers and was accepted with high linkages to care. We recommend self-sampling for CT/GC in HICs but additional evaluations in LMICs. Digital innovations impacted engagement and may reduce disease burden in hard-to-reach populations.

PROSPERO registration number CRD42021262950.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Self-sampling strategies combined with digital support (eg, website-based, text message-based, video-based instructions and/or result communication) have been shown to increase linkage to care, partner referrals and first-time tester proportions in the HIV field.

⇒ In the context of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infections, genital self-sampling followed by nucleic acid amplification tests (NAATs) has been shown to have similar accuracies as conventional testing (ie, sampling by health professionals).

WHAT THIS STUDY ADDS

⇒ Self-sampling strategies followed by NAAT have comparable diagnostic accuracy as conventional testing for extragenital (ie, rectal and pharyngeal) sampling in cis-women and men who have sex with men for both CT and GC in high-income countries. We found vaginal self-sampling for women of low-income countries to have lower accuracy, prompting the need for more research on the experience of these populations.

⇒ Self-sampling strategies reached first-time testers, were accepted/preferred, led to high linkages to care and increased engagement when combined with digital innovations.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our review offers evidence of strengths and limitations of self-sampling strategies in diverse populations and income settings, which will be useful for policymakers when implementing screening strategies that can be customised to key populations.

INTRODUCTION

Rationale

According to the WHO, global annual incidence of common sexually transmitted infections (STIs), *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC), is 128 million and 82 million cases, respectively.[1] CT/GC infections can have profound

impacts on physical, social and psychological health of key populations such as men who have sex with men (MSM), sex workers, people who use injection drugs and pregnant women.[1] Untreated infections can cause infertility, pregnancy defects and pelvic inflammatory diseases or increase the risk of acquiring HIV.[1] In addition, antimicrobial resistance is a concern with GC, compromising infection control efforts.[1]

To remain on track with WHO STI elimination targets for 2030 and to address disruptions in STI screening services due to the COVID-19 pandemic, our healthcare systems require an increased use of contactless, affordable, rapid, reliable, point-of-care test (POCT)-based self-sampling (SS) and/or self-testing (ST) technologies.[1] SS-based STI testing can be conducted independently by participants in a clinic setting, at home or in other dedicated locations.[2] SS requires that participants receive their results from healthcare workers, while ST enables them to obtain their results directly.[3] SS has multiple advantages including ensuring confidentiality and convenience of key populations who struggle with lack of access to conventional testing.[2] SS can be combined with digital health innovations to engage these populations.

Digital health innovations are defined by the WHO as online-based, mobile-based or computing technologies that support health interventions.[1 4] Currently, digital innovations (eg, apps, websites, messenger-based assistants) are in development for ST/SS POCT.[5] Evidence from HIV ST indicates that these tools may offer advantages of increased linkage to care, proportion of first-time testers and partner referrals.[6] Disseminating best practices and adoption of evidence-based digital health interventions are two WHO strategies for STI-endemic countries.[1 4] To date, very few studies have compared conventional testing for CT/GC with SS-based testing coupled with digital innovations, justifying the rationale for this review. Furthermore, little is known about the effect of digital innovations on SS performance in populations of varying health and digital literacy across diverse income settings.

A systematic review reported higher accuracy of nucleic acid amplification tests (NAATs) for CT detection compared with antigen-based tests but failed to evaluate SS.[7] A systematic review by Lunny *et al*, published 8 years ago, reported comparable accuracy of self-obtained samples with clinician-obtained samples (n=6100 paired samples).[8] However, extragenital (ie, rectal and pharyngeal) sampling sites, which are more crucial for MSM, were excluded from their meta-analysis.[8] To date, no systematic review has evaluated evidence beyond accuracy such as patient-reported or implementation research outcomes (ie, acceptability/preference, feasibility and impact). To address these limitations and to generate evidence for guideline and product development, we conducted this review.

Objectives

From global data on observational and randomised clinical trial (RCT) studies, we aimed to determine whether SS for CT/GC with or without a digital innovation was accurate, feasible, and impacted patient-reported or implementation research outcomes, compared with conventional testing.

MATERIALS AND METHODS

Search strategy

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for reporting, Cochrane guidelines for conducting the review (online supplemental document 1) and registered the protocol with PROSPERO (registration number: CRD42021262950).

For the period of 1 January 2000–6 January 2023, four reviewers (MM, AdW, FV, AA) searched three electronic databases (PubMed, Embase and LILACS; search string described in online supplemental document 2) without language restrictions and retrieved full-text studies or conference abstracts. Two authors (AA, FV) independently performed a double screening of all publications (figure 1).

Eligibility criteria

We included publications on SS quantitative accuracy, feasibility, patient-centred and impact outcomes for CT/GC testing with or without digital health interventions.

We excluded editorials, commentaries, reviews, case reports, qualitative, narrative and modelling studies, those in non-English/Spanish language or without SS-specific, CT/GC-specific outcomes.

Data abstraction

Two reviewers (FV, AA) independently abstracted final data from 45 studies. A senior reviewer (NPP) verified data abstraction and resolved disagreements.

Abstracted data included: study design, study location, sample size, study population, digital innovation type, socioeconomic setting, outcome measures and associated metrics.

For diagnostic accuracy, we abstracted 2×2 table values when available and contacted authors for additional data. We narratively synthesised all other outcomes (ie, acceptability, preference, feasibility and impact).

Summary outcome measures and narrative synthesis of results

Table 1 describes abstracted CT/GC outcome measures. We defined digital innovations as assisting with either (1) test procurement via websites or social media; (2) SS conduct via mobile application or online material; and/or (3) communication of results and treatment steps via text messages or online portals.

Data analysis

All statistical analyses were performed in R (V.4.1.2 or later).[9] We abstracted true positive, false positive (FP), false negative (FN) and true negative data for CT/GC SS (index test) versus clinician sampling (reference test). We generated sensitivity and specificity forest plots using the Mantel-Haenszel method within the meta package.[10] We assessed heterogeneity using I^2 as indicator and excluded categories with less than three studies.

We performed random-effects bivariate regression models.[11] We obtained summary values with 95% CIs using the restricted maximum likelihood method within the bivariate-based mada package and generated summary receiver operating characteristic (SROC) curves pooled by pathogen, sampling site and study populations.[12] SROC curves represent summary plots of sensitivity and specificity, with 95% joint intervals in two-dimensional space using diagnostic OR as the outcome to determine overall accuracy.[11] We assessed publication bias using funnel plots and Egger's test.[10]

Sensitivity analysis

We compared test accuracy in low/middle-income (LMICs) to high-income countries (HICs) and performed sensitivity analyses by removing poor-quality studies.

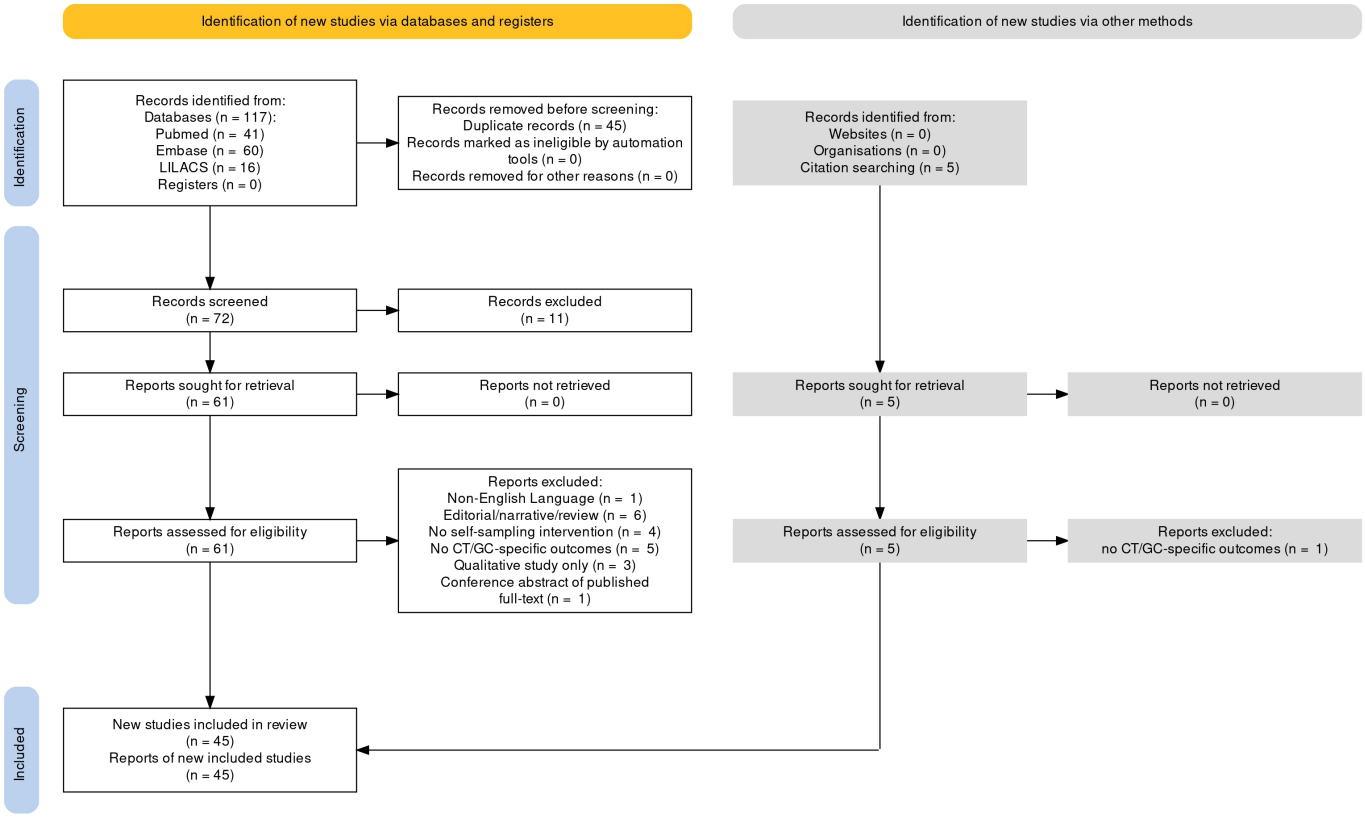

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow chart of included studies. CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*.

Quality assessment

Two independent reviewers (FV and AA) performed quality assessment. We used Cochrane Risk of Bias Tool-2, Newcastle–Ottawa Scale (NOS) and Quality Assessment of Diagnostic Accuracy Studies-2 for RCTs, cohort/cross-sectional studies and diagnostic accuracy studies, respectively.[13–15] A senior reviewer (NPP) was consulted.

RESULTS

Study selection

Of 122 initial records, 45 studies were included in our synthesis (figure 1). Characteristics and key findings of included studies are summarised in online supplemental tables 1 and 2.

Table 1 Outcome descriptions for study inclusion and synthesis

Outcome	Definition
Accuracy	Sensitivity and specificity of index self-sampling as compared with laboratory-confirmed reference standards.[65 66]
Preference	Patient preference for an SS option over clinician-based sampling, documented as a proportion over the total number of participants who were offered testing.[62]
Feasibility	Feasibility of SS strategies for CT/GC testing, measured by completion rate, test return rate, patient ability to interpret results and reasons for not returning the test.[62]
Impact	Net change from baseline in a particular group attributable to an SS strategy for the following metrics: (1) linkage to care; (2) number of first-time testers who used the SS option; (3) partner referrals; (4) turnaround time (TAT) to test results; (5) detection of new CT/GC cases; and (6) test uptake from baseline.[62] Metrics were reported as proportions with CIs. TAT was reported as median time with ranges.

CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*; SS, self-sampling.

Study characteristics

Studies were conducted in 18 countries (figure 2A).

Of these countries, 10 were HICs (75.6%; 34 of 45) and 8 were LMICs (24.4%; 11 of 45).

All studies, except two RCTs, were observational (ie, cross-sectional (80.0%; 36 of 45), cohort (15.6%; 7 of 45)). Of these, 16 were diagnostic accuracy studies (37.2%).

Sample sizes varied from 23 to 5061 participants (median=480 participants).

Most studies evaluated the use of SS for CT/GC screening in clinic settings (57.8%; 26 of 45). Fifteen (33.3%) and four (8.9%) studies evaluated SS at home and in outreach sites (ie, sauna, community centres or university), respectively.

Studies were focused on women (24.4%; 11 of 45) and MSM (20.0%; 9 of 45). Few studies were focused on men (4.4%; 2 of 45). Key populations included were transwomen (2.2%; 1 of 45), women having sex with women and men (2.2%; 1 of 45), juvenile correctional facility detainees (2.2%; 1 of 45), female sex workers (FSWs; 4.4%; 2 of 45) and people living with HIV (PLWHIV; 4.4%; 2 of 45). Other groups studied were male clients of FSWs (2.2%; 1 of 45), high school students (2.2%; 1 of 45), university students (2.2%; 1 of 45), emergency department attendees (2.2%; 1 of 45), HIV-negative people (4.4%; 45), attendees of a youth clinic (2.2%; 1 of 45) and employees of a private industry (2.2%; 1 of 45). Figure 2B shows classification of demographics.

CT/GC SS and digital innovations

Of all studies, 26.7% (12 of 45) integrated digital innovations (figure 2C).[16–27] These included six with websites to obtain SS kits and/or information on test conduct, combined with notification

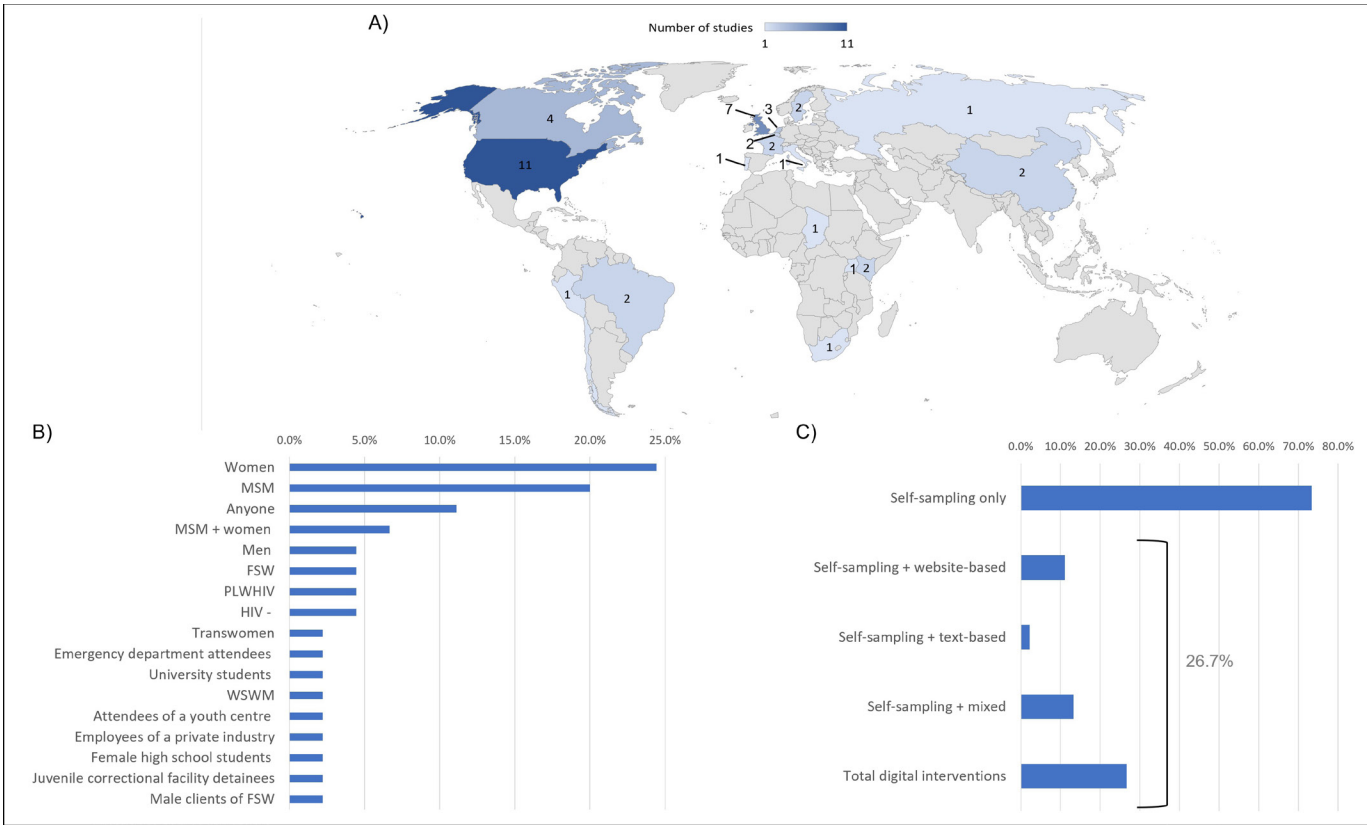

Figure 2 Geographical map, demographics and testing types described in included studies (n=45). (A) Heatmap of countries and percentages of (B) populations and (C) self-sampling strategies with or without a digital health component. FSW, female sex worker; MSM, men who have sex with men; PLWHIV, people living with HIV; WSWM, women having sex with women and men.

of results via text (13.3%),[17 18 20 24 25 27] five website-based only (11.1%)[16 19 22 23 26] and one text-based only (2.2%) strategies.[21]

Accuracy of SS: meta-analysis

Eighty per cent of studies (36 of 45) detected newly diagnosed positive CT/GC infections and 42.2% of studies (19 of 45) measured test accuracy.[16 17 20 22–55] Seventeen studies reported 2×2 table values.[22 28 30–33 35 36 38–43 51–53] We excluded four studies where reference test was unclear/not reported.[22 31–33]

See online supplemental table 3 for case positivity, sensitivity and specificity for CT/GC SS tests.

We generated pooled diagnostic accuracy values (table 2) and SROC curves (figure 3) by sampling site and study population for CT/GC from 13 studies.[28 30 32 35 38–43 51]

Bivariate regression results revealed overall high specificity and sensitivity for CT and GC with no statistically significant difference between pathogens across included studies (table 2).

Table 2 Sensitivity, specificity and DOR of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* self-sampling-based tests with associated 95% CIs, I^2 metric and p values

		Sensitivity (95% CIs)	P value	Specificity (95% CI)	P value	DOR (95% CI)	I^2
C. trachomatis	Overall	88.2 (81.9–92.6)	Ref	99.3 (98.9–99.5)	Ref	1110 (472–2220)	87.6
Sampling site	Vaginal	79.6 (62.1–90.3)	Ref	99.0 (98.2–99.5)	Ref	479 (124–1290)	84.2
	Pharyngeal	92.5 (86.5–95.9)	0.20	99.7 (99.5–99.8)	**0.02**	4550 (1710–9880)	0.0
	Rectal	93.1 (87.8–96.2)	**0.01**	99.4 (98.8–99.7)	0.25	2490 (638–6770)	79.0
Study population	Women	85.0 (73.5–92.1)	0.30	99.3 (98.7–99.6)	0.74	895 (262–2260)	87.1
	MSM	91.6 (84.9–95.5)	Ref	99.2 (98.8–99.4)	Ref	1390 (551–2940)	21.0
N. gonorrhoeae	Overall	88.9 (84.2–92.3)	0.79	99.1 (98.6–99.4)	0.38	937 (459–1710)	78.3
Sampling site	Vaginal	79.9 (68.6–87.9)	Ref	99.1 (98.4–99.5)	Ref	502 (182–1120)	70.8
	Pharyngeal	94.3 (89.6–96.9)	**0.003**	99.3 (97.1–99.8)	0.99	3370 (422–12 600)	70.8
	Rectal	91.6 (86.0–95.1)	**0.01**	99.2 (98.4–99.6)	0.88	1620 (426–4340)	63.8
Study population	Women	83.5 (74.1–89.9)	**0.026**	99.3 (98.8–99.6)	**0.033**	838 (298–1890)	73.6
	MSM	92.9 (88.1–95.9)	Ref	97.7 (96.9–98.3)	Ref	573 (307–980)	46.2

Significant values are bolded.
DOR, diagnostic OR; MSM, men who have sex with men.

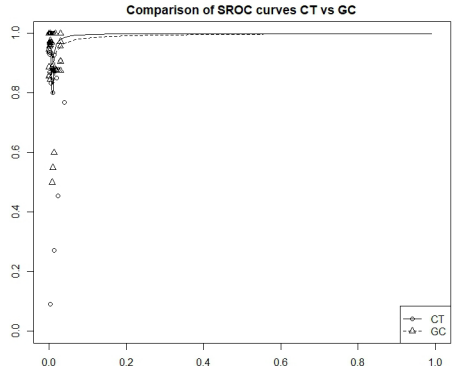

Figure 3 Summary receiver operating characteristic (SROC) curves for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) (n=13).

However, we found statistically significant differences in specificity and sensitivity by sampling site and populations (table 2).

For CT, sensitivity estimates (with 95% CI) were 93.1 (87.8–96.1) for rectal to 79.6 (62.1–90.3) for vaginal samples; while specificity remained high: 99.7 (99.5–99.8) for pharyngeal to 99.0 (98.2–99.5) for vaginal samples.

For GC, sensitivity estimates (with 95% CI) were 94.3 (89.6–96.9) for pharyngeal to 79.9 (68.6–87.9) for vaginal samples, with no differences in specificity.

In women compared with MSM, we also found a statistically significant lower sensitivity (83.5 (74.1–89.9) vs 92.9 (88.1–95.9)) but higher specificity (99.3 (98.8–99.6) vs 97.7 (96.9–98.3)).

We excluded a single study with SS urine compared with pooled clinician-collected pharyngeal and rectal samples from the regression analysis, with sensitivity of 30.0% (16.0%–47.0%) for CT and 33.0% (21.0%–48.0%) for GC, because we could not generate a pooled estimate for this different type of sampling.[40]

The funnel plot coefficient slope was −1.30 with a p value of 0.39, indicating low publication bias (online supplemental figure 1).

SS without digital innovations

Acceptability for SS was high (80.0%–100.0%; n=21).[28 30 32–35 41 42 44–46 49–52 55–60] Participants found SS easy (n=14) and comfortable (ie, painless; n=9), and would recommend it to others (n=3).[28 30 33 35 41 44–46 49 51 52 57–60] Only one study in MSM from China reported a lower acceptability for rectal SS (43.6%; 133 of 306) but 100% acceptability for urine SS (306 of 306).[55]

Preference for SS over clinician sampling ranged from 23.1% (823 of 3082) to 83.7% (429 of 512) (n=13).[28 30 32 34 42–44 49 51 52 58–60] High trust in accuracy and privacy were cited as reasons for preferring SS (n=3).[44 51 60]

Feasibility was evaluated in 10 studies.[33–35 42 44 51 52 55 57 60] SS completion rate was high (83.8% (341 of 363)–99.0% (346 of 350); n=5).[35 42 44 55 57] Reasons for refusing or choosing SS were documented in four other studies.[51 52 59 60] Participants in a European study were willing to pay between €10 and €20 for at-home SS.[33]

Impact was measured in five studies.[34 44 49 50 55] In two studies, all positive participants (100.0%) from the UK (5 of 5) and Uganda (14 of 14) were linked to care.[44 50] Partner referrals were higher in China (91.7%; 278 of 303) than Uganda (58.8%; 10 of 14).[44 55] SS reached 46.7% (14 of 30), 51.0% (116 of 228) and 70.0% (19 of 27) of first-time testers in PLWHIV from Uganda, university students and juvenile correctional facility detainees from the USA, respectively.[34 44 49]

SS with digital innovations

Due to heterogeneity in reported metrics and limited number of studies (n=12), we were unable to provide ranges for reported outcomes.

Acceptability of SS with digital innovations (website based only or mixed with text reminders) was reported by participants rating the intervention as: acceptable (93.0%; 1660 of 1785), very satisfactory (95.5%; 407 of 426) or easy to use (89.0%; 336 of 396) in three studies.[16 18 19]

Preference for SS and digital innovation was reported by 54.3% (969 of 1785) of participants who indicated they would still test for CT/GC if at-home SS was not available to them, but would do so less often in one study.[19] In two other studies, 51.5% (103 of 200) and 77.0% (307 of 399) of participants preferred this strategy over clinician-based in-hospital testing.[16 24]

Feasibility of these strategies was reported in six studies.[17–19 21 23 25] Text-based reminders increased kit return (43.8% (28 of 64)–57.1% (16 of 28) in MSM) and engagement in repeat testing (65.0%; 278 of 427 in women).[18 21 23] Website-based questionnaires maintained high completion rates (66.5%, 69 of 105 and 92%, 134 of 146; n=2), showing that online-based digital tools can engage individuals with CT/GC testing.[17 23] One study reported that all returned SS kits were correctly used by participants.[21] Reasons for not accepting SS were: not sexually active, no perceived risk or recently tested for STIs.[21] Cost was also associated with unwillingness to pay for home-based testing (37.0%; 660 of 1785) in one study and led to a lower completion rate (75.0%; 531 of 708) in another.[18 19] In one study with online-based ordering, kit return was 56.8% (1948 of 3428)[25]

Impact of SS with digital innovations was reported in five studies.[17 20 21 23 24] SS was successful in detecting 36.8% (14 of 38) and 17.9% (5 of 28) of new infections and detecting 33.1 CT cases per 100 person-years (51/154.29 years) and 29.9 GC cases per 100 person-years (48/160.77 years).[20 21 24] Test uptake was high (85.3%; 110 of 129) in one study offering SS kits via text messaging.[21] In one UK study, 89.0% (93 of 105) of positive participants were linked to care, with 57.0% (60 of 105) accessing their results, consultation and treatment remotely through the website.[17] Turnaround time to treatment was same day to 24 days (median of 1 day; IQR 0–4).[17] In the same study, out of 105, 13 partners were notified and 9 received treatment.[17]

Quality

Overall, most (91.7%; 22 of 24) cross-sectional studies (figure 4A) selected a representative sample and assessed exposure correctly but rated poorly in description of non-respondents (unclear for 54.2%; 13 of 24). Cohort studies (figure 4B) had good representativeness (100%; 4 of 4), acceptable comparability between cohorts (75.0%; 3 of 4) and scored poorly on remaining NOS criteria. We assessed one RCT that had low risk of bias for all criteria but performance and detection. Accuracy studies (figure 4C) had low risk for most bias (10–16 of 16; 62.5%–100.0%), except in inclusion criteria (6 of 16; 37.5%). In 62.5% of studies, it was unclear whether results from reference standards and index tests were interpreted without knowledge of one another (10 of 16). Overall, quality of included studies varied with studies rating poorly in selection but highly in comparability criteria when the information was available.

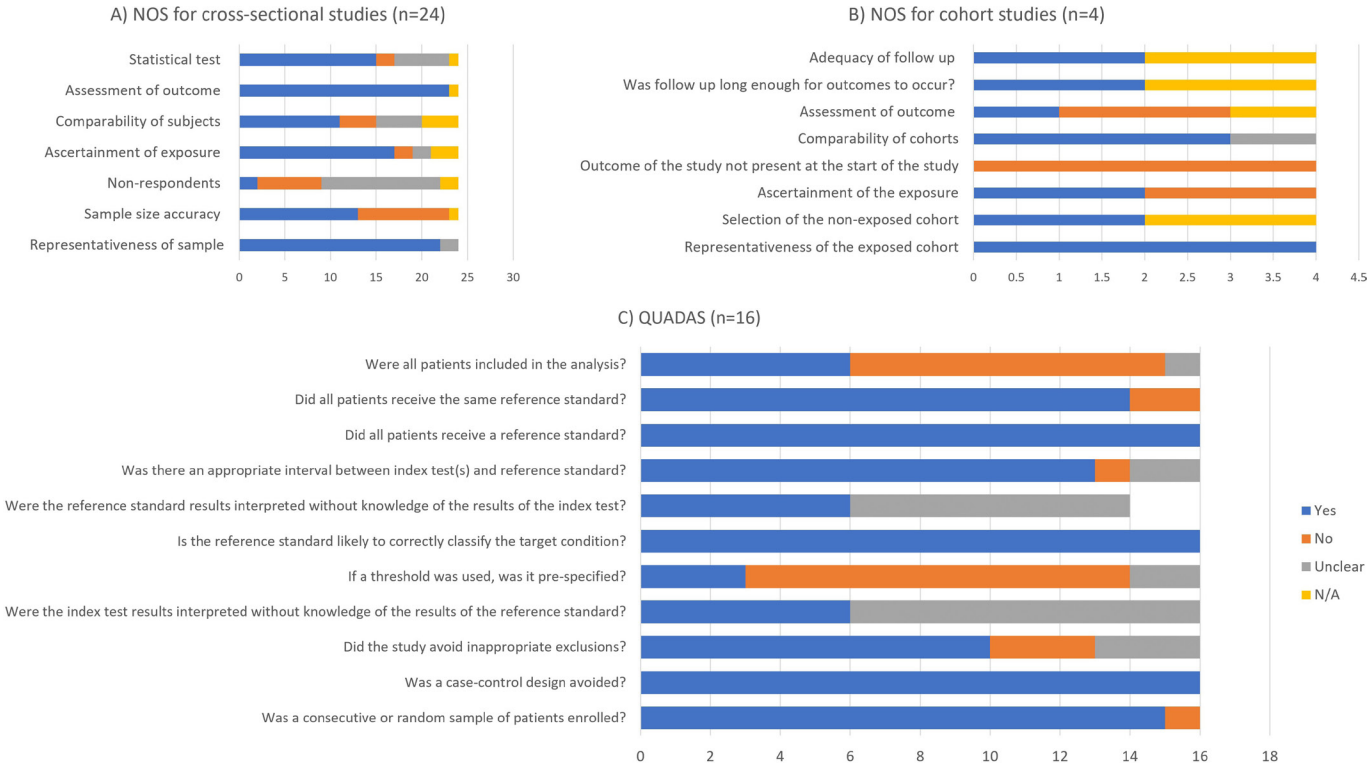

Figure 4 Quality assessment of included studies. (A) Cross-sectional studies (n=24) and (B) cohort studies (n=4) were assessed using the Newcastle–Ottawa Scale (NOS); (C) diagnostic accuracy studies (n=16) using the tool for Quality Assessment of Diagnostic Accuracy Studies (QUADAS). N/A, not applicable to a particular study

Sensitivity analysis

We observed that pooled sensitivity and specificity of CT tests and sensitivity of GC tests conducted in LMICs were significantly lower than those from HICs (online supplemental table 4). In addition, when restricting analysis to HICs only, the sensitivity of vaginal SS increased to 86.0% (76.6%–92.1%) for GC and 86.2% (76.0%–92.5%) for CT (online supplemental table 4). Excluding low-quality studies (n=6) resulted in higher pooled sensitivity and specificity than those obtained above (table 2) with statistically significant differences by sampling site but not by study population (online supplemental table 5).

DISCUSSION

Summary of results

Results from our meta-analysis and bivariate regressions indicated that CT/GC diagnostic accuracy values were higher for extragenital SS (ie, pharyngeal and rectal) than for vaginal SS, and that sensitivities for GC were higher for MSM than for women. However, studies conducted in LMICs may have decreased overall sensitivity by sampling site and study population because they reported lower sensitivity compared with those in HICs and excluded extragenital sampling and MSM populations. Reasons for this lower sensitivity may have been due to SS kit type, quality, storage conditions or lack of instructions on proper conduct of vaginal SS. These issues highlight the need for research on SS technologies and integrated digital innovations to improve sensitivity. Specificity was consistently higher than sensitivity, indicating a higher probability of FN than FP results.

Our results are in accordance with a meta-analysis conducted by Zhou *et al*[7] on POCTs (NAATs or antigen-detection tests) for CT screening that excluded POCT performance with SS. Our results complement a meta-analysis comparing SS with clinician sampling for CT/GC conducted by Lunny *et al* 8 years ago. However, including data published from 2015 to 2022 allowed inclusion of extragenital sampling in our analysis with stratified results by study population and country type.[8] We found a lower vaginal SS pooled sensitivity for CT (79% overall, 86.0% for high-quality studies only) compared with this previous study (92%). If truly lower in LMICs, test sensitivity could lead to increased probability of FN individuals (2 in 10), which could delay their access to treatment and increase their likelihood of transmitting CT/GC.

Pooled sensitivities and specificities of pharyngeal and rectal sampling reached the WHO-recommended target product profile for CT (sensitivity=90.0% and specificity=98.0%) and GC (sensitivity=90.0% and specificity=90.0%), but caution must be employed when ruling pharyngeal and rectal SS as most accurate due to low study number (n=3), with none being from LMICs.[5]

We conclude that extragenital SS followed by NAAT for CT/GC detection is as accurate as conventional testing regardless of sampling site for MSM and women in HICs. However, for LMICs, studies are needed to understand the source and variability in sensitivity of vaginal compared with extragenital SS.

Acceptability for SS was very high (80.0%–100%) whether digital innovations were present or not, but did not always translate to patient preference for SS.[16 18 19 28 30 32–35 41 42 44–46 49–52 55–60] Studies with lowest preference values (23.1%–50.9%) were conducted in women, MSM and PLWHIV from LMICs, and women, juvenile correction detainees and university students from one HIC.[24 34 42 44 52 58 59] It should be noted that patient preference was sometimes dependent on the number of options provided. The preference for each option was reduced when given the choice between three (SS, clinician sampling or no

preference)[24 44 52] versus two (SS or clinician sampling)[32] options because of a higher denominator. Highest preference for specific sampling sites also changed in key populations (eg, urine in juvenile correction detainees, urethral and rectal for transwomen).[34 60] Cost was a major deterrent in studies reporting preference for SS.[19 23 33 59] Pain during insertion, low perceived risk of infection and absence of a healthcare professional for test result interpretation were also identified as concerns.[21 28 32 42 51 52 55]

Digital innovations improved participation and engagement via text-based reminders or website-based questionnaires.[17–19 21 23 25] Higher percentages of repeat testers through internet-based SS tests and HIV ST with digital innovations have been reported previously.[6 61]

Finally, impact outcomes are important to consider to ensure greater proportions of people remaining in the STI care cascade.[62] SS was instrumental in reaching first-time testers in key populations, increasing detection and expanding access for those facing barriers to access conventional testing.[20 21 24 34 44 50] Furthermore, linkages to care were high overall.[17 44 50]

Strengths and limitations

To our knowledge, this is the first comprehensive systematic review of outcomes beyond diagnostic accuracy (ie, acceptability, preference, feasibility and impact) for all key populations in LMICs who desperately need CT/GC SS services.[1] This review offers valuable data on effective strategies to advance the WHO's STI elimination strategy by 2030.[1] This first meta-analysis includes CT/GC studies with SS compared with clinician-collected sampling. This review offers insights on how to maximise the use of SS coupled with digital innovations that are needed in any pandemic context by offering alternatives to clinic-based testing and limiting physical contact.

Studies evaluating accuracy of SS in populations other than MSM or women, and those that included digital innovations were limited, thereby preventing generalisation. Fewer studies (11 of 45; 24%) were conducted in LMICs despite their higher global STI disease burden.[1] Use of different references than clinician-collected samples for urine SS constitutes a limitation.

The quality of studies also varied. Lack of data on non-respondents introduced information bias. Lack of confounding data (eg, age, sex, socioeconomic status) limited our ability to assess it. More than half (10 of 16) of the diagnostic accuracy studies did not report test blinding. High-quality RCTs were also limited.[42 57] Finally, we could not exclude publication bias except for studies with accuracy estimates.

Implications

SS methods maintained comparable accuracy with clinician-obtained sampling, with high acceptability, high proportions of first-time testers and high linkages to care.[7 8 63 64] Thus, these tests will contribute to decrease the disease burden of untreated CT/GC infections. Cost remains a hurdle for implementation of innovative digital diagnostic tools, especially in LMICs. Furthermore, implementing these methods based on characteristics of target populations requires understanding of their preferences. Future direction for research and policy requires consideration of customising SS strategies to specific subpopulations of interest, especially in LMICs where evidence remains thin.

Our results provide support to the WHO's call to implement innovative STI diagnostic strategies including digital innovations integrated with SS.[1 4] They can be accessed by traditionally hard-to-reach populations and address inequities in care exacerbated by the COVID-19 pandemic. In the context of digitisation of healthcare, integrated digital innovations that offer promise to improve SS procedures, reporting, access and linkage could be useful. However, implementation research in robust cohort, quasi-randomised trials or RCTs is warranted to determine their effectiveness.

CONCLUSION

Our analysis reveals that high accuracy of SS followed by NAATs was comparable with clinician-sampled tests for extragenital sampling sites, regardless of populations in HICs (ie, women or MSM), and could consequently be recommended for implementation to diagnose CT/GC in similar settings. SS constitutes an innovative opportunity to reduce global STI burden by addressing obstacles associated with conventional testing. SS could be performed by individuals at home or at the clinic, in privacy and anonymity, expanding access to testing. SS, if combined with digital innovations, could potentially enhance access, simplify conduct, interpretation and linkage for key populations. However, impact and effectiveness need to be proven in studies with robust designs. Finally, our comprehensive review could gain credence if policymakers recommend innovative CT/GC screening strategies for key populations worldwide.

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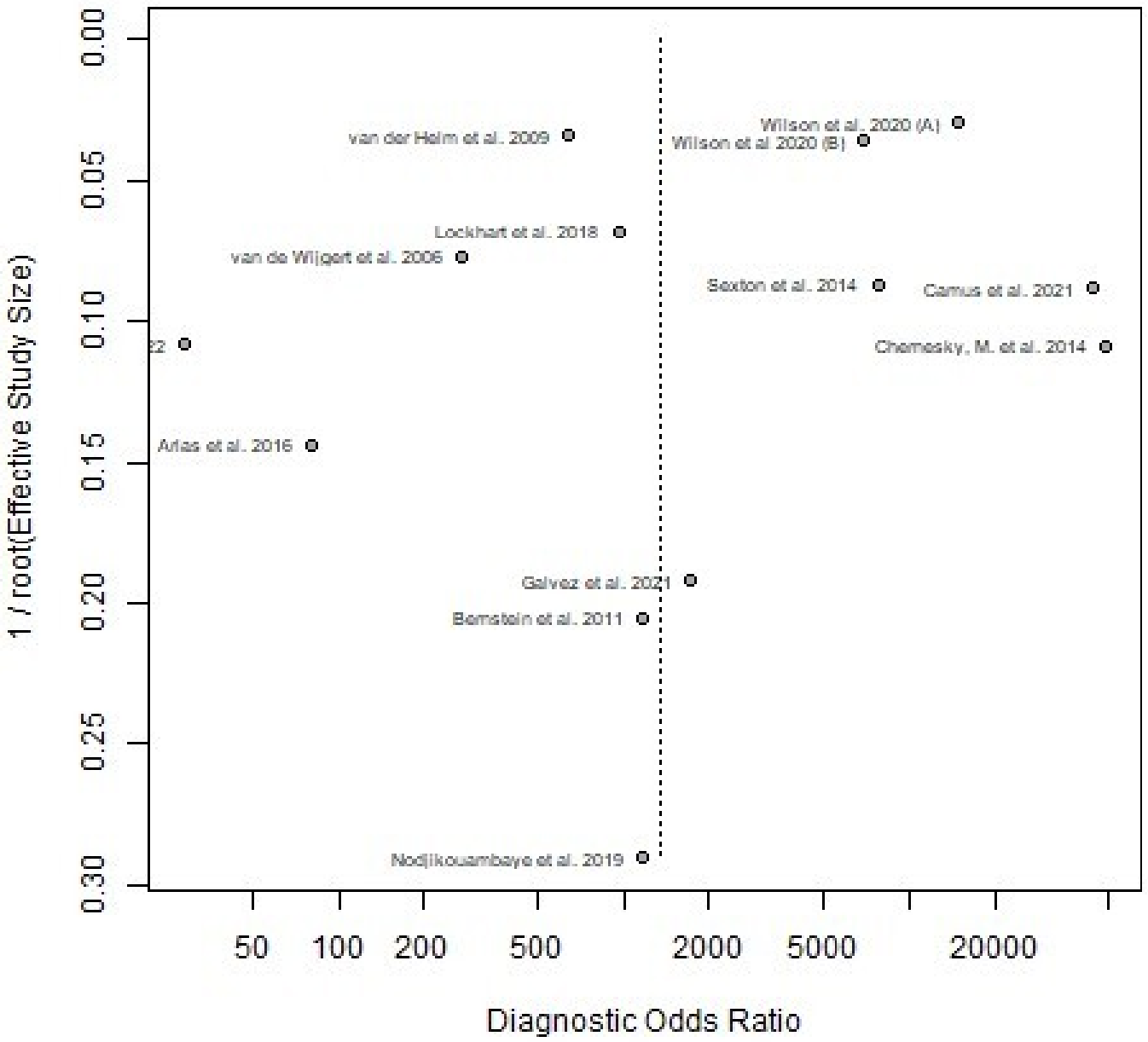
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Table 1. Summary table of included studies (n=37) and the self-sampling intervention evaluated.

Reference	Study Design	Sample size	Country	Study population	Type of digital intervention	Sampling site	Intervention description
Arias et al. 2016[1]	Cross-sectional DAS	189	Canada	Women who visited the youth street clinic or the abortion clinic	None	Vaginal	Participants were given the choice between self-sampling or conventional sampling by physician.
Bernstein et al. 2011[2]	Cross-sectional DAS	480	USA	English-speaking MSM	None	Pharyngeal	Participants presenting to the clinic were tested using conventional testing and then asked to perform self-sampling without examiner present.
Berry and Stanley 2017[3]	Cross-sectional DAS	1306	UK	Men visiting a sexual health clinic	None	Meatal	Participants were requested to provide a self-sampled swab and a urine sample for conventional testing.
Camus et al. 2021[4]	Cross-sectional DAS	1028	France	Women visiting STI clinics	None	Vaginal	Women presenting with vaginal/cervical sampling indications were invited to participate to test the non-inferiority of self-sampling compared to conventional sampling by clinician.
Chai et al. 2010[5]	Cross-sectional	501	USA	Men ≥14 years	Website-based	Urine and urethral	Participants ordered free-sampling kits online and were provided with a questionnaire.
Charin et al. 2021[6]	Cross-sectional	5061 returned kits	UK	Asymptomatic cisgender MSMs	Website-based	Rectal, pharyngeal and urine	Self-testing kits results were analysed from an administrative database to determine prevalence of extra-genital CT/GC.

Chernesky et al. 2014[7]	Cross-sectional	562	Canada	Women attending a gynaecology clinic or youth health clinic	None	Vaginal and cervical	Participants were asked to self-sample a vaginal swab and two conventional swabs were taken.
Chinnock et al. 2020[8]	Cohort DAS	533	USA	Emergency department attendees (Spanish- and English-speaking)	None	Vaginal	Participants were given the option to provide a self-sample in addition to conventional testing.
Conejero et al. 2013[9]	Cross-sectional	344	Chile	Women aged 18-25 who are sexually active and not pregnant or menstruating at the time of the study	None	Vaginal	Participants who attended the clinic were given a self-sampling test and surveyed.
De Baetselier et al. 2019[10]	Cohort DAS	213	Belgium	MSM using PrEP	None	Urine	Participants were tested using conventional testing at 3 biological sites and asked to self-sample at home.

Dukers-Muijrers et al. 2020[11]	Cohort	4916	the Netherlands	Women, who were 18 years or older, diagnosed with a vaginal or rectal CT infection during the inclusion period, and negative for HIV, syphilis, and GC	Online questionnaire and text messages	Vaginal and rectal	Participants were communicated a website link to the study via a text message. They self-collected at home or at the clinic and received reminder texts during the length of the study.
Estcourt et al. 2017[12]	Cross-sectional DAS	2143	UK	Anyone aged 16–24 years and able to read and understand English	Website and text	Urine (males) or vulvovaginal (females)	Participants were given the choice to access all care online or request in-person counselling/treatment at multiple steps of the pathway.
Galvez et al. 2021[13]	Cohort	206	Peru	Women between 18 and 50 years of age	None	Endocervical	Participants conducted a self-sampled test and conventional test at the clinic. They were asked to fill a questionnaire.
Grabert et. al 2022[14]	Cross-sectional DAS	399	Kenya	FSWs with and without HIV	None	Vaginal	Women who engage in sex work were randomized to using wet and dry brushes sampling methods compared to conventional sampling to determine test positivity.
Grandahl et al. 2020[15 16]	Cross-sectional	1785	Sweden	Anyone over the age of 15	Website-based	Urine, vagina, cervix, rectum, throat, other	Participants ordered a free self-sampling kit and filled a questionnaire on demographics, behaviour and about their experience with the test.
Habel et al. 2018[11]	Cross-sectional	3082	USA	Male and female university students	None	Urine (men), vaginal (women)	Students accessing the healthcare centre could request a self-testing option as opposed to conventional testing and were surveyed.

Harvey-Lavoie et al. 2021[17]	Cross-sectional	1179	Canada	Cis- and trans-GBMs	None	Rectal, pharyngeal and urine	Respondent driven sampling was used to recruit GBM who self-sampled to detect CT/NG. Prevalence estimates of CT/NG, overall and by anatomical site were calculated and respondent-driven sampling–adjusted.
Holland-Hall et al. 2002[18]	Cross-sectional	133	USA	Juvenile correctional facility detainees aged 12-17 years	None	endocervical	Participants were tested by conventional testing and/or invited to perform a self-test swab.
Kanji et al. 2016[19]	Cross-sectional DAS	606	Canada	Female STI clinic attendees aged 15 to 52 years from three Alberta clinics	None	Urine and endocervical	Participants accessing the clinic were invited to self-collect a sample or by a nurse.
Ladd et al. 2014[20]	Cross-sectional	205	USA	Women who returned rectal testing kits ordered through a website	Website-based	Vaginal and rectal	Participants ordered the rectal and vaginal free-sampling kits online and were provided with a questionnaire.
Leenen et al. 2020[21 22]	Cross-sectional	129	Netherlands	Dutch-speaking HIV positive MSM 18 years of age or older	Text messaging	Oral, anorectal, urinal	Home sampling kits were offered to clinic patients and text-message reminders were sent. Results were communicated via text or phone call.
Lippman et al. 2007[15]	RCT	818	Brazil	Low-income women	None	Vaginal	Participants were randomized to receive home-based collection kits or clinic based self collection and conventional testing.

Lockhart et al. 2018[23]	Cohort DAS	350	Kenya	Female sex workers	None	Cervicovaginal	Participants self-collected a sample and healthcare provider collected a sample.
Mabonga et al. 2021[24]	Cross-sectional	363	Uganda	People living with HIV 14 years and older	None	Vaginal and/or urine	Participants were asked to provide a sample and a questionnaire.
Masek et al. 2009[25]	Cross-sectional DAS	2000	USA	Anyone who accessed the website, no restrictions provided	Internet-based kit request and delivery of results	Vaginal	Self-sampling kits and questionnaires were ordered by participants through a website and shipped for testing and results were communicated by phone.
McCartney et al. 2022[26]	Cross-sectional	23	Brazil	Transgender women	None	Rectal, urethral, vaginal pharyngeal and urine	Consecutive potential participants from an existing cohort study were invited interview to determine the acceptability and practicability of mucosal STI screening.
Nodjikouambaye et al. 2019[27]	Cross-sectional DAS	251	Chad	Adult women	None	Vaginal	Participants randomized to a conventional testing with cervical swab or self-sampling with a veil.
Perkins et al. 2013[28]	Cross-sectional	514	USA	HIV negative adults	None	Urine, throat and/or rectal	Self-sample swabs were completed by participants, and they filled a survey.
Plattteau et al. 2022[29]	Cross-sectional	154	Belgium	Male clients of sex workers	Online questionnaire and text message communication of results	Rectal and urine	Time Location Sampling was used to recruit clients of sex workers who were interested in getting tested for STIs to determine positivity.

Rahib et al. 2022[30]	Cross-sectional	3428	France	HIV negative MSMs	App-based recruitment, online recruitment and text message reminders	Rectal, pharyngeal and urine	Participants were recruited online to study the feasibility of a at-home screening program, the rate of positive test results, and the factors associated with positivity.
Regimbal-Éthier et al. 2018[31]	Cross-sectional	708	Canada	Anyone with access to the website	Online questionnaire	Not specified	Participants accessing the website completed a self-assessment and presented to the clinic for a self-sampling collection.
Sambri et al. 2017[32]	Cross-sectional	78	Italy	Employees of a private industry	None	Vaginal	Subjects were given two self-sampling diagnostic tools to conduct at home and a questionnaire.
Schick et al. 2015[33]	Cross-sectional	80	USA	WSWM	None	Oral, vaginal and/or anal	Participants were interviewed and performed self-sampling swab tests, notified of results by their method of choice and email.
Sexton et al. 2013[34]	Cross-sectional DAS	374	USA	MSM who had sex with a man in the previous 6 months	None	Pharyngeal and rectal	Patients requesting a STI test performed self-sampling kit after viewing written and pictorial instructions and were also screened by clinic staff.

Shipitsyna et al. 2013[35]	Cross-sectional	1207	Russia	Sexually active attendees of a youth centre (15 – 25 years old)	None	Vaginal (female) and urine (male)	Participants were asked to provide a self-sample and a questionnaire.
Silva et al. 2020[36]	Cross-sectional	680	Portugal	Women of childbearing age from 2010 to 2016	None	Vaginal	Participants were asked to provide a self-sample and fill a questionnaire.
Sultan et al. 2016[37]	Cross-sectional	154	UK	Men and women	None	Not specified	Participants that had tested positive for a conventional test at the clinic were asked to provide a self-sample done at home.
van de Wijgert et al. 2006[38]	RCT DAS	450	South Africa	Adult women	None	Vaginal	Participants were surveyed and asked to self-sample with one tampon, or two swabs observed by nurse and nurse collected three vaginal swabs.
van der Helm et al. 2009[39]	Cross-sectional DAS	2394	the Netherlands	MSM and women who attended two STI clinics	None	Rectal	Participants were invited to test with self-sampling in addition to conventional testing and filled a questionnaire.
Weng et al. 2022[40]	Cross-sectional	306	China	MSMs visiting an outreach centre	None	Rectal and urine	Rectal-self-collection was offered in 2 non-clinic settings to study prevalence of CT/GC and self-sampling acceptability.
Wiesenfeld et al. 2001[41]	Cross-sectional	228	USA	Female high-school students	None	Vaginal	Participants were asked to self-sample for a STI test and surveyed.
Wilson et al. 2020[42]	Cross-sectional DAS	1793	UK	Women and MSM 16 years of age or older	None	Pharyngeal, rectal, and first-catch urine (males)/vulvovaginal swabs (females)	Participants presenting to the clinic were tested using self-sampling in addition to conventional testing and filled a questionnaire.

Wilson et al. 2020[43]	Cross-sectional DAS	1793	UK	Women and MSM 16 years of age or older	None	Pharyngeal, rectal, and first-catch urine (males)/vulvovaginal swabs (females)	Participants presenting to the clinic were tested using self-sampling in addition to conventional testing and filled a questionnaire.
Wong et al. 2022[44]	Cohort	204	China	HIV negative MSMs	Website-based test ordering and text message reminder	Rectal, pharyngeal and urine	HIV-negative MSM aged 18 years or older made appointments on a designated website for baseline and follow-up visits at 3-monthly intervals to determine engagement with self-sampling program and prevalence of CT/NG and other STIs.
Wood et al. 2014[45]	Cohort	30	UK	MSM attending a sauna	None	Pharyngeal, urine and rectal	Participants had the option of choosing a self-sampling kit at home, at the site of outreach or conventional testing at the site of outreach.

MSM: men who have sex with men; PrEP: pre-exposure prophylaxis; CT: *Chlamydia trachomatis*; HIV: human immunodeficiency virus; GC: *Neisseria gonorrhoeae*; STI: sexually transmitted infection; WSWM: women who have sex with women and men

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Supplementary Table 2. Key findings of included studies (n=37).

Reference	Key Findings
Arias et al. 2016[1]	Women reported self-collection with HerSwab to be easy (97.1%) and comfortable (88.3%). They preferred self-collection over physician collection (80.9%) and would consider using HerSwab for self-collection at home (79.7%). Samples of SCV and PCV showed an overall agreement of 94.7% (κ = 0.64) for CT and of 98.4% (κ = 0.56) for GC, and HerSwab collection detected 7 more positive patients than PCV collection. The overall prevalence of infection was 10.6% for CT and 2.6% for GC.
Bernstein et al. 2011[2]	The prevalence of pharyngeal GC and CT infection was 6.7% (32/480) and 1.3% (6/480), respectively. The percent agreement between self-collected and clinician-collected GC and CT specimens using nucleic acid amplification testing was 96.6% with a κ of 0.766 (95% confidence interval: 0.653–0.879) and 99.4% with a κ of 0.766 (95% confidence interval: 0.502–1.000), respectively. Acceptability was high among participants.
Berry and Stanley 2017[3]	We found an overall prevalence of 10.5 % for CT infections and 4.2% for GC infections in our patient population. Meatal swab testing had a sensitivity and specificity of 91 and 99% with a negative predictive value (NPV) of 99% and a positive predictive value (PPV) of 96% for CT testing compared to a sensitivity and specificity of 100 and 99% with an NPV of 100% and a PPV of 98% for urine samples. The sensitivity and specificity of meatal swabs was 100 and 99%, respectively, for GC detection with an NPV of 100% and PPV of 89% compared to urine which had 93% sensitivity and 99% specificity with an NPV and PPV of 99 and 93%, respectively.
Camus et al. 2021[4]	Self-sampling was not inferior to conventional-sampling for the detection of STIs. 322 (31%) women preferred self-sampling and 268 (26%) preferred conventional sampling (p = 0.045) (43% did not have a preference. Of the 1027 surveyed participants, 84% (867) would recommend the use of self-sampling.
Chai et al. 2010[5]	Of 501 samples received for testing, 106 (21%) were positive for at least one STI, 64 (13%) for chlamydia, 4 (1%) for gonorrhea, and 49 (10%) for trichomonas. In multivariable analyses, age, race, household income, and frequency of condom use were independently associated with infection with at least one STI. Of the total respondents, 34% had a prior STI; 29% reported having a partner with an STI, but only 13% reported always using a condom. Among the men who participated in this study, 77% preferred a self-administered specimen versus attending a clinic, 89% reported that swab use was easy, and 89% reported that they would use internet-based screening again.
Charin et al. 2021[6]	Among 5051 valid CT and 5040 valid NG asymptomatic test results, overall prevalence was 5.9% (298/5051) and 4.5% (228/5040), respectively. Among MSM with asymptomatic CT, 71.8% (214/298) had extragenital infection only, $\chi 2$ (1, n=298) =56.71, p<0.001. Among those with asymptomatic NG, 89.9% (205/228) had extragenital infection only, $\chi 2$ (1, n=228) =145.281, p<0.001.

Chernesky et al. 2014[7]	There was a total of 22 CT, 19 TV and 2 GC infections with dual infections in 6 people (one CT and GC, one GC and TV and four CT and TV). Prevalence were as follows: CT 3.9% (GYC 1.3% and YHC 12.6%); GC 0.3% (2.0% in YHC); TV 3.4% (GYC 0.4% and YHC 13.4%). Sensitivity for CT infections were CSCT 100%, PC 100%, SP 81.8%; VSCT-self 100%, VSCT-physician 95.4%: for TV infections CSCT 89.4%, PC 84.2%, SP 63.2%; VSCT 100%: for GC all collections 100%. There were no false positives (% specificity 100). Results of the survey revealed that the majority of patients found opening the package, self sampling, insertion of the SCT swab into preservation media and uncapping and recapping the tube were relatively easy to perform. Eighty-two per cent experienced no discomfort using the SCT kit for collection.
Chinnock et al. 2020[8]	A total of 533 patients completed enrollment and answered survey questions, 515 of whom had laboratory results for both SOVS and PPES. There were 86 patients with a positive result: 29 with GC, 47 with CT, and 10 with coinfection. SOVS had a sensitivity of 95% (95% confidence interval = 88% to 99%) for the detection of GC/CT when compared to PPES. SOVS were felt to be an acceptable collection method in 93% of patients and 75% preferred SOVS to PPES.
Conejero et al. 2013[9]	We studied 344 patients with an average age of 21.7 years. Detection of *C. trachomatis* was positive in 7.9% women, and it was not found in any of the patients studied for *N. gonorrhoeae*. 98% considered self-sampling instructions easy to understand, 87.5% felt comfortable taking the sample.
De Baetselier et al. 2019[10]	A total of 473 home-based samples from 213 MSM were received with a mean age of 38.5 years. TV was not detected. A very good to almost perfect agreement was found for CT, GC and MG of κ=0.75, 0.87 and 0.85, respectively. Using the Colli-Pee device only one low positive CT and two MG infections were missed, however, three additional CT, two GC and six MG infections were detected.
Dukers-Muijrers et al. 2020[11]	Among the 4,916 women, 1,763 (35.9%) were preselected, of whom 560 (31.8%) were included. The study population had diverse baseline characteristics: study site, migration background, high education, and no STI history were associated with non-preselection and non-inclusion. Retention was 76.3% (n = 427). Attrition was 10.71/100 person/month (95% confidence interval 9.97, 12.69) and was associated with young age and low education.
Galvez et al. 2021[12]	In 206 women of childbearing age, we identified some sexually transmitted infections such as *Chlamydia trachomatis* or *Trichomonas vaginalis* in 9/206 (4.4%). We obtained a high degree of agreement in the identification of Candida spp. (k = 0.97), *Chlamydia trachomatis* (k=0.92) and *Trichomonas vaginalis* by microscopy (k=1.00), and a considerable agreement for the identification of *Trichomonas vaginalis* by culture (k=0.66).
Grabert et. al 2022[13]	Detection of *T. vaginalis* and *N. gonorrhoeae* in dry and wet samples was similar, but *C. trachomatis* detection in dry samples appeared lower.
Estcourt et al. 2017[14]	Between July 21, 2014, and March 13, 2015, 2340 people used the eSHC. Of 197 eligible patients from genitourinary medicine clinics, 161 accessed results online. Of the 116 who consented to be included in the study, 112 (97%, 95% CI 91-99) received treatment, and 74 of those were treated exclusively online. Of the 146 eligible NCSP patients, 134 accessed their results online, and 105 consented to be included. 93 (89%, 95% CI 81-94) received treatment, and 60 were treated exclusively online. In both groups, median time to collection of treatment was within 1 day of receiving their diagnosis. 1776 (89%) of 1936 NCSP patients without chlamydia accessed results online. No adverse events were recorded.

Grandahl et al. 2020[15 16]	Of the 1,785 participants 69.4% were women. The majority of participants (77.1%) were single and heterosexual (88.2%) and 5.3% of samples tested positive. The self-sampling service was appreciated, with > 90% considering it good/very good. The main reason subjects gave for testing was to check their health after unprotected sex (72.9%). Almost half (44.7%) had regretted having sex after alcohol intake. Differences in attitudes were seen between categories: born vs not born in Sweden, employed vs student, single vs married/having a partner. Participants were happy with the self-sampling test service, and sexual risk behaviours motivated use of the test.
Habel et al. 2018[11]	In 2015, University Health Services experienced a 28.5% increase in chlamydia (CT)/gonorrhea (GC) testing for male individuals and 13.7% increase in testing for female students compared to 2013 (baseline). In 2015, 12.4% of male students and 4.8% of female students tested positive for CT/GC via clinician testing, whereas 12.9% of male students and 12.4% of female students tested positive via self-testing. Female students were more likely to test positive for CT/GC when electing to test via self-test versus a clinician test ($\chi^2(1, N = 3068) = 36.54$, $P < 0.01$); no significant difference in testing type was observed for male students. Overall, 22.5% of students who opted for the self-test option completed the acceptability survey; 63% reported that their main reason for testing was unprotected sex. In the past year, 42% reported 4 or more partners. The majority were very satisfied and likely to use the service again (82%).
Harvey-Lavoie et al. 2021[17]	Among 1177 GBM, the prevalence of rectal, urogenital, pharyngeal, and overall were respectively 2.4%, 0.4%, 0.4%, and 2.8% for CT infections, and 3.1%, 0.4%, 3.5%, and 5.6% for NG infections. If testing had been limited to the urogenital site, 80% and 94% of CT and NG infections, respectively, would have been missed.
Holland-Hall et al. 2002[18]	Twenty-four percent of sexually active subjects had one or more infections diagnosed by self-testing: 11.3% had *C. trachomatis*, 8.5% had *N. gonorrhoeae*, and 11.7% had *T. vaginalis*. Only 30% of subjects with infections had pelvic exams while detained; therefore 70% of girls with infections would have been missed in the absence of the self-testing option. The self-collection technique was acceptable to 95% of subjects.
Kanji et al. 2016[19]	We obtained a total of 606 vaginal specimens, 341 nurse collected and 265 self-collected. The sensitivity and specificity of SCV versus urine were 86.7% and 99.1% for CT, 100% and 100% for GC, respectively. For HCV versus EC the sensitivity and specificity were 100% and 97.9% for CT and 71.4% and 99.4% for GC, respectively.
Ladd et al. 2014[20]	Of the 205 rectal samples returned and eligible for testing, 38 (18.5%) were positive for at least one STI. The women were young (mean age 25.8 years), mostly African American (50.0%), and only 14.0% always used condoms. After adjusting for age and race, Black race (AOR=3.06) and vaginal STI positivity (AOR=40.6) were significantly correlated with rectal STI positivity. Of women testing positive for rectal STIs who also submitted vaginal swabs, 29.4% were negative in the vaginal sample.

Leenen et al. 2020[21] [22]	Adoption was 85.3% (110/129), participation was 58.2% (64/110), and sampling-kit return was 43.8% (28/64). Of the tested MSM, 64.3% (18/28) did not recently (< 3 months) undergo a STI test; during the programme, 17.9% (5/28) were diagnosed with an STI. Of tested MSM, 64.3% (18/28) was vaccinated against hepatitis B. MSM reported that the sampling kits were easily and conveniently used. Care providers (hospital and STI clinic) considered the programme acceptable and feasible, with some logistical challenges. All (100%) self-taken chlamydia and gonorrhoea samples were adequate for testing, and 82.1% (23/28) of MSM provided sufficient self-taken blood samples for syphilis screening. However, full syphilis diagnostic work-up required for MSM with a history of syphilis (18/28) was not possible in 44.4% (8/18) of MSM because of insufficient blood sampled.
Lippman et al. 2007[15]	Slightly more women responded to the initiative within 2 weeks in the home group (80%) than in the clinic group (76%) with younger women showing improved response to home-based screening. Ninety-four percent of home group participants successfully completed self-collection and self-testing on their first attempt.
Lockhart et al. 2018[23]	Baseline STI prevalence was 2.9% for *N. gonorrhoeae*, 5.2% for *C. trachomatis*, 9.2% for *T. vaginalis*, and 20.1% for MG in self-collected samples, and 2.3%, 3.7%, 7.2%, and 12.9%, respectively, in physician-collected samples. κ Agreement was consistently strong (range, 0.66–1.00) for all STIs over the 18-month study period, except for MG, which had moderate agreement (range, 0.50–0.75). Most participants found self-collection easy (94%) and comfortable (89%) at baseline, with responses becoming modestly more favorable over time.
Mabonga et al. 2021[24]	Three hundred and sixty-three PLHIV had an STI screen. Asymptomatic STIs were only diagnosed in women (prevalence 5.7%), overall prevalence 3.9% (n = 14). Factors independently associated with an STI in women were being under 25 years (OR 9.63 95% CI 1.56–59.5) and having more than one sexual partner (OR 8.06 95% CI 1.07–60.6). Four hundred and seven completed the acceptability questionnaire. More than 95% of patients found self-sampling easy and comfortable and 83.8% would believe the results. Women significantly preferred the option of self-sampling, 56.9% versus 29.3% of men (p < 0.001). Acceptability of self-sampling was high.
Masek et al. 2009[25]	Of the first 500 swabs submitted, 46 were *C. trachomatis* infected (9.2%) and 5 were *N. gonorrhoeae* infected (1.0%), and 3 of these were coinfected (0.6%). All *C. trachomatis* and *N. gonorrhoeae* Combo2-positive/ProbeTec-negative samples were confirmed as true positives by an alternative NAAT. For *C. trachomatis*, ProbeTec, Combo2, and PCR had sensitivities of 82.6%, 100%, and 100%, with specificities of 100%, 100%, and 99.3%, respectively. For *N. gonorrhoeae*, ProbeTec, Combo2, and PCR had sensitivities of 80%, 100%, and 100%, with specificities of 100%, 100%, and 98.8%, respectively. Of the total 1,000 swabs submitted, 92 were *C. trachomatis* infected (9.2%) and 15 were *N. gonorrhoeae* infected (1.5%), and 7 of these were coinfected (0.7%). There were no ProbeTec-positive/Combo2-negative samples. For *C. trachomatis*, ProbeTec and Combo2 had sensitivities of 81.5% and 100%, with specificities of 100% and 100%, respectively. For *N. gonorrhoeae*, ProbeTec and Combo2 had sensitivities of 80% and 100%, with specificities of 100% and 100%, respectively. Overall, ProbeTec had 17 *C. trachomatis* false-negative results (1.7%) and 3 *N. gonorrhoeae* false-negative results (0.3%), while Combo2 had none. Our results were consistent with the sensitivities and specificities stated by the manufacturers. NAATs perform well for detection of chlamydia and gonorrhea with self-obtained vaginal swabs shipped in a dry state to a laboratory. For 1,000 self-collected vaginal swabs tested by NAATs, the sensitivities for *C. trachomatis* and *N. gonorrhoeae* for Combo2 were 100% and 100%, while they were 81.5% and 80%, respectively, for ProbeTec. For 500 PCR samples, the *C.*

	trachomatis sensitivity was 100% and the *N. gonorrhoeae* sensitivity was 100%, with specificities of 99.3% and 98.8%, respectively.
McCartney et al. 2022[26]	All survey respondents (100%; n = 23) indicated willingness to provide samples for STI screening during a future study visit. Preference was for self-collection of urine samples (83%; n = 19), urethral swabs (82%; n = 18), and anorectal swabs (77%; n = 17). A lower preference for self-collection of oropharyngeal swabs (48%; n = 11) was observed. Most respondents (78%; n = 18) indicated that they would not prefer specimens to be collected by a health professional, mainly due to 'more privacy' (72%; n = 13). All respondents indicated that they would feel comfortable to provide a self-collected sample based on instructional diagrams shown. In FGDs, although the collection by a health professional was described as a technically safer option for some participants, there was a preference for self-collection to avoid discomfort and embarrassment in exposing the body.
Nodjikouambaye et al. 2019[27]	A total of 251 women (mean age, 35.1 years) were prospectively enrolled. Only seven (2.8%) women were found to be infected with at least one common STIs [*C. trachomatis*: 3 (1.2%), *N. gonorrhoeae*: 1 (0.4%), *M. genitalium*: 4 (1.6%) and *T. vaginalis*: 1 (0.4%)], while the prevalence of genital mycoplasmas was much higher (54.2%) with a predominance of *Ureaplasma parvum* (42.6%). Self-collection by veil was non-inferior to clinician-based collection for genital microorganisms DNA molecular testing, with “almost perfect” agreement between both methods, high sensitivity (97.0%; 95%CI: 92.5-99.2%), and specificity (88.0%; 95%CI: 80.7-93.3%). Remarkably, the mean total number of genital microorganisms detected per woman was 1.14-fold higher in self-collected specimens compared to that in clinician-collected specimens.
Perkins et al. 2013[28]	The sample included: 413 (80.4%) men and 101(19.6%) women. The median age was 30 (range 15–72) years. Among the men: 135 (32.7%) African-American; 211 (51.1%) White; 262 (63.4%) men who have sex with men only; 34 (8.2%) men who have sex with both men and women. Among the women: 74 (73.3%) African-American; 18 (17.8%) White; 6 (5.9%) women who have sex with women only; 8 (7.9%) women who have sex with women and men. Among men, the prevalence of CT was 10.7% (2.7% throat, 5.8% rectal and 3.4% urine); for GC 8.5% (6.5% throat, 3.4% rectal and 1.2% urine). Among women, the prevalence of CT 12.9% (4.9% throat, 8.9% rectal and 8.9% urine); GC 3.0% (1.0% throat, 3.0% rectal and 1.0% urine). 95.9% of the individuals reported high acceptance of self-testing with 97.6% willing to do repeat testing and 96.7% to recommend self-testing to someone else.
Plattteau et al. 2022[29]	In total, 154 male clients of sex workers with a median age of 38 participated. A total of eight Ct and one Ng infections were detected. TLS analysis revealed a Ct/Ng prevalence of 8.2%.
Rahib et al. 2022[30]	Overall, 1556 out of 1908 (81.6%) blood samples were tested for at least HIV. A total of eight participants (0.5%) were newly diagnosed with HIV and four with HCV (0.3%). No new infection was confirmed for HBV. Overall positivity was 9.3% for CT and 9.6% for NG. The highest positivity was reported in rectal swabs for CT (7.3%) and in pharyngeal swabs for NG (7.2%). Factors associated with extragenital CT/NG were age under 30 years (for pharyngeal and rectal infections) and having at least 10 partners in the past 6 months ($p<0.001$) (for pharyngeal infections only).

Regimbal-Éthier et al. 2018[31]	Prélib registered 708 profiles within 5 months post-launch, 66.5% of whom attended ≥1 appointment. Completion rates for each step were >75% (lowest was observed for payment/scheduling). Among 471 appointment attendees, mean number of partners in the past 2 months was 2.6 [median=2], 25.5% were men who have sex with men, 74.1% reported condomless anal or vaginal sex, and 23.6% reported first-time screening. STI prevalence was 6.5%, driven by GC and CT. Extragenital GC and CT were most prevalent. No HIV or HCV infections were identified.
Sambri et al. 2017[32]	No failure results have been observed, the IC of all samples were amplified (average Ct 30). The real time PCR assay was able to identify 2/78 CT, 4/78 UU, 40/78 UP, 6/ 78 MH, 1/78 TV positive patients. No MG and GC positive patients have been detected. Women reported self-collection with HBSV easy and comfortable (100%).
Schick et al. 2015[33]	Over two-thirds (67.5%, n=54) of the participants completed the baseline scheduled and attended the interview. The majority of these participants provided vaginal (87.0%, n=47), oral (85.2%, n=46) and/or anal (61.1%, n=33) samples. Participants with a history of anal play were significantly more likely to provide an anal sample. *C. trachomatis* infection was identified in the samples of 6.8% (n=3) of the participants including 4.5% (n=2) of the vaginal samples and 3.3% (n=1) of the anal samples. None of the samples were positive for *N. gonorrhoeae* or *T. vaginalis*. Participants who reported a recent history of anal sexual behaviour with a male partner were significantly more likely to self-collect an anal sample.
Sexton et al. 2013[34]	Among those receiving specific tests, 8% of patients tested positive for R-GC, 9.3% for P-GC, 12.7% for R-CT, and 1.3% for P-CT. We performed McNemar tests, stratified by infection type and anatomic site to evaluate concordance. Self-administered testing was significantly better at identifying P-GC (discordant: 3%) and R-GC (discordant: 2.9%) (P ≤.01) and had results similar to provider- administered testing for P-CT (discordant: 0.5%) and R-CT (discordant: 1.1%) detection.
Shipitsyna et al. 2013[35]	The overall prevalence of the examined STIs was 8.1% (85 of 1053) in the women and 7.8% (12 of 154) in the men. *C. trachomatis*, *N. gonorrhoeae*, *M. genitalium* and *T. vaginalis* were detected in 70 (6.6%), 6 (0.6%), 12 (1.1%) and 3 (0.3%) women, respectively. The prevalence of *C. trachomatis* and *M. genitalium* in the men was 6.5% (10 of 154) and 1.3% (2 of 154). *N. gonorrhoeae* or *T. vaginalis* were not detected in any men. In 7 women, multiple agents were found, i.e., *C. trachomatis* and *N. gonorrhoeae* (n = 3), *C. trachomatis* and *M. genitalium* (n = 2), and *M. genitalium* and *T. vaginalis* (n = 1).
Silva et al. 2020[36]	GC and TV prevalence was 1.3% (95% confidence interval (CI) 0.7−2.5%) and 1.0% (95% CI 0.5−2.1%), respectively. The prevalence of TV was significantly higher in women aged >22 years (p = .003), with >6 years after sexual intercourse (p = .003), and who reported previous pregnancy (p = .004). Our study suggests that GC and TV are rare in Portuguese women of childbearing age.
Sultan et al. 2016[37]	102 men (87 MSM) and 52 women were recruited to the study, 84 had GC infection and 71 had CT infection. The median age was 28 years. Unprotected sexual intercourse in the last month was reported by 68% of MSM, 56% of heterosexual men and 51% of women. Symptoms were reported by 25% of MSMs, 50% of heterosexual men and 51% of women. 86% of participants found the information clear and easily understandable. 85% felt confident taking their own samples. 58% found the samples easy to take, 75% were happy to take their own swabs and 78% were happy to take samples at home.

van de Wijgert et al. 2006[38]	Self-sampling resulted in satisfactory validity for *N gonorrhoeae, C trachomatis*, bacterial vaginosis, and *Candida* species (tampons and swabs) and high-risk human papillomavirus (swabs only) when tested with molecular tests or microscopy, but not for *T vaginalis* by culture. Self-sampling was feasible and acceptable, but some women preferred speculum examinations, which allow the clinician to view the vagina and cervix.
van der Helm et al. 2009[39]	Prevalence of rectal CT was 11% among the 1458 MSM and 9% among the 936 women. Rectal GC prevalence was 7% and 2%. In 98% of both MSM and women, SRS and PRS yielded concordant CT test results, for GC agreement was 98% for MSM and 99.4% for women. SRS performance for CT and GC diagnosis was good in both groups and was comparable for both study regions. Slightly more (57% of MSM, 62% of women) preferred SRS to PRS or had no preference; 97% would visit the STI clinic again if SRS was standard practice.
Weng et al. 2022[40]	Of the 306 MSM who were offered to perform rectal self-sampling, 133 (43.46%) accepted, and 96.24% (128/133) of them successfully provided a valid rectal sample. The prevalence of urogenital CT and NG infections among 303 MSM was 4.29 and 0.66%, respectively. The prevalence of rectal CT and NG infections among 128 participants was 31.25 and 9.38%, respectively.
Wiesenfeld et al. 2001[41]	The prevalence of any STD was 18%. Trichomoniasis, chlamydia, and gonorrhea were diagnosed in 10%, 8%, and 2% of students, respectively. Nearly 13% of females who had never previously had a gynecologic examination tested positive for an STD, and 51% of infected students would not have pursued testing by traditional gynecologic examination if self-collection was not offered. Self-collection of vaginal swabs was almost uniformly reported as easy to perform (99%) and preferable to a gynecologic examination (84%). Nearly all (97%) stated that they would undergo testing at frequent intervals if self-testing were available.
Wilson et al. 2020[42]	Of 1793 participants (1284 females, 509 MSM), 116 had GC detected (75 urogenital, 83 rectum, 72 pharynx); 9.4% infected females and 67.3% MSM were urogenital-negative. A total of 276 had CT detected (217 urogenital, 249 rectum, 63 pharynx); 13.1% infected females and 71.8% MSM were urogenital-negative. Sexual history did not identify those with rectal infections. There was no difference in diagnostic accuracy between clinician- and self-taken samples from the rectum or pharynx. Clinicians took swabs more quickly than participants, so costs were lower. However, in asymptomatic people, nonqualified clinicians would oversee self-swabbing making these costs lower.
Wilson et al. 2020[43]	Of 1793 participants (1284 females, 509 MSM), 116 had GC detected (75 urogenital, 83 rectum, 72 pharynx); 276 had CT detected (217 urogenital, 249 rectum, 63 pharynx). There was no difference in sensitivities between clinician triple samples and self-pooled specimens for GC (99.1% and 98.3%), but clinician samples analyzed individually identified 3% more chlamydia infections than pooled (99.3% and 96.0%; P = .027). However, pooled specimens identified more infections than VVS/FCU alone. Pooled specimens missed 2 GC and 11 CT infections, whereas VVS/FCU missed 41 GC and 58 CT infections. Self-taken pooled specimens were the most cost-effective.
Wong et al. 2022[44]	At baseline, the overall STI (CT, NG, or syphilis) prevalence was 30%, with CT at 18%, NG at 13%, and syphilis at 5%. During follow-up, the incidences were 59.08/100 person-years (py) for any STI, 33.05/100 py for CT, 29.86/100 py for NG, and 10.4/100 py for syphilis. The detection rates of CT and NG in urine samples were lower than with pharyngeal swabs and rectal swabs. The scores for convenience, confidence of correct sampling, and accuracy of self-sampling were high (7 to 8 out of 10).

Wood et al. 2014[45]	Thirty men were included in each group. Users of the nurse-delivered and postal services were older (nurse service median age 57.5 years vs. postal kit service 47 years vs. clinic 35.5 years, $p \leq 0.001$). Outreach groups were less likely to have undertaken sexually transmitted infection testing previously than the clinic group (53.3% and 60% vs. 93.3%, $p \leq 0.001$). *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing uptake was comparable across groups (nurse outreach 86.6%, 'do it yourself' postal kit 100% vs. clinic 100%, $p = 0.032$), but uptake for blood tests was lower in the postal kit group (nurse outreach 83.3%, postal kit 53.3% vs. clinic 100%, $p \leq 0.001$). No significant difference in active sexually transmitted infection positivity across the groups was observed.

SCV: self-collected vaginal; PCV: physician-collected vaginal; TV: *Trichomonas vaginalis*; GYC: gynaecology clinic; YHC: youth health clinic; CSCT: cervical specimen collection and transportation kit; VSCT: vaginal specimen collection and transportation kit; PC: PreservCyt liquid; SP: SurePath liquid; GC: *Neisseria gonorrhoeae*; SOVS: self-obtained vaginal swabs; PPES: provider-obtained endocervical swabs; MG: *Mycoplasma genitalium*; eSHC: e-sexual health clinic ;NCSP: national chlamydia screening program; HCV: healthcare provider-collected vaginal; EC: endocervical; AOR: adjusted odds ratio; PLHIV: people living with HIV; HIV: human immunodeficiency virus; OR: odds ratio; NAAT: nucleic acid amplification test; STI: sexually transmitted infection; HCV: hepatitis C virus; UP: *Urvea parvum*; UU: *Ureaplasma urealyticum*; HBSV: home-based self-sampling vaginal kit; P-GC: pharyngeal-GC/CT; R-GC/CT: rectal-GC/CT; MSM: men who have sex with men; STD: sexually transmitted disease; SRS: self-collected rectal swabs; PRS: physician-collected rectal swabs; VVS/FCU: vulvo-vaginal swabs/first-catch urine;

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Supplementary Table 3. Molecular test type, index test, reference test, case positivity, sensitivity, and specificity values of diagnostic accuracy studies evaluating the performance of self-sampled CT/GC tests.

Chlamydia trachomatis	Molecular test	Index test	Reference test	Case positivity	Sensitivity (95% CIs)	Specificity (95% CIs)
Arias et al. 2016[1]	HerSwab + Aptima combo 2	Self-taken vaginal swab	Clinician taken vaginal swab	5.3	76.9	96.0
Bernstein et al. 2011[2]	Aptima combo 2	Self-taken pharyngeal swab	Clinician taken pharyngeal swab	1.1	83.3	99.6
Berry and Stanley 2017[3]	BD Viper XTR	Self-taken penile meatal swab	Self-collected urine sample	8.3	89.4	99.6
Camus et al. 2021[4]	Copan ESwab & Cobas 4800	Self-taken vaginal swab	Clinician taken vaginal swab	3.3	100 (N/A)	85.7 (59.8–100)
Chai et al. 2010[5]	Aptima Gen-Probe,	Self-taken urine and urethral		13.0		
Charin et al. 2021[6]	Aptima Combo 2	Self-taken urine		1.7		
		Self-taken pharyngeal swab		0.9		
		Self-taken rectal		4.3		
Chernesky, M. et al. 2014[7]	Aptima combo2	Self-taken cervicovaginal		3.9	100.0	100.0

Chinnock, B. et al. 2020[8]	Cepheid Xpert CT, NG	Self-taken vaginal swab	Clinician taken endocervical swab	9.7	94.3 (84.0–99.0)	98.9 (98.0–100.0)
De Baetselier et al. 2019[9]	Abbott Real Time (RT) CT, NG assay	Self-taken urine at home next day	Self-taken urine at clinic	1.3	85.7	99.3
Estcourt et al. 2017[10]	Not specified	Self-taken urine or vaginal swab		6.3		
Galvez et al. 2021[11]	Aptima combo 2	Self-taken vaginal swab	Clinician taken endocervical swab	2.9	85.7	100.0
Grabert et. al 2022[12]	Aptima Combo 2	Self-taken wet vaginal swab	Clinician taken vaginal swab	3.5	45.45	97.68
		Self-taken dry vaginal swab		0.5	9.09	99.74
Harvey-Lavoie et al. 2021[13]	COBAS 4800 CT/NG	Self -taken urine		0.8		
		Self-taken rectal		2.9		
Holland-Hall et al. 2002[14]	COBAS Amplicor CT, NG Test	Self-taken cervicovaginal		11.3		
Kanji et al. 2016[15]	Aptima 2 combo	Self-taken cervical	Self-taken urine		86.7	99.1
Ladd et al. 2014[16]	Aptima Gen-Probe,	Self-taken vaginal and rectal		12.7		

Lockhart et al. 2018[17]	Aptima Cervical Specimen Collection and Transport cytobrush	Self-taken cervicovaginal cytobrush	Clinician-taken cervicovaginal	2.7	92.9	98.7
Mabonga et al. 2021[18]	ProbeTecTM ET CT, NG test;	Self-taken vaginal and urine		1.7		
Masek et al. 2009[19]	Aptima combo 2 or Probetec SDA	Self-taken vaginal	Both test having concordant results	7.5	100.0	98.2
Nodjikouambaye et al. 2019[20]	Allplex STI Essential Assay, Seegene,	Self-taken veil-based cervicovaginal	Clinician taken endocervical swab	1.2	100.0	99.6
Perkins et al. 2013[21]	Not reported	Self-taken rectal, pharyngeal and urine (men)		10.7		
	Not reported	Self-taken rectal, pharyngeal and urine (women)		12.9		
Platteau et al. 2022[22]	Abbott RealTime CT/NG assay	Self-taken urine or rectal swab		5.2		
Rahib et al. 2022[23]	Cobas R PCR Dual Swab Sample Kits or Abbott R multi-Collect Specimen Collection Kit	Self-taken rectal swab		7.2		
		Self-taken pharyngeal swab		1.8		
		Self-taken urine		1.9		

	and Copan UriSwab™					
Regimbal-Éthier et al. 2018[24]	Not specified	Not specified		6.5		
Sambri et al. 2013[25]	Anyplex II STI-7	Self-taken vaginal		2.6		
Schick et al. 2015[26]	COBAS Amplicor CT, NG Test	Self-taken pharyngeal, vaginal, and rectal		6.8		
Sexton et al. 2013[27]	Aptima combo 2	Self-taken rectal swab	Clinician taken rectal swab	11.6	100.0	98.8
		Self-taken pharyngeal swab	Clinician taken pharyngeal swab	0.8	100.0	99.5
Shipitsyna et al. 2013[28]	AmpliSens Ct, GC MULTIPRIME-FRT	Self-taken urine		6.5		
Silva al. 2020[29]	Metabion	Self-taken vaginal		6.6		
van de Wijgert et al. 2006[30]	COBAS Amplicor CT, NG Test	Self-sampled vaginal tampon	Clinician-collected vaginal swab	8.8	90.9 (80.9–100)	97.0 (94.9–99.0)
		Self-sampled vaginal swab	Clinician-collected vaginal swab	9.0	80.0 (66.9–93.1)	98.9 (97.7–100)

Van der Helm et al. 2009[31]	COBAS Amplicor CT, NG Test	Self-taken rectal swab (MSM)	Clinician-taken rectal	9.5	87.6 (81.0-91.0)	98.9 (98.0–99.0)
		Self-taken rectal swab (women)	Clinician taken rectal	8.3	88.2 (80.0–93.0)	98.9 (98.0–99.0)
Weng et al. 2022[32]	Cobas® 4800 CT/NG	Self-taken urine		4.3		
		Self-taken rectal swab		31.3		
Wiesenfeld et al. 2001[33]	Amplicor	Self-taken vaginal		8.0		
Wilson et al. 2020[34]	Aptima combo 2	Self-taken rectal swab	Clinician taken rectal swab	13.5	97.2 (94.3–98.9)	99.8 (99.4–100.0)
		Self-taken pharyngeal swab	Clinician taken pharyngeal swab	3.3	93.7 (84.5–98.2)	99.8 (99.5–100.0)
Wilson et al. 2020[35]	Aptima combo 2	Self-taken triple swab analyzed individually	Clinician taken triple swab	15.3	99.6 (98.0–100.0)	99.5 (99.1–99.8)
		Self-taken vulvovaginal swab (VVS) or first-catch urine (FCU)	Clinician taken pharyngeal and rectal swab	12.1	79.2 79.2 (73.9–83.9)	99.9 (99.6–100.0)
		Self-taken triple swab pooled and analyzed together	Clinician taken triple swab pooled and analyzed together	14.8	96.0 (93.0–98.0)	99.5 (99.1–99.8)

Wong et al. 2022[36]	Aptima Combo 2	Self-taken rectal swab		8.5		
		Self-taken urine		2.5		
Wood et al. 2014[37]	Aptima combo2	Self-taken rectal, pharyngeal and urine (women)		13.3		
Neisseria gonorrhoeae						
Arias et al. 2016[1]	HerSwab + Aptima combo 2	Self-taken vaginal swab	Clinician taken vaginal swab	1.1	100.0	98.4
Bernstein et al. 2011[2]	Aptima combo 2	Self-taken pharyngeal swab	Clinician taken pharyngeal swab	6.1	90.6	97.1
Berry and Stanley 2017[3]	BD Viper XTR	Self-taken penile meatal swab	Self-collected urine sample	2.6	92.9	99.5
Camus et al. 2021[4]	Copan ESwab & Cobas 4800	Self-taken vaginal swab	Clinician taken vaginal swab	1.0	99.9 (99.7–100)	100 (N/A)
Chai et al. 2010[5]	Aptima Gen-Probe,	Self-taken urine and urethral		1.0		
Chernesky, M. et al. 2014[7]	Aptima combo2	Self-taken cervicovaginal		0.4	100.0	100.0
Chinnock, B. et al. 2020[8]	Cepheid Xpert CT, NG	Self-taken vaginal swab	Clinician taken endocervical swab	7.4	97.4 (88.0–99.0)	99.8 (99.0–100.0)
Charin et al. 2021[6]	Aptima Combo 2	Self-taken urine		0.5		

		Self-taken pharyngeal swab		2.8		
		Self-taken rectal		2.2		
De Baetselier et al. 2019[9]	Abbott Real Time (RT) CT, NG assay	Self-taken Urine at home next day	Self-taken urine at clinic	1.5	100.0	99.6
Grabert et. al 2022[12]	Aptima Combo 2	Self-taken wet vaginal swab	Clinician taken vaginal swab	2.0	50.00	99.23
		Self-taken dry vaginal swab		2.8	60.00	98.71
Harvey-Lavoie et al. 2021[13]	COBAS 4800 CT/NG	Self -taken urine		0.4		
		Self-taken rectal		2.9		
Holland-Hall et al. 2002[14]	COBAS Amplicor CT, NG Test	Self-taken endocervical		8.5		

Kanji et al. 2016[15]	Aptima 2 combo	Self-taken cervical	Self-taken urine		100.0	100.0
Ladd et al. 2014[16]	Aptima Gen-Probe,	Self-taken vaginal and rectal		2.4		
Lockhart et al. 2018[17]	Aptima Cervical Specimen Collection and Transport cytobrush	Self-taken cervicovaginal cytobrush	Clinician-taken cervicovaginal	1.3	96.2	99.6
Mabonga et al. 2021[18]	ProbeTecTM ET CT, NG test;	Self-taken vaginal and urine		2.2		
Masek et al. 2009[19]	Aptima combo 2 or Probetec SDA	Self-taken vaginal	Both tests having concordant results	1.2	100.0	99.7
Nodjikouambaye et al. 2019[20]	Allplex STI Essential Assay, Seegene,	Self-taken veil-based cervicovaginal	Clinician taken endocervical swab	0.8	100.0	100.0
Perkins et al. 2013[21]	Not reported	Self-taken rectal, pharyngeal and urine (men)		8.5		
	Not reported	Self-taken rectal, pharyngeal and urine (women)		3.0		
Platteau et al. 2022[22]	Abbott RealTime CT/NG assay	Self-taken urine or rectal swab		0.7		
Rahib et al. 2022[23]	Cobas R PCR Dual Swab Sample Kits or	Self-taken rectal swab		4.3		

	Abbott R multi-Collect Specimen Collection Kit and Copan UriSwab™	Self-taken pharyngeal swab				
Rahib et al. 2019[38]	COBAS 6800	Self-taken urine		7.2 0.5		
Regimbal-Éthier et al. 2018[24]	Not specified	Not specified		0.0		
Sambri et al. 2013[25]	Anyplex II STI-7	Self-taken vaginal		0.0		
Schick et al. 2015[26]	COBAS Amplicor CT, NG Test	Self-taken pharyngeal, vaginal and rectal	Clinician taken rectal swab	5.1	100.0	96.9
Sexton et al. 2013[27]	Aptima combo 2	Self-taken pharyngeal swab	Clinician taken pharyngeal swab	6.3	95.8	97.1
Shipitsyna et al. 2013[28]	AmpliSens Ct, GC MULTIPRIME-FRT, AmpliSens Ct, GC MULTIPRIME-FRT	Self-taken vaginal		0.6		
Silva al. 2020[29]	Metabion	Self-taken vaginal		1.3		

van de Wijgert et al. 2006[30]	COBAS Amplicor CT, NG Test	Self-sampled vaginal tampon	Clinician-collected vaginal swab	6.1	87.5 (73.9–100)	97.0 (95.1–99.0)
		Self-sampled vaginal swab	Clinician-collected vaginal swab	6.3	87.5 (73.9–100)	98.0 (96.3–99.6)
Van der Helm et al. 2009[31]	COBAS Amplicor CT, NG Test	Self-taken rectal swab (MSM)	Clinician taken rectal	6.2	87.9 (78.0–94.0)	98.3 (97.0–99.0)
		Self-taken rectal swab (women)	Clinician taken rectal	1.6	84.6 (58.0–96.0)	99.7 (99.0–100.0)
Wiesenfeld et al. 2001[33]	Amplicor	Self-taken vaginal		2.0		
Weng et al. 2022[32]	Cobas® 4800 CT/NG	Self-taken urine		0.7		
		Self-taken rectal swab		9.4		
Wilson et al. 2020[34]	Aptima combo 2	Self-taken rectal swab	Clinician taken rectal swab	4.5	97.6 (91.6–99.7)	99.6 (99.2–99.9)
		Self-taken pharyngeal swab	Clinician taken pharyngeal swab	3.9	95.8 (88.3–99.1)	99.8 (99.5–100.0)
Wilson et al. 2020[35]	Aptima combo 2	Self-taken triple swab analyzed individually	Clinician taken triple swab	6.4	98.3 (93.9–99.8	99.5 (99.0–99.8)
		Self-taken Vulvovaginal swab(VVS) or first-catch urine(FCU)	Clinician taken VVS, FCU	4.0	63.7 (54.1–72.6)	100.0 (99.8–100.0)

		Self-taken triple swab pooled and analyzed together	Clinician taken triple swab pooled and analyzed together	6.3	98.2 (99.5–100.0)	99.8 (92.3–99.1)
Wong et al. 2022[36]	Aptima Combo 2	Self-taken rectal swab		6.8		
		Self-taken urine		1.6		
Wood et al. 2014[37]	Aptima combo2	Self-taken rectal, pharyngeal and urine (women)		6.3		

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Supplementary Table 4. Sensitivity, Specificity and DOR of *Chlamydia Trachomatis* and *Neisseria gonorrhoea* Self–Sampling Based Tests by Country Type and Sampling Sites for High-Income Countries Only with Associated 95% CIs, i^2 Metric, and p-values. Significant Values are Bolded.

		Sensitivity [95% CIs]	**p-value**	**Specificity [95% CIs]**	**p-value**	**DOR [95% CIs]**	I^2
Chlamydia trachomatis	High Income	91.6 [84.9–95.5]	<0.001	99.2 [98.8–99.4]	0.008	1390 [551–2940]	87.0
	Vaginal[1]	86.0 [76.6–92.1]	Ref	99.7 [97.6–100]	Ref	4060 [165–21400]	84.2
	Pharyngeal[1]	92.5 [86.5–95.9]	0.79	99.7 [99.5–99.8]	0.57	4550 [1710–9880]	0.0
	Rectal[1]	93.1 [87.8–96.2]	0.34	99.4 [98.8–99.7]	0.81	2490 [638–6770]	79.0
	Low Income	70.7 [45.7–87.4]	Ref	98.5 [97.9–98.9]	Ref	181 [56–442]	81.9
Neisseria gonorrhoea	High Income	92.9 [88.1–95.9]	<0.001	97.7 [96.9–98.3]	0.25	573 [307–980]	75.2
	Vaginal[1]	86.2 [76.0–92.5]	Ref	99.8 [98.6–100]	Ref	6740 [353–33400]	70.8
	Pharyngeal[1]	94.3 [89.6–96.9]	0.07	99.3 [97.1, 99.8]	0.20	3370 [422–12600]	70.8
	Rectal[1]	91.6 [86.0–95.1]	0.27	99.2 [98.4–99.6]	0.19	1620 [426–4340]	63.8
	Low Income	77.4 [61.4–88.0]	Ref	98.8 [97.9–99.3]	Ref	309 [114–682]	74.8

[1] values are for studies from high-income countries only

Supplementary Table 5. Sensitivity, Specificity and DOR of *Chlamydia Trachomatis* and *Neisseria gonorrhoea* Self–Sampling Based Tests with Associated 95% CIs, i^2 metric, and p-values for studies of high quality only (n=7). Significant values are bolded.

		Sensitivity [95% CIs]	**p-value**	**Specificity [95% CIs]**	**p-value**	**DOR [95% CIs]**	I^2
Chlamydia trachomatis	Overall	91.0 [87.3–93.8]	Ref	99.3 [98.8–99.6]	Ref	1590 [587–3500]	88.9
Sampling Site	Vaginal	86.4 [82.5–89.5]	Ref	98.7 [97.0–99.5]	Ref	557 [192–1280]	80.2
	Pharyngeal	93.3 [87.4–96.5]	0.18	99.8 [99.6–99.9]	**<0.001**	8280 [2550–20300]	83.5
	Rectal	93.4 [87.7–96.6]	**0.034**	99.4 [98.8–99.7]	**0.011**	3160 [641–9650]	0
Study population	Women	90.0 [85.1–93.5]	0.60	99.2 [98.4–99.6]	0.44	1340 [393–3390]	83.8
	MSM	91.7 [83.4–96.0]	Ref	99.5 [98.3–99.9]	Ref	4030 [322–17800]	60.3
Neisseria gonorrhoea	Overall	91.4 [88.2–93.9]	0.78	99.3 [98.9–99.6]	0.98	1600 [707–3130]	80.7
Sampling site	Vaginal	88.3 [82.0–92.6]	Ref	99.0 [97.4–99.6]	Ref	902 [245–2370]	68.2
	Pharyngeal	95.6 [90.3–98.0]	0.054	99.8 [99.1–99.9]	**0.045**	12300 [2360–38600]	72.8
	Rectal	92.6 [87.1–95.9]	0.35	99.4 [98.8–99.7]	0.23	2270 [619–5970]	0
Study population	Women	89.4 [84.3–92.9]	0.54	99.4 [98.5–99.7]	0.89	1470 [466–3570]	67.1
	MSM	92.8 [84.1–96.9]	Ref	99.2 [97.7–99.7]	Ref	2370 [272–9230]	74.9

PRISMA 2020 Main Checklist

TITLE			
Title	1	Identify the report as a systematic review.	p.1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	pp. 4-5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p.5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	p.5
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	p.5
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	p.5
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	p.5

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(continued)

Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	p.5
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	pp.5-6 and Table 1
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	p.5
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p.7
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	p.6
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item 5)).	p.6

(continued)

	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	p.6
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	p.6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	p.6
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	p.6
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	p.7
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	p.6
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	p.6
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	p.7 and Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Figure 1
Study characteristics	17	Cite each included study and present its characteristics.	p.7 and Supplementary Table 1

(continued)

Risk of bias in studies	18	Present assessments of risk of bias for each included study.	p.11 and Figure 3
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	p. 8, Table 2 and Supplementary Table 3 (only done for accuracy studies)
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	pp.8-11 and Figure 2
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	pp. 8-9 and Table 2 (only done for accuracy studies)
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	pp.8-9 and Table 2 (only done for accuracy studies)
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	p.11 and supplementary Tables 4-5
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	p.11 and Figure 3
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	p.8 and Table 2 (for accuracy only)
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	pp. 11-12
	23b	Discuss any limitations of the evidence included in the review.	p.13
	23c	Discuss any limitations of the review processes used.	p.13

(continued)

	23d	Discuss implications of the results for practice, policy, and future research.	p.14
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	p.5
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	p.5
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	n/a
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	p.15
Competing interests	26	Declare any competing interests of review authors.	p.15
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	p.15

PRIMSA Abstract Checklist

TITLE			
Title	1	Identify the report as a systematic review.	Yes
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	Yes
Synthesis of results	6	Specify the methods used to present and synthesize results.	Yes
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	No
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	No
Registration	12	Provide the register name and registration number.	Yes

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. MetaArXiv. 2020, September 14. DOI: 10.31222/osf.io/v7gm2. For more information, visit: www.prisma-statement.org

SEARCH STRING STRATEGY

Pubmed

((chlamydia trachomatis[Text Word]) AND/OR (neisseria gonorrhoeae[Text Word]) OR (ct/gc[Text Word])) AND ((self-testing[Text Word] OR self testing[Text Word] OR self-sampling[Text Word] OR self sampling[Text Word])). Filters applied: from 2000/1/1 - 2023/01/6.

LILACS

(chlamydia trachomatis and neisseria gonorrhoeae or ctgc) AND (self-testing or self testing or self-sampling or self sampling). Filters applied: from 2000/1/1 - 2023/01/6.

Embase search history

Libraries: Embase <1996 to 2021 Week 47> and Embase Classic+Embase <1947 to 2021 Week 47>

1 ((chlamydia trachomatis and neisseria gonorrhoeae) or ctgc).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word] 5566
2 limit 1 to yr="2000 -Current" 4245
3 (self-testing or self testing or self-sampling or self sampling).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word] 3113
4 limit 3 to yr="2000 -Current" 2975
5 2 and 4 44

Contexte : *Chlamydia trachomatis* (CT) et *Neisseria gonorrhoeae* (GC) ont été à l'origine de plus de 200 millions de nouvelles infections sexuellement transmissibles (IST) l'année dernière. Les stratégies d'auto-prélèvement, seules ou combinées à des innovations numériques (c'est-à-dire des technologies en ligne, mobiles ou informatiques permettant l'auto-prélèvement), pourraient améliorer les méthodes de dépistage. Les preuves sur toutes les sortes de résultats n'ont pas encore été synthétisées. C'est pourquoi nous avons mené une revue systématique et une méta-analyse pour remédier à cette lacune.

Méthodes : Nous avons recherché des rapports sur l'auto-prélèvement pour les tests CT/GC dans trois bases de données (période : du 1er janvier 2000 au 6 janvier 2023). Les résultats que nous avons pris en compte pour l'inclusion étaient : la précision, la faisabilité, ceux centrés sur le patient et l'impact (c'est-à-dire les changements dans le lien avec les soins, les personnes qui testent pour la première fois, l'utilisation, le délai d'exécution ou les références attribuables à l'auto-prélèvement). Nous avons utilisé des modèles de régression bivariés pour faire une méta-analyse des mesures de précision des tests CT/GC auto-prélevés et obtenir des estimations de sensibilité/spécificité groupées. Nous avons évalué la qualité des études à l'aide du « Cochrane Risk of Bias Tool-2 », de l'échelle de « Newcastle-Ottawa » et de l'outil « Quality Assessment of Diagnostic Accuracy Studies-2 ».

Résultats : Nous avons résumé les résultats de 45 études portant sur l'auto-prélèvement seul (73,3 % ; 33 sur 45) ou combiné à des innovations numériques (26,7 % ; 12 sur 45) menées dans 10 pays à revenu élevé (PRE ; n=34) et 8 pays à revenu faible/moyen (PRFM ; n=11). 95,6 % (43 sur 45) étaient des études observationnelles, tandis que 4,4 % (2 sur 45) étaient des essais cliniques randomisés. Nous avons noté que la sensibilité regroupée (n=13) pour la CT/GC était plus élevée pour les auto-prélèvements extra-génitaux (>91,6 % (86,0 %-95,1 %)) que pour les auto-prélèvements vaginaux (79,6 % (62,1 %-90)). Les participants ont trouvé l'auto-prélèvement très acceptable (80,0 %-100,0 % ; n=24), mais avaient une préférence variée (23,1 %-83,0 % ; n=16). L'auto-prélèvement a atteint 51,0 %-70,0 % (n=3) des personnes qui se faisait tester pour la première fois et a entraîné 89,0 %-100,0 % (n=3) de liens avec les soins. Les innovations numériques ont entraîné un engagement de 65,0 % à 92 % et des taux d'achèvement de 43,8 % à 57,1 % (n=3). La qualité des études s'est démontrée être variable

Discussion : L'auto-prélèvement avait une sensibilité variable, atteignait les personnes qui se faisaient tester pour la première fois et était accepté avec des liens élevés avec les soins. Nous recommandons l'auto-prélèvement pour la CT/GC dans les PRE, mais des évaluations supplémentaires dans les PRFM. Les innovations numériques ont eu un impact sur l'engagement et peuvent donc réduire les taux de morbidité dans les populations difficiles à atteindre.

Numéro d'enregistrement PROSPERO : PROSPERO CRD42021262950.