McMaster University | Health Forum

Rapid evidence profile

Self-testing for gynecological and urological conditions

27 February 2025

[MHF product code: REP 89]

Appendices

Appendix 1: Methodological details

We use a standard protocol for preparing rapid evidence profiles (REP) to ensure that our approach to identifying research evidence is as systematic and transparent as possible in the time we were given to prepare the profile.

Identifying research evidence

For this REP, we searched Health Systems Evidence, ACCESSSS, and PubMed for:

1) evidence syntheses
2) protocols of evidence syntheses
3) single studies.

We searched Health Systems Evidence using an open text search for (self test OR self-test OR self screen OR self screen) combined with a filter limiting results to the past 10 years. In ACCESSSS, we used an open text search for (self test OR self screen). In PubMed, we used medical subject headings for Sexually Transmitted Diseases OR Vaginal Diseases combined with an open text search for ((self test* OR self-test* OR self-screen* OR self screen* OR self sampl* OR self-sample) NOT (("HPV" OR human papilloma OR cancer) combined with a 10 year filter and product filter for reviews.

Each source for these documents is assigned to one team member who conducts hand searches (when a source contains a smaller number of documents) or keyword searches to identify potentially relevant documents. A final inclusion assessment is performed both by the person who did the initial screening and the lead author of the REP, with disagreements resolved by consensus or with the input of a third reviewer on the team. The team uses a dedicated virtual channel to discuss and iteratively refine inclusion/exclusion criteria throughout the process, which provides a running list of considerations that all members can consult during the first stages of assessment. Following this process, we included 42 evidence documents.

During this process we include published, pre-print, and grey literature. We do not exclude documents based on the language of a document. However, we are not able to extract key findings from documents that are written in languages other than Chinese, English, French, or Spanish. We provide any documents that do not have content available in these languages in an appendix containing documents excluded at the final stages of reviewing. We excluded documents that did not directly address the research questions and the relevant organizing framework.

Assessing relevance and quality of evidence

We assess the relevance of each included evidence document as being of high, moderate, or low relevance to the question.

Two reviewers independently appraised the quality of the guidelines we identified as being highly relevant using AGREE II. We used three domains in the tool (stakeholder involvement, rigour of development, and editorial independence) and classified guidelines as high quality if they were scored as 60% or higher across each of these domains.

Two reviewers independently appraise the methodological quality of evidence syntheses that are deemed to be highly relevant using the first version of the AMSTAR tool. Two reviewers independently appraise each synthesis, and disagreements are resolved by consensus with a third reviewer if needed. AMSTAR rates overall methodological quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. High-quality evidence syntheses are those with scores of eight or higher out of a possible 11, medium-quality evidence syntheses are those with scores between four and seven, and low-quality evidence syntheses are those with scores less than four. It is important to note that the AMSTAR tool was developed to assess evidence syntheses focused on clinical interventions, so not all criteria apply to those pertaining to health-system arrangements or implementation strategies. Furthermore, we apply the AMSTAR criteria to evidence syntheses addressing all types of questions, not just those addressing questions about effectiveness, and some of these evidence syntheses addressing other types of questions are syntheses of qualitative studies. While AMSTAR does not account for some of the key attributes of syntheses of qualitative studies, such as whether and how citizens and subject-matter experts were involved, researchers' competency, and how reflexivity was approached, it remains the best general quality-assessment tool of which we're aware. Where the denominator is not 11, an aspect of the tool was considered not relevant by the raters. In comparing ratings, it is therefore important to keep both parts of the score (i.e., the numerator and denominator) in mind. For example, an evidence synthesis that scores 8/8 is generally of comparable quality to another scoring 11/11; both ratings are considered 'high scores.' A high score signals that readers of the evidence synthesis can have a high level of confidence in its findings. A low score, on the other hand, does not mean that the evidence synthesis should be discarded, merely that less confidence can be placed in its findings and that it needs to be examined closely to identify its limitations. (Lewin S, Oxman AD, Lavis JN, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP): 8. Deciding how much confidence to place in a systematic review. *Health Research Policy and Systems* 2009; 7 (Suppl1): S8.)

Preparing the profile

Each included document is cited in the reference list at the end of the REP. For all included guidelines, evidence syntheses, and single studies (when included), we prepare a small number of bullet points that provide a summary of the key findings, which are used to summarize key messages in the text. Protocols and titles/questions have their titles hyperlinked, given that findings are not yet available.

We then draft a summary that highlights the key findings from all highly relevant documents (alongside their date of last search and methodological quality).

Appendix 2: Details about each identified evidence synthesis

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations

• Purpose of test
  ○ Screening
• Conditions
  ○ STIs
• Test type
  ○ Other
• Processing of results
  ○ Sent to laboratory
• Outcomes
  ○ Acceptability
	While there are some concerns with internet-based testing, it was largely determined to be a positive experience due to the convenience and lack for stigma (1)
	• Explores the use of internet-based testing services through a self-sampling kit, which is then returned to a laboratory for testing before receiving remote results
	• The evidence synthesis included 11 studies predominantly from the U.K. and the U.S.
	• Two of the included studies reported the experience of users who had accessed internet-based testing, while the remaining nine explored hypothetical services
	• The studies favoured those under 30, women, and one study focused exclusively on Black participants
	• There was a broad consensus across the included studies that internet-based testing is acceptable, with positive aspects including the convenience, lack of stigma associated with face-to-face testing, avoidance of negative interactions with clinic staff, and accessibility
	• Some concern was reported about ordering a test from a webpage, limited access to internet, questions regarding privacy, and higher cost, while others reported some concern about the lack of education and ability to speak with a healthcare provider and challenges in self-sampling (e.g., errors or inaccuracies)
		High	No	3/9	December 2018	• No	• Gender/sex
							• Race/ethnicity

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ Chlamydia
  ▪ Gonorrhoea
• Test types
  ○ Other
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
  ○ Adverse events
	Diagnostic testing for both chlamydia and gonococcal was highly accurate for females and have strong records of sensitivity, though some studies reported lower diagnostic accuracy (2)
	• Evidence synthesis explores the use of screening for chlamydial infection and one sub-question specifically examined the accuracy of clinician- and self-collected vaginal samples for diagnosis
	• Sensitivity was found to be between 90% and 100% for clinical-collected samples and 90% and 98% for self-collected samples, while an additional study reported sensitivities of 56% for clinician-collected and 52% for self-collected using a different methodology
	• An additional question in the synthesis examined harms from diagnostic testing and reported mixed false-positive rates, with
		High	No	6/10	May 2021	No	• Not reported

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
	higher rates for self-collected compared to clinician collected samples; for gonorrhoea testing, false positive rates were found to be considerably lower						

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ Chlamydia
  ▪ Gonorrhoea
• Test types
  ○ Other
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
	Self-sampling had mixed sensitivity but when combined with digital innovations increased engagement with hard-to-reach populations (3)
	• The evidence synthesis examined self-sampling strategies alone or combined with digital innovations
	• Though the populations of interest are somewhat different and include men who have sex with men, pooled sensitivity for chlamydia and gonorrhoea was higher in extragenital self-sampling (around 92%) than in vaginal sampling (around 80%), though pooled specificity remained high
	• Digital innovations led to 65% to 92% engagement and 43% to 57% kit return rates
		High	No	7/11	January 2023	No	• Not reported

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ HIV
  ▪ Trichomonas
  ○ Bacterial infection
• Populations
  ○ Military
• Test types
  ○ Real-time PCR
  ○ Vaginal PH test
  ○ Tests for specific pathogens
  ▪ Trichomonas
  ○ Other
• Processing of results
  ○ Point-of-care/immediate
  ○ Sent to care provider
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
	The synthesis found that self-diagnosis of vaginal infection lacks sufficient accuracy as self-swabs and pH strips had low sensitivity with the exception of the panty liner test (but results were limited to a single study); similarly for HIV, pooled sensitivity was reduced to 88% when laboratory testing and venous samples were used as reference, which do not support the use of the test given the possible ramifications of a false-positive (4)
	• The synthesis examined self-diagnosis of conditions commonly managed in primary care, including vaginal infections and HIV
	• Meta-analysis was not possible for either vaginal infection or HIV
	• Five studies reported on the accuracy of self-diagnosis of bacterial vaginosis and/or trichomonas
	  ○ For bacterial vaginosis, two studies used a vaginal pH strip with lab testing and reported sensitivity ranging from 0.45 (95% CI 0.34–0.56) to 0.60 (95% CI 0.55–0.66) with a pH cut of > 4.7, and a specificity ranging from 0.5 (95% CI 0.43–0.56) to 0.81 (95% CI 0.75–0.85) with a pH cut off of 4.7
	  ○ For the diagnosis of vaginosis and or/trichomonas, a panty liner test kit for vaginal discharge was assessed and reported a sensitivity of 0.91 (95% CI 0.85–0.94) and specificity of 0.81 (95% CI 0.76–0.86) for the diagnosis of bacterial vaginosis.
	  ○ One study reported on the use of a rapid immunochromatographic T. vaginalis test for use at home and reported a sensitivity of 0.68 (95% CI 0.43–0.87) and specificity of 1.0 (95% CI 0.99–1.00) for self-diagnosis
		High	No	6/11	January 2021	No	• Not reported

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
	○ For candida vaginitis one study included as part of a military self-testing kit reported a sensitivity of 0.18 (95% CI 0.12–0.25) and specificity of 0.89 (95% CI 0.85–0.92) • Nine studies also reported on the diagnostic accuracy of self-testing and self-diagnosis of HIV using oral fluid test manufactured by OraSure Technologies ○ Pooled sensitivity was 92.8% (95% CI 86%–96.5%) and pooled specificity was 99.8% (95% CI 99.1%–99.9%) ○ In all tests, though the sample was self-provided, diagnosis was provided by clinician						
• Purpose of test ○ Diagnosis • Conditions ○ STIs ▪ Chlamydia ▪ Gonorrhoea • Test types ○ Other • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity ○ Acceptability	Offering self-collection at home resulted in a higher number of tests for chlamydia and gonorrhoea and a higher proportion of positive chlamydia tests received, likely due to asymptomatic individuals findings testing more convenient, though no change was reported for rates of gonorrhoea testing (5) • The evidence synthesis examined how offering at-home specimen self-collection would affect testing uptake, test results, diagnosis and linkage to care when compared with collection in clinical settings • Nucleic acid amplification tests are recommended for the screening and diagnosis of chlamydia gonorrhoea using a vaginal swab or urine test that is then mailed to a healthcare facility • Comparison was specimen collection within a healthcare facility, either self-collected or healthcare provider collected • As compared to clinical setting, more individuals collected and returned specimens testing at home, with no significant difference detected between men and women, but men were 3.5 times more likely to get testing at home compared to clinical settings • Meta-analysis found a significantly greater proportion of positive chlamydia tests in the individuals who collected specimens at home compared to the specimens collected in clinical settings • Included studies generally demonstrated low risk of bias across all outcomes • There was a significant difference in connection to treatment following testing, with 88.6% of the intervention group treated compared with 93.9% of the comparison group • Four of the included studies evaluated the test concordance for specimens collected at home as compared with clinic settings by the same individual	High	No	6/11	April 2023	No	• Not reported

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
	○ For chlamydia concordance was 96.7% for vaginal swabs, 96.5% for urine, and 96.3% for pooled specimens ○ For gonorrhoea, the highest concordance was 92.3% for vaginal swabs and 100% for urine and pooled specimens • More people in home specimen kit reported some level of difficulty in understanding instructions and about 2.6% to 17% reported pain or discomfort compared to 12.3% in the clinical self-collection group • Self-collection at home and in clinic showed generally similar numbers of invalid test results						
• Purpose of test ○ Screening • Conditions ○ STIs ▪ HIV • Test types ○ Real-time PCR • Processing of results ○ Point-of-care/immediate • Outcomes ○ Acceptability ○ Adverse events	HIV self-testing is an accessible and acceptable form of screening that can provide timely access to care, convenience for hard-to-reach populations, autonomy over testing, and normalize HIV care (6) • The purpose of this review was to synthesize qualitative research regarding the use of HIV self-testing • HIV self-testing was acceptable and accessible ○ Self-testing was more convenient than facility-based testing facilitating access to hard-to-reach populations ○ Self-testing provided patients with more autonomy and control (e.g., timing and location) ○ Testing could be obtained from easily accessible locations (e.g., community centres, pharmacies, bars) • HIV self-testing provided privacy, helping to reduce stigma of seeking testing ○ The increased accessibility and visibility of screening helped to normalize the act of seeking care ○ Facilitated partner testing, which could help to inform sexual decision making • Possible adverse events related to self-testing were anticipatory anxiety and psychological distress • Self-testing could supplement existing resources in the community, but not replace	High	No	7/9	2016	Not available	• Gender/sex
• Purpose of test ○ Screening • Conditions ○ STIs ▪ Chlamydia ▪ Gonorrhoea • Test types ○ Real-time PCR	The self-collected tests with the highest sensitivity and specificity, compared to clinically collected tests, were vaginal swabs in females and urine tests in males, suggesting they could be good alternatives for hard-to-reach populations (7) • The purpose of this study was to compare self-collected vaginal, urine, pharyngeal, and rectal samples to the standard clinical testing for chlamydia and gonorrhoea	High	No	7/11	2013	Not available	• Gender/sex

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
○ Urine sample ○ Other • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity ▪ Positive predictive values ▪ Negative predictive values	• Sensitivity and specificity of self-collected urine versus clinical standard for chlamydia in men: ○ sensitivity: 0.90 (0.84–0.94) ○ specificity: 0.99 (95% CI 0.89–1.00) ○ these values changed when a study with high prevalence was removed: sensitivity 0.89 (95% CI 0.82–0.93) and specificity 0.99 (0.98–1.00) • Sensitivity and specificity of self-collected urine versus clinical standard for chlamydia in women: ○ sensitivity: 0.87 (95% CI 0.81–0.91) ○ specificity: 0.99 (95% CI 0.98–1.00) • Sensitivity and specificity of self-collected vaginal versus clinical standard for chlamydia in women: ○ sensitivity: 0.92 (95% CI 0.87–0.95) ○ specificity: 0.98 (95% CI 0.97–0.99) ○ results for just swab analysis: sensitivity 0.89 (95% CI 0.82–0.94) and specificity 0.98 (95% CI 0.97–0.99) ○ results for single assay: sensitivity 0.90 (95% CI 0.83–0.95) and specificity 0.98 (95% CI 0.97–0.99) • Sensitivity and specificity of self-collected rectal swabs versus clinical rectal swabs for females with chlamydia: ○ sensitivity: 0.88 (95% CI 0.79–0.94) ○ specificity: 0.99 (95% CI 0.98–0.99) • Sensitivity and specificity of self-collected rectal swabs versus clinical rectal swabs for males with chlamydia: ○ sensitivity: 0.88 (95% CI 0.81–0.92) ○ specificity: 0.99 (95% CI 0.98–0.99) • Sensitivity and specificity of self-collected pharyngeal swabs versus clinical swabs for men with chlamydia: ○ sensitivity: 0.83 (95% CI 0.36–1.00) ○ specificity: (95% CI 0.98–1.00) • Sensitivity and specificity of self-collected urine versus clinical collected for gonorrhoea in men: ○ sensitivity: 0.92 (95% CI 0.83–0.97) ○ specificity: 0.99 (95% CI 0.98–1.00) • Sensitivity and specificity of self-collected urine versus clinical collected for gonorrhoea in women: ○ sensitivity: 0.79 (95% CI 0.70–0.88) ○ specificity: 0.99 (95% CI 0.99–1.00)						

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations

	• Sensitivity and specificity of self-collected vaginal swabs versus clinical collected for gonorrhoea in women:
	  ○ sensitivity: 0.98 (95% CI 0.88–1.00)
	  ○ specificity: 0.97 (95% CI 0.94–0.99)
	• Sensitivity and specificity of self-collected rectal swabs versus clinical collected for gonorrhoea in women:
	  ○ sensitivity: 0.85 (95% CI 0.55–0.98)
	  ○ specificity: 1.00 (95% CI 0.99–1.00)
	• Sensitivity and specificity of self-collected rectal swabs versus clinical collected for gonorrhoea in men:
	  ○ sensitivity: 0.88 (95% CI 0.78– 0.95)
	  ○ specificity: 0.98 (95% CI 0.97–0.99)
	• Sensitivity and specificity of self-collected pharyngeal swabs versus clinical collected for gonorrhoea in men:
	  ○ sensitivity: 0.91 (95% CI 0.75–0.98)
	  ○ specificity: 0.97 (95% CI 0.95–0.98)						

• Purpose of test
  ○ Screening
• Conditions
  ○ STIs
  ▪ Chlamydia
• Populations
  ○ Age
  ▪ Under 25
• Test types
  ○ Real-time PCR
• Outcomes
  ○ Uptake
  ○ Acceptability
  ○ Cost-effectiveness
	Information regarding the acceptability and cost-effectiveness of HIV rapid screening tests is limited; future screening implementation programs should address healthcare providers hesitancy and the unique needs of high-risk and underrepresented populations (8)
	• The purpose of this study was to assess the effectiveness of chlamydia screening interventions and the factors impacting their success
	• Most reviews included in this review focused on adolescent girls
	• The review noted the importance of screening for young boys
	• The review noted the importance of routine lab testing (e.g., papanicolaou smears) over rapid testing for high-risk populations
	• Overall, the review stated that it was challenging to determine the effectiveness of screening measures
	  ○ Healthcare providers may hesitate to screen young asymptomatic women
	  ○ One included study found a 3% increase in screening rates post implementation of a screening program for females in a juvenile detention centre
	  ○ Across studies there was little information on cost-effectiveness
		Low	No	5/10	Not specified	Not available	• Gender/sex

• Purpose of test
  ○ Screening
• Conditions
  ○ STIs
	Chlamydia and gonorrhoea screening programs demonstrate okay participation and return rates, additional research is needed to determine the exact effectiveness of programs (9)	Low	No	4/9	2011	Not available	• Gender/sex

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
▪ Chlamydia ▪ Gonorrhoea • Test types ○ Real-time PCR • Processing of results ○ Point-of-care/immediate • Outcomes	• The purpose of this evidence synthesis was to review the strategies and outcomes of chlamydia and gonorrhoea screening programs outside of clinics • The median participation rate in screening programs varied across different contexts ○ The overall median participation rate was 68.9% ○ The median participation rate of home programs with immediate results was 83%, with a return rate of 96.5% ○ The median participation rate of postal test kits with a formal intervention was 37.1%, with a return rate of 78.9% ○ The median participation rate of postal test kits without a formal intervention had a return rate 31.8% ○ The median participation rate with postal test kits with an in-person invitation was 46.4%, with a 21.4% return rate ○ The median participation rate with postal test kits picked up from a designated location had a return rate of 18.6%						
• Purpose of test ○ Diagnosis • Conditions ○ STIs ▪ HIV • Processing of results ○ Point-of-care/immediate • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity	Self-testers can achieve the same results as healthcare workers when using HIV rapid diagnostic tests and diagnostic accuracy of rapid diagnostic tests for self-testing is high (10) • This review assessed the reliability and performance of HIV rapid diagnostic tests when used by self-testers, compared with healthcare workers • 25 studies met the inclusion criteria • This review suggests that blood-based rapid diagnostic tests had higher sensitivity and specificity than oral fluid tests • 16 out of 20 reports from 16 studies had a specificity greater than 98% • Sensitivity varied significantly, with 18 reports showing sensitivity of at least 80% • Applying the estimated sensitivity (80–100%) and specificity (95.1–100%) to a hypothetical group of 100,000 people with 1% HIV prevalence would result in zero to 200 missed HIV-positive cases and zero to 4,851 false positives	High	No	7/11	2016	No	• None reported
• Purpose of test ○ Diagnosis • Conditions ○ STIs ▪ HIV • Outcomes ○ Accuracy	HIV self-testing is an acceptable testing alternative for risk groups and can be performed accurately by the majority of self-testers (11) • The review evaluated the acceptability of HIV self-testing (HST) and the benefits and challenges linked to the introduction of HST • Studies consistently showed high acceptability of HST, especially with saliva-based rapid tests, across all evaluated populations	Low	No	5/10	2012	No	• Place of residence

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
○ Uptake ○ Acceptability	• Acceptability was high in two home sample collection studies (81% and 67%) • HST promoted testing equally among both genders and encouraged repeat and first-time testing in hard-to-reach groups • In African countries with established testing programs, HST expanded access, with 41% of participants in Malawi having never tested before and 78% had not tested in over a year, highlighting how HST expanded HIV testing reach, even in countries with established testing programs						
• Purpose of test ○ Diagnosis • Conditions ○ STIs ▪ HIV • Processing of results ○ Point-of-care/immediate • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity ▪ Positive predictive values ▪ Negative predictive values	Oral OraQuick demonstrated lower sensitivity but similar specificity to its whole-blood counterpart, with high positive predictive values in high-prevalence settings, though it showed a low positive predictive value in low-prevalence settings, and the slightly reduced sensitivity and positive predictive values in these areas should be carefully considered when planning global initiatives with this widely used test (12) • This review compared the diagnostic accuracy of a rapid HIV-antibody-based point-of-care test (Oraquick advance rapid HIV-1/2, OraSure Technologies Inc, PA, U.S.) when used with oral versus blood-based specimens in adults • In a head-to-head comparison, oral specimens showed a pooled sensitivity 2% lower (98.03%) than blood-based specimens (99.68%), with similar specificity (oral 99.74%, blood 99.91%) • Negative likelihood ratios were similar (oral 0.019, blood 0.003), but positive likelihood ratios were higher for blood (1105.16) compared to oral (383.37) • While positive predictive values were similar in high-prevalence settings (oral 98.65%, blood 98.50%), oral specimens had lower positive predictive values in low-prevalence settings (88.55%) compared to blood (97.65%)	Low	No	8/10	2011	No	• None reported
• Purpose of test ○ Screening • Conditions ○ STIs ▪ Chlamydia ▪ Gonorrhoea • Populations ○ Age ▪ Under 25	Universal primary-care screening for chlamydia in the general non-pregnant sexually active population may result in little-to-no difference in transmission, female risk of pelvic inflammatory disease, or ectopic pregnancy in those aged 16 to 29 years, while the prevalence of infection and screening rates may moderate the benefits of screening in females for both chlamydia and gonorrhoea (13) • Little-to-no difference in transmission was found for screening conducted at home compared to at a clinic	Low	No	10/10	January 2020	Yes	• Gender/sex

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Living status	Quality (AMSTAR)	Last year literature searched	Availability of GRADE profile	Equity considerations
▪ Between 25 and 64 ▪ Over 65 • Test types ○ Urine sample ○ Other • Processing of results ○ Sent to laboratory ○ Sent to care provider • Outcomes ○ Acceptability	• Screening may result in harms in a small number of individuals, manifesting as feelings of anxiety and stigmatization about future infertility, while little-to-no difference was found for general anxiety, self-esteem, or relationship break-ups • In terms of patient preferences, the benefits of screening may outweigh the potential harms, with variability among individuals • The study was interested in the clinical outcomes of chlamydia and gonorrhoea screening, with limited contextualization to self-test kits or their screening and diagnostic accuracy						
• Purpose of test ○ Screening ○ Diagnosis • Conditions ○ STIs ▪ Chlamydia • Populations ○ Age ▪ Under 25 ▪ Between 25 and 64 • Test types ○ Urine sample ○ Other • Outcomes ○ Acceptability	Chlamydia screening may be more acceptable to women if they can access tests that are non-invasive, conducted at home, free, quick, easy, private, and/or offered in a range of options (e.g., urine, self-administered swab) (14) • Women reported the importance of being "in control" of their chlamydia tests and results, including the ability to choose or refuse • Time and cost were among the pragmatic considerations of women's views on chlamydia testing where acceptability was weakened by the need for a physical visit to the clinic and discomfort with the collection of samples • Discussion of self-test kits were limited and information on screening and diagnostic test accuracy was not reported	Low	No	3/9	August 2005	No	• Gender/sex

Appendix 3: Details about each identified single study

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ Chlamydia
  ▪ Gonorrhoea
• Populations
  ○ Age
  ▪ Under 25
  ▪ Between 25 and 64
• Test types
  ○ Real-time PCR
  ○ Urine sample
• Processing of results
  ○ Sent to laboratory
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
  ▪ Positive predictive values
  ▪ Negative predictive values
  ○ Acceptability
• Variables that may affect outcomes
  ○ Education on use of test
	Self-swabs used for diagnosis of chlamydia and gonorrhoea were found to have high acceptability and had a high rate of agreement with swabs collected by healthcare providers (15)
	• Examined the validity, feasibility, and acceptability of sexually transmitted infection (STI) testing using self-collected swabs versus swabs collected by a healthcare (HC) provider for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) for patients in an STI clinic
	  ○ Additionally aimed to examine the usability and acceptability of self-sampling devices
	• The self-sampling kit was accompanied with a video and detailed instructions including handwashing recommendations and written/graphic instructions to collect swabs
	• Self-samples and HC provider samples for Chlamydia showed 94% agreement (κ=0.78)
	• Self-samples and HC provider samples for gonorrhoeae showed 95% agreement (κ=0.86)
	• The study found no disparity between diagnoses of Chlamydia or gonorrhoeae resulting from HC provider samples or self-samples
	• Overall sensitivity for chlamydia self-samples was 81%
	  ○ Information for sensitivity of self-samples from different areas of the body (e.g., vaginal, pharyngeal) is included in the paper
	• Overall sensitivity for gonorrhoeae self-samples was 93%
	  ○ Information regarding sensitivity of self-samples from different body locations is included in the paper
	• Positive predictive values for chlamydia self-samples were 83.3% overall
	  ○ Information from different sample locations is included in the paper
	• Positive predictive values for gonorrhoea self-samples were 85.4% overall
	  ○ Information from different sample locations is included in the paper
	• Negative predictive values for chlamydia self-samples were 96.2% overall
		High	*Publication date*: 2024
			
			Jurisdiction studied: Madrid, Spain
			
			Methods: Prospective single-blind cross-sectional study
				• None reported

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations
	○ Information from different sample locations is included in the paper • Negative predictive values for gonorrhoea self-samples were 97.8% overall ○ Information from different sample locations is included in the paper • Specificity for chlamydia and gonorrhoea self-samples were greater than 93% for all sampling locations ○ Overall specificity for chlamydia was 97% ○ Overall specificity for gonorrhoea was 95% • Overall accuracy rate for gonorrhoea and chlamydia self-samples was 93% • Over 75% of participants reported that self-sampling kits were easy to understand and use • 99% of participants reported they were satisfied (25.5%) or very satisfied (70.6%) with the self-sampling kits			
• Purpose of test ○ Diagnosis • Conditions ○ STIs ▪ Chlamydia ▪ Gonorrhoea ▪ HIV ▪ Syphilis • Populations ○ Age ▪ Under 25 ▪ Between 25 and 64 ▪ Over 65 ○ 2SLGBTQIA+ • Test types ○ Urine sample ○ Other • Processing of results ○ Sent to laboratory ○ Sent to care provider • Outcomes ○ Uptake ○ Acceptability	Self-testing kits for STIs dispensed from freely available vending machines were found to be convenient, easy to use, and an overall positive experience (16) • Freely available public vending machines dispensing STI and HIV test kits were installed in the communities of Brighton and Hove and North Somerset and South Gloucestershire ○ People who used the machines were invited to complete a questionnaire gathering information on their experience; 8% (n=208) of users completed the questionnaire • A steady trend of increasing use of vending machines was observed ○ There was a total of 2,536 interactions with the machine during the one-year study period across both locations • The most common reasons for accessing the vending machines were convenience (55.3%), instant access (51.9%), and increased privacy (33.7%) • If the vending machines were unavailable, 55.8% of respondents would have accessed testing from clinics, 38.0% would have accessed tests online, and 26.9% would not have tested • 91.8% of users reported the machine was user-friendly and 97.1% would recommend the machines	High	*Publication date*: 2024 *Jurisdiction studied*: Brighton and Hove and Bristol, North Somerset and South Gloucestershire, United Kingdom *Methods*: Online questionnaire	• Race/ethnicity/ culture/language • Gender/sex • Personal characteristics associated with discrimination

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations
	• Users reported that machines were convenient (86.5%), easy to find (64.9%), and could be used without assistance (66.3%) • 42% of users reported safety concerns and 66% reported privacy concerns			

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ Chlamydia
  ▪ Gonorrhoea
  ▪ HIV
  ▪ Syphilis
  ○ Bacterial infections
  ▪ Bacterial vaginosis
• Test types
  ○ Vaginal PH test
  ○ Tests for specific pathogens
  ▪ Trichomonas
  ○ Urine sample
  ○ Other
• Processing of results
  ○ Point-of-care/immediate
• Outcomes
  ○ Uptake
  ○ Acceptability
  ○ Cost-effectiveness
• Variables that may affect outcomes
  ○ Timing of test
	United States military obstetricians/gynecologists identified economic and non-economic barriers with STI point-of-care tests including test procurement, purchasing equipment, interruptions to workflow, and time-driven steps (17)
	• Questionnaires regarding STI point-of-care tests (POCTs) were distributed to United States military obstetrician/gynecologists
	• Barriers to using STI POCTs included economic ones such as the cost of the test from the manufacturer (58.9%), provider reimbursement, and military funding/stocking decisions
	• Non-economic barriers included purchasing equipment to run the tests (60.8%), interruption to workflow (57.8%), time-driven steps (57.8%), consistent test performance (31.4%), increased patient wait time (19.6%), and ambiguous results (7.8%)
		High	*Publication date*: 2025
			
			Jurisdiction studied: United States or overseas U.S. military bases
			
			Methods: Online questionnaire
				• Occupation

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ Chlamydia
  ▪ Gonorrhoea
  ▪ Hepatitis B
  ▪ HIV
  ▪ Syphilis
• Populations
  ○ Age
	Participants spoke positively about their experiences with internet-based STI testing services and said they were convenient and private, though they found some of the self-sampling methods challenging and missed interpersonal interactions with clinic staff (18)
	• Semi-structured interviews were used to gain insight into patient experiences of using an internet-based STI testing service
	• Participants widely reported that this method of testing was a more convenient option than traditional sexual health clinics
		High	*Publication date*: 2024
			
			Jurisdiction studied: Birmingham and Solihull, England
			
			Methods: Semi-structured interviews and thematic analysis
				• Race/ethnicity/ culture/language
				• Personal characteristics associated with discrimination

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations
▪ Under 25 ▪ Between 25 and 64 ○ 2SLGBTQIA+ • Test types ○ Urine sample ○ Other • Processing of results ○ Sent to laboratory • Outcomes ○ Acceptability • Variables that may affect outcomes ○ Transportation and storage of test	• Participants also reported privacy concerns as a reason for choosing internet-based testing, especially among gay or bisexual men • Participants found some of the self-sampling methods to be challenging (i.e., sampling blood, urine sample, vaginal swabs), and expressed concerns about the integrity of their samples, especially as they were being sent to test by mail • Some participants reported missing the interaction with clinic staff when self-testing at home • The majority of participants were satisfied to have their SMS messages communicated via SMS			
• Purpose of test ○ Diagnosis • Conditions ○ Bacterial infections ▪ Bacterial vaginosis • Test types ○ Other ▪ Microscopy and culture • Processing of results ○ Sent to laboratory • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity ▪ Positive predictive values ▪ Negative predictive values • Variables that may affect outcomes ○ Transportation and storage of test	Self-taken low vaginal swabs (LVS) are a valid alternative to clinician-taken high vaginal swabs (HVS) for diagnosing bacterial vaginosis (BV) and vulvovaginal candidiasis (VVC), demonstrating high sensitivity and specificity, with strong agreement between the two methods (19) • The purpose of this review was to assess whether self-taken low vaginal swabs are a valid alternative to clinician-taken high vaginal swabs for the diagnosis of bacterial vaginosis and vulvovaginal candidiasis in symptomatic women • The study enrolled 104 females between the ages of 16–65 years; the median age for participants was 26 years old • 97 patients had a positive result for bacterial vaginosis and 99 patients had a positive result for vulvovaginal candidiasis • Seven participants were removed from the study due loss of sample during transportation to the laboratory • Low vaginal swabs and high vaginal swabs samples were transported to the laboratory to be cultured and stained under a microscope • Sensitivity and specificity of diagnostic accuracy of bacterial vaginosis infection self-taken low vaginal swabs, with clinician-taken high vaginal swabs used as reference, was: ○ sensitivity: 88.5 (95% CI 68.7–97.0) ○ specificity: 95.8 (95% ci 87.3–99.0)	High	*Publication date*: May 2017 *Jurisdiction studied*: United Kingdom *Methods*: Case-control study	• Gender/sex
• Purpose of test ○ Diagnosis • Conditions ○ STIs ▪ Trichomonas	A molecular assay demonstrated high accuracy for diagnosing BV, VVC, and trichomoniasis (TV), while self-collected vaginal swabs performed comparably to clinician-collected swabs, supporting their potential use in clinical and at-home settings to improve diagnostic accessibility (20)	High	*Publication date*: July 2017 *Jurisdiction studied*: United States	• Gender/sex

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations
○ Bacterial infections ▪ Bacterial vaginosis • Test types ○ Other ▪ Molecular assay • Processing of results ○ Sent to laboratory • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity ▪ Positive predictive values ▪ Negative predictive values	• The purpose of this review was to evaluate the clinical accuracy of a molecular assay testing for diagnosing BV, VVC, and TV using both clinician-collected and self-collected vaginal swabs • The study enrolled 1,686 females over the age of 18, with 1,067 participants in the study between the ages of 18–29 years old • Sensitivity and specificity of clinician-collected for BV infection in women: ○ sensitivity: 90.5 (95% CI 88.3–92.2) ○ specificity: 85.8 (95% CI 83.0–88.3) • Sensitivity and specificity of self-collected for BV infection in women: ○ sensitivity: 90.7 (95% CI 88.6–92.5) ○ specificity: 84.5 (95% CI 81.6–87.0) • Sensitivity and specificity of clinician-collected for TV infection in women: ○ sensitivity: 93.1 (95% CI 87.4–96.3) ○ specificity: 99.3 (95% CI 98.7–99.6) • Sensitivity and specificity of self-collected for TV infection in women: ○ sensitivity: 93.2 (95% CI 87.6–96.4) ○ specificity: 99.3 (95% CI 98.7–99.6)		*Methods*: Cross-sectional study	
• Conditions ○ STIs ▪ Chlamydia ▪ Gonorrhoea • Test types ○ Urine sample • Processing of results ○ Sent to laboratory • Outcomes ○ Accuracy ▪ Sensitivity ▪ Specificity ▪ Positive predictive values ▪ Negative predictive values	Cobas demonstrated high sensitivity, specificity, positive predictive value, and negative predictive value for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in various urogenital samples from both symptomatic and asymptomatic men and women (21) • The objective of this study was to evaluate the clinical performance of Cobas for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in urogenital samples from symptomatic and asymptomatic men and women • Cobas showed >95% sensitivity and >99% specificity for detecting *Chlamydia trachomatis* in female urogenital samples, and 100% sensitivity and >99% specificity in male urine samples • For *Neisseria gonorrhoeae*, sensitivity was >96% and specificity was >99% in female urogenital samples, and 100% sensitivity and >95% specificity in male urine samples	High	*Publication date: March 2019* *Jurisdiction studied: United States* *Methods: Prospective*	• Gender/sex

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations
	• Sensitivity and specificity were similar between symptomatic and asymptomatic individuals and consistent across all collection sites			

• Purpose of test
  ○ Screening
• Conditions
  ○ STIs
  ▪ Chlamydia
  ▪ Gonorrhoea
  ▪ Trichomonas
  ○ Bacterial infections
  ▪ Bacterial vaginosis
• Populations
  ○ Age
  ▪ Between 25 and 64
• Test types
  ○ Real-time PCR
  ○ Tests for specific pathogens
  ▪ Trichomonas
• Processing of results
  ○ Sent to laboratory
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
  ○ Uptake
  ○ Acceptability
• Variables that may affect outcomes
  ○ Education on use of test
  ○ Timing of test
	Vaginal self-sampling (VSS) was just as accurate as clinician-collected sampling (VCS) for detecting genital infections, STIs, and group B streptococcus, with high agreement rates (90.3–99.9%), comparable detection rates across all infections, and strong participant preference (84%) for VSS due to its ease of use and potential to improve screening access (22)
	• This study examined the acceptability, efficacy, and non-inferiority of vaginal self-sampling compared to vaginal classical sampling for detecting genital infections, STIs, and group B streptococcus
	• The study included 1,027 women recruited from 11 clinical centres in France, with 224 pregnant participants (21.8%), with sensitivity at 94.4% and specificity at 99.6% (i.e., close agreement)
	• The study's findings highlighted that increasing the use of vaginal self-sampling could encourage more people to get tested, make screening easier to access, and help catch and treat infections sooner
		High	*Publication date: 2021*
			
			Jurisdiction studied: France
			
			Methods: Cross-sectional study
				• Gender/sex

• Purpose of test
  ○ Diagnosis
• Conditions
  ○ STIs
  ▪ Trichomonas
  ○ Bacterial infections
  ▪ Bacterial vaginosis
• Populations
  ○ Age
  ▪ Between 25 and 64
	Self-collected vaginal swabs were accurate for diagnosing bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis (i.e., sensitivity from 81% to 95% and specificity from 90% to 98%), making them a reliable alternative to physician-collected swabs (23)
	• The study compared how reliable self-collected vaginal swabs were to physician-collected swabs for diagnosing vaginal discharge
	• The study involved 550 women who visited a sexually transmitted infection/reproductive tract infection clinic,
		Low	*Publication date: 2019*
			
			Jurisdiction studied: India
			
			Methods: Cross-sectional study
				• Gender/sex

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations

• Test types
  ○ Tests for specific pathogens
  ▪ Trichomonas
  ○ Other
• Processing of results
  ○ Sent to laboratory
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
  ▪ Positive predictive values
  ▪ Negative predictive values
  ○ Acceptability
• Variables that may affect outcomes
  ○ Education on use of test
	excluding those who were pregnant, had recently used antibiotics, had HIV, or were unwilling to participate			

• Purpose of test
  ○ Screening
  ○ Diagnosis
• Conditions
  ○ Syphilis
• Populations
  ○ 2SLGBTQIA+
• Test types
  ○ Other
• Processing of results
  ○ Point-of-care/immediate
• Outcomes
  ○ Accuracy
  ▪ Sensitivity
  ▪ Specificity
  ▪ Positive predictive values
  ▪ Negative predictive values
	[Protocol – results not yet available] A study assessing the real-world effectiveness of public health outreach rapid syphilis point-of-care testing and immediate treatment for underserved populations is currently being conducted (24)
	• The protocol aims to assess real-world implementation and effectiveness of rapid syphilis point-of-care testing combined with immediate treatment and public health outreach on reducing syphilis rates, especially in high-risk populations
	• The purpose of the protocol is to address the dramatic increase in syphilis rates, and overcome barriers in access to testing and treatment, especially for underserved populations
	• The study will employ the INSTI Multiplex HIV-1/HIV-2/Syphilis Antibody test, which offers results within five minutes, at various public health locations including mobile units, shelters, and safe-consumption sites
	• Trained public health nurses will provide immediate treatment of suspected syphilis cases with benzathine penicillin G
		Low	*Publication date: December 2024*
			
			Jurisdiction studied: Ontario, Canada
			
			Methods: Mixed-methods implementation study
				• Socio-economic status
				• Gender/sex

• Purpose of test
  ○ Screening
  ○ Diagnosis
• Conditions
  ○ HIV
• Populations
  ○ Age
  ▪ Under 25
	POCT at community pharmacies was the most cost-effective HIV-testing strategy compared to standard lab testing and self-testing while also preventing new infections, deaths, and increasing additional quality-adjusted life-years (QALYs) in this study (25)
	• Using a dynamic transmission model, the study compared three HIV tests: POCT, HIV self-testing, and standard laboratory testing for individuals aged 15–64 over a 30-year period to evaluate the effectiveness of each testing strategy
		High	*Publication date: June 2023*
			
			Jurisdiction studied: Canada
			
			Methods: Cost-effectiveness dynamic transmission model
				• None identified

Dimension of organizing framework	Declarative title and key findings	Relevance rating	Study characteristics	Equity considerations
▪ Between 25 and 64 • Test types o Other • Processing of results o Point-of-care/immediate o Sent to laboratory • Outcomes o Cost-effectiveness	• POCT resulted in CAD $885 million in testing cost savings over 30 years compared to standard laboratory settings and was more effective than self-testing • Other POCT outcomes included more HIV diagnoses and treatments, and lower HIV transmission and deaths compared to other testing methods • POCT increased greater than 5000 additional QALYs and was the most cost-effective study compared to the willingness to pay threshold compared to the other testing methods			
• Purpose of test o Screening o Diagnosis • Conditions o Bacterial infections ▪ Bacterial vaginosis • Tests o Urine sample o Other • Processing of results o Sent to laboratory • Outcomes o Accuracy o Sensitivity	Urine samples performed similarly to vaginal swabs in detecting two types of bacteria, showing potential for urine samples as a non-invasive testing method for bacterial vaginosis in pregnant women, but it may not fully replace vaginal swabs for a comprehensive testing (26) • The study evaluated whether urine samples can be used as an alternative testing strategy to vaginal swabs for BV • 100 self-collected vaginal swabs and urine samples were collected from pregnant women >18 years old and tested in laboratory • Urine sample testing performed similarly to vaginal swabs for detecting *Gardnerella vaginalis* and *Prevotella bivia*, but performed worse in detecting *Atopobium vaginae* • The analysis showed a good correlation between the two sample types (r=0.63) for *Gardnerella vaginali* and (r=0.50) for *Prevotella bivia*; however, for *Atopobium vaginae* a weak correlation between urine and swabs was observed (r=0.21) • No significant difference in bacterial concentrations were found between testing methods in BV-negative participants	Low	*Publication date: June 2021* *Jurisdiction studied: South Africa* *Methods: Cross-sectional study*	• None identified

Appendix 4: Details identified from the jurisdictional scan

Country	Key findings
Australia	• Those wishing to join the military in Australia are required to undertake a pathology test for HIV, hepatitis B, and hepatitis C • We did not identify additional information on testing available within the Australian Defence Force, but we did find that in November 2024, the first self-testing device for chlamydia and gonorrhoea was approved and included in the Australian Register of Therapeutic Goods and will shortly be made available for purchase in drug stores • In addition, self-testing kits for HIV has been widely available for some time with a confirmation test from a doctor or sexual health clinic provided if a positive test is identified
Canada	• Testing for sexually transmitted infections are listed under military benefits within the Canadian Armed Forces, but we did not identify any details about how this testing is provided • We did identify that in 2023 a sexual health and wellness clinic opened in Canadian Forces Health Services Centre (Atlantic), which is open to all Canadian Armed Forces members who need these services including testing and treatment for sexually transmitted and blood-borne infections, administration of hepatitis A and B vaccines, and consultations for birth control and pre-exposure prophylaxis medication
New Zealand	• The New Zealand Defence Health Hub recommends making an appointment at the local Defence Health Centre to see a nurse or Government Procurement Office • The Defence Health Hub supports the self-collected of specimen for STI testing including for chlamydia and gonorrhoea, however these are collected within a clinic and then specimen are sent to a laboratory • In New Zealand, point-of-care self-test kits for STIs are not approved for widespread sale within New Zealand, but self-testing is available within New Zealand sexual health clinics if there are no signs of infection for a $26 fee, after which tests are sent to a medical laboratory and the results are returned
United Kingdom	• We did not find specific information about the availability of STI testing in the U.K. military, but we did find a range of STI testing options available within the wider National Health Service, including remote self-sampling whereby an individual collects a sample themselves outside the clinic and sends the sample to a lab for analysis
United States	• U.S. TRICARE covers STI testing as part of the annual health promotion and disease prevention exam at no cost, but details of how this test is performed were not provided • As of November 2023, the U.S. Food and Drug Administration granted marketing authorization for the Simple 2 Test, an over-the-counter diagnostic test for chlamydia and gonorrhoea with at-home sample collection that is then sent for laboratory testing • Oral HIV self-test (OraQuick HIV Self-Test) is approved for use in the U.S. as a point-of-care diagnostic for HIV

Appendix 5: Documents excluded at the final stages of reviewing

Document type	Hyperlinked title
Single study	Testing for extragenital Neisseria gonorrhoeae and Chlamydia trachomatis: At-home pharyngeal and rectal self-swabs are non-inferior to those completed in healthcare settings

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