McMaster University | Health Forum

Rapid evidence profile

Self-testing for gynecological and urological conditions

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Context

- Recent reports indicate that the rates of sexually transmitted infections (STIs) among young Canadian Armed Forces recruits are higher than civilian rates and if not treated appropriately can result in significant long-term health challenges.(1)
- For those serving in challenging environments with limited access to clean water, sanitation, and medical facilities – which may be the case during military deployment – the ability to screen and diagnose gynecological and urogenital infections can be essential for rapid detection and treatment.
- Self-testing can support increased uptake of screening and diagnosis, particularly for equity-deserving populations such as 2SLGBTQIA+ individuals, those with a history of sexual assault, or those that have had particularly negative experiences with the health system or health professionals.

Box 1: Evidence and other types of information

+ Global evidence drawn upon

Evidence syntheses selected based on relevance, quality, and recency of search

+ Forms of domestic evidence used (🍁 = Canadian)

Evaluation

Qualitative insights

+ Other types of information used

Jurisdictional scan ('Five Eyes' countries: AU; CA; NZ; UK; US)

*** Additional notable features**

Prepared in the equivalent of three business days using an 'all hands on deck' approach

Questions

1) What is the screening and diagnostic test accuracy of self-test kits to identify gynecological and urological infections?
2) What self-test kits are being used by the armed forces in each of the Five Eyes countries to support the identification of gynecological and urological infections and cancers in both operational and deployment contexts?

High-level summary of key findings

- We found 18 highly relevant evidence documents, including eight evidence syntheses and 10 single studies.
- Findings from the included evidence documents cover most of the organizing framework (see below), but the majority of the evidence identified focuses on self-sampling (i.e., submitting samples to a laboratory) rather than self-testing (e.g., using a point-of-care test).
- Much of the included evidence focused on the sensitivity and specificity of self-sampling for chlamydia and gonorrhoea rather than other types of infections.
- We were unable to find much literature related to the military context, but we have highlighted findings from one qualitative study.
- The evidence documents generally found acceptable levels of sensitivity and specificity for self-sampling and high concordance with clinician-collected samples, though some mixed results for the sensitivity of vaginal self-sampling were reported.

- We found self-tests for bacterial infections generally lacked sufficient accuracy for widespread use.
  - However, self-sampling demonstrated high levels of sensitivity and specificity and high concordance with clinician-collected samples.
- Self-sampling was generally perceived as being acceptable, with evidence syntheses citing positive aspects such as convenience, lack of stigma, and avoidance of negative interactions with staff, but also noting some discomfort, difficulty understanding instructions, and limited opportunity for follow-up with a clinician.
- For the jurisdictional scan, we were unable to identify information about whether self-testing or self-sampling approaches are used in any of the military health systems.
  - However, we did identify the recent approval of self-testing kits for STIs in Australia and the U.S., as well as the use of self-sampling in New Zealand and the U.K.

Framework to organize what we looked for

- Purpose of test
  - Screening
  - Diagnosis
- Conditions
  - STIs
    - Chlamydia
    - Gonorrhoea
    - Hepatitis B
    - Hepatitis C
    - HIV
    - Syphilis
    - Trichomoniasis
  - Bacterial infections
    - Bacterial vaginosis
- Populations
  - Age
    - Under 25
    - Between 25 and 64
    - Over 65
  - Menopausal status
  - 2SLGBTQIA+
  - Those that have experienced sexual assault

Box 2: Approach and supporting materials

We identified evidence addressing the question by searching Health Systems Evidence, ACCESSSS, and PubMed. All searches were conducted on 6 February 2025. The search strategies used are included in Appendix 1. In contrast to synthesis methods that provide an in-depth understanding of the evidence, this profile focuses on providing an overview and key insights from relevant documents.

We searched for full evidence syntheses (or synthesis-derived products such as overviews of evidence syntheses) and protocols for evidence syntheses.

We appraised the methodological quality of evidence syntheses that were deemed to be highly relevant using the first version of the AMSTAR tool. AMSTAR rates overall quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality, medium-quality evidence syntheses are those with scores between four and seven, and low-quality evidence syntheses are those with scores less than four. The AMSTAR tool was developed to assess reviews focused on clinical interventions, so not all criteria apply to evidence syntheses pertaining to delivery, financial, or governance arrangements within health systems or implementation strategies.

A separate appendix document includes:

- methodological details (Appendix 1)
- details about each identified synthesis (Appendix 2)
- details about each identified single study (Appendix 3)
- details from the jurisdictional scan (Appendix 4)
- documents that were excluded in the final stages of review (Appendix 5).

This rapid evidence profile was prepared in the equivalent of three days of a 'full-court press' by all involved staff.

- Test types
  - Real-time PCR
  - Vaginal PH test
  - Tests for specific pathogens
    - Trichomonas
  - Urine sample
  - Other
- Processing of results
  - Point-of-care/immediate
  - Sent to laboratory
  - Sent to care provider
- Outcomes
  - Accuracy
    - Sensitivity
    - Specificity
    - Positive predictive values
    - Negative predictive values
  - Uptake
  - Acceptability
  - Cost-effectiveness
  - Adverse events
- Variables that may affect outcomes
  - Deployment status/access to medical care
  - Transportation and storage of test
  - Education on use of test
  - Timing of test

What we found

We identified 26 evidence documents relevant to the question, of which we deemed 18 to be highly relevant. The highly relevant documents include:

- eight evidence syntheses
- ten single studies.

This rapid evidence profile provides an overview of the key findings from evidence documents deemed highly relevant. The remaining evidence documents were determined to be of low relevance to the question due to the context, population of focus, or date of literature search/publication of the evidence document.

Coverage by and gaps in existing evidence syntheses and domestic evidence

While the included evidence documents cover most of the organizing framework, the highly relevant evidence syntheses focused on the sensitivity and specificity of self-sampling (i.e., where a patient rather than a clinician is responsible for collecting a sample to be sent for testing in a lab), particularly for chlamydia and gonorrhoea, rather than point-of-care self-testing for either these infections or others. This may be a result of relatively few self-testing kits having been approved or recommended for use in high-income countries.

To ensure coverage of the organizing framework, we specifically included additional single studies to cover sensitivity and specificity of self-sampling and self-testing for bacterial infections, as well as some evidence documents that address self-testing for HIV. It should be noted that self-testing for HIV using an oral swab has been common practice

for some time, and therefore the age of some of this evidence precluded much of it from being included in our searches. We did not identify any self-testing or self-sampling related to hepatitis B or C.

We were unable to find much literature related specifically to the military context; however, we did identify one qualitative study of the views of military gynecologists and obstetricians on the barriers to testing for STIs among active military members.

Finally, while we found evidence related to the acceptability of self-sampling and self-testing, we found very little related to either the cost-effectiveness of these approaches or the variables that may affect their outcomes.

Key findings from included evidence documents

Key findings related to the sensitivity and specificity of self-sampling or self-testing for gynecological and urological infections

Chlamydia and gonorrhoea

Four medium-quality evidence syntheses (three recent and one older) and three recent single studies examined the sensitivity and specificity of self-sampling for chlamydia and gonorrhoea. The evidence documents generally found acceptable levels of sensitivity and specificity for self-sampling, though some mixed results for the sensitivity of vaginal self-sampling were reported.

One recent medium-quality evidence synthesis reported similar levels of sensitivity and specificity for clinician-collected (90–100%) and self-collected (90–98%) vaginal samples for chlamydia.(2) The evidence synthesis also reported similar levels of sensitivity (100% for both methods) and specificity (100% and 99.7%) for clinician-collected versus self-collected swabs for gonorrhoea.(2) Similarly, one older medium-quality evidence synthesis comparing self-collection by vaginal swab to clinician-collected found self-collection of vaginal swab had the highest sensitivity (92%) and specificity (98%) compared to other types of self-collected tests such as urine samples.(3) Similarly, results for gonorrhoea were reported with self-collected vaginal swabs having a high sensitivity (98%) and specificity (99%).(3)

A third recent medium-quality evidence synthesis examining the use of self-sampling for chlamydia and gonorrhoea using tests with a digital component (e.g., online portal or mobile texting of results once processed by a lab) found mixed sensitivity for vaginal self-sampling for women (79.6% for chlamydia and 79.9% for gonorrhoea) but higher sensitivity for extragenital (i.e., rectal and pharyngeal) sampling (92.5–93.1% for chlamydia and 91.6–94.3% for gonorrhoea).(4) Pooled specificity remained high for all self-samples.(4)

A fourth recent medium-quality evidence synthesis examined test concordance for self-samples collected at home compared to those collected within a clinic and found high concordance for vaginal swabs and urine samples for chlamydia testing (96.7% for vaginal swabs and 96.5% for urine) as well as for gonorrhoea (92.3% for vaginal swabs and 100% for urine).(5)

For single studies, three recent single studies reported on sensitivity and specificity of self-sampling for tests for chlamydia and gonorrhoea. One recent single study from Spain found high levels of agreement between vaginal self-samples and clinician-collected samples for chlamydia (95%) and gonorrhoea (95%). However, it should be noted this finding is based on relatively few tests (n=20).(6) The second study evaluated the sensitivity and specificity of the Cobas test and found high levels for both (sensitivity: 98.6% and 99.2%; specificity: 99.2% and 99.0%) for self-collected and clinician-collected vaginal swabs for chlamydia.(7) Similar results were reported for self-collected and clinician collected vaginal swabs for gonorrhoea (sensitivity: 100% and 100%; specificity: 99.7% and 99.7%).(7) Finally, the third study compared vaginal self-sampling and clinician-collected sampling for a range of STIs. The study found high agreement in tests using self-sampling to those using clinician sampling for STIs generally (99.4%), as well as for chlamydia (99.9%) and gonorrhoea (99.9%).(8)

Bacterial infection

One recent medium-quality evidence synthesis and three single studies examined the sensitivity and specificity of self-testing or self-sampling for bacterial infections. The recent medium-quality evidence synthesis found self-tests supporting diagnosis (through self-swabs and pH strips) of vaginal bacterial infection lack sufficient accuracy (both sensitivity and specificity) to be widely used.(9) The exception to this was a panty liner test kit for the collection and testing of vaginal discharge, but this finding was based on a single study with relatively few participants.(9)

For self-sampling, one older single study identified high sensitivity and specificity for self-collected low-vaginal swabs compared to clinician-collected high vaginal swabs for bacterial vaginosis.(10) The study reported a sensitivity of 88.5% and specificity of 95.8%.(10) A second older single study identified similar results, reporting comparable sensitivity and specificity for self-collected and clinician collected swabs for bacterial vaginosis (90.5% and 85.8% clinician-collected; 90.7% and 84.5% self-collected) and trichomoniasis (93.1% and 99.3% clinician-collected; 93.2% and 99.3% self-collected).(11) The final recent single study compared self-collected to clinician-collected vaginal swab samples and found high agreement for diagnosis of bacterial vaginosis (95.7%) and yeast infection (92.2%).(8)

HIV

Two recent medium-quality evidence syntheses examined the accuracy of HIV self-tests. The first recent medium-quality evidence synthesis reported a pooled sensitivity of oral self-samples for HIV of 92.8% and pooled specificity of 99.8%.(9) The second recent medium-quality evidence synthesis reported high agreement (97–98%) between self-testing and health-care worker testing for HIV.(12) The ranges of sensitivity of the self-tests were reported as being between 80% and 100% and specificity of between 95.1% and 100%, with the sensitivity and specificity of blood-based rapid diagnostic self-tests (i.e., a finger prick) being reportedly higher than oral fluid rapid diagnostic tests.(12) That said, the evidence synthesis noted that there were far fewer studies reporting on blood-based self-testing as compared to oral fluid.(12)

Key findings related to the acceptability of self-sampling or self-testing for gynecological and urological infections

Three evidence syntheses (one recent medium quality, one older medium quality, and one older low quality) and two recent single studies addressed the acceptability of self-sampling and self-testing for gynecological and urological infections and generally found positive results; however, some concerns regarding privacy and lack of continuity with a health professional were reported for tests involving a digital component.

One older low quality evidence synthesis examined the acceptability of self-samples for STI tests with a digital component (e.g., online results portal) and generally found them to be acceptable. Positive aspects reported in the evidence synthesis include the convenience, lack of stigma associated with face-to-face testing, avoidance of negative interactions with clinic staff, and accessibility.(13) However, the evidence synthesis reported some concerns related to privacy and difficulties not being connected to a healthcare provider in the event of a positive test result.(13) Similar results were reported in an older medium-quality evidence synthesis on self-testing for HIV, which reported that self-testing was more convenient than facility-based testing and provided patients with greater levels of autonomy and control.(14)

One recent medium-quality evidence synthesis found that offering self-sampling at home resulted in a higher number of tests for chlamydia and gonorrhoea being taken and returned to the clinic than individuals opting to get tested with a traditional clinician-collected approach.(5)

Single studies reported similar findings. One recent single study reported that 75% of participants found self-sampling kits for chlamydia and gonorrhoea to be easy to understand and 99% reported being satisfied or very satisfied with the

testing experience.(6) A second recent single study reported positive experiences from using self-test kits that were freely available from a vending machine.(15)

Key findings related to adverse events of self-sampling or self-testing for gynecological and urological infections

Two medium-quality evidence syntheses and one recent single study included adverse events from self-sampling. One recent medium-quality evidence synthesis noted that more individuals reported difficulty understanding instructions and experiencing some pain or discomfort when using a self-sampling test kit than when using a clinician-collected approach.(5) Similarly, one recent single study reported challenges with self-sampling and expressed concerns regarding the integrity of their samples.(16)

One older medium-quality evidence synthesis found that possible adverse events related to self-testing for HIV were anticipatory anxiety and psychological distress upon receiving results.(14)

Key findings related to the cost-effectiveness of self-sampling or self-testing for gynecological and urological infections

Only two of the included evidence documents, both recent single studies, included insights related to costs and cost-effectiveness. The first single study examined military gynecologists and obstetricians' perspectives on barriers to STI testing for active military members.(17) The study identified lack of reimbursement for the point-of-care test as being a critical barrier. The second study examined the cost-effectiveness of point-of-care testing at community pharmacies and found it to be more cost-effective than standard laboratory testing. The study calculated a cost-effectiveness ratio of CAD $47,475 per quality-adjusted life-year gained.(18)

Key findings from jurisdictional scan of 'Five Eyes' countries about coverage and use of self-testing for gynecological and urological infections

We identified relatively little information from our jurisdictional scan of the 'Five Eyes' countries – Australia, Canada, New Zealand, the United Kingdom, and the United States – about whether self-tests were covered and provided within military health systems.

The military health systems in all 'Five Eyes' countries, with exception of the U.K. where we were unable to find any information, cover testing for STIs and other types of urological infections. However, we were unable to determine the types of tests that are used or whether self-sampling/self-testing is offered.

However, we did identify that some of the 'Five Eyes' countries have recently approved self-sampling and self-testing kits for particular STIs, including:

- in Australia, in November 2024, the first self-testing point of care device for the diagnosis of chlamydia and gonorrhoea was approved and included in the Australian Register of Therapeutic Goods
- in New Zealand, tests that use self-sampling are available within New Zealand sexual health clinics if there are no signs of infection, and these are then sent to a laboratory for testing
- in the U.K. remote self-sampling is used within the National Health Service for a range of STI testing and then is sent to a laboratory
- in the U.S., in 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 are then sent for laboratory testing.

In addition, Australia, New Zealand, Canada, the U.K., and the U.S. have all permitted point-of-care self-testing for HIV for some time using oral swabs.

Next steps based on the identified evidence

Based on the included evidence documents and jurisdictional scan, next steps could focus on:

- monitoring the approval of self-testing devices in 'Five Eyes' countries and any relevant evidence that emerges about their use
- commissioning evidence that examined preferences among active Canadian military members for self-sampling for remote testing, particularly among priority populations
- determining whether additional pathways to screening (e.g., mailed tests, vending machines, internet testing requests) make sense in a Canadian military context to support increased uptake.

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