Urine collected through Colli-Pee® offers potential for self-sampling at home for detection of sexually transmitted infections

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June 2022

INTRODUCTION

Sexually transmitted infections (STIs) continue to remain a global health problem. They can affect quality of life, as well as compromise an individual's sexual and reproductive health.

Annually 374 million new cases of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) are estimated among people aged 15 to 49 years (WHO estimates).

Routine screening is critical for prevention and control of STIs, particularly since many infections do not present symptoms[1,2].

CHALLENGES OF SCREENING PROGRAMS

Unfortunately, methods to detect STIs are underutilized because traditional sampling methods can be invasive, time consuming, and require a clinician. Moreover, many individuals often feel embarrassed or uncomfortable to discuss their sexual activity and are reluctant to visit a clinic for testing.

As self-collection approaches address these barriers, they have the potential to increase uptake of testing services and reach individuals at higher risk of STIs. Several studies even suggest self-collection of samples for STI testing may be cost-effective compared with clinician-collected samples[3].

Additionally, the COVID-19 pandemic has brought several challenges to healthcare. Many public health department resources were redeployed to address the COVID-19 pandemic[4] and lockdowns and fear of getting the infection caused many patients to cancel or delay visits.

- In England the number of sexual health screens (tests for chlamydia, gonorrhoea, syphilis or HIV) in 2020 decreased by 25% compared to 2019[5].
- A survey conducted by the "USA National Coalition of STD Directors" in March 2020, found that 83% of Sexual Transmitted Diseases (STD) programs were deferring STD services and that 60% of clinics were experiencing reduced capacity to treat STIs[4].

To address these challenges innovative self-collection approaches not requiring in-person visits are needed[4].

Already in 2019, before the COVID-19 pandemic, substantial expert agreement existed concerning the benefits of this approach resulting in a WHO recommendation.

"Self-collection of samples for NG and CT should be made available as an additional approach to deliver STI testing services."

WHO consolidated guideline on selfcare interventions for health: sexual and reproductive health and rights

URINE AS AN ALTERNATIVE SOLUTION TO INCREASE PARTICIPATION IN STI SCREENING PROGRAMS

Urine, in particular first-void/first-catch urine (FVU, first 20 mL of urine flow) collected at any time of the day has shown great promise in STI screening. Infections including CT, NG, *Mycoplasma genitalium* (MG) and Human Papilloma Virus (HPV) can be detected in urine[2,6].

"Urine testing with Nucleic Acid Amplified Tests (NAATs) is at least as sensitive as testing with endocervical specimens, clinician- or self-collected vaginal specimens, or urethral specimens in clinical settings."

US Preventive Services Task Force Recommendation Statement[7]

BENEFITS OF URINE SAMPLING

Urine sampling is attractive for many reasons[8,9,10]:

- Self-sampling potential
- Non-invasive
- User-friendly
- Private

IMPORTANCE OF FIRST-VOID URINE COLLECTION

Several studies have shown that for STIs, first-void urine samples allow for improved sensitivity. This fraction of urine contains high concentration of elements, such as CT elementary bodies, antigens as well as inflammatory enzymes[11,12]. As a result, first-void urine performs better for detection of CT, NG and MG infections in men[6].

Additionally, for women, while testing methods are not as standardized, urine has also shown to be a good indicator, and offers similar sensitivities to cervical and vaginal specimens for detection of CT and NG[13].

However, collecting first-void urine in a regular urine container is not standardized and can be awkward, messy and inconvenient for the user.

Colli-Pee®, Novosanis' first-void urine collection device, allows easy capture of first-void urine. Recent data by the Tropical Institute of Medicine in Antwerp, Belgium compared routine clinic-based urine collection through a regular urine cup with home-collected urine sampling using Colli-Pee®, among Men who have Sex with Men (MSM) Pre-Exposure Prophylaxis (PrEP) users[6]. A high correlation was found between clinic-based and home-collected urine samples for CT, NG, and MG, κ=0.75, 0.87 and 0.85 respectively. TV was not detected in any of the samples.

Only one low positive CT and two positive MG infections were not detected in the home-collected urine samples. A total of 11 additional STIs (three CT, two NG and six MG infections) were detected in the home-collected samples using Colli-Pee®*, and not found in the equivalent clinic-collected urine samples[6], highlighting the importance of capturing first-void urine, rather than a random or midstream sample for improved accuracy.

*Research done in Europe with Colli-Pee® prefilled with UCM® preservative. In the USA Colli-Pee® UCM® is available in RUO version.

TRANSPORT AND STABILITY

In addition to urine collection, storage, transport and handling are critical to gain accurate results. Colli-Pee® (10 mL and 20 mL) devices can be prefilled with non-toxic Novosanis proprietary UCM®, which allows the preservation of urine during storage and transport.

FVU collected in the Colli-Pee® device prefilled with UCM® :

- Short-term storage at room temperature: 7 days
- Mid-term storage at -20°C: 7 to 90 days
- Long-term storage at -80°C: Aliquoted into cryovials for up to 12 months

This offers opportunities for home-based testing where sample quality is maintained during storage and sample shipment to the laboratory by regular postal mail.

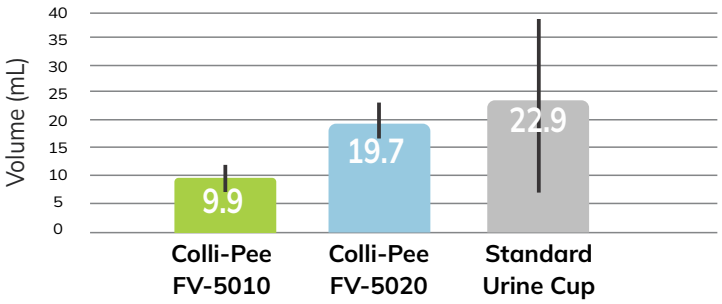
COMPATIBILITY WITH HIGH-THROUGHPUT AUTOMATION

To shorten turnaround time, decrease hands-on time and reduce the risk of cross-contamination of specimens, pipetting error, or other pre-analytic errors attributable to human labor, STI screening tests are mainly performed on highly automated sample-to-result platforms[13].

To achieve this goal, Novosanis developed Colli-Pee® Small Volumes collector tubes that are compatible with high-throughput instruments.

STANDARDIZED AND VOLUMETRIC COLLECTION

Lower variability in collected volume was observed with Colli-Pee® 20 mL & 10 mL compared to urine cups, highlighting the importance of a collection device that allows for standardized and volumetric collection.

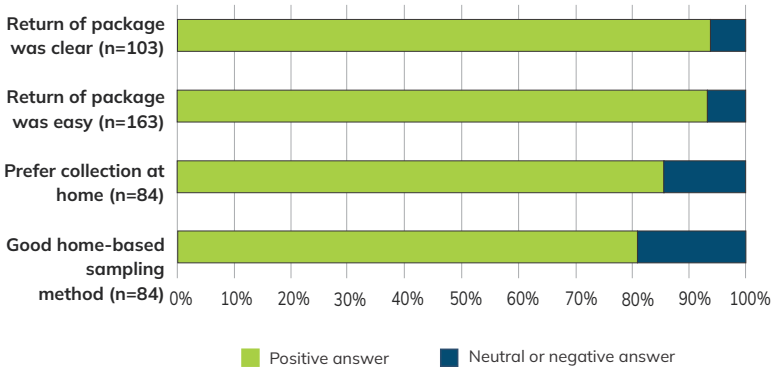


POSTAL DELIVERY AND SELF-SAMPLING IN STI DETECTION

The results of the study performed by the Tropical Institute of Medicine also highlight that self-collection followed by postal delivery of urine samples did not influence STI detection. This methodology offers opportunities to reach a wider population, especially high-risk individuals or participants that are reluctant to access traditional STI health services[2,6]. Performing a test independently at home also means that results can be made available to a physician prior to consultation[6].

To allow for distribution to the patient's home and for the return of the collected sample to the lab, Novosanis developed a postal kit compliant with UN3373 regulations as well as the Colli-Pee® FV-5010 device for first-void urine home-based self-sampling.

Three different studies with this kit showed that returning the package was clear for 93.8% of the participants (n=103, 2 studies) and considered easy by 93.3% of participants (n=163, 3 studies). For a next urine collection with Colli-Pee®, 85.7% would prefer to do it at home (n=84, 1 study). Using Colli-Pee® to collect a urine sample was considered a good method for home-based sampling by 80.9% (n=84, 1 study) of the participants.



CONCLUSION

Making home-based urine collection and mail transport available for STI testing lowers the barrier for getting tested and enables the opportunity to reach a wider population, improving patient flow and allowing for treatment to begin immediately.

REFERENCES

1. Paudyal P et al. PLoS One 2015 PMID: 25909508
2. Shih SL et al. Curr Opin Infect Dis. 2011 PMID: 21124216
3. Ogale Y et al. BMJ Glob Health 2019 PMID: 31139454
4. Melendez J et al. Sex Transm Dis 2021PMID: 33229964
5. Ratna N et al. Sexually transmitted infections and screening for chlamydia in England 2020. Public Health England
6. De Baetselier I et al. BMJ Open. 2019 PMID: 30948618
7. Davidson KW et al JAMA 2021 PMID: 34519796
8. Ducancelle A et al. J Infect. 2015 PMID: 25964233.
9. Sellors JW et al. CMAJ. 2000 PMID: 11006761
10. Vorsters A et al. Eur J Clin Microbiol Infect Dis. 2012 PMID: 21818524
11. Wisniewski CA et al. J Clin Microbiol 2008PMID: 18234860
12. Rönn MM et al. BMJ Open 2019 PMID: 30659036
13. Buchan BW et al. Clin Microbiol Rev. 2014 PMID: 25278575