

STIs and Self-Sampling: Copan's Role in the Future of Sexually Transmitted Infections Prevention and Management

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INTRODUCTION

The World Health Organization recently reported that more than 1 million sexually transmitted infections (STIs) are acquired every day worldwide, the majority of which are asymptomatic. Of an estimated 347 million new infections every year, 1 in 4 is caused by a curable STI such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* (trichomoniasis)¹.

STIs can have a direct impact on sexual and reproductive health through stigmatization, infertility, cancers, and pregnancy complications and can increase the risk of HIV. STI screening is recommended in high-risk populations, such as sex workers, men who have sex with men (MSM), adolescents in some settings, and pregnant women¹. While syndromic management is adopted in several countries, especially in limited resource settings, effective diagnosis is recommended through the integration of laboratory testing.

Routine STIs diagnosis takes place at sexual clinics or hospitals from clinician-taken samples (urethral, oropharyngeal, anal, or vaginal swabs or urine samples) and analyzed with nucleic acid amplification test (NAAT) or cultured for confirmatory diagnostic results. Co-testing with culture is recommended to identify the presence of antibiotic-resistant isolates, mostly for *Neisseria gonorrhoea* and *Mycoplasma genitalium*².

However, high-risk populations for STIs often do not have access to healthcare facilities. Therefore, self-sampling presents as an attractive alternative to clinician-collected sampling to improve access

and avoid concerns about stigma and lack of privacy that might prevent some people from seeking out testing from a clinic or health provider³. The WHO recently updated its guidelines, recommending that self-collection of samples for chlamydia and gonorrhea detection should be offered in addition to current STI prevention services⁴.

SELF-COLLECTED SAMPLES AS AN EFFECTIVE PREVENTION TOOL FOR STIS

Effective STI prevention is achieved by screening asymptomatic patients in high-risk populations, but while recommended, it is still not implemented due to a lack of healthcare professionals, inconvenience of sampling methods, and time constraints. Self-sampling implementation is a possible solution to address this issue. Therefore, several studies aimed to demonstrate the effectiveness of patient self-collected samples compared to clinician-collected samples for screening of gonorrhea and chlamydia infections⁵.

Most Recently, Weidlich and colleagues evaluated Copan FLOQSwabs® 552C for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG) screening in asymptomatic MSM population. In this study, patients were instructed to self-collect oropharyngeal and rectal swabs following pictogram-based instructions. Then clinicians would collect oropharyngeal and rectal samples using Copan eSwab®, as per routine sampling. The authors showed high acceptability of oropharyngeal and rectal self-sampling compared to clinician-collected samples. 75.2% and 88.1% rated "very easy" and "easy" rectal and

oropharyngeal sampling, respectively. The performance resulted comparable between self and clinician-collected samples, showing 93.3% sensitivity for both sampling methods for CT detection, while for NG, sensitivity was 90.0% and 95.0% for self and healthcare provider-collected samples, respectively⁶.

In another study, Dangerfield and colleagues demonstrated in both men and women that oropharyngeal self-sampling is highly acceptable for STI testing. In this study, the clinician first performed oropharyngeal collection using Copan FLOQSwabs[®]. Participants were then given a self-sampling kit including Copan FLOQSwabs[®] and instructions on how to self-collect a pharyngeal specimen and were asked to self-swab their throat and complete a brief survey. Over 75% reported the collection of the swab was 'easy' or 'very easy' to use; 90% were willing to test for STIs at home in the future⁷. Performance was comparable since 100% of results from clinician and self-collected samples were concordant. Both studies, together with recent evidence from scientific literature⁵, show that self-collected samples are as accurate as clinician-collected samples for STI detection, and that self-sampling is highly acceptable, both for genital and extragenital collection sites^{6,7}.

STI PREVENTION FROM HOME: INTERNET-BASED SELF-SAMPLING PROGRAMS

Several Services Worldwide now provide the possibility to get tested remotely from home, using self-collection kits that can be ordered online⁸. Dry shipped swabs by mail have been shown to be valid samples for the detection of CT, NG, and TV by nucleic acid amplification tests⁹ also for extragenital sites¹⁰.

"IWantTheKit" (IWTK) program has been particularly successful in recent years, providing convenient home self-sampling testing kits to participants who wanted to test remotely¹¹. IWTK provides a kit that can include up to three regular Copan FLOQSwabs[®] to be used for penile or vaginal, rectal and oropharyngeal self-sampling depending on user's request¹². The swabs are shipped back to the IWTK centralized laboratory

dry and further processed for CT and NG detection on Hologic Aptima Combo 2 Assay. Between April and October 2020, IWTK program recorded a rapid increase in the testing rate for CT, NG and HIV from the online platform¹³. Additionally, the program showed increased value in adding extragenital sampling (oropharyngeal self-sampling) in detecting CT/NG positive cases¹⁴. Interestingly evidence from Dize and colleagues showed that penile self-sampling is an effective alternative to urethral sampling, simplifying self-collection for men and facilitating mail transport¹⁵. Furthermore, self-penile samples have been shown to be an acceptable alternative to urine samples¹⁶. Other internet-based self-sampling providers, such as Preventx, ship a kit directly home including Copan swabs with urine collection containers. This innovative service offered in the UK by sh.uk in partnership with NHS, includes a personalized self-sampling kit based on a sexual behavior questionnaire compiled by individuals requesting the service¹⁶. These described services, together with other programs⁸ offer an example of how STIs prevention can effectively happen from home and how it can be extended to underserved and hard-to-reach populations. A recent study demonstrated that self-sampling could even be extended to adolescents, since evidence shows they can accurately self-collect pharyngeal and rectal specimens¹⁷.

SAMPLE POOLING: A COST-EFFECTIVE SOLUTION FOR STI PREVENTION

Copan FLOQSwabs[®] have been evaluated on several diagnostic assays for accuracy, showing excellent performance^{18,19,20,21}. Pooling samples from different sites collected by the same patient could be a cost-effective approach to increase diagnosis while cutting costs²². For screening programs, it can be expensive to perform three tests per patient accounting for each anatomic site. Interestingly, Prazuck et al showed the effectiveness of pooling two self-collected Copan FLOQSwabs[®] eluted in Copan eNAT[®] together with urine samples²³. In this study, swabs were first resuspended in the Copan eNAT elution buffer, and then aliquots from the three samples were combined into one prior test. The study

showed that sensitivity for the pooled samples was comparable to the one from the different sites pooled together, demonstrating that sample pooling did not have a dilution effect on the combined samples and did not affect the diagnostic accuracy²³.

CONCLUSION

This brief scientific literature review highlights self-sampling advantages for STI prevention in terms of performance, convenience, patient comfort and cost effectiveness.

These findings demonstrate that Copan's devices are highly acceptable by diverse users and compatible with several diagnostic assays. Samples self-collected with Copan's devices show comparable performance to clinician-collected samples and are currently adopted in successful internet-based home self-sampling programs (such as IWTK and Preventx). Copan's devices can be adopted to increase STI prevention programs cost-effectiveness, by allowing samples pooling before molecular testing, saving on the diagnostic workflow costs and processing time.

In conclusion, Copan's devices are uniquely positioned to successfully aid sexually transmitted infections prevention and management by facilitating testing through self-sampling, allowing access to testing to a broader population.

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