

STI sampling at home: Telemedicine usage and high negative predictive values of self-collection STI screening

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Introduction

Routine sexually transmitted infection (STI) screening is a critical part of health monitoring among sexually active individuals and an important public health issue.

Demand for self-collected sampling (SCS) screening for STIs has sharply increased during the pandemic.¹ SCS in combination with telemedicine services for managing and treating STIs address barriers to in-person STI screening standard of care (SOC), including privacy concerns, stigma, cost, and inconvenience.²

There is evidence for high specificity of SCS for HIV and syphilis testing³ and high negative predictive values (NPVs) of hepatitis C (HCV), HIV, and syphilis⁴ using healthcare provider-collected samples as a comparator. However, these studies were often conducted with small sample sizes and did not include mail-in SCS tests. Further, real-world performance and utility of mail-in SCS tests have not been widely reported. Evaluation of real-world data may establish greater confidence in this modality of testing and strengthen the case for widespread adoption of mail-in SCS for HCV, HIV, syphilis, and trichomoniasis screening.

Objectives

The aims of this study were to evaluate 1) the utilization of follow-up telemedicine for consultation and STI treatment and 2) the real-world performance of at-home self-collection for STI screening.

Methods

Study Design

This was a real-world analysis of four representative at-home, self-collection, mail-in STI tests (Everlywell, Inc). Individual samples for HCV, HIV, and syphilis were assessed via dried blood spot (DBS), while trichomoniasis samples were self-collected via vaginal swab or urine. All samples were processed at CLIA certified laboratories.

Participants

The sample used in this study included any individual at least 18 years of age in any state, excluding New York state, in the U.S. who purchased an STI test from everlywell.com between January 2017 and October 2021. Additionally, mail-in tests may have been purchased at physical retailers except for New Jersey and Rhode Island where kits were only available online at everlywell.com.

Telemedicine

Two types of telemedicine appointments were available: 1) a treatment consultation where physicians could prescribe medication or 2) a non-treatment, informational-only consultation. Treatment telemedicine consultations were offered only to individuals with a positive trichomoniasis test. Non-treatment consultations were available to any individual regardless of test result. All individuals with positive HCV, HIV, or syphilis test results were contacted and referred to in-person care, education, and counseling.

Retesting for NPV

A subsample of negative STI results were confirmed by retesting 1,476 individuals using independent labs between June 2020 and August 2021. Independent lab confirmation was conducted by in-person standard of care (Quest Diagnostics; n=416) or by a second, self-collected sample and assessed by an independent validated laboratory developed test (n=1,060, MTL, Inc; Vancouver, WA). The average time between the original and retest sample collections was 150 days.

Statistical Analysis

Descriptive statistics and NPV were calculated using R version 4.0.5 on a Macintosh.

Ethics

WCG IRB review determined the study qualified as exempt research.

Results

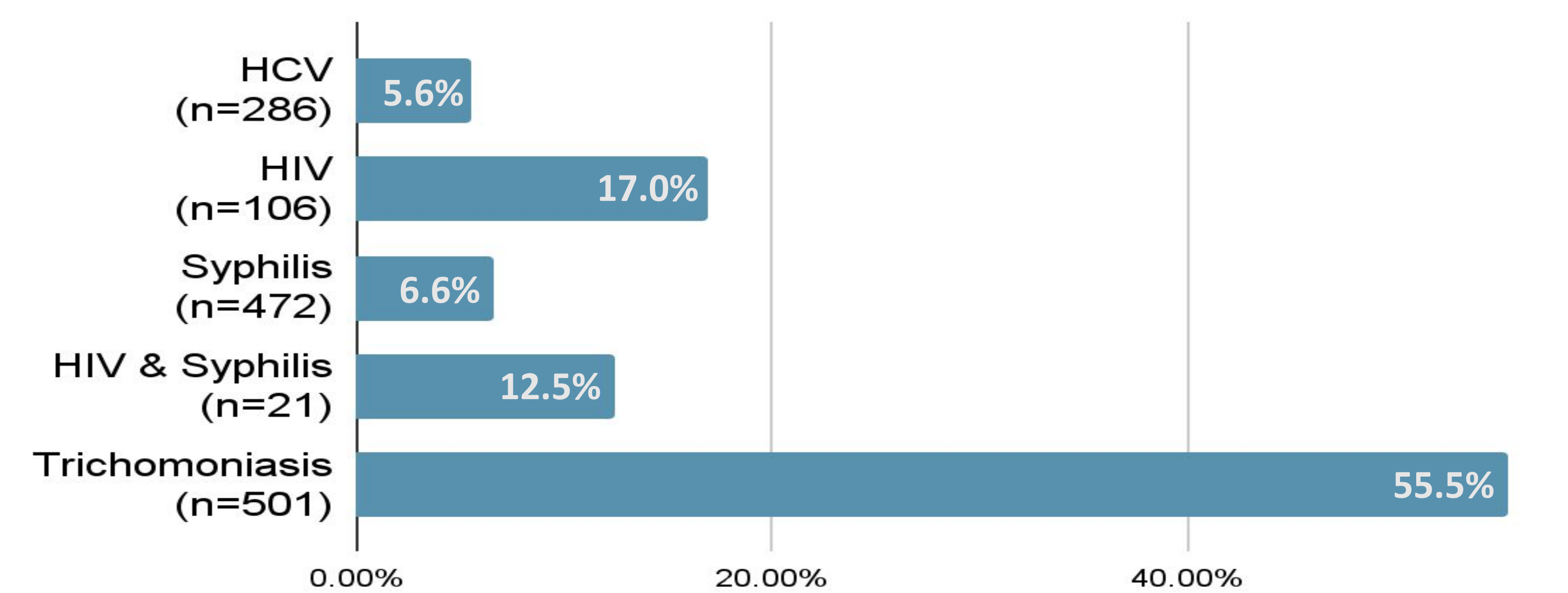
Table 1. Demographic characteristics of at-home STI test users

	Female (vs Male)	18 to 29 years	30 to 44 years	45 to 55 years	56 to 70 years	70 and older
Mail in-test use (N= 44 856)	21 757 (48.5%)	16 180 (36.1%)	21 410 (47.7%)	5 346 (11.9%)	1 771 (3.9%)	149 (0.3%)
Telemedicine Utilization (N=1 899)	1 108 (58.3%)	768 (40.4%)	847 (44.6%)	219 (11.5%)	61 (3.2%)	4 (0.2%)

Table 2. STI test utilization by sex and age and prevalence of positive tests

	Female (N, %)	Mean Age (SD)	Prevalence	95% CIs	Pos. Tests	Neg. Tests	Total Tests
HCV	17 766 (48.6%)	34.7 (10.0)	0.8%	(0.7 - 0.9)	286	36 251	36 537
HIV	18 593 (47.8%)	34.4 (9.9)	0.3%	(0.2 - 0.3)	106	38 752	38 858
Syphilis	17 750 (47.9%)	34.5 (9.8)	1.3%	(1.2 - 1.4)	472	36 620	37 092
Trichomoniasis	18 396 (49.5%)	34.5 (9.8)	1.4%	(1.2 - 1.5)	501	36 680	37 181
Total	21 757 (48.5%)	34.6 (10.1)	2.9%	(2.7 - 3.1)	1 296	43 360	44 656

Figure 1. Percentage of Customers who Opted for Telehealth Consultations by STI



Each STI label refers to total number of individuals who tested positive for that STI. Only positive Trichomoniasis tests were eligible for treatment consultations.

Table 3. Negative Predictive Values of HCV, HIV, Syphilis, and Trichomoniasis tests by confirmatory testing method (N= 1 476)

	Confirmatory Testing Method	Confirmed Neg. Tests	Original Neg. Tests	Negative Predictive Value	95% CI
HCV	In-person SOC	309	310	99.7%	(98.2 - 99.9)
	SCS Mail-in	781	783	99.7%	(99.1 - 99.9)
HIV	In-person SOC	355	355	100%	(99.0 - 100)
	SCS Mail-in	938	938	100%	(99.6 - 100)
Syphilis	In-person SOC	287	291	98.6%	(96.5 - 99.5)
	SCS Mail-in	778	779	99.9%	(99.3 - 100)
Trichomoniasis	In-person SOC	265	265	100%	(98.6 - 100)
	SCS Mail-in	708	708	100%	(99.5 - 100)

In-person SOC refers to standard of care at Quest Diagnostics. SCS mail-in tests were assessed by an independent validated laboratory developed test.

Conclusions

This is among the largest real-world studies to examine performance characteristics of mail-in SCS for HCV, HIV, syphilis, and trichomoniasis tests and utilization of follow-up telemedicine consultations.^{3,4}

Most eligible individuals (i.e., those that tested positive for trichomoniasis) opted for follow-up treatment telemedicine consultations and received treatment. Individuals with positive results for HCV, HIV, or syphilis were contacted and encouraged to seek in-person care, which may explain why a smaller proportion of these individuals opted for a follow-up non-treatment telemedicine consultation. Past research has found telemedicine for STI screening, treatment, and prevention is well received among patients⁵ and our findings indicate that most individuals will choose treatment consultations when available.

All tests exhibited similarly high NPVs with both in-person collection and confirmatory self-collection samples. Studies have found high specificity (>99%) using self-collection DBS (versus serum) for HIV and syphilis screening (n=217)³ and high NPVs (>98%) for HCV, HIV, and syphilis screening (n=429).⁴ Together, these findings suggest high confidence in negative test results, which supports the utility of at-home self-collection of DBS samples for routine STI screening.

The prevalence of positive HCV⁶ and HIV⁷ tests found in this study are consistent with national estimates, while syphilis⁸ was higher. National estimates of the prevalence of trichomoniasis are limited, but a large cross-sectional study found a higher prevalence of positive trichomoniasis tests⁹ than in this study. The high prevalence of syphilis among the individuals within this study compared to national estimates may indicate self-selection among higher risk or symptomatic individuals.

Future research is needed to further understand the public health implications of mail-in SCS and telemedicine models for STI screening and treatment. Positive predictive values can be calculated from confirmatory testing of positive tests and would provide both consumers and physicians an estimate of confidence in positive test results. It is also important to examine outcomes among those who tested positive for HCV, HIV, and/or syphilis including rates of follow up with primary care physicians, treatment, and symptom resolution.

At-home SCS for routine STI screening with follow-up telemedicine consultation for treatment are effective and convenient ways to engage sexually active adults in their own healthcare.

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Disclosures

This study was funded by Everly Health, Inc.