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Advances in STI Testing at Home and in Non-Clinical Settings Close to the Home

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Short Summary for the Table of Contents

A commentary on recent successes and challenges for home STI specimen collection, for point-of-care test usage close to the home, and implications of COVID-19 self-tests for future STI self-test development.

Introduction

Prompt and high performing testing is key to STI treatment and transmission interruption. The COVID-19 pandemic brought a plethora of new SARS-CoV-2 testing approaches. An unprecedented availability of new rapid test formats reached the U.S. market under emergency use authorization. New STI testing approaches are also rapidly evolving, partially out of necessity, like pandemic-related obstacles to traditional STI testing, e.g., supply shortages, closed STD clinics or an overburdened laboratory workforce. New internet-based STI test offerors and remote laboratories have sprung up despite regulatory uncertainty and despite quality and technical challenges, as recently described in an in-depth technical review article (1). The home testing or home specimen self-collection activities have even been noticed in the media (2). In contrast to our previous technology review (1), this commentary describes three emerging testing strategies. First, telehealth concepts with specimen home collection have emerged. Second, usage of new point-of-care tests (POCTs) close to the home is becoming possible. Third, emerging features of COVID-19 self-tests are discussed. Their accelerated market entry is a success and raises the possibility that similar STI tests may become available.

Testing strategy 1: Emerging home specimen self-collection models with send-off to testing laboratory

There is no STI self-test currently available, except for one oral HIV-1/−2 antibody detection test (3). The HIV test is an over-the-counter test with need for confirmatory testing in a medical setting. Due to the lack of other STI home tests, some programs have implemented specimen self-collection at home, followed by testing in a distant laboratory. There has been robust interest in this approach during the pandemic, allowing much-needed access

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to testing. Many programs are embedding the approach in a telehealth approach which provides great linkage to care. Specifically, a patient first interacts with the healthcare provider who selects and orders tests, answers questions, then facilitates shipping of collection kits to the home or arranges pick-up. The patient self-collects the specimen at home or anywhere, sometimes with remote medical oversight through communication technologies. This is particularly popular for gonorrhea and chlamydia testing by laboratory-based NAAT (nucleic acid amplification test), using urine or self-collected swab specimens. There is strong evidence of high test result agreement when self-collected and physician-collected mucosal swab specimens are compared for such NAATs (4, 5). The specimen then goes to a central laboratory. Specimen stability analyses for dry and wet transport indicate prolonged stability for up to three weeks for gonorrhea and chlamydia NAAT (6). Offerors include academic research programs and private-public partnerships, e.g., in programs like “I want the kit” (7) or “Take me home” (8), among many other local successful providers.

A major barrier to this approach is that currently no STI test systems are FDA-cleared for home specimen self-collection. There is considerable uncertainty whether specimen self-collection outside of clinical settings meets regulatory standards. Accordingly, the FDA may enforce regulation of specimen self-collection devices going forward. There is also uncertainty if the approach is permissible as a “laboratory-developed test” after validation data is acquired by each laboratory (1). Moreover, current regulation of laboratory-developed tests may change in the future (9). This makes future availability of this approach uncertain. Another obstacle to widespread implementation is the piecemeal approach of each laboratory submitting their own validation data to the local clinical laboratory director and undergoing CMS (Centers for Medicare and Medicaid Services) inspection reviews. A unified solution could be that an offeror submits performance data to FDA for review. This could lead to permanent clearance and availability of such approaches.

There is a distinction between “direct-to-consumer” testing and a telehealth approach (10). During the former, a consumer purchases collection kits directly from a seller, often online, as previously reviewed (1). These businesses have sprung up and have caused concerns with oversight and quality. This American Sexually Transmitted Diseases Association (ASTDA) published a position statement advising of additional data, education and recommendation needs to reduce potential harm (10).

In contrast to gonorrhea and chlamydia testing programs, syphilis testing has been more challenging to embed in telehealth models. Serologic tests require blood collection. Blood self-collection is a challenge, as is blood transport to a central laboratory, as previously discussed (1). Moreover, non-treponemal serology tests require quantitative titer determinations and are not successful after Dried Blood Spots or other transport conditions (1).

Testing Strategy 2: Point-of-care testing at home or close to someone’s home

A major success for the STI field is that the list of rapid or point-of-care STI tests is growing. This could bring STI testing closer to people in need of testing, as the requirement

for centralized high-complexity laboratories diminishes. It has the potential for greater access, convenience and speed. Of particular interest are tests with a CLIA-waiver. This designation is given by FDA if suitable data are submitted. It generally indicates the test is easy to use, has low complexity and limited training needs, among other attributes previously reviewed (1) and can thus be performed outside of traditional laboratories. Best suited for uses close to the home and outside of traditional healthcare facilities are CLIA-waived tests without any instrument or with a portable device. The first easily portable, CLIA-waived test termed “Sexual Health Test” (Visby Medical™) for chlamydia, gonorrhea and *Trichomonas vaginalis* detection was cleared in August 2021 (11). It is a 30 min PCR test performed on a disposable, single use, hand-held device. It is currently cleared for self-collected vaginal swabs in a health care setting, i.e., only in women and under medical supervision. The “binx health io CT/NG Assay” (binx bealth Inc.) is another new CLIA-waived 30 minute NAAT (12). It was first cleared in March 2020 and a CLIA waiver was added in March 2021 (13). It accepts similarly collected specimens and urine from males. The test requires a small instrument, however it is not portable or disposable, is not for single-use like the Visby Medical ™ test and not designed for one person’s repeated use. In contrast, a recent molecular detection COVID-19 self-test, the Cue™ COVID-19 Test for Home and Over The Counter (OTC) Use, requires a portable cartridge reader smaller than a cell phone which can be positioned in a home and re-used for serial testing (14). It could be explored if the larger, desktop binx health io instrument could be positioned close to the home, e.g., in a mobile van. Lastly, another rapid gonorrhea/ chlamydia test is the Cepheid “Xpert® CT/NG” NAAT (15). It takes 90 min, needs an instrument, and is currently not CLIA-waived. However, it could be used near patients at rapid clinics or pharmacies. It is not clear yet how market uptake and widespread use of the novel POC tests for gonorrhea and chlamydia testing will unfold in future.

The Syphilis Health Check Treponemal Antibody test (SHC, Trinity Biotech) is a CLIA-waived rapid test (16). Reportedly, Chembio Diagnostic Systems Inc, the maker of a recently cleared rapid HIV/syphilis test, the “DPP® HIV-Syphilis System” (17) is in the process of applying for the CLIA waiver. Both the SHC and the DPP are treponemal antibody screening tests and if positive, require follow-up with a non-treponemal test elsewhere. They can be performed on fingerstick whole blood without need for phlebotomy and give results in approximately 15 minutes by visual inspection (SHC) or with a small reader (DPP). These are promising approaches, however, a rapid test for active infection without need for additional laboratory testing would be more effective for rapid syphilis intervention. Such tests currently don’t exist but could be developed. For example, a NAAT for direct *Treponema pallidum* detection or a rapid treponemal and non-treponemal dual antibody detection test might be suitable. WHO has developed target product profiles to describe test features that a panel of experts deemed desirable for point-of-care tests. A draft report is publicly available since May 2021 (18).

Specimen Collection or Use of POC Tests by Disease Intervention Specialists (DIS)

The current U.S. administration announced a new initiative to hire and train additional current disease intervention specialists (DIS) in response to COVID-19 (19, 20). They will conduct case investigations and contact tracing for COVID-19 with capacity for other

infectious diseases including STIs. They present an opportunity to deliver more rapid STI testing to the home. DIS could support patient specimen self-collection by providing instructions, being available for questions and/or transporting specimens like current DIS already do for HIV testing and other STI services (21). This opens the exciting new opportunity of rapid home intervention in one visit, without need for waiting for test results, returning to bring drugs and the associated potential loss to follow-up. Currently, the regulatory requirements related to the supervision of specimen self-collection of existing STI tests are not well defined. Alternatively, DIS could refer patients to a near-by testing facility with rapid testing capacity.

Testing Strategy 3: Home self-testing - how the STI field can benefit from the recent roll-out of COVID-19 self-tests

Many COVID-19 self-tests have received emergency use authorization (EUA), beginning in 2020 (22). Their availability is continuing to evolve. Their introduction into the US market is a major development in the diagnostic testing landscape. A recent commentary discussed whether self-sampling and testing will become the norm for other infectious diseases diagnostics (23), e.g., STI. The advantages are accessibility, convenience, speed and reduction in needed health care workers, in facilities and personal protective equipment (PPE). I will discuss potential benefits and challenges specifically for the STI field, informed by a recent review of evaluation studies of nine COVID-19 self-tests (24).

Test feature 1: Need for confirmatory testing

Some COVID-19 home self-tests require confirmatory testing for some results. This means the test result is considered “presumptive”, for example, if a symptomatic person tests negative. Abbot’s BinaxNOW™ COVID-19 antigen self-test was an early available tests in the US and is an example (25). It remains to be determined if such tests would be useful for curbing STI transmission, e.g., by prompting behavior change while a person awaits a clinic appointment and confirmatory test results.

Test feature 2: Suitability for screening of asymptomatic persons

Some early COVID-19 rapid and/ or self-tests were initially only intended for use in symptomatic persons with high pre-test probability (24). Quidel’s QuickVue™ At-Home OTC COVID-19 Test (26) is an example. Instructions for use state the test is for “individuals aged 14 years or older with symptoms of COVID-19 within the first six days of symptom onset” (26). Serial screening is recommended in persons “with or without symptoms or other epidemiological reasons to suspect COVID-19” (26). It is unclear if similar tests would be successful in the STI testing market with millions of annual screening tests in asymptomatic persons, e.g., for sexually active young women, pregnant persons, MSM (men-who-have-sex with men).

Test features 3 – 5: Suitability for teenagers, prescription requirements, pricing

Some COVID-19 self-tests have limits in their authorization for use in teenagers. For example, the already mentioned BinaxNOW™ COVID-19 antigen self-test can currently

be self-performed starting at age 15 years. The specimen must be collected by an adult in younger ages (25). Some tests require a pre-test prescription like one version of the QuickVue™ At-Home COVID-19 Test not labelled “OTC” (over-the-counter) (27), possibly with implications for insurance re-imbursements. Pricing can be a key factor, according to a literature review by Stevens et al on the effectiveness of HIV self-testing (28). Interestingly, the BinaxNOW™ COVID-19 antigen test initially had the remarkably low cost of approximately five dollars in government-negotiated procurements for use by professionals. The price was higher when purchased in consumer retail for over-the-counter use (29). Research and evaluation are needed to determine whether such test features meet STI prevention and control needs and would be purchased by persons in need of testing.

In summary, this commentary discusses three areas of recent diagnostic successes and remaining challenges: (1) STI specimen self-collection at home with send-off to a remote laboratory, (2) Recent market introduction of CLIA-waived STI POCTs. They have the potential to bring rapid testing closer to people’s homes and provide greater access, speed and convenience, and (3) while STI self-tests are currently not available, COVID-19 self-testing is re-shaping the testing landscape. This highlights opportunities and challenges for adoption of these strategies in the STI field.

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