Conference Summaries

National STD Curriculum Podcast

Point-of-Care Tests and Express Clinics

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Season 1, Episode 8

This episode reviews a few oral abstracts from the 2020 STD Prevention Conference, which took place virtually in September 2020, specifically looking at topics covering point-of-care tests and express clinic models.

Topics:

- Chlamydia
- STDs
- STIs
- Gonorrhea
- POCT
- Point-of-Care Tests
- Express Clinics

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Disclosures

Disclosures for Meena S. Ramchandani, MD, MPH
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References

Reference #1 **Reference #2**

Transcript

Read along with the audio or jump to a particular chapter.

In this episode:

[00.00] Introduction
Hello everyone. My name is Meena Ramchandani. I'm an infectious disease physician at the University of

Washington in Seattle. This podcast is dedicated to an STD [sexually transmitted disease] literature review for health care professionals who are interested in remaining up-to-date on the diagnosis, management, and prevention of STDs.

[00.22] Background

In this episode, we'll continue to review some oral abstracts that were presented at the 2020 STD Prevention Conference, and these are specifically looking on the topics of novel STD prevention and management. There were a few interesting abstracts that discussed point-of-care tests and express clinics, which I'd like to summarize and may be helpful for your practice. Both of these topics are important when thinking about decreasing barriers to STD diagnosis and management, as well as increasing clinic capacity to meet the needs of patients, especially as the rates of STDs continue to increase in the U.S. Of note, I'm going to use the terms STI and STD interchangeably for this episode.

[01.11] Topic #1: Point-of-Care Testing for STDs [Reference #1]

The first topic I'd like to introduce is point-of-care testing for STDs. There's a huge need for point-of-care testing to be adopted into clinical practice for STDs, and I find this is a hot topic among clinicians. In my practice, for example, I find that it may be difficult to get a hold of some patients to provide test results, let's say if they don't have a phone or a stable place to live. Some patients may live far away from the clinic, and then returning for treatment several days later after a test might return positive can be a burden. Point-of-care testing can improve STD diagnosis and treatment in acute care settings, such as, for example, the emergency room or urgent care facilities. These abstracts were taken from two sessions: "Missing the point: When will point-of-care STI testing be available for primetime?" as well as "Novel developments in STI diagnostics and testing." Please refer to our website for details on the presenters and titles of each abstract in this session. So, some interesting points of these sessions I'd like to highlight:

1. The first speaker was Dr. Charlotte Gaydos, who presented an overview of several different point-of-care tests for various STDs.

- The first test that she described is called the Cepheid GeneXpert, and it's a rapid PCR [polymerase chain reaction] test for both gonorrhea and chlamydia that can produce results in just 90 minutes. It is FDA-cleared to evaluate genital, rectal, and oropharyngeal specimens for both of these bacteria. The Cepheid GeneXpert has been found to have a sensitivity of 95–100%, as well as a specificity of 99–100%, and the cool thing is that it can process multiple samples at one time. So if you have, for example, a large clinic with a lot of patients coming in, this might be a great test to use.
- A study that was conducted by Dr. Gaydos, as well as colleagues, published in 2019 in the *Annals of Emergency Medicine*, they evaluated 254 women attending an emergency room for chlamydia and gonorrhea testing. These women were randomized to a rapid test by the GeneXpert or a traditional nucleic acid amplification test (and that test had a 2- to 3-day turnaround time). This study showed that when compared with the traditional nucleic acid amplification testing, the GeneXpert rapid test improved appropriate treatment for women with chlamydia and gonorrhea, as well as reduced overtreatment of women who did not have either of these infections.
- The second test that was described is called the Binx io test. It's also a PCR test for gonorrhea and chlamydia, and it can provide results in just 30 minutes—so very quick turnaround time. I could see this test being used in a place such as a mobile medical van as it's a relatively small machine. Now, one specimen is processed at a time with a single cartridge, and it is both CLIA [Clinical Laboratory Improvement Amendments]-waived and FDA-cleared for vaginal swabs for women as well as urine specimens for men.

2. Dr. Van Der Pol reviewed the Binx io chlamydia/gonorrhea PCR assay in more detail. In a recent study by Dr. Van Der Pol and colleagues published in *JAMA Network Open* in 2020, they found the Binx io works very well.

- So, for example, for chlamydia, the sensitivity of the test was 96% and the specificity of 99% in women; and in men, the sensitivity was 93%, and specificity was 99%.

- For gonorrhea, in women, the sensitivity of the test was 100% and specificity 99%; and in men, the sensitivity was 97%, and specificity was 100%. So, overall, it did quite well.
- What's interesting is that greater than 94% of the testing in their analysis was performed by nonlaboratory personnel. They found that the test only added on about 11 minutes to a routine clinic visit, and the medical provider was able to treat the patient before the patient left the clinic that day.

3. Now, taking a look at a different organism—*Trichomonas vaginalis*—there were two different rapid assays that were described in this oral abstract. The OSOM rapid *Trichomonas vaginalis* antigen test is a small kit that provides results in just 10 minutes, and it is CLIA-waived. It has a sensitivity of 83–90% and a specificity of 98–100%. The other *Trichomonas vaginalis* assay that was discussed is the Solana Trichomonas Assay. It's a nucleic acid amplification test that has a turnaround time of about 35 minutes—so a little bit longer. A study that was done by Dr. Gaydos and colleagues on the Solana Trichomonas Assay was published in *Expert Review of Molecular Diagnostics* in 2017. What they found is that this assay showed a sensitivity and specificity of 90% and 99% for vaginal swabs and 100% and 99% for urine specimens.

4. Now, taking a look at rapid point-of-care tests for syphilis, there is a point-of-care Syphilis Health Check, which is a rapid treponemal antibody test. Because this test is a treponemal antibody test, it wouldn't necessarily be helpful in someone who has a history of syphilis since treponemal tests always remain positive for many years. So, we have this test in our clinic—it's pretty easy to use, and results only take 10 minutes. The nice thing is that you can use serum, plasma, whole blood, or even a fingerstick sample in order to do the assay. The Syphilis Health Check is both FDA-cleared and CLIA-waived. And in one of the oral abstracts, Dr. Jeffrey Klausner discussed this assay in a little bit more detail.

- In a meta-analysis written by Dr. Bristow and colleagues published in *Clinical Infectious Diseases* in 2020, they analyzed 15 Syphilis Health Check studies. Overall, what they found is that the clinical utility of this test varies, really depending on the patient population as well as the prevalence of syphilis in that patient population. But they did find that in analyzing these 15 studies, the Syphilis Health Check assay had a sensitivity of 87–98% and a specificity of 96%.

So, when thinking about point-of-care tests and which might be applicable to your clinic, there are several things to keep in mind, including where your practice is, who the patients are, as well as the complexity of the test, turnaround time, as well as how to implement getting test results to patients, and who's going to manage those positive test results. So far, it seems as though the test performance of the point-of-care tests that I've discussed are pretty good, and they have several potential advantages. Some such advantages include increasing the percentage of persons diagnosed with an STI who receive treatment, potentially reducing empirical antimicrobial treatment, as well as minimizing loss to follow-up—all of which may be helpful to decrease transmission of STDs in the community. So I encourage you to research these tests a bit further if you feel like they might be helpful for your practice or patient population.

[08.22] Topic #2: Express STD Clinics [Reference #2]
The second topic I'd like to cover describes STD express clinics that have been developed in various U.S. cities to help expedite STD care. These abstracts are taken from several sessions titled "STI care," "Missing the point: When will point-of-care STI testing be available for primetime?" as well as "Novel strategies for implementing STI testing." Please refer to our website for details on the presenters and titles of each abstract. So, some summary points from these sessions:

1. Chad Hendry described a community-based STI Express Clinic model, which was started in two different neighborhoods in Chicago.

- The STI express clinics were housed in storefront locations of a nondescript space, and that was to help reduce stigma. These clinics included two kiosks for paperless registration, two interview rooms, two bathrooms, and a microbiology lab for free HIV and STD tests without an appointment.
- The services provided were all free. They were actually supported under grant funds, 340b cost savings, as well as agency corporate funds. The tests that patients could get were third- and fourth-

generation rapid HIV testing; lab-based, fourth-generation antigen/antibody HIV testing; rapid and lab-based syphilis testing; nucleic acid amplification testing for gonorrhea and chlamydia from urine and extragenital sites through self-collected specimens; rapid and lab-based hepatitis C testing; as well as rapid pregnancy screening. The lab-based test results were available in 1–2 days, as opposed to the rapid tests that were available the same day.

- Besides testing for STDs, the clinic also provided free personal hygiene kits, healthy snacks, as well as low-cost produce in collaboration with other programs, and that helped to really engage patients.
- During the time period from April 1 through August 24, 2020, so over about 5 to 6 months, they saw about 965 patients. They described the patients that they saw, and the age of the patients ranged anywhere from 15 to 71 years old. At the two different locations, the clinic sites were able to reach a very diverse patient population.
- The presenters found that those individuals accessing the express clinics were more likely to have no income or health insurance, they were experiencing homelessness, and/or had active substance use.
- They found that the average express visit appointments were around 40 minutes and much shorter than the non-express visits, with a difference of about 2 hours. Not surprisingly, the persons accessing these clinics expressed high levels of satisfaction with the model.

2. Dr. Cecilia Kretz and Kelly Jamison discussed another type of express clinic called the Chelsea Sexual Health Express Clinic based in New York City, and this is a cost-free clinic that provides STI testing for asymptomatic persons through self-collected specimens. The express STI testing model at the Chelsea Health Clinic was designed to help improve the flow and increase throughput of patients.

- The express clinic did not actually have a medical provider in that designated space, but they had a lab called the “Quickie Lab,” and this Quickie Lab processed specimens for gonorrhea and chlamydia using the Cepheid GeneXpert (as I described earlier), and this helped ensure a more rapid turnaround time. A lab scientist reviewed the results and was able then to release the results directly to the patient via text message and through a protected patient portal.
- In this model, patients first registered and underwent rapid HIV testing. They then went to a phlebotomy area, where a venipuncture was performed to test for lab-based syphilis and HIV testing. Patients also obtained self-collected specimens from urine and extragenital sites for gonorrhea and chlamydia nucleic acid amplification testing.
- The presenters found that the turnaround time from patients presenting to the clinic to receiving results was about three hours. Most patients were seen in the afternoon and evenings.
- They analyzed this clinic from March 2018 to January 2019, so around 10 months, where they performed about 46,000 tests. They found the positivity rate of gonorrhea was about 3% in the urine, 10% in the oropharynx, and 9% in the anorectal area. The positivity rate on chlamydia, on the other hand, was 5% in the urine, 2% in the oropharynx, and 8% in the anorectal area. So, pretty high numbers!
- Using the Quickie Lab model, they found 76% of those 698 patients who needed treatment for gonorrhea and chlamydia received treatment in a sexual health clinic within 30 days of receiving test results. This compared to 84% of those patients prior to the Quickie Lab implementation. However, what the authors found is that 67% of patients with positive results from the Quickie Lab, who didn’t actually return for treatment in the sexual health clinic, they found that these patients were actually treated elsewhere after they accessed their test results online through the patient portal.
- Now, with regards to treatment for an STD once positive results were made available, the presenters found a substantial decrease in time-to-treatment in those patients who used the Quickie Lab and the patient portal. For example, on average, those who used the Quickie Lab were able to get treated for an STD within two days vs. eight days prior to the Quickie Lab model being implemented.

These sessions help to show that quick, high throughput, and low barrier options to increase STD testing, including extragenital testing, is emerging as a new care model that can be implemented into clinic settings. They may be expensive to initially fund, depending on the point-of-care test being used, but the express clinics combined with point-of-care tests is a great way to potentially increase clinic capacity but decrease the time needed from clinicians or health care staff. I’m really looking forward to hearing more about these clinics

in the future as they develop.

Overall, these were great sessions that discussed new ways to diagnose and manage STIs, which is something our clinic and others around us are always searching for as the STD rates continue to increase. Point-of-care testing—I have to say—is an exciting new field, and it seems as though some great progress has been made for a quick diagnosis to help treat the patient before they walk out that clinic door.

[14.55] Summary
To conclude, I'd like to summarize some key points from this session:

1. Point-of-care tests for STDs have great potential for successful implementation into health care facilities.

2. Point-of-care tests now also include PCR-based assays that can quickly make a diagnosis of chlamydia, gonorrhea, or *Trichomonas vaginalis*. Most are FDA-cleared and CLIA-waived.

3. Lastly, there are opportunities to introduce express type of clinics for STD testing of asymptomatic patients, and successful examples have been implemented in both Chicago and New York City.

[15.35] Credits
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