Conference Summaries

National STD Curriculum Podcast

2022 STD Prevention Conference: Innovative STI Testing Options

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Season 3, Episode 10

This episode reviews three oral abstracts about these innovative STI testing methods and their clinical impacts: point-of-care gonorrhea and chlamydia testing; point-of-care rapid syphilis testing in jails; and the addition of a *Mycoplasma genitalium* test to initial evaluations for non-gonococcal urethritis (NGU). The abstracts were presented during the September 2022 STD Prevention Conference Oral Sessions 7 and 8.

Topics:

- point-of-care
- Gonorrhea
- Chlamydia
- Mgen
- NGU

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Disclosures

Disclosures for Meena S. Ramchandani, MD, MPH

Consulting Fee: Innoviva Specialty Therapeutics

References

STD Journal

Transcript

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introduction**[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.

background**[00:20] Background**

American Sexually Transmitted Diseases Association, International Union against Sexually Transmitted Infections. Molecular detection of *Neisseria gonorrhoeae* antimicrobial resistance and STI strain characterization. In: 2022 STD prevention Conference September 19–22, 2022. Sexually Transmitted Diseases 49(10S):pp S28-S29, 32 October 2022. **[STDJournal]** to download the PDF.

For this episode, we are going to review a few more oral abstracts that were presented at the STD Prevention Conference virtually held in September of 2022. I'd like to focus on the topic of testing for STIs in the clinical setting. Please refer to our website for details on the presenters and title of each abstract in this session. Now there were quite a few interesting presentations related to this topic, but here are a few that I selected to share in this episode.

gc-ct**[00:51] GC and CT**

Garcia S, Gilliams EA, Hamil, MM. Point of Care Gonorrhea and Chlamydia Testing Reduces Antimicrobial Over-Treatment in Public Sexual Health Clinics in Baltimore, Maryland. In: 2022 STD prevention Conference September 19–22, 2022. Sexually Transmitted Diseases 49(10S):p S28, October 2022.

Van Der Pol B, Gaydos CA. A profile of the binx health io® molecular point-of-care test for chlamydia and gonorrhea in women and men. Expert Rev Mol Diagn. 2021 Sep;21(9):861-868. **[PubMed Abstract]**

This first presentation was discussed by Suzanne Garcia, who's a Nurse Practitioner in Baltimore, and the title of the presentation is "Point-of-care gonorrhea and chlamydia testing reduced antimicrobial over-treatment in public sexual health clinics in Baltimore, Maryland."

Now, from January to May of 2022 is when they did this study, and what they did is they evaluated differences in antibiotic treatment when assay, which is called the binx *io*, was introduced into two sexual health clinics to help inform clinical care. Now let's take a step back and first describe the binx *io*. So, it's a molecular platform which is used to diagnose gonorrhea and chlamydia, only from urogenital and vaginal swabs, as a point-of-care test. It's an FDA-cleared as well as a CLIA-waived test, and results return in about 30 minutes.

1. So, in these sexual health clinics, prior to running the point-of-care test, which is the binx *io* that I just described, clinicians took a survey indicating how they would empirically treat patients based on the clinical history, symptoms, as well as a gram stain and/or urine analysis with those results alone. Once the point-of-care test was then completed, clinicians indicated the change in treatment plan based on the results from the point-of-care test and if there were any differences pre- to post-test results.
2. Now, patients who presented in these sexual health clinics, they had a variety of complaints. Most commonly, they had urethral discharge, dysuria, or they presented with both symptoms—both urethral discharge as well as dysuria.
3. Overall, 79% were men, 82% were African American, and 88% were men who have sex with women, which is really reflective of the population typically seen in the Baltimore City Health Department services.
4. What they found is that for the patients who presented with urethral discharge, 12 patients were positive and treated for gonorrhea based on the point-of-care testing with binx *io,* but another 18 patients would have been empirically treated with antibiotics had point-of-care testing not been done. For the patients who presented with dysuria, seven were positive for gonorrhea, but ten would have

been empirically treated with antibiotics had the point-of-care testing not been done.
5. Now for chlamydia infection, in those patients who had presented with urethral discharge, two were positive and treated for chlamydia, but 16 would have been treated without results of the point-of-care testing. For patients who presented with dysuria, actually zero were positive for dysuria, but eight patients would have been treated for chlamydia infection had the point-of-care testing not been done.

I'm interested in this session because I love the idea of introducing point-of-care tests into the clinical setting and discussing the potential impact on antimicrobial therapy to reduce unnecessary antibiotic exposure. The point-of-care tests are wonderful because they can inform medical management in real-time as well as allow for treatment rapidly, thereby potentially decreasing transmission as well.

The authors in this study didn't discuss comparing the results of the binx *io* point-of-care test to NAAT [nucleic acid amplification test] specimens. But an article that was published in September of 2021 by Dr. Van Der Pol and Dr. Gaydos in *Expert Review of Molecular Diagnostics* evaluated the studies on the binx *io* test and found that the sensitivity ranged from 93-96% and specificity from 98-99% to detect chlamydia on vaginal swabs. For the diagnosis of gonorrhea on vaginal swabs, the sensitivity and specificity was about 100%. Now, in men, the performance of this test—the binx *io*—for chlamydia infection was 93% and specificity of 99%. For gonorrhea in men, the sensitivity was 97% and specificity of 100%.

Now, the study that was presented at the STD Prevention Conference found that the point-of-care test was pretty easy to use in the clinical setting and reduced antimicrobial over-treatment in the public health sexual health clinics in Baltimore, Maryland. The authors indicate for those patients diagnosed with gonorrhea, 33% presenting with discharge and 30% with dysuria would have been potentially overtreated with antimicrobial therapy had point-of-care testing not been done. For chlamydia infection, they found that 88% of patients who presented with discharge and 100% of patients who presented with dysuria would have been overtreated. Now, I'd like to see if these numbers change after the results of NAAT testing for gonorrhea and chlamydia in those same patients who got the point-of-care test to better evaluate the sensitivity of the point-of-care assay in this setting.

syphilis**[05:33] Syphilis**

Chew RA, Nguyen TQ, Leiva D, Decker A, Shaw R, Cohen EC. Yield from rapid and lab-based syphilis screening in jails, San Francisco Jul 2019- Dec 2021. In: 2022 STD prevention Conference September 19–22, 2022. Sexually Transmitted Diseases 49(10S):p S29, October 2022.

The second abstract to discuss was presented by Dr. Rilene Chew Ng, and it was titled "Yield from rapid and lab-based syphilis screening in jails, San Francisco Jul 2019-Dec 2021." In this study, the authors compared the yield of new cases identified from syphilis screening by a point-of-care rapid syphilis test, which is called the Syphilis Health Check, and a traditional, lab-based testing that was done in San Francisco jails from 2019-2021.

So, a bit of some background. This rapid testing for syphilis, which is called the Syphilis Health Check, is quick. The turnaround time is only about 10-15 minutes and can sometimes be more acceptable to patients than a blood draw because it uses a fingerstick whole blood sample. However, the rapid syphilis tests currently available are treponemal antibody tests, so they're *only* really helpful in someone who has never had a history of syphilis. It can't distinguish new syphilis cases from previously treated infection. So those patients who had the rapid syphilis tests, a positive test necessitates review of the medical chart to identify persons with a history of syphilis and then a blood draw for further syphilis testing.

1. So, back to the study, tests were ordered by jail health from 2019-2021, and they categorized persons into non-randomized groups—rapid or lab-based testing for syphilis—and this was depending on the patient preference for the type of syphilis testing that they would get or a history of syphilis if they've

had a history of treated infection. Overall, the authors found that 10-15% of total jail population received STI testing, and 70-80% of women in jails received STI testing. So that's a good number.
2. There were about 2300 participants in each type of syphilis testing group. What they found is that there were 51 new syphilis cases, which was about 2% of all persons tested with the rapid syphilis test. This resulted in a new case rate of 51%. They defined the case rate as the number of new syphilis cases identified divided by the number of positive test results by this assay. In the rapid testing group, the median number of days from test to treatment was two days.
3. Now let's turn to the lab-based testing group. What they found is there were 112 new cases among the lab-based testing group for syphilis, which was 5% of all persons tested by this method. This resulted in a new case rate of 28%. In the lab-based testing group, the median number of days from test to treatment was four days, so a little bit longer.
4. Most of the cases were staged as late latent syphilis or syphilis of unknown duration, and this is important because these cases would have been likely missed had testing not been done because patients didn't have symptoms at presentation.

Overall in this study, while the lab-based testing had higher case yield (or new cases among those tested), the new case rate among those who tested positive was higher in the rapid testing group. The authors point out this might be due to the fact that persons with a known history of syphilis, for example, if they had a history of treated syphilis, are more likely to have the lab-based testing. I think it's important to note that the authors found that syphilis testing, both rapid and lab-based, in San Francisco jails helped to identify and treat new cases of syphilis. What they also found is that offering point-of-care rapid tests presents a lower barrier to syphilis testing for persons who would otherwise decline phlebotomy.

mgen-ngu**[09:11] Mgen and NGU**

Cohen S, Sankaran M, Kohn RF, Bacon O. Decline in persistent urethritis after change in clinical protocols for the diagnosis and management of non-gonococcal urethritis (NGU). In: 2022 STD prevention Conference September 19–22, 2022. Sexually Transmitted Diseases 49(10S):p S32, October 2022.

Johnson KA, Sankaran M, Kohn RP, Bacon O, Cohen SE. Testing for *Mycoplasma Genitalium* and using doxycycline as first-line therapy at initial presentations for non-gonococcal urethritis (NGU) correlate with reductions in persistent NGU. Clin Infect Dis. 2022 Dec 28:ciac977. **[PubMed Abstract]**

The next abstract to discuss was presented by Dr. Stephanie Cohen and is titled "Decline in persistent urethritis after change in clinical protocols for the diagnosis and management of non-gonococcal urethritis." And so, at the sexual health clinic in San Francisco, they changed clinical protocols for the diagnosis and management of nongonococcal urethritis, which is also known as NGU, and I'm going to use NGU for short. They did this in 2020 to see if it improved care and management of these patients. They implemented two changes: First, they started testing for *Mycoplasma genitalium* (or *M. genitalium* for short) in addition to standard testing for chlamydia and gonorrhea infection in the initial evaluation of those patients who are presenting with symptoms of NGU. They also changed the first-line recommendation of treatment for NGU to doxycycline, with azithromycin as an alternative. And this was before the 2021 CDC STI Treatment Guidelines were released, recommending the same approach to treatment for patients who presented with NGU. The authors then analyzed two time periods to see if the incidence of persistent NGU declined after implementing the two changes in protocol. Now, persistent NGU is defined as repeat NGU within 30 days of an NGU episode. So the proportion of visits for NGU in their clinic was about 7% in the two different time periods, so that was comparable.

1. In period 1, before the changes were made, 15% of cases of NGU were due to chlamydia, 3% were due to gonorrhea, 5% trichomonas, and 82%, a very high number, had no microbiologic diagnosis. It's unclear how many cases of NGU were due to *M. genitalium*, as testing was not done during this time period. Remember, this was before the changes in protocol had been made.
2. In period 2, this was after the changes in protocol, 11% of cases of NGU were due to chlamydia, 5%

due to gonorrhea, 3% trichomonas, and 18%, so a pretty high amount, was found to be due to *M. genitalium,* 69% had no microbiologic diagnosis. The authors didn't state, but I'm assuming that those patients with a new *M. genitalium*diagnosis were treated for this infection.
3. With regards to persistent NGU, in period 1, 8% of NGU visits resulted in persistent NGU. So that ended up to be a total of 195 visits of persistent NGU in period 1. In period 2, 3% of NGU visits resulted in persistent NGU, only 48 visits of persistent NGU.
4. Patients with NGU seen in period 1 had a 2.5-increased odds of developing persistent NGU compared to those patients seen in period 2.

In summary, the percentage of NGU visits with subsequent persistent NGU diagnosis declined significantly after the implementation of these new clinical protocols. Eighteen percent of patients with NGU in period 2 had a positive urine NAAT test for *M. genitalium,* suggesting that by not testing for this organism, a microbiologic diagnosis for NGU might be missed. If you're interested in learning more about this study, the authors recently published their findings in *Clinical Infectious Diseases* in December of 2022.

summary**[12:33] Summary**

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

1. Point-of-care testing for gonorrhea and chlamydia from urogenital swabs might be helpful from an antibiotic stewardship perspective.
2. Syphilis testing can help to identify new cases of syphilis in jails, and rapid testing can help to initiate more timely treatment.
3. Integrating *M. genitalium* NAAT testing in the initial evaluation of NGU should be considered, especially in high-prevalence settings.

credits**[13:04] Credits**
This podcast is brought to you by the National STD Curriculum, the University of Washington STD Prevention Training Center, and is funded by the Centers for Disease Control and Prevention.

Transcripts and references for this podcast series can be found on our website, the National STD Curriculum, at www.std.uw.edu. Thank you so much, and have a wonderful day.

innovative-sti-testing-options