STI Testing: New Point-of-Care Advances

December 9, 2021
Agenda

- Welcome
- Rising Rates of STIs
- Traditional STI Testing Methods and Challenges
- Benefits Presented by Point-of-Care Testing
- Impact on Health Department Services and Care with Point-of-Care Testing
- Q&A
Speakers

• Rebekah Horowitz, National Association of County and City Health Officials (NACCHO)
• Gary Schoolnik, Chief Medical Officer, Visby Medical and Professor of Medicine at Stanford University
• Jennifer Mahn, National Coalition for STD Directors (NCSD)
Setting the Stage
Prevention and Control of STIs

Based on five major strategies:

1. Accurate risk assessment and education and counseling of persons at risk;
2. Pre-exposure vaccination for vaccine preventable STIs;
3. Identification of asymptotically infected persons and persons with symptoms;
4. Effective diagnosis, treatment, counseling, and follow-up for infected persons; and
5. Evaluation, treatment, and counseling of sex partners of persons who are infected with an STI.
Rising Rates of Reportable STDs

In 2019:

- 1,808,703 cases of chlamydia were reported to the CDC—making it the most common notifiable condition in the US that year
  - Corresponds with a rate of 552.8 cases per 100,000 population, an increase of 2.8% from 2018
  - Rates increased among males and females, in all regions of the US, and among all racial/ethnic groups.

- 616,392 cases of gonorrhea were reported to the CDC—making it the second most common notifiable condition in the US
  - Rates have increased 92% since historic low in 2009
  - Overall rate increased 5.7% from 2019
  - Rates increased among males and females, in all regions, and among all racial/ethnic groups.

For more information visit www.cdc.gov/nchhstp/newsroom
Disparities in Reportable STDs

In 2019:

- Over half (55.4%) of reported cases of STDs were among adolescents and young adults (aged 15-24)
- 36% of all cases of chlamydia, gonorrhea, and syphilis were among non-Hispanic Blacks, even though they represent only ~12.5% of population
- MSM were also disproportionately impacted
Trichomoniasis

- Trich is not required to be reported to CDC and as a result, it is likely underdiagnosed and under reported
- CDC recommends testing for trich in all women seeking treatment for vaginal discharge
- 70-85% of trich occurs as asymptomatic in women
- Trich increases the risk of contracting HIV by 2-3X
Traditional STI Testing and Challenges
Part A

Patient case - STD Differential Diagnosis

Under-treatment Rates
Over-treatment Rates
Ms. Smith presents to the county sexual health clinic.

**Chief complaint:** Increase in her vaginal discharge of 10 days duration and, most prominently, concern about having a new sexual partner in a relationship that began two weeks before.

**Past medical history:**
- Positive HPV test one year ago
- 1 episode Bacterial vaginosis eight months ago
- 3 episodes UTI during the past three years
- On her annual screening tests (last administered 11 months ago), tested negative for NG, CT, syphilis and HIV

**Clinic course:**
The triage nurse at the clinic, focusing on Ms. Smith’s concern about a new sexual partner.
- Patient collected vaginal swab
- **Swab sent to central lab**
- Complete medical history and pelvic exam performed
Vaginal Swab

Sample-To-Result
Central Lab: 72 hours

Sample-To-Treatment
Central Lab: 168 hours

Ms. Smith’s Vaginal Swab Sample Collected (Day 1)
Sample sent to a Central Lab For Testing (Days 1-3)
Result Obtained (Day 3)
Patient 3 contact attempts (Day 4)
Patient Returns to Clinic Patient Treated (Day 7)
SCENARIO A: Under-treatment/Delayed treatment of an STD

Treatment Decision
Clinician elected **not to treat** due to absence of compelling symptoms or physical exam signs

72 hours later: Central lab reported detection of NG

This is an example of **Under-Treatment / Delayed-Treatment**
Ms. Smith’s Vaginal Swab Sample Collected (Day 1)

Sample sent to a Central Lab For Testing (Days 1-3)

Result Obtained Positive: NG (Day 3)

Patient 3 Contact attempts (Day 4)

Patient Returns to Clinic Rx: Ceftriaxone 500 mg I.M. (Day 7)

Delayed Treatment
Consequences of Under-Treatment / Delayed-Treatment of an STD

- Onward Transmission of an STD pathogen: epidemic propagation
- Delayed treatment resulting in complications of an untreated progressive infection
  - Pelvic inflammatory disease (NG and CT)
    - Infertility
    - Ectopic pregnancy
    - Chronic pelvic pain
- Delayed expedited partner treatment
- Reduced opportunity for result-enabled, face-to-face clinician—patient dialogue
- Inefficient clinic workflow: staff needs to contact patient by phone (often problematic) and schedule return appointment for treatment.
- Reduced patient-satisfaction
- Reduced clinician-satisfaction
Scenario B: Over-treatment of an STD

**Treatment Decision**
Clinician elects to treat before lab results are provided for the vaginitis syndrome because patient complained of a slight change in her normal vaginal discharge. Based on that assumption, patient receives:
Metronidazole P.O. for 7 days for treatment of possible BV and TV.

72 hours later: Central lab reported negative for NG, CT, TV, BV

This is an example of over-treatment of an STD
Consequences of Over-Treatment of an STD

- Unnecessary exposure of the patient to a medication leading to possible adverse effects
- Selection of antibiotic-resistant microorganisms thus contributing to the further emergence of antibiotic-resistant infections.
- Ineffective or misleading clinician—patient dialogue because discussion will be biased by an incorrect diagnosis.
- Inefficient clinic workflow: staff needs to contact patient by phone (often problematic) and schedule return appointment for the correct treatment.
- Reduced patient-satisfaction
- Reduced clinician-satisfaction
### Rates of Under- and Over-treatment for CT/NG

<table>
<thead>
<tr>
<th>Authors</th>
<th>Title</th>
<th>% pts OVER-treated</th>
<th>% pts UNDER-treated</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaene et al, International Journal of Infectious Diseases, 53 (2016) 34-38</td>
<td>“Factors associated with the over-treatment and under-treatment of gonorrhea and chlamydia in adolescents presenting to a public hospital emergency department”</td>
<td>21.6%</td>
<td>43.4%</td>
<td>Emergency department in large safety-net public hospital in Chicago, IL</td>
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<tr>
<td>Dawkins et al, In Press Sexually Transmitted Diseases (Dec 2021)</td>
<td>“Clinical Integration of a Highly Accurate PCR Point-of-care Test Can Inform Immediate Treatment Decisions for Chlamydia, Gonorrhea and Trichomonas”</td>
<td>87%</td>
<td>12%</td>
<td>Urgent care center in Baton Rouge, LA</td>
</tr>
<tr>
<td>Bergquist et al, International Journal of STD and AIDS, 2020 Vol 31(2) 166-173</td>
<td>“Undertreatment of chlamydia and gonorrhea among pregnant women in the emergency department”</td>
<td>15.6%</td>
<td>80%</td>
<td>Emergency Department, St. Louis, MO</td>
</tr>
<tr>
<td>Dretler et al, Am J Emerg Med 38 (2020) 566–570</td>
<td>“The influence of race and sex in gonorrhea and chlamydia treatment in the emergency department”</td>
<td>67.5% women</td>
<td>85.7% women</td>
<td>Emergency department, St. Louis, MO</td>
</tr>
</tbody>
</table>

…for patients with gonorrhea or chlamydia, women are at a much higher risk of not receiving proper treatment compared to men.”

“Pregnant women may not be receiving appropriate treatment when they present to the ED with chlamydia or gonorrhea.”

Dretler et al 2020

“Pregnant women may not be receiving appropriate treatment when they present to the ED with chlamydia or gonorrhea.”

Bergquist et al, 2020

"Women may not be receiving appropriate treatment when they present to the ED with chlamydia or gonorrhea.”

Dretler et al, 2020
Part B

Lost to follow-up
lost-to-care
SCENARIO C: Patient Lost-to-Care (patient does not follow-up)

Treatment Decision:
Clinician elected not to treat due to absence of compelling symptoms or physical exam signs.

72 hours later: Central lab reported detection of NG

Despite multiple calls by clinic staff and by a county public health worker, the patient could not be contacted.

This is an example of a patient who is Lost-to-Care
Consequences of a STD-positive Patient Who Is Lost-to-Care

- Onward Transmission of an STD pathogen: epidemic propagation
- Delayed treatment resulting in complications of an untreated progressive infection
  - Pelvic inflammatory disease (NG and CT)
    - Infertility
    - Ectopic pregnancy
    - Chronic pelvic pain
- No opportunity to proceed with expedited partner treatment
- No opportunity for a result-enabled, face-to-face clinician—patient dialogue
- Inefficient clinic workflow: fruitless attempts by clinic staff to contact patient by phone to schedule a return appointment for treatment.
- Health care provider discontent, stress and apprehension
Patients are lost to follow-up across health-care settings

**Emergency Departments**

- 40% of adolescent females presenting to ED in Grand Rapids, MI were lost to follow up\(^1\)
  - Retrospective study of females presenting with symptoms to the ED in 4 academic medical centers over 36-month period
- 40% of young women were lost to care after the initial ED visit in Cincinnati, OH\(^4\)
- ~8% of patients positive for CT or NG were lost to care in an urban ED setting in Philadelphia, PA\(^5\)
  - Even though 92% were successfully contacted, only 13% were treated within 9 days; median time to treatment was 36 days

**STD/Family Planning Clinics**

- 26% of patients tested in STD and family planning clinics in VA were lost to follow up\(^2\)
  - Retrospective analysis of data from clinics in VA in 2016
- 18% of patients presenting to an STD clinic in Washington DC were lost to follow up\(^3\)
  - Even though 82% were successfully contacted, only 34% were treated within 14 days, with some individuals receiving treatment 30-60 days after a positive test result

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Get In, Get Tested, Get Care: STD Services in Urban Urgent Care Centers\(^6\)

“Our patient level challenges included ... delivering patient results once labs were received after visit. There is no system for follow up the way a primary provider’s office can.”

Benefits from Point-of-Care Testing
Part C

Rapid, Accurate STD Point-of-Care Diagnostics Can Transform Patient Care and Reduce Over-Treatment Rates Under-Treatment Rates Patients Lost-to-Follow up
Ms. Smith's Vaginal Swab Sample Collected (Day 1)

Sample sent to a Central Lab For Testing (Days 1-3)

Result Obtained Positive: NG (Day 3)

Patient Contacted (Three phone calls) (Day 4)

Patient Returns to Clinic Rx: Ceftriaxone 500 mg I.M. (Day 7)

Sample tested In the clinic using Point-Of-Care Device Positive: NG (28 minutes after presentation, Day 1)

Patient Notified of Result Clinician-Patient Dialogue (35 minutes after presentation, Day 1)

Patient Treated Rx: Ceftriaxone 500 mg I.M. (42 minutes after Presentation, Day 1)

 Expedited Partner Rx Initiated (45 minutes after Presentation, Day 1)
SCENARIO D: Correct and Prompt Treatment of an STD

Ms. Smith presents to the county sexual health clinic.

Chief complaint: Increase in her vaginal discharge of 10 days duration and, most prominently, concern about having a new sexual partner in a relationship that began two weeks before.

Past medical history:
- Positive HPV test one year ago
- 1-episode Bacterial vaginosis eight months ago
- 3 episodes UTI during the past three years
- On her annual screening tests (last administered 11 months ago), tested negative for NG, CT, syphilis and HIV

Clinic Course:
The triage nurse at the clinic, focusing on Ms. Smith’s concern about a new sexual partner.
- Patient collected vaginal swab
- Swab immediately dispensed into POC test
- Complete medical history and pelvic exam performed
- 28 minutes later: NG Positive

Treatment Decision:
Clinician followed CDC treatment guidelines:
Rx: Ceftriaxone 500 mg IM (administered 42 minutes after the patient entered the clinic).

Correct and prompt treatment was enabled by a POC test
No lost to follow-up.
Specific Clinician-Patient educational dialog.
Expedited partner treatment initiated.
Rapid / Accurate STD Point-of-Care Tests Can Prevent Over-treatment, Under-treatment / Delayed treatment of STDs
And reduce Patient Lost-to-Care Rates

8 Advantages of STD Point-Of-Care Tests

- Enables result-driven, effective treatment within the span of a single clinic visit.
- Reduces the probability that an untreated infection with NG or CT will progress into the fallopian tubes and result in chronic pelvic pain, infertility and ectopic pregnancy.
- Reduces the probability of ongoing transmission of the pathogen to sexual partners by providing effective treatment on the initial clinic visit. It thus helps reduce the spread of STDs in the population.
- Enables the prompt treatment of the diagnosed person’s sexual partner(s) via the CDC-sanctioned expedited partner treatment program.
- Enables the “teachable moment” by providing an accurate diagnosis at the conclusion of a patient’s clinic appointment.
- Increases patient satisfaction by providing the patient with an accurate diagnosis and effective treatment.
- Increases physician satisfaction by providing a clinician with an accurate diagnosis (which is essential for being able to provide effective treatment).
- By expediting the test and treat paradigm, it improves clinic workflow, increases the efficiency of clinic staff and likely positively impacts that clinic’s cost effectiveness.
Performance of a single-use, rapid, point-of-care PCR device for the detection of Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis: a cross-sectional study

Published November 23, 2020

Summary Background
Timely detection and treatment are important for the control of Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis. The objective of this study was to measure the performance of the Visby Medical Sexual Health Test, a single-use, point-of-care PCR device.

Highlights:
Performance and usability

Benefits at POC
Impact on community spread
Impact on clinician & patient
Simplicity of vaginal patient self-collection - not having to gown (+ benefit of patient involvement)

Authors: Sheldon R Morris, MD Claire C Bristow, PhD Michael R Wierzbicki, PhD Mark Samo, eJD Lenore Asbel, MD Audrey French, MD Charlotte A Gaydos, DrPH Lydie Hazan, MD Leandro Mena, MD Purnima Madhivanan, MD Susan Philip, MD Saara Schwartz, MD Constance Brown, MD David Styers, BS Toni Waymer, BA Jeffrey D Klausner, MD

https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30734-9/fulltext
## Clinical Performance

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<th>PPA</th>
<th>NPA</th>
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<tr>
<td>CT</td>
<td>97.4%</td>
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<tr>
<td>NG</td>
<td>97.8%</td>
<td>99.1%</td>
</tr>
<tr>
<td>TV</td>
<td>99.3%</td>
<td>96.7%</td>
</tr>
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</table>

**PPA: Positive Percent Agreement**  
(The percentage of comparator positive results that are called as positive by the test.)

**NPA: Negative Percent Agreement**  
(The percentage of comparator negative results that are called as negative by the test.)
Part D

A new study on PCR POC test for STI
Clinical Integration of a Highly Accurate PCR Point-of-care Test Can Inform Immediate Treatment Decisions for Chlamydia, Gonorrhea and Trichomonas

Dawkins, Megan PA¹; Bishop, Lisa DNP¹; Walker, Paula MV (DVM)²; Otmaskin, Danielle BS²; Ying, Julia MS²; Schmidt, Ryan MBA²; Harnett, Glenn MD³; Abraham, Teresa PhD²; Gaydos, Charlotte A. MS, MPH, DrPH⁴; Schoolnik, Gary MD²; DiBenedetto, Kevin MD¹

In Press: Sexually Transmitted Diseases: November 22, 2021
doi: 10.1097/OLQ.0000000000001586
Study questions

- Outcomes study at an urgent care center to see how the Visby POC test affects:
  - Time to treatment
  - Accuracy of treatment
  - Clinician Satisfaction
  - Patient Satisfaction

- Assess how a rapid PCR POC test can be implemented in a clinic setting
Clinician survey: Test-and-treat model provides value

A. Q1 I would prefer test results right away versus waiting for several days.
   Q2 I would consider same-day test results to customize the treatment plan for each patient.
   Q3 I am concerned with treating patients empirically.
   Q4 I am an advocate for Antibiotic Stewardship.
   Q5 I would find value in discussing the results of the test right away with my patients.
   Q6 My patients are fine waiting an extra 30 minutes to get important same-day test results.
   Q7 My patients are fine waiting an extra 60 minutes to get important same-day test results.
   Q8 I am concerned with losing contact with these patients once they leave.

B. Value of Test & Treat to Providers

<table>
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<tr>
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<th>Pre-Study</th>
<th>Post-Study</th>
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<tbody>
<tr>
<td>Strongly Agree</td>
<td></td>
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</tr>
<tr>
<td>Agree</td>
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<tr>
<td>Neutral</td>
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<td>Disagree</td>
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<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td></td>
<td></td>
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</table>

“I would prefer test results right away versus waiting for several days.”

Strongly Agree

“I am an advocate for Antibiotic Stewardship.”

Strongly Agree

“I would find value in discussing the results of the test right away with my patients.”

Strongly Agree
Patient survey: There is value in same-day testing

A. Q1 I would prefer to find out my results right away versus waiting for several days.
Q2 I am fine waiting an extra 30 minutes to get my test results.
Q3 I am fine waiting an extra 60 minutes to get my test results.
Q4 I would find value in discussing the results of my test right away with a doctor or nurse.
Q5 If I needed treatment, I would prefer to get it the same day as my visit.
Q6 I would prefer not to take medication (antibiotic) if I don’t need it.
Q7 I would prefer the most accurate treatment during my visit.

B. Value of Same-Day Testing to the Patient

Strongly Agree
Agree
Neutral
Disagree
Strongly Disagree

“I would prefer to find out my results right away versus waiting for several days.”
Strongly Agree

“If I needed treatment, I would prefer to get it the same day as my visit.”
Strongly Agree

“I would prefer not to take medication (antibiotic) if I don’t need it.”
Strongly Agree
**Patient survey: Self-collected vaginal swabs are easy to use**

A. Q1 I know what the Vaginal Specimen Collection Kit is meant to do.
Q2 I found the Vaginal Specimen Collection Kit to be hard to use.
Q3 I would need the support of a clinician/nurse to be able to use the Vaginal Specimen Collection Kit.
Q4 I found the various instruction steps of the Vaginal Specimen Collection Kit easy to understand.
Q5 The Vaginal Specimen Collection Kit was easy to use.
Q6 I would imagine that most people would learn to use this Vaginal Specimen Collection Kit quickly.
Q7 I found this Vaginal Specimen Collection Kit awkward to use.
Q8 I felt confident using the Vaginal Specimen Collection Kit.
Q9 The instructions contained the necessary information to use the Vaginal Specimen Collection Kit.
Q10 I know when I completed the self-collection procedure.

B. **Ease of Use of Swab Kit**

- **Agree / Strongly Agree**
  - “The Vaginal Specimen Collection Kit was easy to use.”
  - “I felt confident using the Vaginal Specimen Collection Kit.”
- **Strongly Agree**
  - “I would need support of a clinician / nurse to be able to use the Vaginal Specimen Collection Kit”
- **Disagree**
Study results
Test results within a patient visit window can inform more accurate treatment

<table>
<thead>
<tr>
<th>Syndromic Treatment vs SoC*</th>
<th>SoC</th>
<th>Visby STI Panel Predictions of Over- and Under-Treatment</th>
<th>% Over/undertreated compared to SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
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<td>CT</td>
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<td></td>
<td>No</td>
<td>7</td>
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<tr>
<td>NG</td>
<td>Yes</td>
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</tr>
<tr>
<td></td>
<td>No</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>TV</td>
<td>Yes</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>6</td>
<td>39</td>
</tr>
</tbody>
</table>

If treatment were based on Visby results:
- 33/33 cases of overtreatment could have been prevented
- 13/15 cases of undertreatment could have been prevented

*Lab results were missing for one patient

Note. SOC = Standard of Care; STI = Sexually Transmitted Infection; CT = Chlamydia trachomatis; NG = Neisseria gonorrhoeae; TV = Trichomonas vaginalis
Part E

Rapid PCR point-of-care STD tests can optimize clinic workflow
Suggested patient and clinic-friendly workflow

1. Get patient chief complaint

   Patient chief complaint - if present, proceed with Step 2
   • Lower abdominal tenderness or pain
   • Increased vaginal discharge
   • Abnormal vaginal bleeding
   • Risky sexual encounter
   • My partner(s) has an STI
   • Blisters
   • Painful urination, increased frequency
   • Painful or bleeding after intercourse

2. If patient mentions these symptoms, then provide Visby Medical Vaginal Self Collection Kit and send patient to private room/rest room

   a. Patient is triaged to waiting area
   b. Run Visby Medical Sexual Health Click test immediately

3. Get patient history and examine patient

4. Provide Visby Medical PCR test results, patient education and treatment in same visit
Summary of Main Points

• A Nucleic Acid Amplification Point-Of-Care (POC) test has been developed and FDA approved that detects three important STD pathogens: NG, CT and TV; clinical trials have demonstrated that they have the accuracy of large laboratory instruments in centralized laboratories.

• This FDA approved STD POC test can provide a result in < 30 min and thus enables a patient to be accurately diagnosed and correctly treated within the span of a single clinic visit. In addition, it is easy to use by non-technical staff, requires < 1 minute of hands-on time, and the results are easily interpreted. Its use will reduce the likelihood that a patient will be over-treated, under-treated or lost to follow-up.

• This POC test can be easily deployed to a variety of clinic settings including urgent care clinics, ERs, student health centers, STD clinics and mobile vans—and eventually even for use at home.

• By providing an accurate result during the span of a single clinic visit, its use will increase patient and clinician satisfaction, enable the “teachable moment” between clinician and patient, increase clinic efficiency and improve clinic cost-effectiveness.

• Future STD POC tests will not only detect a pathogen, but also, simultaneously, identify effective antibiotics for that pathogen, ushering in an era of personalized medicine for infectious diseases.

• Use of these devices will play an important role in the control of the “other epidemic”, the ongoing epidemic of STDs, a public health crisis and that places at risk the health of all.
Health Department Perspectives on Point-of-Care Testing
Several studies among clinicians have pointed to:

- High cost of POCTs (Hseigh et al, 2011; Rompalo et al, 2018; Toskin et al, 2017)

- Rapid results, ease of use, non-invasiveness, and high validity and reliability (Hsieh et al, 2010) as key considerations for their use

- There is a significant gap in our understanding of the perspectives of key stakeholders in decision-making processes surrounding the adoption of POCTs
In early 2021, NCSD recruited 27 participants for in-depth interviews and conducted 2 focus group discussions with medical and allied health professionals on their experiences with POCTs.

Eligibility was defined as individuals with any experience using or prescribing POCTs in a clinical or field setting for the purposes of diagnosing an STI.

Participants were approached electronically for voluntary participation in the study and snowball sampling was used to identify additional respondents.

Participants represented diversity of geography including the Eastern, Central, Southern, and Western areas of the US to ensure representativeness.

Included clinic/procurement directors, nursing supervisors, and STI program managers.
Emergent Themes

<table>
<thead>
<tr>
<th>Types of tests</th>
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<tr>
<td>Home testing</td>
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<td>POCT opinions</td>
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<tr>
<td>Relationships</td>
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<td>Insurance</td>
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<td>Outreach services</td>
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<td>HIV care</td>
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<td>COVID-19</td>
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Pros for Clients

- Clients may feel empowered by the immediate knowledge of their diagnoses, and might expect a standard of service which necessarily included the availability of POCTs:

  - “Point of care tests, I think it's so empowering, for patients [...] It's empowering for people because they know what diagnosis they have, so they can be more secure in the treatment that they're getting because their provider has diagnostic certainty

  - “Offering an option, or several options to a client is good customer service and it creates opportunity to test based on that client’s needs”
Pros for Providers

Participants discussed the difficulty with retaining vulnerable populations within their systems for regular follow-up including people experiencing homelessness, sex workers, and injection drug users.

Testing that required lab processing time beyond the visit event precluded an immediate diagnosis and treatment.

Testing capable of producing a result with the patient on-site is seen as invaluable for ensuring accurate and timely treatment initiation.
Cons for Providers/Clients

Tests producing binary results (qualitative tests) were widely seen as not being able to provide the necessary granularity for an accurate diagnosis and were considered inferior tests able to provide infection intensity (quantitative tests)

Qualitative tests, such as Gram stains, gave some clinicians the ability to economize their prescription of antibiotics which was seen as a particularly valuable feature when quantitative testing was unavailable

Some participants noted that certain POCTs often require a second gold standard confirmatory test, which is typically a NAAT or PCR as mandated by the state, and not wanting patients to go through secondary screenings due to time, cost, and the burden to the lab and patient

Poor sensitivity and specificity and test readability were noted as the primary reasons a patient would have to go in for an undesirable second reading
Funding Challenges

• Clinics were recipients of either state, federal, or private funding which often mandated the nature and use of funding for types of POCT offered by clinics

• The management of these sources of funding and the various donor requirements was seen as having significant influence on the provision of services and the adoption of any POCT

• The specific parameters of use for these funding sources included participation in the approval processes, which can create difficulties for clinics as they attempt to secure additional funding for the services that their priority populations need
Many participants noted that their clinics couldn’t offer all the tests they wanted to because of funding limitations.

A majority of participants shared the feeling of being constrained by funders; some clinics had to apply a great deal of pressure to funding sources to obtain the tests that they needed:

“In our HIV STD high risk clinic, we have all of these materials, but [...] in our pediatric clinic we had to like beg, borrow, and steal to get [NAAT rapid testing] for STD care.”
Additional Findings

Test features such as turnaround time, complexity and cost, as well as operational considerations including who performs the test were strong barriers to use.

The differing roles of POCT from the embodied perspective of the patient, clinic and administrator constitute a confluence of considerations that may substantially influence their use.

Clinics were reluctant to offer new POCTs if it sustainably impacted their clinic routines, were cost ineffective, and required a CLIA license.

It was uncommon for any one of these pieces to be considered in isolation, and there was some heterogeneity in the precise combination of factors that clinics and programs had to contend with.
• Challenges around the reimbursement for tests was not spoken about extensively by our study participants

• Most of our participants expressed that their clinics do what they can to keep costs low for patients, including costs of testing

• While utilizing multiple streams of funding can allow clinics to provide services that are needed by their target population at a low cost, managing multiple funding sources is complex and many clinicians avoid involvement in the funding process

• As such, a distinct gap was noted between those that utilize POCTs and those that manage the funding
Conclusions

Lack of the patient perspective was a strong limitation in this study.

For some clinics, the pandemic was a means to re-energize existing plans to provide those services which involved expedited dialogue with funders.

Managing multiple sources of funding was an additional challenge for many clinics, and reimbursement for testing was not an issue discussed by many working in publicly funded clinics.

It is imperative that developers and regulators work with client and clinician end-users to streamline steps toward adoption of POCTs for faster and more efficient diagnosis and treatment of STIs.