

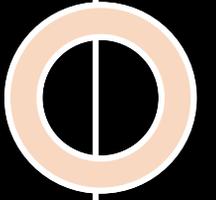
STI Testing: New Point-of-Care Advances

December 9, 2021

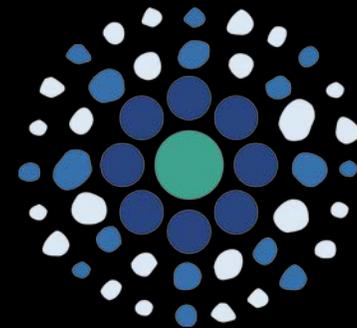


NACCHO

National Association of County & City Health Officials



NASTAD



NCSO

National Coalition
of STD Directors



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

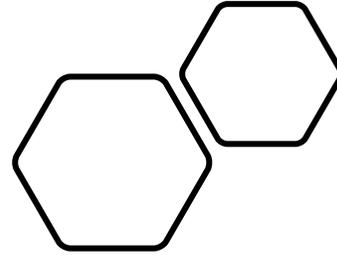


Q&A

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.

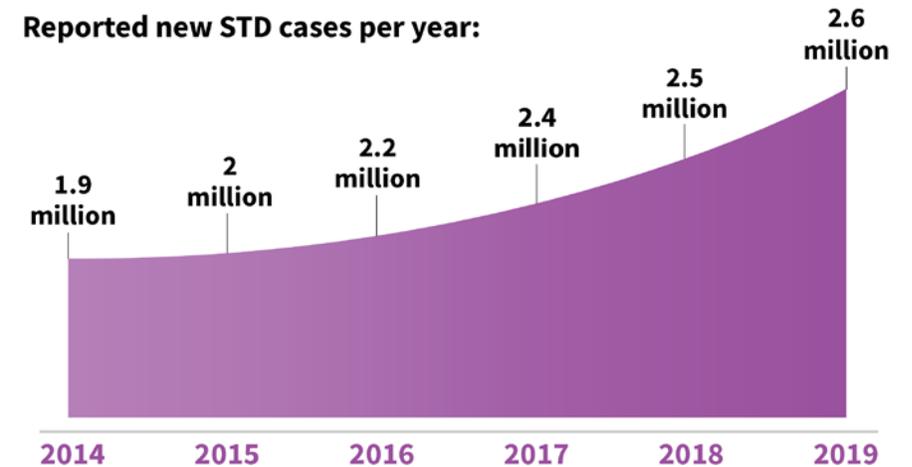
Rising Rates of Reportable STDs

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

6th consecutive year of **RECORD-BREAKING** STD cases

Reported new STD cases per year:



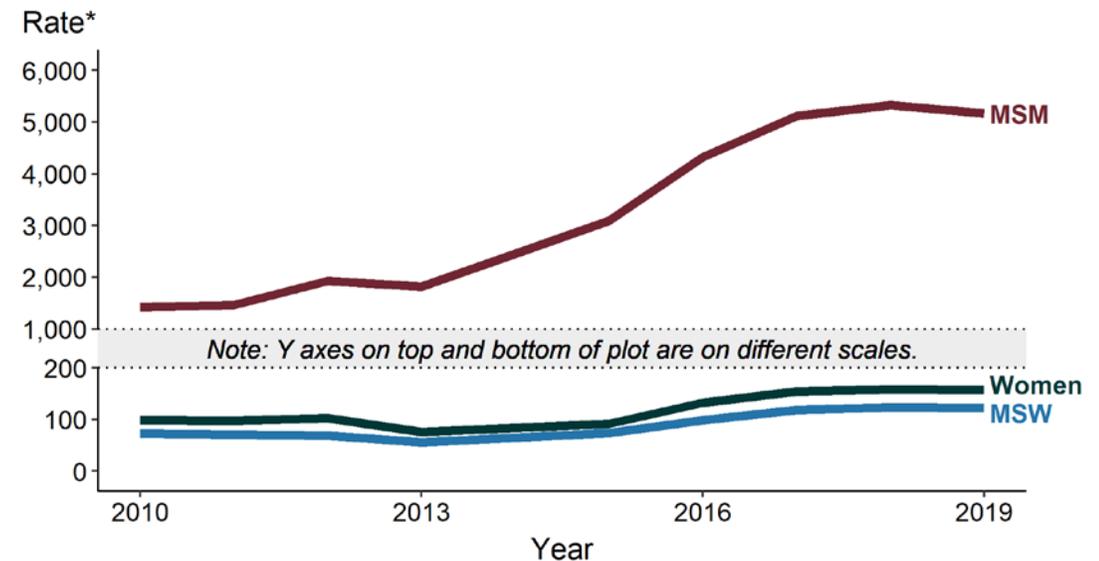
For more information visit www.cdc.gov/nchhstp/newsroom

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

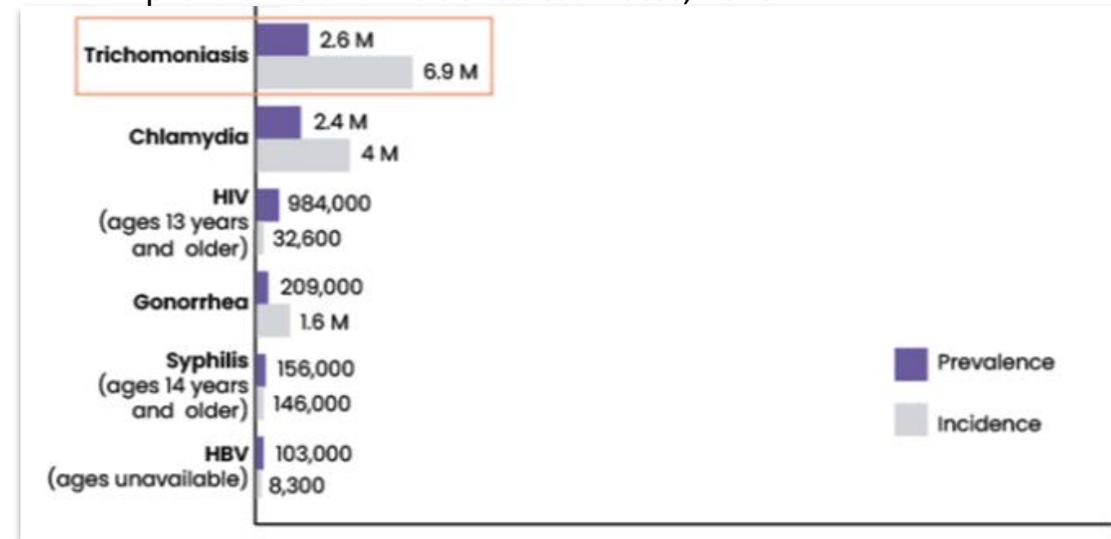
Estimated Rates of Reported Gonorrhea Cases by MSM, MSW, and Women, STD Surveillance Network (SSuN), 2010–2019

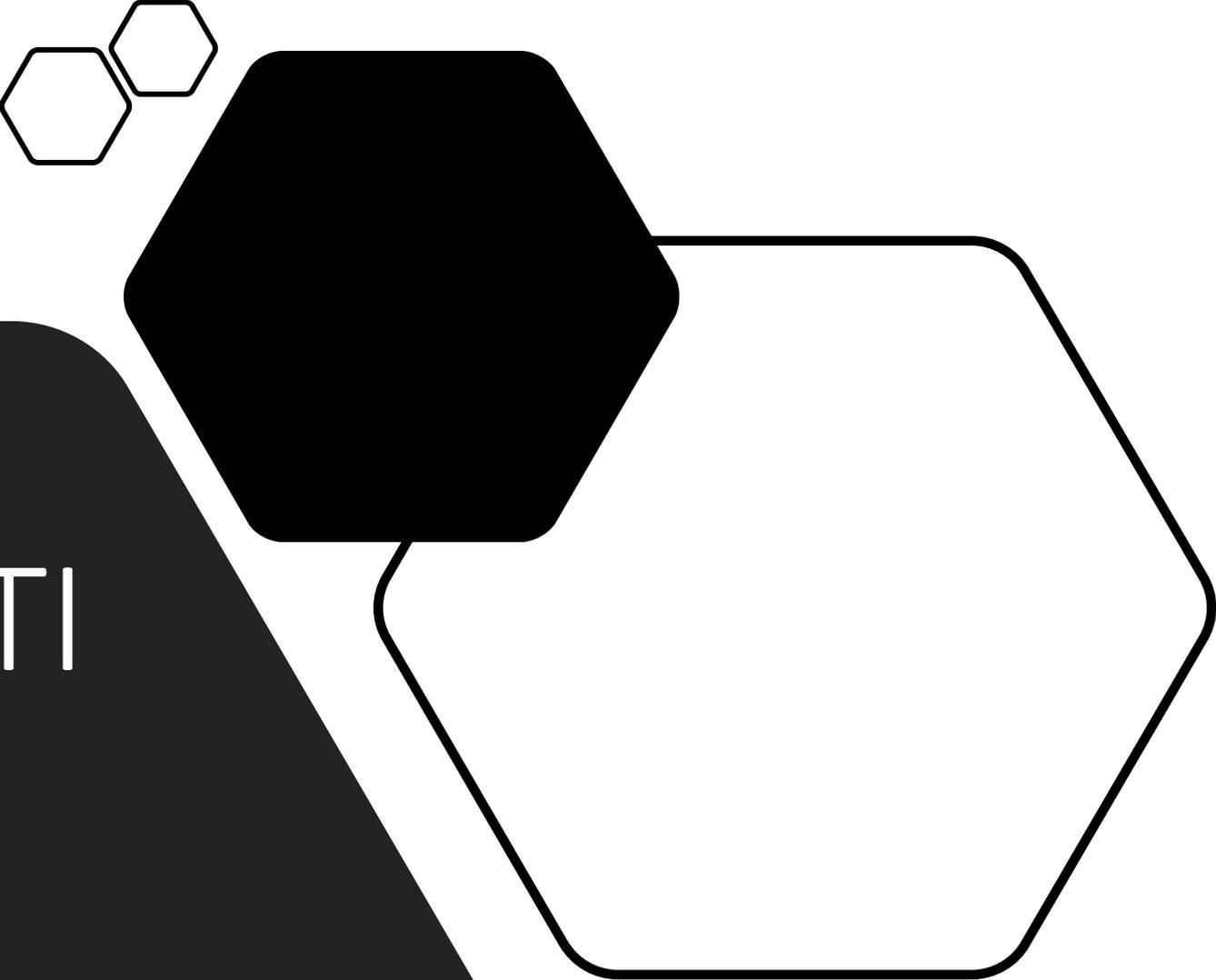


Trichomoniasis

- 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

Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2018.



A decorative graphic consisting of several hexagons. At the top left, two small white hexagons with black outlines are positioned. Below them, a large solid black hexagon is partially overlapping a larger white hexagon with a black outline. The white hexagon has rounded corners and is positioned to the right of the black one.

Traditional STI Testing and Challenges

Part A

Patient case - STD Differential Diagnosis

Under-treatment Rates
Over-treatment Rates

Case Presentation



NG: *Neisseria gonorrhoeae*
CT: *Chlamydia trachomatis*

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

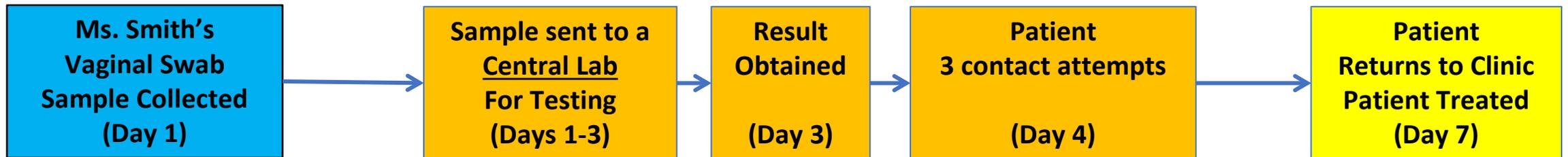
Vaginal Swab

Sample-To-Result

Central Lab: 72 hours

Sample-To-Treatment

Central Lab: 168 hours



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

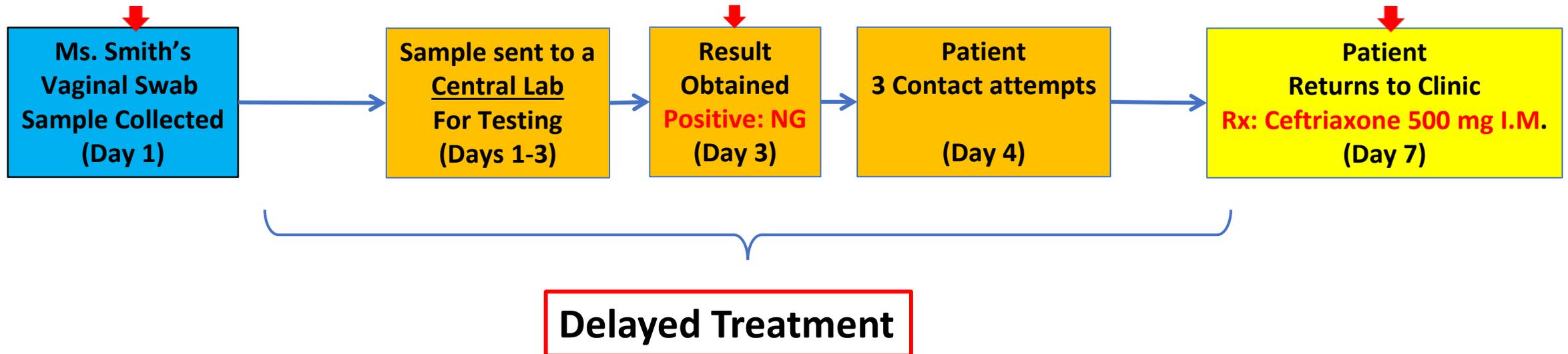
This is an example of Under-Treatment / Delayed-Treatment

Vaginal Swab: Sample-To-Result Timeline

Central Laboratory Based Testing

Test Result: 3 days after initial clinic visit

Patient Treated: 7 days after initial clinic visit



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

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

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

Empiric
treatment;
CT/NG negative
lab results

No empiric
treatment;
CT/NG positive
lab results

Authors	Title	% pts OVER-treated	% pts UNDER-treated	Setting
Anaene et al, International Journal of Infectious Diseases, 53 (2016) 34-38	“Factors associated with the over-treatment and under-treatment of gonorrhea and chlamydia in adolescents presenting to a public hospital emergency department”	21.6%	43.4%	Emergency department in large safety-net public hospital in Chicago, IL
Holley, et al, Am J Emerg Med, 2015 Sep 33(9):1265-8	“Overtreatment of gonorrhea and chlamydial infections in 2 inner-city emergency departments”	86%	4%	2 inner city emergency departments
Dawkins et al, In Press Sexually Transmitted Diseases (Dec 2021)	“Clinical Integration of a Highly Accurate PCR Point-of-care Test Can Inform Immediate Treatment Decisions for Chlamydia, Gonorrhea and Trichomonas”	87%	12%	Urgent care center in Baton Rouge, LA
Gaydos et al, Ann Emerg Med, 2019 Jul: 74(1):36-44	“Use of a Rapid Diagnostic for Chlamydia trachomatis and Neisseria gonorrhoeae for Women in the Emergency Department Can Improve Clinical Management: Report of a Randomized Clinical Trial”	46.7%	43.8%	Urban academic Emergency Department
Bergquist et al, International Journal of STD and AIDS, 2020 Vol 31(2) 166-173	“Undertreatment of chlamydia and gonorrhea among pregnant women in the emergency department”	15.6%	80%	Emergency Department, St. Louis, MO
Dretler et al, Am J Emerg Med 38 (2020) 566–570	“The influence of race and sex in gonorrhea and chlamydia treatment in the emergency department”	67.5% women	85.7% women	Emergency department, St. Louis, MO

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 up¹**
 - 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, OH⁴**
- **~8% of patients positive for CT or NG were lost to care in an urban ED setting in Philadelphia, PA⁵**
 - Even though 92% were successfully contacted, only 13% were treated within 9 days; median time to treatment was 36 days

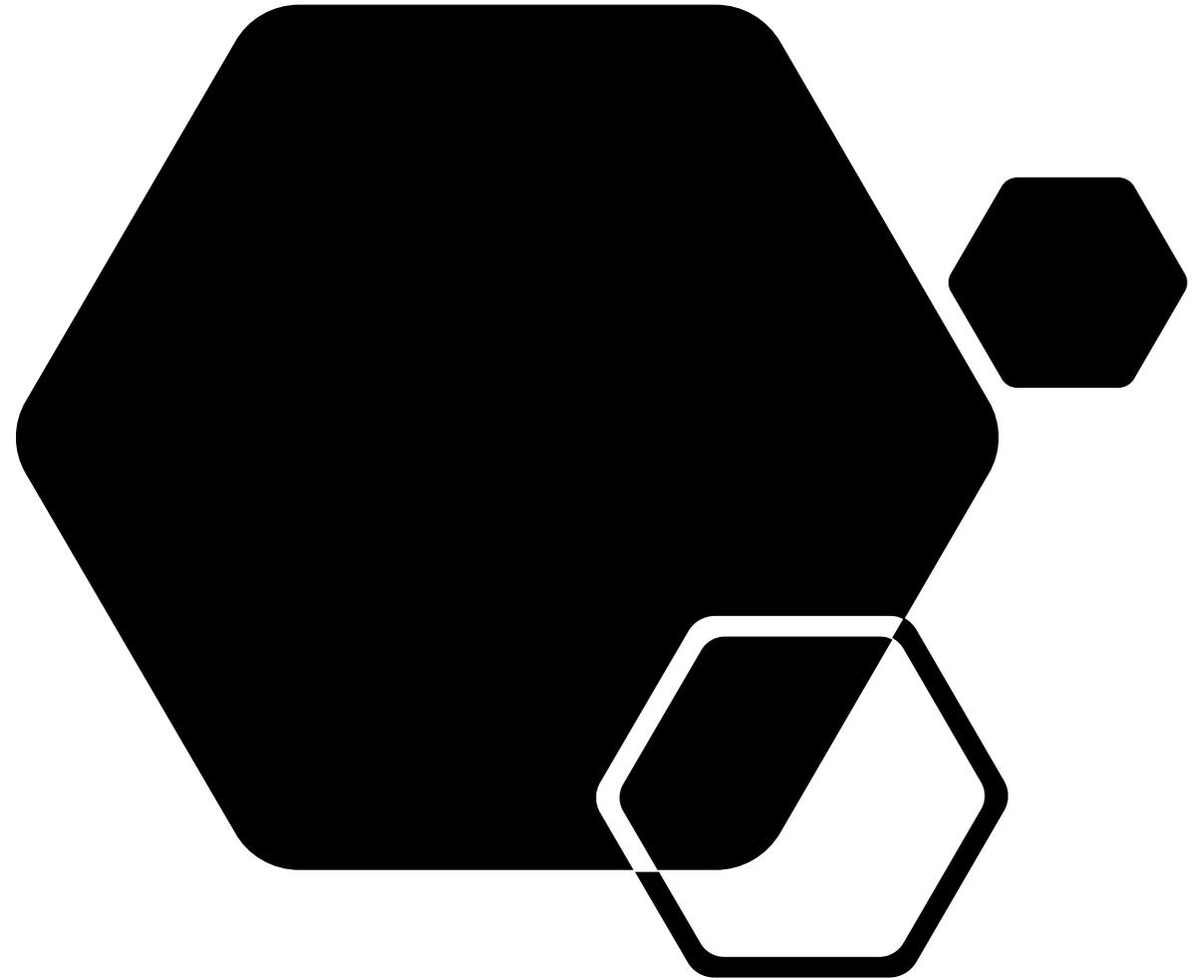
STD/Family Planning Clinics

- **26% of patients tested in STD and family planning clinics in VA were lost to follow up²**
 - 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 up³.**
 - 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

Get In, Get Tested, Get Care: STD Services in Urban Urgent Care Centers⁶

“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



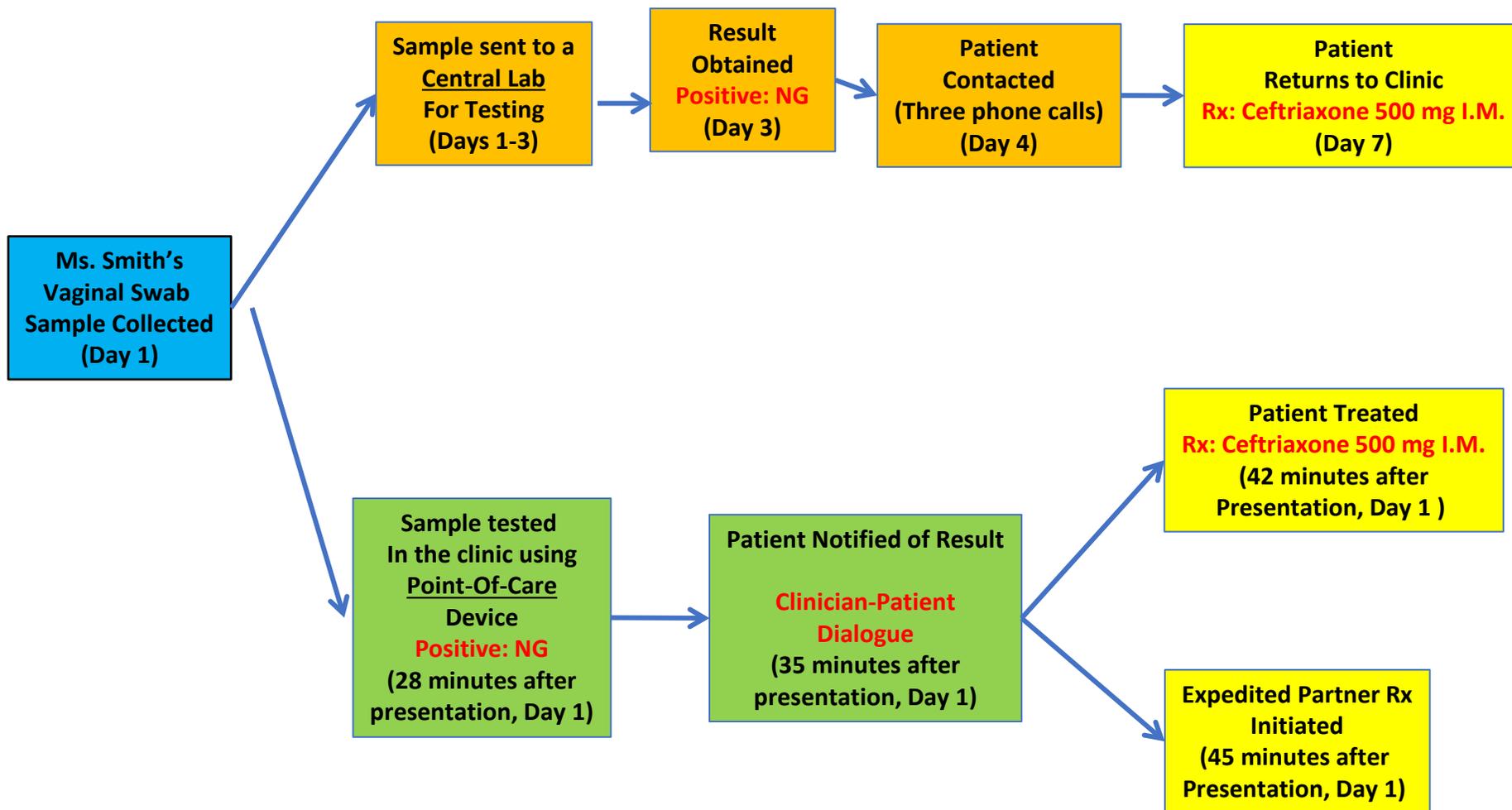
Part C

**Rapid, Accurate STD Point-of-Care
Diagnostics Can Transform Patient Care
and
Reduce
Over-Treatment Rates
Under-Treatment Rates
Patients Lost-to-Follow up**

Vaginal Swab: Sample-To-Result Timeline

Central Lab: 72 hours sample-to-result
 168 hours sample-to-treatment

Point-of-Care (POC): 28 minutes sample-to-result
 42 minutes sample-to-treatment



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.

THE LANCET

Infectious Diseases

The screenshot shows the article page on the Lancet Infectious Diseases website. The title is "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". The authors listed are Sheldon R Morris, MD, Claire C Bristow, PhD, Michael R Wierzbicki, PhD, Mark Sarno, eJD, Lenore Asbel, MD, Audrey French, MD, et al. The article was published on November 23, 2020, with a DOI of 10.1016/S1473-3099(20)30734-9. The page includes a summary section with a background paragraph: "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." and a methods paragraph: "Women aged 14 years and older who presented consecutively to ten clinical sites across seven US states were enrolled for a cross-sectional, single-visit study. Patients who consented to participate, and who had not used any exclusionary products in the genital area in the previous 48 h, provided self-collected vaginal swabs for testing with the investigational device. Untrained operators received the specimens and ran the device using the guide provided. Specimens had to be run within 2 h of collection to be considered valid. For comparison, patient-infected status was derived by testing clinician-collected vaginal specimens with the Hologic Aptima Combo 2 Assay and Aptima *Trichomonas vaginalis* Assay, as well as the BD ProbeTec.

Authors: Sheldon R Morris, MD Claire C Bristow, PhD Michael R Wierzbicki, PhD Mark Sarno, 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

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)

Clinical Performance

	PPA	NPA
CT	97.4%	97.8%
NG	97.8%	99.1%
TV	99.3%	96.7%

PPA: Positive Percent Agreement

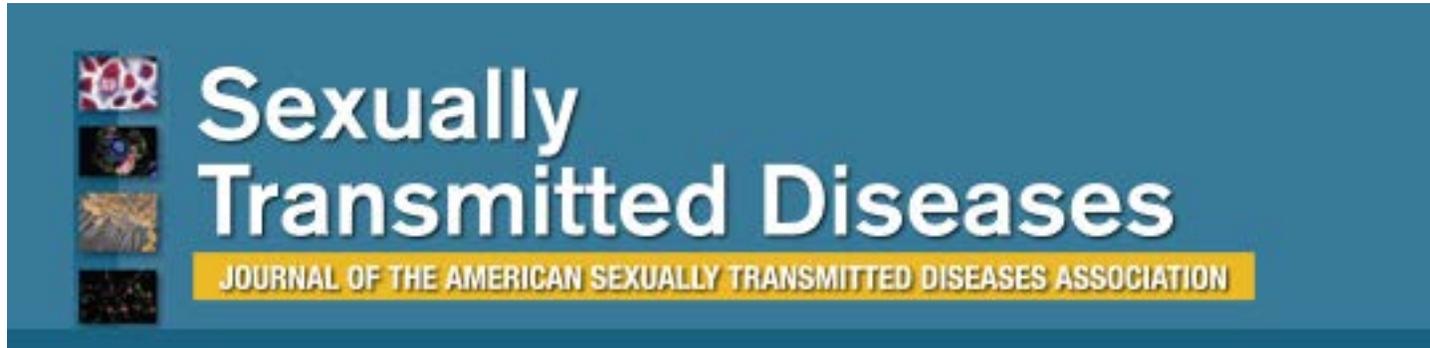
(The percentage of comparator positive results that are called as positive by the test.)

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

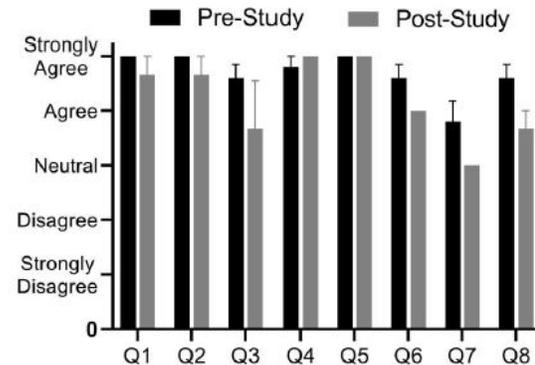
- Outcomes study at an urgent care center to see how the Visby POC test affects:
 - Time to treatment
 - Accuracy of treatment
 - Clinician Satisfaction
 - Patient Satisfaction
- Assess how a rapid PCR POC test can be implemented in a clinic setting



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



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

Strongly Agree

“I am an advocate for Antibiotic Stewardship.”

Strongly Agree

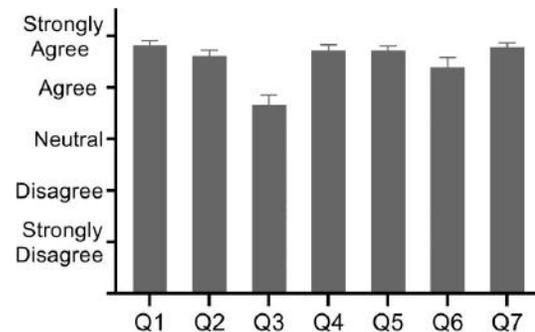
“I would find value in discussing the results of the test right away with my patients.”

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**



“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.”

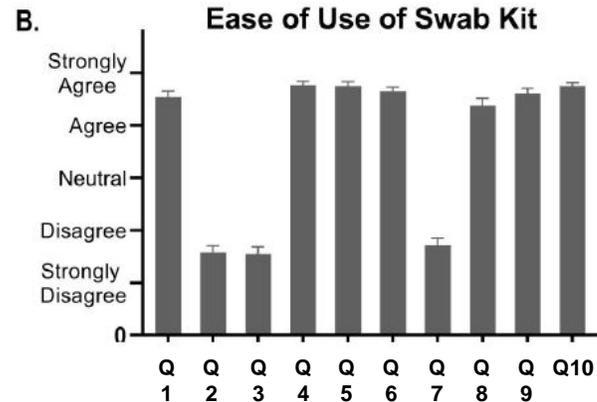
Strongly Agree

“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 knew when I completed the self-collection procedure.



“The Vaginal Specimen Collection Kit was easy to use.”

Agree / Strongly Agree

“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

Syndromic Treatment vs SoC*		SoC		Visby STI Panel Predictions of Over- and Under-Treatment	% Over/undertreated compared to SOC
		Positive	Negative		
CT					
Syndromic Treatment	Yes	3	14	Negative in 14/14 cases of overtreatments	82.4%
	No	7	30	Positive in 7/7 cases of undertreatments	18.9%
NG					
Syndromic Treatment	Yes	1	11	Negative in 11/11 cases of overtreatments	91.7%
	No	2	40	Positive in 1/2 cases of undertreatments	4.8%
TV					
Syndromic Treatment	Yes	1	8	Negative in 8/8 cases of overtreatments	88.9%
	No	6	39	Positive in 5/6 cases of undertreatments	13.3%

*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*

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

Part E

Rapid PCR point-of-care STD tests can
optimize clinic **workflow**

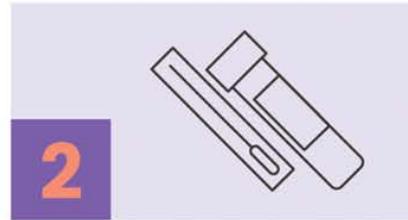
Suggested patient and clinic-friendly workflow



Get patient chief complaint

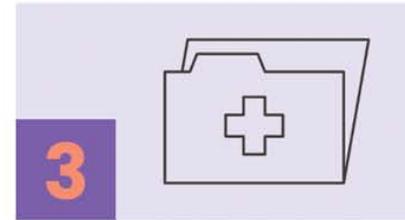
Patient chief complaint - if present, proceed with Step 2

- 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



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



Get patient history and examine patient



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

Health Department Sexual Health Services' Attitudes on POCT

- 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

Types of tests

Home testing

POCT opinions

Relationships

Insurance

Funding

Outreach services

HIV care

COVID-19



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



Funding Challenges Continued

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

Additional Findings

- 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

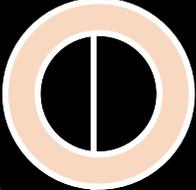
Lack of the patient perspective was a strong limitation in this study

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

Q&A

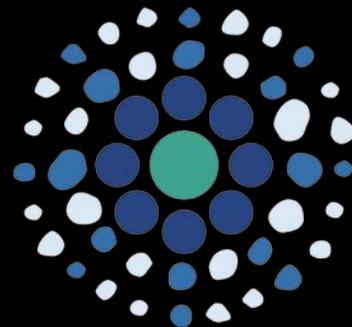


NACCHO

National Association of County & City Health Officials



NASTAD



NCSO

National Coalition
of STD Directors