

Advances in Point-of-Care Testing to Address the Sexually Transmitted Infection Epidemic

Dr. Gary Schoolnik

Learning Objectives

- Review the rising rates of Sexually Transmitted Infections (STI) in the United States and globally.
- Review today's STI testing methods
- Discuss the challenges and implications of today's testing methods for the patient, clinician, and public health.
- Examine how Point-Of-Care testing for STIs can improve patient care, reduce the rates of STIs, improve patient and clinician satisfaction scores and improve clinic workflow, efficiency and cost-effectiveness.

Disclosures

Chief Medical Officer of Visby Medical.

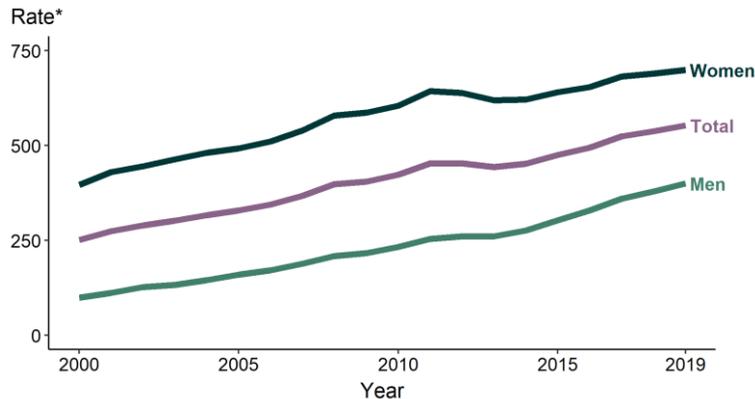
POLL

Does your clinic currently send STI samples out for testing?

- Yes
- No
- Not sure

Chlamydia is the most common notifiable condition in the US

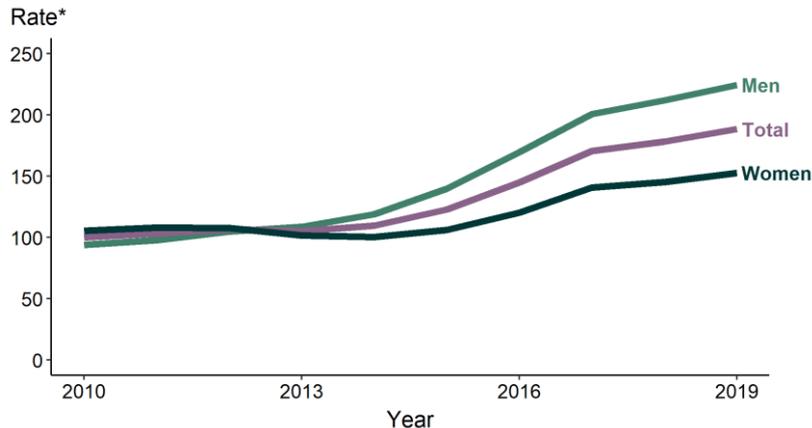
Chlamydia – Rates of reported cases by sex [2000-2019]



- During 2018–2019, rates of reported chlamydia increased among both males and females, in all regions of the United States, and among all racial/Hispanic ethnicity groups.
- Among females aged 15–24 years, reported cases of chlamydia increased by 10.0% from 2015.
- In women, untreated chlamydia can spread to and damage uterus or fallopian tubes and cause PID
 - Symptomatic PID occurs in 10-15% of women with untreated chlamydia
 - Damage can lead to chronic pelvic pain, tubal factor infertility, and ectopic pregnancy.

Gonorrhea is the 2nd most common notifiable condition in the US

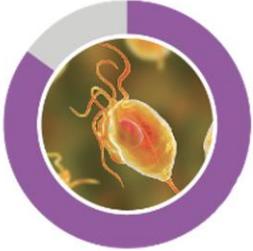
Gonorrhea – Rates of reported cases by sex [2010-2019]



- During 2018–2019, the overall rate of reported gonorrhea increased 5.7%.
- Rates among women increased 5.1% during 2018–2019 and 43.6% during 2015–2019.
- Untreated gonorrhea can cause serious and permanent health problems – In women this can result in PID, complications include ectopic pregnancy, infertility, chronic abdominal pain.
- Untreated gonorrhea increases the risk of HIV transmission.

Trichomoniasis – most common curable STD

Trichomoniasis



70-85% of women are asymptomatic

2-3x

Increased risk of contracting HIV⁴

- CDC estimates that there were 2.6 million trichomoniasis infections in 2018
- The epidemiology of trichomoniasis comes from population based and clinic-based surveillance studies
 - The U.S. population-based prevalence is 2.1% among females with the highest rates among Black females (9.6%)
- Infection is more common in women – 70-85% of women are asymptomatic
- *T. vaginalis* causes reproductive morbidity – 1.4x greater likelihood of pre-term birth, premature rupture of membranes, and infants who are small for gestational age
- Trichomoniasis can increase the risk of getting or spreading HIV

POLL

How many STI tests does your clinic perform per month?

- 0 - 20
- 21 - 50
- 51– 100
- 100+

Case Presentation



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

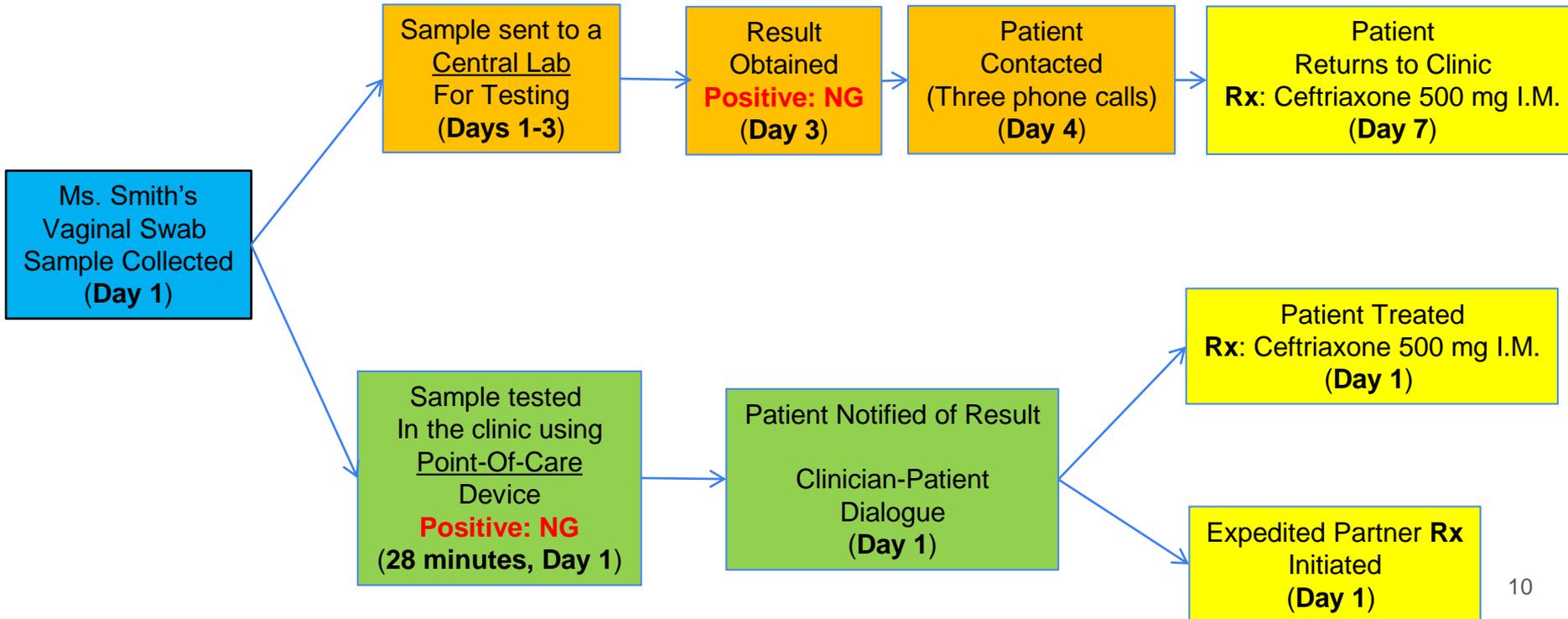
Ms. Smith, a 23 year old G1P1 administrative assistant in a Silicon Valley electronics company, presents to the county sexual health clinic with the following chief complaint: an increase in her normal vaginal discharge of 10 day's duration and, most prominently, concern about having a new sexual partner in a relationship that began just two weeks before.

Past Medical History: remarkable for a positive HPV test one year before, one episode of bacterial vaginosis eight months ago, and three UTI episodes during the past three years. On her annual screening tests (the last administered 11 months ago), she was negative for NG and CT and her syphilis and HIV serology results were negative.

Clinic Course: The triage nurse at the clinic, focusing on Ms. Smith's concern about a new sexual partner, asked the patient to obtain a self-collected vaginal swab. The swab sample was then sent to a central lab for testing. Then, a complete medical history was obtained and a pelvic exam performed.

Vaginal Swab: Sample-To-Result Timeline

Central Lab: 72 hours
Point of Care (POC): 28 minutes



What is Point-Of-Care Testing?

Point-Of-Care testing is an investigation undertaken at the time of the consultation in the clinic (urgent care, emergency room, STI clinic, student health center, mobile van, or even at home) that produces an accurate result within 30 min, and that provides the clinician with the results she needs to make immediate and informed decisions about patient care. Ordinarily, a Point-Of-Care diagnostic result will lead to data-driven treatment within the span of the initial clinic visit.

POLL

What is the average turnaround time to get results for STI?

Chlamydia

- 30 mins
- 90 mins
- Up to 6 hours
- 6-12 hours
- 12-24 hours
- + 2 days

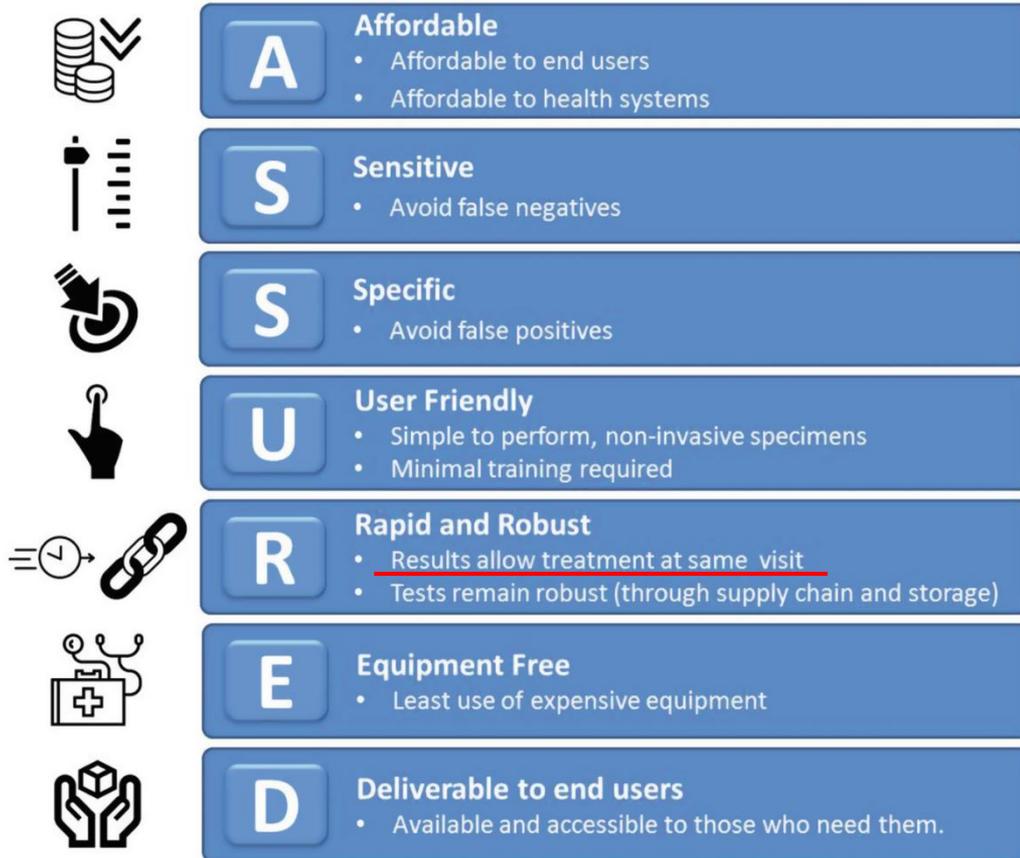
Gonorrhea

- 30 mins
- 90 mins
- Up to 6 hours
- 6-12 hours
- 12-24 hours
- + 2 days

Trichomonas

- 30 mins
- 90 mins
- Up to 6 hours
- 6-12 hours
- 12-24 hours
- + 2 days

“ASSURED” Seven Criteria for an Ideal STD Point-of-Care Test



2004
WHO Special Program for Research and
Training in Tropical Diseases:
Urgent Need for New Point-of-Care
Diagnostic Tests for Bacterial STDs

**POCTs should return results in
less than 30 minutes**

After Adamson, Loeffelholz and Klausner. *Arch Pathol Lab Med.* 144: 1344-1351, 2020

“Presumptive”, “Empiric”, “Syndromic” Treatment of STDs

Long Delays in Test Result Turn-Around-Time for Samples Sent to Central Laboratories Often Lead Clinicians to Treat Before a Lab Result is Obtained

- Empiric Treatment
- Presumptive Treatment
- Syndromic Treatment (WHO)

Medical treatment based on the experience of the clinician.

Treatment begun on the basis of an educated guess and in the absence of complete or perfect information.

Treatment occurs before confirmation of a definitive diagnosis.

By Contrast: result-driven or data-driven treatment is treatment guided by, or informed by, a test result.

Identifying easily recognized signs and symptoms to guide treatment in low resource settings where laboratory testing may not be available. Problem: NG and CT infections in women are often asymptomatic. Relying on signs and symptom to treat NG and CT often leads to under-treatment in women.

And Yes, we all use clinical judgement—and as Clinicians, we at times NEED to make critical Clinical Decisions based on an incomplete database. But we need to recognize the limitations.

Scenario A: Under-treatment of an STD

Ms. Smith, a 23 year old G1P1 administrative assistant in a Silicon Valley electronics company, presents to the county sexual health clinic with the following chief complaint: an increase in her normal vaginal discharge of 10 day's duration and, most prominently, concern about having a new sexual partner in a relationship that began just two weeks before.

Past Medical History: remarkable for a positive HPV test one year before, one episode of bacterial vaginosis eight months ago, and three UTI episodes during the past three years. On her annual screening tests (the last administered 11 months ago), she was negative for NG and CT and her syphilis and HIV serology results were negative.

Clinic Course: The triage nurse at the clinic, focusing on Ms. Smith's concern about a new sexual partner, asked the patient to obtain a self-collected vaginal swab. The swab sample was then sent to a central lab for testing. Then, a complete medical history was obtained and a pelvic exam performed.

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.



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

Consequences of Under-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

Ms. Smith, a 23 year old G1P1 administrative assistant in a Silicon Valley electronics company, presents to the county sexual health clinic with the following chief complaint: an increase in her normal vaginal discharge of 10 day's duration and, most prominently, concern about having a new sexual partner in a relationship that began just two weeks before.

Past Medical History: remarkable for a positive HPV test one year before, one episode of bacterial vaginosis eight months ago, and three UTI episodes during the past three years. On her annual screening tests (the last administered 11 months ago), she was negative for NG and CT and her syphilis and HIV serology results were negative.

Clinic Course: The triage nurse at the clinic, focusing on Ms. Smith's concern about a new sexual partner, asked the patient to obtain a self-collected vaginal swab. The swab sample was then sent to a central lab for testing. Then, a complete medical history was obtained and a pelvic exam performed.

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 detection of NG.

This is an example of combined over-treatment and under-treatment (NG not treated) of an STD



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

Six 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	% of subjects overtreated	% of subjects undertreated	Setting
Anaene et al, International Journal of Infectious Diseases, 53 (2016) 34-38	<i>“Factors associated with the over-treatment and under-treatment of gonorrhea and chlamydia in adolescents presenting to a public hospital emergency department”</i>	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	<i>“Overtreatment of gonorrhea and chlamydial infections in 2 inner-city emergency departments”</i>	86%	4%	2 inner city emergency departments
Dawkins et al, Manuscript submitted for review (Sept 2021)	<i>“Clinical Integration of a Highly Accurate PCR Point-of-care Test Can Inform Immediate Treatment Decisions for Chlamydia, Gonorrhea and Trichomonas”</i>	87%	12%	Urgent care center in Baton Rouge, LA
Gaydos et al, Ann Emerg Med, 2019 Jul: 74(1):36-44	<i>“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”</i>	46.7%	43.8%	Urban academic Emergency Department
Bergquist et al, International Journal of STD and AIDS, 2020 Vol 31(2) 166-173	<i>“Undertreatment of chlamydia and gonorrhea among pregnant women in the emergency department”</i>	15.6%	80%	Emergency Department, St. Louis, MO
Dretler et al, Am J Emerg Med 38 (2020) 566–570	<i>“The influence of race and sex in gonorrhea and chlamydia treatment in the emergency department”</i>	41% [67.5% women]	40% [85.7% women]	Emergency department, St. Louis, MO

Rapid and Accurate STD Point-of-Care Tests Can Prevent Over-treatment and Under-treatment of STDs

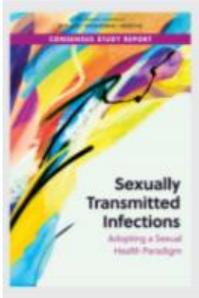
Eight Critical Advantages of STD Point-Of-Care Tests

- 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. (More on this later)
- Increases patient satisfaction by providing the patient with an accurate diagnosis.
- 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.

Eight Qualities of an Effective and Impactful Point-Of Care Diagnostic

- Panel composition: NG + CT + TV; NG + CT; TV only; other panels e.g. vaginitis panel; genital ulcer panel; HPV screening panel; labor and delivery panel
- Sample type. Urogenital samples: vaginal swab; urine; penile meatal swab. Extra-genital samples: pharyngeal swab; rectal swab.
- Sample-to-Answer turn around time: ideally < 30 min.
- User simplicity: < 1 minute operator time; does not require the user to have technical skills
- Surge-capacity: capacity to handle multiple samples simultaneously (if multiple patients present simultaneously)
- Instrument Free: does not require an instrument that needs to be purchased, maintained or have a large footprint in situations where shelf space is limiting.
- Accurate: sensitivity and specificity equal to large laboratory instruments that reside in central labs.
- Positive effect on clinic workflow, physician and patient satisfaction, and cost-effectiveness as proven by health economic studies.

National Academies of Science Engineering, Medicine - STI (2021)



Committee on Prevention and Control of Sexually Transmitted Infections in the U.S.

A Consensus Study Report

- No instrument, integrated
- PCR
- Vaginal, self-collected

TABLE 7-1 Point-of-Care Tests Available and in Development for STIs

Assay	Io CT/NG	GeneXpert CT/NG	Medical Sexual Health Test	<i>ResistancePlus</i> GC	Syphilis Antibody Rapid Test	DPP POC Test for HIV and Syphilis Serology	OSOM Rapid POC TV Antigen Test
Company	Binx Health	Cepheid	Visby	Speedx	Syphilis Health Check	Chemio	Sekisui
Platform	Table Top Integrated	Table Top Integrated	None required Integrated	Table Top PCR machine	Lateral Flow Immunochromagrapic	Lateral Flow	Immunochroma-graphic
Technology	NAAT Small molecule chemistry	Real-time PCR	Real-time PCR	<i>Plex</i> PCR	Antigen-antibody serology	Antigen-antibody serology	<i>Trichomonas vaginalis</i> membrane proteins Mouse antibodies
Sample Type	Self- and clinician-collected vaginal swabs; male urine	Swabs (cervical, self-collected vaginal); male and female urine	Self- and clinician-collected vaginal swabs	Swabs (cervical, vaginal, pharyngeal, and ocular); male and female urine	Blood, plasma, serum	Blood, plasma, serum	Vaginal swabs
Procedure	~4 steps	~4 steps	~2 steps	~4 steps	~2 steps	~3 steps	~3 steps

THE LANCET Infectious Diseases

Log in Register Subscribe Claim

ARTICLES | VOLUME 21, ISSUE 5, P668-676, MAY 01, 2021

Purchase Subscribe Save Share Reprints Request

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

Sheldon R Morris, MD, Claire C Bristow, PhD, Michael R Wierzbicki, PhD, Mark Sarno, eJD, Lenore Asbel, MD, Audrey French, MD, et al. Show all authors

Published: November 23, 2020 DOI: [https://doi.org/10.1016/S1473-3099\(20\)30734-9](https://doi.org/10.1016/S1473-3099(20)30734-9) Check for updates PlumX Metrics

Request Your Institutional Access

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.

Methods

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 CT/CC 2 Amplified DNA Assay and BD ProbeTec *Trichomonas*

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)

[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30734-9/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30734-9/fulltext)

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.)

Table 3. Clinical Performance of the Visby Test for CT vs. Composite Comparator Results, by Symptom Status

Symptom Status	N	TP	FP	TN	FN	Prevalence %	PPA (95 CI)	NPA (95 CI)
Symptomatic	918	95	26	795	2	10.6%	97.9% (92.8%-99.4%)	96.8% (95.4%-97.8%)
Asymptomatic	856	54	10	790	2	6.5%	96.4% (87.9%-99.0%)	98.8% (97.7%-99.3%)
Overall	1774	149	36	1585	4	8.6%	97.4% (93.5%-99.0%)	97.8% (96.9%-98.4%)

PPA=Positive Percent agreement with CCR; NPA=Negative Percent Agreement with CCR;
TP=true positive; FP=false positive; TN=true negative; FN=false negative

Table 4. Clinical Performance of the Visby Test for NG vs. Composite Comparator Results, by Symptom Status

Symptom Status	N	TP	FP	TN	FN	Prevalence %	PPA (95 CI)	NPA (95 CI)
Symptomatic	929	25	8	896	0	2.7%	100.0% (86.7%-100.0%)	99.1% (98.3%-99.6%)
Asymptomatic	857	19	8	829	1	2.3%	95.0% (76.4%-99.1%)	99.0% (98.1%-99.5%)
Overall	1786	44	16	1725	1	2.5%	97.8% (88.4%-99.6%)	99.1% (98.5%-99.4%)

PPA=Positive Percent agreement with CCR; NPA=Negative Percent Agreement with CCR;
TP=true positive; FP=false positive; TN=true negative; FN=false negative

Table 5. Clinical Performance of the Visby Test for TV vs. Patient Infected Status, by Symptom Status

Symptom Status	N	TP	FP	TN	FN	Prevalence %	Sensitivity % (95 CI)	Specificity % (95 CI)
Symptomatic	916	83	35	797	1	9.2%	98.8% (93.6%-99.8%)	95.8% (94.2%-97.0%)
Asymptomatic	849	53	18	778	0	6.2%	100.0% (93.2%-100.0%)	97.7% (96.5%-98.6%)
Overall	1765	136	53	1575	1	7.8%	99.3% (96.0%-99.9%)	96.7% (95.8%-97.5%)

TP=true positive; FP=false positive; TN=true negative; FN=false negative

A Point-Of-Care Device Should Have a Good Limit of Detection (LoD) (Equal to Large Laboratory Instruments) To Avoid False-Negative Results

The LoD for each organism is shown in the table below.

Table 9. LoD of CT Serovars, NG strains, and TV strains in Clinical Negative Vaginal Sample Matrix

Organism	LoD
CT Serovar H (VR-879)	16.0 EB/mL
CT Serovar D (VR-885)	5.9 EB/mL
NG (ATCC 19424)	5.7 CFU/mL
NG (ATCC 49226)	6.2 CFU/mL
TV (ATCC 30001) (metronidazole susceptible)	1.2 troph/mL
TV (ATCC 30238) (metronidazole resistant)	0.24 troph/mL

Source: Visby Medical Sexual Health Click Test Instructions For Use

A Point-of-Care Test Should Be Easy to Interpret.



A Point-of-Care Device should be Easy to Operate (< 15 seconds hands-on-time)

Step 1: Sample



Input sample

Step 2: Run Test



Close button 1



Press buttons 1, 2, 3

Step 3: Result



Read results

Scenario C: Correct and Prompt Treatment of an STD

Ms. Smith, a 23 year old G1P1 administrative assistant in a Silicon Valley electronics company, presents to the county sexual health clinic with the following chief complaint: an increase in her normal vaginal discharge of 10 day's duration and, most prominently, concern about having a new sexual partner in a relationship that began just two weeks before.

Past Medical History: remarkable for a positive HPV test one year before, one episode of bacterial vaginosis eight months ago, and three UTI episodes during the past three years. On her annual screening tests (the last administered 11 months ago), she was negative for NG and CT and her syphilis and HIV serology results were negative.

Clinic Course: The triage nurse at the clinic, focusing on Ms. Smith's concern about a new sexual partner, asked the patient to obtain a self-collected vaginal swab. The swab sample was then introduced immediately to the Visby Medical Sexual Health PCR device at the Point-Of-Care. Then, a complete medical history was obtained and a pelvic exam performed.

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

28 Minutes Later: NG Positive

**Treatment Decision: Clinician followed CDC treatment guidelines:
Rx: Ceftriaxone 500 mg IM (administered 40 minutes after the patient entered the clinic). Expedited Partner Treatment initiated.**

Correct and Prompt Treatment was enabled by a POC device.



Eight Critical Advantages of STD Point-Of-Care Tests **(Focus: The Teachable Moment)**

- 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.
- 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.

Teachable Moment

Includes:

- ❑ Cause of the STI
- ❑ Treatment and the effectiveness of treatment
- ❑ Potential complications of the diagnosed STI
- ❑ The practice of safe sex to avoid future STIs
- ❑ Treatment to the patient's sexual partner(s)



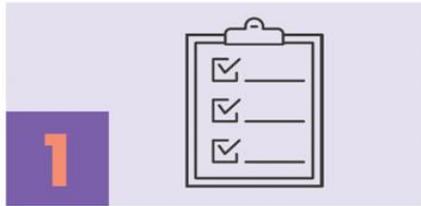
Test → Get Result → Talk → Treat
A Clear Result Enables
Effective Clinician-Patient Dialogue, Which We Term:
The Teachable Moment

Introducing Point-Of-Care Diagnostics Into Your Clinic

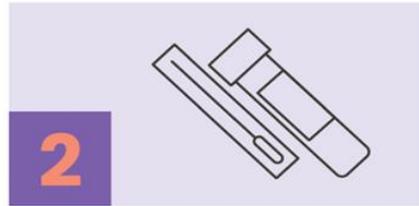
This may require a change in patient workflow and a period for staff education

Remember, we want to test, get the result, talk, and treat all on the same clinic visit.

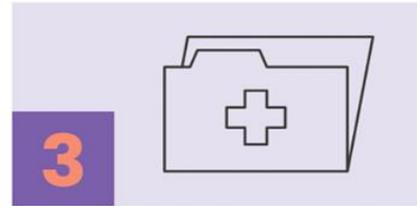
A suggested workflow is shown below.



A nurse obtains the patient's chief medical complaint (reason for the clinic visit)



Patient self-collects vaginal swab sample.
Staff starts the Point-Of-Care test to detect NG, CT, TV.



Clinician obtains patient medical history and examines patient.



The Point-Of-Care test provides a result, the result is discussed with the patient, and the patient is treated, all in the same visit.

A Look Into The Future

Point-Of-Care Testing For Infectious Diseases
Provides “Personalized” Treatment For Each Patient
Based on the Pathogen Detected and its Antibiotic Susceptibility Genotype

Competing Platforms: ~4 days, sample-to-treatment



< 1 hour, sample-to-treatment



Rapid
Non-individualized
Standard treatment

"Personalized Medicine" in Infectious Diseases

< 1 hour, sample-to-treatment



Unique, rapid
Individualized
Standard treatment

Summary of Main Points

- Nucleic Acid Amplification Point-Of-Care (POC) tests have been developed and FDA approved that detect three important STD pathogens: NG, CT and TV; clinical trials have demonstrated that they have the accuracy of large laboratory instruments in centralized laboratories.
- These FDA approved STD POC tests can provide a result in < 30 min and thus enable a patient to be accurately diagnosed and correctly treated within the span of a single clinic visit. In addition, they are easy to use by non-technical staff, require < 1 minute of hands-on time, and the results are easily interpreted. Their use will reduce the likelihood that a patient will be over-treated, or under-treated.
- These POC tests 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, their 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 women, men and children.

Thank you!

We invite your questions