Economic Impact of Multiplex Point-of-Care Testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Mycoplasma genitalium*: Development of a Modeling Framework

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Background

Chlamydia trachomatis (CT), *Neisseria gonorrhoeae* (NG), and *Mycoplasma genitalium* (MG) are sexually transmitted pathogens that often present as genital tract infections with similar symptoms, posing diagnostic challenges for clinicians

Inappropriately treated or untreated sexually transmitted infections (STIs) can lead to substantial costs in terms of unnecessary antibiotic use, additional medical visits, and downstream complications such as pelvic inflammatory disease and infertility

Innovative, multiplex molecular point-of-care (POC) testing for CT, NG, and MG, with an approximate 20-minute turnaround time, in which test results are received and appropriate treatment can be initiated during the initial provider visit, may improve care, thereby reducing costs and improving outcomes

Objective

To develop a decision modeling framework to assess the holistic clinical and economic value of multiplex molecular POC testing with an approximate 20-minute turnaround time in people at increased risk for STIs

Methods

- A targeted search of the published and grey literature was performed to characterize patient unmet needs, disease incidence and burden, and existing clinical and economic data
- The influence of diagnostics at different stages of the treatment pathway was assessed
- This was used to create a validated patient care pathway and decision-tree modeling framework
- The framework was constructed, tested, and reviewed by clinicians. Three simulations, which reflect common variations in real-world testing and treatment patterns in the United States, are presented to demonstrate the performance of the framework

Results

Decision-Tree Modeling Framework

- The decision-tree modeling framework (Figure 1) compares two testing approaches:
  - POC: Use of a multiplex molecular POC test covering CT, NG, and MG with an approximate 20-minute turnaround time
  - Standard of care (SOC): Use of central laboratory polymerase chain reaction (PCR) tests to identify CT, NG, or MG (of any combination of the pathogens)
- The framework enables inclusion of clinical judgement and real-world practice patterns associated with medical visits and empiric antibiotic treatment which can be applied from any country perspective
- The construct allows for easy input from real-world clinical studies assessing the use of diagnostics and treatment appropriateness[11]
- The framework is constructed around inappropriate treatment defined as under and/or overtreatment on the day of the medical encounter based on Centers for Disease Control and Prevention recommendations for the pathogen-specific results obtained by external laboratory PCR testing
- Data captured by the framework includes pathogen epidemiology, infection rates, treatment success, medical resource use, long-term sequelae, costs (adjusted to 2024 USD), and quality-of-life (Table 1)
- Antibiotic stewardship, in terms of appropriate and inappropriate use of antibiotics (number of patients impacted and number of prescriptions used), and associated costs are captured
- Coinfections (infection caused by more than 1 pathogen) and long-term sequelae are captured so as not to undervalue appropriate treatment

Figure 1: Decision-Tree Modeling Framework

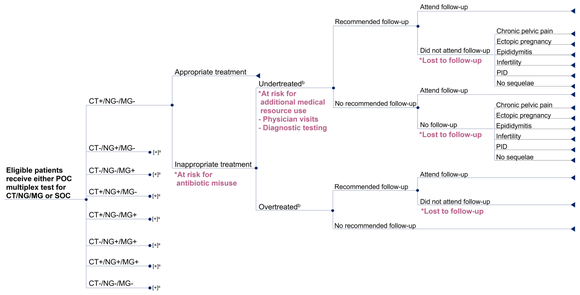


Figure legend: CT+ = *Chlamydia trachomatis* positive, CT- = *Chlamydia trachomatis* negative, MG+ = *Mycoplasma genitalium* positive, MG- = *Mycoplasma genitalium* negative, NG+ = *Neisseria gonorrhoeae* positive, NG- = *Neisseria gonorrhoeae* negative, PID = pelvic inflammatory disease; POC = point-of-care.

[+] Indicates the same decision-tree structure as above.

[a] The structure is the same as the CT+/NG-/MG- branch.

[b] Undertreated = Failure to provide pathogen-appropriate antibiotics either alone or in combination. Overtreated = Provision of 2 or more antibiotics when only 1 is necessary, or provision of any unnecessary antibiotics.

Literature Review Results

Table 1: Example Data Captured by Framework

Parameter	Value
Pathogen incidence	CT: 0.3% - 4.6% [4,7] NG: 0.1% - 1.7% MG: 0.8% - 1.1%
Infections inappropriately treated	20.0% - 40.0% [1,6,11,13,15]
Undertreated	15.4% - 33.3% [11]
Overtreated	66.7% - 84.6% [11]
Provider recommends patient follow-up	50.0% [8]
Patient attends follow-up	70.0% [12]
Percentage of patients treated empirically	85.0% [8]
Percentage of undertreated SOC patients who fill antibiotic prescription after central lab testing results are available	50.0% [21]
Percentage of MG infections that are antibiotic resistant	64.4% [3]
Sequelae incidence among undertreated patients (pathogen/gender specific)	**Value**
Pelvic inflammatory disease	3.8% - 10.0% [17, 18, 24]
Chronic pelvic pain	1.0% - 2.6% [18, 24]
Ectopic pregnancy	0.4% - 1.0% [5, 18, 24]
Infertility	0.3% - 0.8% [18, 23, 24]
Epididymitis	0.0% - 4.3% [18]
Costs	**Value**
Diagnostic test cost	$0.00 - $142.63 [9]
Antibiotic treatment costs	$0.97 - $25.41 [19, 25]
Initial or subsequent office visit	$89.39 [10]
Sequelae event costs	**Event cost**
Pelvic inflammatory disease	$1,878.17 [20, 22]
Chronic pelvic pain	$1,382.40 [20, 22]
Ectopic pregnancy	$5,322.61 [20, 22]
Infertility	$7,207.84 [20, 22]
Epididymitis	$495.91 [20, 22]
Sequelae long-term costs	**Annual cost**
Chronic pelvic pain	$126.07 [10]
Infertility	$7,207.84 [20, 22]
Utilities	**Utility**
Age group-specific healthy individuals	0.650 – 0.938 [2]
Symptomatic STI	0.961 – 0.994 [18, 20]
Overtreated	0.997 [16]
Sequelae utilities	**Utility**
Pelvic inflammatory disease	0.864 [18]
Chronic pelvic pain	0.923 [18]
Ectopic pregnancy	0.886 [18]
Infertility	0.993 [18]
Epididymitis	0.872 [18]

CDC = Centers for Disease Control and Prevention, CMS = Centers for Medicare and Medicaid Services, CT = *Chlamydia trachomatis*, MG = *Mycoplasma genitalium,* NG = *Neisseria gonorrhoeae*, SOC = standard of care, STI = sexually transmitted infection, US = United States.

Simulation Results

Specifications for Simulation Runs

Patients at risk for STI incur an initial provider visit for suspected STI. Patients receive assessment via SOC (100% receiving CT + NG testing) or POC

- POC patients receive care according to CDC guidelines based on POC results for CT, NG, and MG[25]
- SOC patients receive empiric antibiotic treatment at providers' discretion. When test results are available, providers prescribe appropriate antibiotic (if needed) via electronic transfer of prescription to pharmacy or an additional provider visit

Appropriate/inappropriate (undertreated or overtreated) treatment is categorized based on outcomes of the initial visit.

- Providers may recommend a follow-up visit
  - Patients may choose to attend or not
  - Patients choosing not to attend the follow-up visit will be lost to follow-up
- Patients lost to follow-up are at risk for sequelae due to inappropriate undertreatment resulting from inadequate or suboptimal management

POC molecular testing is assumed to be highly sensitive and specific in identifying pathogens

Three simulations were run to understand drivers of outcomes:

Simulation 1 (POC vs SOC – Base): Settings as in Table 1. 100% of SOC patients receive testing for CT + NG as this best represents real-world treatment patterns in the United States (clinical opinion)

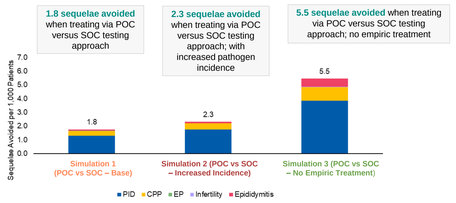
Simulation 2 (POC vs SOC – Increased Incidence): Simulation 1, but incidence of CT, NG, and MG are 13%, 3%, and 17% respectively[14]

Simulation 3 (POC vs SOC – No Empiric Treatment): Simulation 2, but excludes empiric antibiotic treatment as empiric antibiotics are frequently avoided to support antibiotic stewardship (clinical opinion)

Simulation Results

- **POC testing enables sequelae to be avoided (Figure 2)**

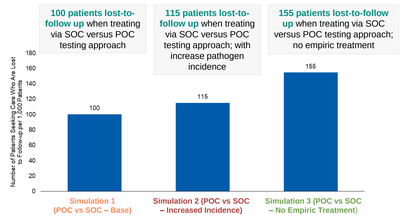
Figure 2. Sequelae Avoided Among Patients Receiving POC Compared with SOC Testing



CPP = chronic pelvic pain, EP = ectopic pregnancy, PID = pelvic inflammatory disease, POC = point-of-care, SOC = standard of care.

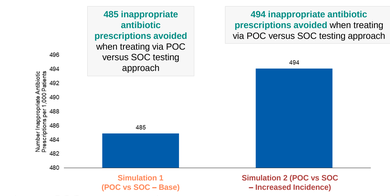
- **POC testing enables patients to not be lost to follow up (Figure 3)**

Figure 3. Patients Lost to Follow when Treating Via a SOC over a POC Testing Approach



- **POC enables providers to avoid inappropriate use of antibiotics (Figure 4)**

Figure 4. Inappropriate Antibiotic Prescriptions Avoided Among Patients Receiving POC Compared with SOC Testing



POC = point-of-care, SOC = standard of care.
Note: Simulation 3, (POC vs SOC - No Empiric Treatment), is not shown in Figure 4 as no inappropriate antibiotic prescribing occurs in POC or SOC testing approach.

Conclusions

In the simulations, which were selected to reflect real-world testing and treatment patterns in the United States, **multiplex molecular POC testing for CT, NG, and MG is predicted to reduce clinical sequelae, the number of patients lost-to-follow-up, and inappropriate antibiotic prescriptions** compared with SOC testing

Having the proper decision modeling framework to assess the clinical and economic impact of providing rapid results of multiplex POC testing for patients at increased risk for STI is important. It helps to:

- **Guide clinical decision-making and ensure appropriate treatment** at the initial medical encounter
- **Demonstrate public health, clinical, and economic impact** of timely POC testing
- **Understand major cost and clinical drivers** and their **implications for patient care**
- **Enable informed decision making for supporting antimicrobial stewardship and optimizing patient outcomes**

Overall, this helps providers, payers, and policymakers understand the **value of POC diagnostics in managing STIs**

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Disclosures

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