Impact of the binx io diagnostic platform on clinical management of urethritis and cervicitis compared with point-of-care gram stain in the MGH Sexual Health Clinic

NCT05564299

Document version date March 30, 2024

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator: Ingrid Bassett, MD MPH

Project Title: Impact of the binx io diagnostic platform on clinical management of urethritis and cervicitis compared with point-of-care gram stain in the MGH Sexual Health Clinic

Version Date: March 30, 2024

---

1. Background and Significance

In recent years there has been a steady rise in the incidence of sexually transmitted infections (STIs), including chlamydia and gonorrhea, in the United States. New cases of chlamydia have increased by 19% between 2015 and 2019, while new cases of gonorrhea have increased by 56% in the same time period.[1] This growth in new infections has occurred despite the availability of highly accurate diagnostic tests and effective antimicrobial therapies. The increase in STI rates is particularly concerning in light of the association between untreated STIs and HIV transmission and acquisition[2,3] and the impacts of untreated STIs on women's reproductive health, including risks of ectopic pregnancy, tubal factor infertility, pelvic inflammatory disease, and adverse obstetric outcomes.[4–6] Despite the availability of effective diagnostic tests and therapies, optimal management of STIs is limited, in part, by long wait times between testing and treatment and the resulting clinical practice of empiric therapy for symptomatic patients.

Decreasing the time between testing and pathogen-directed treatment of gonorrhea and chlamydia with the use of point-of-care tests has the potential to decrease under- and over-treatment,[7] to decrease forward transmission, and consequently to decrease STI incidence.[8] Point-of-care gram stain has been recommended by the CDC for this reason in specialized STI clinics[9], however, this procedure has several shortcomings. It can be labor intensive to maintain as a diagnostic modality and does not scale well to other clinical care settings, such as primary care, urgent care, or emergency departments. Importantly, it can only detect evidence of infection with *Neisseria gonorrhoeae* and does not provide any data on the presence or absence of chlamydial infection, which is either treated empirically or not treated until confirmatory test results are available.

As rapid, molecular diagnostic tests for gonorrhea and chlamydia are becoming available, providing a test result within the time frame of a clinical encounter will become increasingly feasible in the near future. Decreasing the time from specimen collection to STI test result with point-of-care tests has the potential to avoid inappropriate antibiotic treatment, decrease forward STI transmission, and reduce costs.[7,10,11] Thus, it is critical to understand the potential impact of rapid molecular tests on STI management in

specialized STI clinics, which in turn can inform the implementation of point-of-care molecular STI testing in other clinical settings.

The binx *io* is an FDA-approved desktop polymerase chain reaction (PCR) platform for the detection of the etiologic agents of gonorrhea and chlamydia using self-contained cartridges. The platform is CLIA certified and can be set up at the point of care (e.g., within a clinic) and operated by staff without formal laboratory training. The hands-on time of specimen processing is approximately one minute, and qualitative (positive/negative/invalid) results for gonorrhea and chlamydia infection are available in 30 minutes. The platform has demonstrated good sensitivity and specificity for the detection of gonorrhea and chlamydia from male urine or female vaginal swab specimens.[12]

The binx *io* platform has the potential to inform the clinical management of urethritis and cervicitis beyond that of the point-of-care gram stain. The sensitivity and specificity of the binx *io* should allow for a similar detection rate of gonococcal urethritis or cervicitis as with the point-of-care gram stain. In addition, the binx *io* can detect the presence of chlamydia, which can have a direct impact on the antibiotics administered for immediate management of symptomatic urethritis or cervicitis during the clinical encounter. Specifically, with a negative chlamydia result on the binx *io*, patients may be spared from the empiric use of antibiotics for chlamydia. Additionally, an in-clinic diagnosis of chlamydia would allow patients with an indication for expedited partner therapy (EPT) to receive a prescription for partner therapy earlier, decreasing treatment delay among their partners. However, the impact of the binx *io* on management of urethritis and cervicitis has not yet been studied in a specialized STI clinic setting.

In addition to its test characteristics, the binx *io* has additional properties, such as ease of use and rapid specimen processing time, that may be advantageous over the point-of-care gram stain and could ultimately inform CDC recommendations for point-of-care diagnostics in specialized sexual health clinic settings. Furthermore, understanding the implementation process of the binx *io* in specialized STI care settings could inform wider uptake of similar rapid molecular diagnostic tests in other clinical settings where STIs are managed.

2. Specific Aims and Objectives

Aim 1. To evaluate the impact of the binx *io* platform, compared to point-of-care gram stain, on antibiotic use in the clinical management of patients with symptomatic urethritis and cervicitis presenting to the Massachusetts General Hospital Sexual Health Clinic (SHC). We will conduct a randomized controlled pilot trial comparing the mean number of antibiotic courses administered per patient when evaluated with either point of care gram stain (current standard of care in MGH SHC) or the binx *io* platform. Secondary outcomes include concordance of binx *io* and point-of-care gram stain results for gonorrhea, concordance of binx *io* and nucleic acid amplification test (NAAT) results for gonorrhea and chlamydia, and time to provision of

Expedited Partner Therapy (EPT) for eligible patients with chlamydia.
Hypothesis: Clinical management based on the results of the binx *io* will decrease the mean number of antibiotic courses administered per patient by 10%.

Aim 2. To evaluate the implementation of the binx *io* platform in a specialized sexual health clinic using mixed methods. Quantitative analysis will assess process measures including rate of invalid results, equipment errors, processing time, and patient visit duration. We will conduct a focus group discussion with MGH SHC staff to assess impressions of use of the testing platform and other potential uses of point-of-care testing in the STI management pathway.

3. General Description of Study Design

This study is a pilot randomized controlled trial evaluating the use of either a) the binx *io* or b) point-of-care gram stain (current standard of care) to guide clinical management of patients with symptomatic urethritis or cervicitis evaluated in the MGH Sexual Health Clinic. Patients presenting with symptoms of urethritis or cervicitis and meeting inclusion criteria will be randomized to have diagnostic specimens tested during the clinical encounter using either the binx *io* platform or point-of-care gram stain. Patients randomized to the intervention arm of the study will also have a gram stain slide created, which will be held for later interpretation following the clinical encounter. Participants will not be followed longitudinally. Towards the end of the study, we will conduct a focus group discussion with Sexual Health Clinic staff to explore their impressions of use of a rapid STI test in the clinic and other potential uses of rapid STI testing in STI clinical management.

A detailed study schema is attached.

4. Subject Selection

The study will take place in the Massachusetts General Hospital Sexual Health Clinic (SHC), a specialized sexually transmitted infection (STI) clinic operated in partnership with the Massachusetts Department of Public Health. The clinic is staffed by nurse practitioners and physicians, who see patients for scheduled and urgent care visits.

Potential participants will be identified for recruitment by the Sexual Health Clinic staff upon review of the reasons given for scheduled or urgent care appointments for the day. Additionally, any patient who reports symptoms of urethritis or cervicitis during the clinic encounter, regardless of the reported chief complaint for the visit, will be assessed for eligibility by the clinician. Participants will be approached by a research assistant to introduce the study and obtain informed consent. Consenting participants will be

randomized to either the intervention or control group using a randomization function in RedCap.

Patients presenting to the Sexual Health Clinic will be eligible to participate in the study based on the following criteria:

Inclusion criteria

18 years of age or older; of any gender identity; presenting with symptoms of acute (<14 days) urethritis (urethral discharge, dysuria) or cervicitis (dyspareunia, intermenstrual or postcoital bleeding, vaginal discharge); and willing to provide urine or an additional vaginal swab specimen in addition to the routinely collected clinical specimens.

Exclusion criteria

Younger than 18 years old; presenting with symptoms not consistent with urethritis or cervicitis; unable or unwilling to provide a urine or vaginal swab specimen; known to be pregnant; contact of index patients with gonorrhea or chlamydia; known to have been exposed to gonorrhea or chlamydia; reporting concurrent symptoms at a non-genital site that are felt by the clinician to be concerning for extragenital STI; persons under investigation for, suspected of having, or confirmed to have monkeypox (this designation will be made by MGH Sexual Health Clinic clinicians; persons whose primary language is other than English, Spanish, or Portuguese; refusing point-of-care gram stain.

Based on historical data from the Sexual Health Clinic, approximately 270 patients were seen for symptoms of urethritis or cervicitis in calendar year 2020. Thus, we anticipate that it will take approximately 6 months to enroll 100 participants. We anticipate that the demographics of the recruited participants will reflect the demographics of the Sexual Health Clinic patient population in terms of gender identity, race, and ethnicity. For individuals whose primary language is other than English, Spanish, or Portuguese, providing a translated version of the consent form is not practicable. These persons will therefore be excluded from this pilot study.

For the focus group discussion, all regular clinical staff (nurse practitioners and nurses) of the MGH sexual health clinic who have experience using the binx io instrument through the study and provide informed consent will be eligible.

5. Subject Enrollment

The study will be introduced to potential participants by a trained research assistant. The research assistant will obtain written informed consent in a private space in a clinic exam room. For Spanish-speaking or Portuguese-speaking participants, informed consent will be obtained with the assistance of either a trained medical interpreter through MGH Interpreter services or Sexual Health Clinic providers who are qualified to provide care in Spanish or Portuguese. The use of Interpreter Services will be prioritized over clinicians from the Sexual Health Clinic. Informed consent will be obtained using

fully translated consent forms and will be documented using the MGB consent process. Consent procedures will follow MGB IRB policy on Obtaining and Documenting Informed Consent of Subjects who do not Speak English and participants who speak Spanish or Portuguese will be provided with translated informed consent documents.

The patient will be provided a copy of the consent form and ample opportunity to ask questions. Participants who enroll in the study will be provided a $25 gift card.

For the focus group discussion, sexual health clinic staff will be informed about the focus group discussion at a staff meeting. Staff who express interest will be invited to the focus group.

6. STUDY PROCEDURES

All study procedures will take place during the patient's index clinic visit. All participants will undergo routine evaluation and specimen collection per current clinic protocols. This includes a pelvic exam and self-collected or clinician-collected endocervical swabs for female participants; or a genital exam and clinician-collected urethral discharge specimen for male participants per standard clinic collection protocols. For participants randomized to the intervention arm, either one vaginal swab (female participants) or urine sample (male participants) will be collected for testing by the binx platform.

The endocervical and urethral specimens collected for use in this study will be processed immediately for point-of-care gram stain and additional specimen plated for gonorrhea culture as per current clinic protocols; to be sent to the Massachusetts Department of Public Health (DPH). Additional specimens will be sent to the DPH for nucleic acid amplification testing (NAAT) for gonorrhea and chlamydia, as per current clinic protocols. Participants in both the control and intervention arm of the study will have a point-of-care gram stain created, from either vaginal or endocervical swab (for female participants) or urethral swab (for male participants). All point-of-care gram stains will be performed by staff up to date with proficiency testing as per the MGH point of care testing committee. The point-of-care gram stain requires approximately 5-10 minutes for specimen processing/creation of the gram stained slide and reading of the slide. The point-of-care gram stain will be processed and read in the Sexual Health Clinic laboratory space on Cox 5 (room #572). Participants in the control arm will be administered antibiotic therapy in the clinic based on the results of the point-of-care gram stain. Point-of-care gram stain slides for intervention arm participants will be held for later interpretation following the clinical encounter. The gram stain slides from intervention arm participants each week will be labelled with the participant's study number and read at the end of the week. Results will be recorded in the study record.

For participants randomized to the intervention arm, the aliquot of urine (male participants) or the vaginal swab (female participants) will be processed immediately for testing on the binx *io* platform. All point-of-care testing will be conducted in the Sexual Health Clinic laboratory space on Cox 5 (room #572). The MGH Point of Care testing committee will guide the process of quality control for the binx *io* platform.

Participants will be administered antibiotic therapy in the clinic based on results of the point-of-care gram stain in the control arm and according to the binx *io* results in the intervention arm. A positive gram stain for gonorrhea will be defined using standardized clinical criteria, consisting of >4 polymorphonuclear leukocytes (PMNs) per high power field for male specimens and >10 PMNs per high power field for female specimens, along with the presence of intracellular gram-negative diplococci. Treatment for chlamydia, which cannot be detected specifically by the point-of-care gram stain, will be administered per routine clinical practice (either treated empirically or deferred pending confirmatory testing at the Massachusetts DPH) per the discretion of the clinical provider per routine clinical procedures. Results on the binx *io* are qualitative, indicating either the presence or absence (positive or negative result) separately for gonorrhea and chlamydia. For participants with positive test results for chlamydia on the binx io platform, the participant will be counseled on the availability of Expedited Partner Therapy (EPT) as per standard clinical guidelines. The results of binx *io* testing and treatment administered will be recorded in the medical record. For participants who are unwilling or unable to wait for the results of the binx io, clinical management will be at the discretion of the treating clinician and can involve the interpretation of the prepared and stored gram stain if elected by the treating clinician.

Per standard clinic procedures, participants will be contacted by phone with results of NAAT gonorrhea and chlamydia testing from MA DPH if these results require additional treatment that was not provided during the initial clinic visit. Participant contact and treatment will be provided according to standard clinical procedures of the Sexual Health Clinic. After one week following the visit, the study team will review the participant's chart to record DPH test results and any resulting additional treatment. 30 days following the initial visit, the study team will record additional antibiotics prescribed for participants with unresolved symptoms.

In addition to specimens collected for immediate clinical use, all participants in both the intervention and control groups will be asked to provide an additional vaginal or urethral swab for storage. These specimens may be used in future studies of STI diagnostics. Any extra unused urine specimens may also be stored for use in future studies of STI diagnostic tests. Participants will be asked to consent to the collection and use of these additional vaginal, urethral, or urine specimens for future research. These specimens may be cultured in an incubator prior to storage in a freezer in the laboratory space on Jackson 7. Stored specimen will be labelled with a unique identification number. Following the conclusion of this study, each new use of these samples will be submitted in a secondary use protocol for MGB IRB approval. Specimen collection is summarized in the table below.

Table 1: Specimen Collection

	Control Arm	**Intervention Arm**

Consented to research specimen collection?	No	Yes	No	Yes
Male	1) 1 or 2 urethral swabs	1) 1 or 2 urethral swabs 2) Urine sample	1) 1 or 2 urethral swabs 2) Urine sample	1) 1 or 2 urethral swabs 2) Urine sample
Female	1) 2 cervical swabs	1) 2 cervical swabs 2) One vaginal swab	1) 2 cervical swabs 2) 1 vaginal swab	1) 2 cervical swabs 2) 2 vaginal swabs

The focus group discussion will be led by a trained research assistant. All participants will be asked to provide written informed consent, including consent for the session to be recorded. A focus group guide will be used to moderate the focus group discussion; questions will focus on staff impressions of using a rapid PCR test for STI diagnosis in the SHC and impressions of other uses of rapid STI testing in the MGH sexual health clinic or in other clinical settings. A second member of the study team will be present to take notes during the session. The session will be audio recorded; the recording will be transcribed following the focus group discussion and the audio recording will be deleted or destroyed. All participants of the focus group will remain anonymous, no names or identifying information will be included in the audio recording. Informed consent forms will be scanned and uploaded to a secure MGB business dropbox folder and paper copies will be securely disposed. The focus group discussion transcript will be analyzed using content analysis to identify emergent themes.

7. Risks and Discomforts

Physical risks

The study procedures do not differ significantly from routine clinical practice in the Sexual Health Clinic and thus we do not anticipate any substantial risks beyond those associated with routine clinical care. We will collect an additional vaginal swab from female participants (which will be self-collected or clinician-collected, by participant preference), which may result in mild discomfort, although vaginal swab collection is generally well-tolerated. There is a theoretical risk that a participant randomized to the intervention arm will have a false negative gonorrhea result on the binx *io* platform that would have been detected by the standard of care point-of-care gram stain, however, the sensitivity of the binx io platform for gonorrhea is similar to higher than for the point-of-care gram stain (sensitivity for gonorrhea detection, female specimens: 100%, male specimens: 97.3%). Thus, the risk that a participant in the intervention arm would have a delayed gonorrhea diagnosis that would have otherwise been detected is very small. All participants will have specimens sent to the Massachusetts Department of Public

Health as per standard clinic procedures for additional polymerase chain reaction testing for gonorrhea and chlamydia. We do not anticipate any physical risks related to the focus group discussion.

Psychosocial risks
The study does not incorporate additional questionnaires or instruments beyond the data already collected during the course of routine clinical evaluation in the Sexual Health Clinic, thus we do not anticipate any psychosocial risks related to the study procedures. As the focus group discussion will be asking participants about clinical pathways in the sexual health clinic and not about their personal health or any other sensitive personal information, we do not anticipate psychosocial risks associated with participation in the focus group discussion.

Privacy risks
Conducting all discussions in a private space will minimize social risks during the interactions with participants. Privacy risks will be further minimized by handling all research data in a confidential and secure manner. Data collected during the course of the study will be entered either into the existing Sexual Health Clinic RedCap database or into the medical record (results of point of care gram stain and binx *io* tests). RedCap will be accessed on password-protected workstations or an encrypted, password-protected tablet. Informed consent forms will be kept in a locked office and stored for 7 years as per MGB IRB requirements. To assure confidentiality, each participant will receive a unique identification number. Research data will be labeled only with this number.
The focus group discussion will be conducted anonymously; no identifying information will be collected about the participants except for informed consent forms which will be stored securely on a MGB business dropbox folder and accessed only from password-protected Partners desktop or encrypted laptop computers.

8. Benefits

Participants in the intervention arm have the potential for direct benefit from this study by receiving test results for chlamydia during the clinical encounter and thus access to immediate treatment for chlamydia if positive, or avoidance of unnecessary empiric treatment for chlamydia if negative. No direct benefit is expected for participants in the control arm. The study may benefit society as it will provide data on the utility of a new point-of-care test for gonorrhea and chlamydia when used for patients with symptoms of sexually transmitted infections in a specialized STI clinic.

Participants in the focus group discussion may benefit by improving understanding of effective ways to incorporate rapid testing into specialized STI care, thus potentially improving their work experience and ability to care for patients in the future.

9. Statistical Analysis

Sample size calculation

We hypothesize that the use of the binx *io* platform will decrease the mean number of antibiotic courses per patient by 10%. Based on data from 2020, symptomatic patients would receive approximately 1.13 courses of antibiotics per patient. With an alpha of 0.05, we would have a power >90% to detect a decrease of 10% (to 1.017 per patient) with sample size of 100 (50 per arm).

Analysis plan
The primary outcomes for Aim 1 will be compared between patients randomized to clinical management based on the binx *io* and patients randomized to clinical management based on point-of-care gram stain. Demographic and clinical data for both cohorts will be obtained from the SHC RedCap database and supplemented with chart review as necessary.

Standard descriptive statistics will be used to report primary and secondary clinical outcomes, reported as proportions, means with standard deviation, or median with interquartile range as appropriate. Unadjusted and adjusted ordinal logistic regression models will be used to compare the total antibiotics administered between patients for whom the binx *io* vs point of care gram stain was used for clinical management. Adjusted models will incorporate predictors felt clinically to affect likelihood of antibiotic administration as well as those found to be significant in unadjusted analyses, including gender, age, race/ethnicity, and insurance status.

Transcripts from the focus group discussion will be transcribed, coded, and analyzed for key themes deductively and inductively using content analysis.

10. Monitoring and Quality Assurance

Jana Jarolimova, MD MPH and Kevin Ard, MD MPH will be responsible for monitoring and reporting any adverse events in collaboration with the MGB IRB. In order to ensure patient safety, data and safety monitoring will include PI review of all adverse events, enrollment, and protocol deviations recorded by the study staff. Study staff will be responsible for reporting unanticipated problems, adverse events, including breach of participant confidentiality, and serious adverse events to the Principal Investigator and co-investigators. Adverse events are defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Serious adverse events are considered any adverse event that results in death, is life threatening or places the subject at immediate risk of death from the event as it occurred, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, or is another condition which investigators judge to represent significant hazards.

The Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) report will be completed detailing the problem, actions taken, and follow-up steps performed and the form will be submitted to the MGB IRB within 5 working days or 7 calendar days of the date the investigator first becomes aware of the problem, consistent with MBG IRB policy.. Specifically, the following will be reported writing: 1) all serious adverse events associated with the study procedures, and/or 2) any incidents or problems involving the conduct of the study or participation, including problems with the recruitment and/or consent processes. Any action recommended by the IRB will be undertaken. The Principal Investigator and co-investigators will log all adverse events and deviations in a REDCap Adverse Events module included within the study REDCap database.

Data monitoring and quality assurance will be done on an ongoing basis. The principal investigator and co-investigators will monitor study data every month to ensure the completeness of consent forms and other study questionnaires. Data entered into databases will be monitored on a routine basis (at least monthly but likely more frequently depending on the volume of data) using standard data management techniques (e.g., range and validation checks for individual variables; appropriate cross-checks for two variables in the same form or across forms). Given the design of REDCap which has limited data checking capabilities, data checking will primarily be done in Stata® using batch procedures that will automatically generate query reports which will be provided to the site for resolution. Summaries of these reports will be reviewed by Drs. Ard and Jarolimova on a routine basis.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☒ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens

☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research

☐ Additional privacy and/or confidentiality protections

12. References

1. CDC. Sexually Transmitted Disease Surveillance, 2019 [Internet]. Cent. Dis. Control Prev. 2021 [cited 2021 Jun 25];Available from: https://www.cdc.gov/std/statistics/2019/default.htm

2. Sexton J, Garnett G, Rottingen J-A. Metaanalysis and metaregression in interpreting study variability in the impact of sexually transmitted diseases on susceptibility to HIV infection. Sex Transm Dis 2005;32(6):351–7.

3. Jones J, Weiss K, Mermin J, et al. Proportion of Incident HIV Cases among Men Who Have Sex with Men Attributable to Gonorrhea and Chlamydia: A Modeling Analysis. Sex Transm Dis 2019;46(6):357–63.

4. Price MJ, Ades AE, De Angelis D, et al. Risk of Pelvic Inflammatory Disease Following Chlamydia trachomatis Infection: Analysis of Prospective Studies With a Multistate Model. Am J Epidemiol 2013;178(3):484–92.

5. Liu B, Roberts CL, Clarke M, Jorm L, Hunt J, Ward J. Chlamydia and gonorrhoea infections and the risk of adverse obstetric outcomes: a retrospective cohort study. Sex Transm Infect 2013;89(8):672–8.

6. Warr AJ, Pintye J, Kinuthia J, et al. Sexually transmitted infections during pregnancy and subsequent risk of stillbirth and infant mortality in Kenya: a prospective study. Sex Transm Infect 2019;95(1):60–6.

7. Gaydos CA, Ako M-C, Lewis M, Hsieh Y-H, Rothman RE, Dugas AF. 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. Ann Emerg Med 2019;74(1):36–44.

8. Bartelsman M, Vaughan K, van Rooijen MS, de Vries HJC, Xiridou M. Impact of point-of-care management on the transmission of anogenital gonococcal infections among men who have sex with men in Amsterdam: a mathematical modelling and cost-effectiveness study. Sex Transm Infect 2018;94(3):174–9.

9. Barrow RY, Ahmed F, Bolan GA, Workowski KA. Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, 2020. MMWR Recomm Rep 2020;68(5):1–20.

10. Huntington SE, Burns RM, Harding-Esch E, et al. Modelling-based evaluation of the costs, benefits and cost-effectiveness of multipathogen point-of-care tests for sexually transmitted

infections in symptomatic genitourinary medicine clinic attendees. BMJ Open 2018;8(9):e020394.

11. Rivard KR, Dumkow LE, Draper HM, Brandt KL, Whalen DW, Egwuatu NE. Impact of rapid diagnostic testing for chlamydia and gonorrhea on appropriate antimicrobial utilization in the emergency department. Diagn Microbiol Infect Dis 2017;87(2):175–9.

12. Van Der Pol B, Taylor SN, Mena L, et al. Evaluation of the performance of a point-of-care test for chlamydia and gonorrhea. JAMA Netw Open 2020;3(5):e204819.