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Summary of the Fourth Annual American Sexually Transmitted Diseases Association Workshop on Improving Sexually Transmitted Infection Control Efforts Through Cross-Sector Collaboration

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Abstract: The American Sexually Transmitted Diseases Association has, for several years, been conducting a cross-sector workshop to bring together a variety of stakeholders to develop ideas for collaboratively improving the sexually transmitted infection control efforts in the United States. In this summary, we share the content of discussions and ideas of the fourth annual workshop for future research and potential changes to practice with a focus on diagnostic capacity.

BACKGROUND

The American Sexually Transmitted Diseases Association (ASTDA) is a professional society whose mission is to foster scientific knowledge, develop leadership, and champion practice in the field of sexually transmitted infections (STIs). Objectives of the ASTDA are to control, prevent, and ultimately eradicate STIs; support research in all aspects of STI including medical, epidemiologic, laboratory, social, and behavioral studies; recognize outstanding contributions in STI control and prevention; disseminate authoritative information concerning STIs; develop the current and future generations of STI professionals; and promote social justice as an antidote to the structural determinants of STI risk (www.astda.org).

In 2018, ASTDA began an annual series of collaborative workshops to bring together early-career investigators, established academicians, public health agency representatives, regulatory agency representatives, and members of the diagnostic industry. The goal of the workshop has been to facilitate discussions and collaboration among these experts to advocate for new STI diagnostics, improve access to current STI diagnostic tools, and provide new investigators with knowledge, skills, and experience in initiating and conducting industry-sponsored research. This type of collaborative workshop may provide a model for similar engagement among academic, public, and private sectors focusing on issues such as STI vaccine development and deployment, new treatment strategies and products, and other sexual health issues requiring a multidisciplinary approach. As observed with the COVID-19 pandemic, collaboration across sectors is essential and resulted in the rapid development and deployment of new diagnostics, vaccines, and management strategies during the pandemic. These lessons learned should be applied to improving the control of STIs.

Here we describe the topics of discussion from the most recent workshop, a 2-day meeting held in May 2021. Four major themes were discussed: the changing landscape of STI diagnostics (point-of-care [POC] testing, telemedicine, direct-to consumer testing, and STI testing outside of clinical settings), the next steps in STI diagnostics, the role of STI guidelines in developing new diagnostics, and the social and structural determinants impacting STI epidemics with implications for diagnostics development. We conclude with considerations for moving the field forward given increasing STI rates and lack of routine diagnostic testing during the ongoing pandemic.[1] Given the focus on integrating the interests of clinical, public health, and industry stakeholders, the group organized conversations in a pathogen-specific manner because this approach will directly inform diagnostics development and implementation.

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CHANGING LANDSCAPE OF STI DIAGNOSTICS

POC Testing

Nucleic acid amplification tests (NAATs), with their high sensitivity and ease of sample collection and transport, have revolutionized STI diagnostics. However, high-throughput testing requires large, sophisticated instrumentation, which is limited to large hospital, commercial, academic reference, and public health laboratories. Currently, NAATs are underutilized because of limited laboratory infrastructure and cost. In addition, most NAATs involve a significant lag time (up to days) in reporting results, often necessitating syndromic STI management.

To more effectively address the global STI epidemic, testing for symptomatic patients should be performed at the POC while the patient waits,[2] ideally using molecular diagnostic technologies. Both the STI National Strategic Plan (2021–2025)[3] and the 2021 National Academies of Sciences, Engineering, and Medicine report[4] identify molecular POC tests as innovative tools and recommend their implementation to improve STI care. Point-of-care tests allow for immediate, accurate treatment, decreasing the risk of loss to follow-up and potentially reducing transmission rates and prevalence of STIs.[5–7]

Despite known benefits and regulatory approval, challenges exist with POC testing for STIs. Development of POC tests requires consideration of implementation into clinical practice. Barriers to POCs will need to be addressed, such as patient wait time,[8,9] cost of POC systems and test cartridges, staff training, quality management, reimbursement and insurance billing concerns, and data management, including reporting of notifiable diseases.[10,11] Changes to clinic flow and practice may be required to optimize efficiency and minimize time to results, while improving directed therapies and quality of patient care. Addressing these barriers through community-based participatory research and reporting implementation findings are critical next steps to widespread adoption of these new technologies and eventual transfer of POC assays to resource-constrained settings. Too often, a lack of attention to implementation leads to structural inequities. A major driver of the ASTDA Collaborative Workshop is the recognition that it is not sufficient for industry to develop diagnostic tools without understanding the needs of control programs.

Increased Use of Telemedicine

The COVID-19 pandemic resulted in a rapid roll-out of national and local health care policies, allowing for an expedited transition to telemedicine. This transition has proven advantageous by improving convenience for patients, decreasing cost in some settings, and expanding access to care.[12] However, there are concerns with the wide use of telemedicine, including limited access for patients without broadband Internet access or smart phones, privacy concerns, and lack of thorough patient physical examinations.[13,14]

Although the use of telemedicine is expanding, it can limit and/or delay options for STI testing and treatment. Patients attending clinics in person typically undergo STI testing (and sometimes receive results and/or treatment) within 1 clinic visit; however, with telemedicine visits, tests are often ordered and the patient either presents to a laboratory to provide a specimen or performs home self-collection and mails the specimens into the laboratory. The patient must wait for results and prescriptions for treatment—a process resulting in substantial delays in STI diagnosis and treatment. For patients diagnosed with gonorrhea or syphilis, this requires 3 separate appointments: initial telemedicine visit, laboratory collection, and in-person visit for treatment if intramuscular injections are required. Instead of the third visit, providers may choose to treat with suboptimal oral regimens.[15,16] Furthermore, concerns surrounding emergence of antimicrobial resistance (AMR) in some STIs raise additional issues and need for follow-up tests of cure (TOCs) to ensure successful treatment (e.g., pharyngeal gonorrhea). Although telemedicine has the potential to increase access to and reduce stigma associated with STI testing and care, the process of receiving such care must be streamlined to facilitate more rapid testing and treatment.

Direct-to-Consumer Testing

Self-directed health care is increasing with the availability of self-collection and test order kits available in retail outlets and online. This option is attractive to those experiencing symptoms and asymptomatic people who are concerned about a potential exposure or engaging in routine sexual health screening. There are benefits and challenges to this mode of service provision, previously described in the ASTDA position statement.[17] In brief, the issues are related to the quality and reliability of laboratory service providers, costs of testing, and linkage to care. Advantages include empowerment of people for maintaining sexual health, increased privacy, convenience, and reduced stigma.

Screening Outside of Clinical Settings

In addition to clinic-based POC STI testing, expansion of this technology beyond the clinical setting includes use by outreach and community-based testing and at-home testing using over-the-counter (OTC) products. Both of these schemes, community-based POC and individual-controlled OTC, are of great interest and could eliminate common barriers associated with STI testing, including stigma and privacy concerns. These tests, if possible, should be able to detect multiple STIs, including *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV). For example, one of the current Food and Drug Administration (FDA)–cleared POC assays can simultaneously test for CT, GC, and TV without instrumentation and provide results in less than 30 minutes.[18] This assay does not have a claim for OTC use, but is a great option for use in the field as a POC and may develop into an OTC option. Unmet needs remain regarding the development of rapid, sensitive, specific, affordable, and user-friendly OTC technologies and having claims for self-collection in nonclinical settings for the POC assays. Cost limits the utility of such tests, thus preventing implementation in low-income areas where STIs are most prevalent. However, multiple issues exist when implementing such testing, including result management to support linkage to care, treatment provision, reporting of notifiable diseases, and third-party payer coverage, as observed when implementing OTC COVID-19 tests. Therefore, until solutions to these barriers are addressed, OTC testing will not likely be widely adopted even if the technology exists to support self-testing.

WHAT DIAGNOSTIC SOLUTIONS ARE STILL NEEDED?

This workshop occurred before the publication of the 2021 Centers for Disease Control and Prevention (CDC) STI treatment guidelines[1]; however, group members discussed anticipated changes based on the update published for NG[19] and changes summarized in the December 2020 CDC webinar. Based on the expected content of the guidelines, workshop members discussed diagnostic solutions still needed in the field for specific pathogens including NG, *Mycoplasma genitalium* (MG), CT, syphilis, and bacterial vaginosis (BV).

Neisseria gonorrhoeae

Over the last 2 decades, NG culture and phenotypic antimicrobial susceptibility testing (AST) has significantly decreased

because of the reliance on NAATs for diagnosis of gonorrhea, which prevents the collection of viable organisms required for AST. To increase surveillance capacity in the era of NAATs, prediction of AMR based on detection of genetic mutation markers has been proposed and, in some settings, implemented as a suitable alternative to phenotypic AST.[20,21] However, one major challenge with molecular AMR prediction is that genotype does not always predict phenotype.[22] For example, the molecular mechanisms of AMR for cephalosporins are very complex, and detection of 1 or more genetic markers of AMR may lack sensitivity for prediction of reduced clinical susceptibility or resistance to cephalosporins.[22,23] Future work is necessary to identify genetic marker(s) that could more accurately predict and define AMR in NG, particularly to ceftriaxone, the current first-line treatment for NG.

Although molecular detection of AMR based on laboratory developed tests detecting genomic markers is pragmatic, it cannot be used to predict AMR to all antimicrobials. Recent work has suggested that RNA marker quantitation after a short exposure to a given antimicrobial could accurately predict antimicrobial susceptibility in gonorrhea.[24,25] However, these rapid susceptibility assays have only been evaluated with cultured NG strains and not clinical samples. Further work is necessary to evaluate the clinical utility of this approach, and if successful, phenotypic assays measuring RNA or other nucleic acid could be used as a surrogate to rapidly identify AMR in NG at the POC.

Given that pharyngeal NG infections are often asymptomatic and can be difficult to treat, TOC is recommended.[16] However, TOC NAAT cannot accurately differentiate between an active infection and residual DNA after successful treatment. Given that TOC for pharyngeal NG is likely to increase because of recommendations from the CDC treatment guidelines, viability assays that can differentiate between viable and nonviable NG are needed.

Mycoplasma genitalium

Mycoplasma genitalium has a remarkable propensity to rapidly develop resistance to available treatment options.[26,27] *Mycoplasma genitalium* resistance to azithromycin has steadily increased to >50% in many countries, thereby compromising its efficacy and complicating the clinical management of MG infection.[27] Resistance to moxifloxacin has also been increasing globally.[28] In the 2019 CDC Antibiotic Resistance Threats Report, antimicrobial-resistant MG (AMR-MG) was included because of concerns for its wide dissemination without an aggressive AMR mitigation approach.[29] Rapid detection and characterization of *AMR-MG* is crucial to curtailing the spread of AMR-MG infections. However, routine testing for AMR-MG is currently commercially unavailable in the United States, and there are no FDA-approved molecular assays for the detection and characterization of AMR-*M*G, although some providers are currently using laboratory developed tests and analyte-specific reagents from commercial vendors for this purpose. The STI field will benefit immensely from FDA-approved molecular assays for simultaneous detection of MG and macrolide resistance-mediating mutations (e.g., 23S rRNA A2058G, A2059G, A2059C, A2058T, A2058C). These assays should ideally be POC tests to inform resistance-guided treatment of MG infections that can identify effective treatment regimens for symptomatic patients.

Chlamydia trachomatis

Nucleic acid amplification tests are the preferred diagnostic method for CT detection in clinical specimens. However, NAATs are very sensitive and can amplify target DNA/RNA without discriminating between DNA/RNA originating from viable or nonviable organisms. Several studies have documented long duration of CT positivity by NAAT even after treatment with effective antibiotics.[30,31s] Commercial assays that confirm CT viability in clinical specimens could be useful. The implementation of such assays might help to prevent overestimation of true CT infection by currently used NAATs and, supported by epidemiological and clinical data, contribute to antimicrobial stewardship by preventing unnecessary antibiotics use for nonviable CT infections. These issues are relevant to NG as well. However, the clinical utility of such an approach must be well studied before the development of such an assay on a commercial basis.

Syphilis

Novel diagnostics for syphilis are critical for improved clinical evaluation and management because of the rise in syphilis, particularly for use in primary care settings that lack STI-specific expertise or available microscopy.[32s] Although dark-field microscopy is the preferred method for direct detection of *Treponema pallidum* when lesions are present, most clinical settings lack the capacity to perform this test. Thus, development of molecular diagnostics for lesion specimens that are more scalable to a variety of health settings would enhance detection of syphilis.

In addition to examination of lesions, the group discussed serological testing limitations for syphilis, including the difficulty in determining the clinical stage of syphilis using nontreponemal antibody titers, which are nonspecific and can persist despite effective treatment.[33s] Determining the clinical stage of syphilis has implications for treatment and dosing; thus, better syphilis serology tests are needed to assist with staging and determine appropriate response to therapy, but no candidate biomarkers have yet been identified.

BV and Vaginitis

The mainstay of clinical BV diagnosis remains the use of POC wet mount microscopy to determine Amsel's criteria.[34s] The immediate results and low cost associated with this diagnostic modality are appealing.[35s,36s] However, because of various factors, including low provider comfort and skill with microscopy, lack of access to microscopy supplies, lack of the required Clinical Laboratory Improvement Act-waiver to permit billing for this activity, and time pressure,[37s–40s] health care providers infrequently document the full Amsel's criteria or perform microscopy at all.[41s] Unfortunately, this may lead to misdiagnosis and incorrect treatment of patients with BV or other vaginal discharge syndromes or overtreatment of those without these conditions.[38s,42s] Furthermore, evidence suggests that clinical diagnosis of vaginitis is not highly accurate under ideal conditions,[43s] and since the onset of the COVID-19 pandemic, fewer women are receiving pelvic examinations, thus limiting the use of Amsel's criteria in BV diagnosis.

New diagnostic technologies for symptomatic BV,[44s] including molecular diagnostics[45s–47s] and POC enzymatic tests[48s–50s] are now commercially available. These tests offer an alternative to clinical diagnosis with improved accuracy. During the workshop, participants discussed the issue of reimbursement for these tests, because demand from clinicians has been countered by pushback from payers who are refusing to reimburse. One obstacle contributing to the reimbursement issue may be lack of a clear position from guidelines regarding use of these tests.[16] The current 2021 CDC STI Treatment Guidelines describe available FDA-cleared POC diagnostics for BV but provide no language about when these tests should be considered for use aside from the recommendation that they only be used in symptomatic patients.[16]

New BV diagnostics are expensive compared with wet mount microscopy, particularly in resource-limited settings. Cost-effectiveness studies evaluating reduction in return visits as well as improved

treatment accuracy (and thus antimicrobial stewardship) are needed to better understand the true cost impact of using new technologies. Bacterial vaginosis NAATs are not yet available as POC tests, so results are not available as quickly as using Amsel's criteria to establish a clinical diagnosis.[45s] The question becomes whether a poorly sensitive/specific test at the POC is better than a delayed but highly accurate test. Another challenge is that the evaluation of BV, a syndrome related to multiple pathogens and/or imbalance in vaginal flora, is much more complex than diagnosis of NG/CT/TV, owing in part to significant gaps in the scientific understanding of what constitutes BV (which may not be the same for each patient).[51s] Tests that rely on detection of a single organism (e.g., *Gardnerella vaginalis*) may have limited utility because *G. vaginalis* is common in BV but can also be detected in 36% to 55% of women without clinical signs of BV.[44s] Clinicians may be unaware of these nuances when selecting tests, and more guidance is needed to ensure that appropriate tests are developed and adopted. In contrast to NG/CT/TV, there is no recommendation to treat asymptomatic patients with BV,[16] and indeed, there could be danger of misdiagnosis or overdiagnosis of BV if these tests are ordered without sufficient clinical thought. Correct application of the tests will require education and/or clinical guidance for direct to consumer or self-testing.

Impact of STI Guidelines on Development of Diagnostic Methods

Many stakeholders are affected by guidelines, which can influence diagnostic manufacturer pipelines, insurance payer practices, and clinical laboratory offerings. It is critical to recognize that guidelines exert far-reaching influence on all aspects of STI management.

In the previous section, we described gaps in diagnostic tools that were described by workshop participants. The workshop members also discussed the interplay between clinical guidelines development and the lifecycle of diagnostic products. Sexually transmitted infection treatment guideline development by the CDC is an extensive and thorough process, involving collaboration among CDC staff and external subject matter experts performing systematic literature reviews to formulate evidence-based recommendations. Although the focus of these guidelines is on treatment recommendations targeting health care providers, there are many other stakeholders in the STI field looking to these guidelines for prevention and diagnostic testing recommendations, including professional societies, government agencies, and third-party payers. The CDC Guidelines discourage syndromic management and encourage pathogen-directed therapy when feasible. Ideally, STI therapy should be guided by diagnostic (laboratory or POC) testing for specific pathogens and AMR detection to help prevent treatment failures, deter AMR development, and avoid prescribing unnecessary or inappropriate antibiotics. Thus, STI diagnostics are a critical piece of the process to determine of appropriate treatment recommendations for symptomatic individuals; in addition, STI testing considerations are also important for screening recommendations.[16]

Effectively building a business case to bring new tests, to meet the needs described earlier, to market can be impacted by guideline recommendations for specific classes of tests, or by a lack of such recommendations. In addition, guideline recommendations directly inform reimbursement as payers will use guideline language to help determine coverage. Clinical laboratory test menus are influenced by both clinical guidelines and reimbursement, which ultimately determine what types of tests are available for clinicians to order. The level of detail and specific nature of the issues raised for STI detection methods suggests that recommendations for use of STI diagnostics should be updated more frequently (the last such recommendations were written in 2009 and published in 2014)[52s] to keep up with evolving technology in addition to new treatment guidelines. The workshop members, which included representatives for the CDC, felt that it was important to highlight the relevance of guidelines and their impact on changing the landscape of diagnostic options.

When a clear clinical need arises, for example, curbing AMR in NG, which is a public health priority, it is important to state the need for such diagnostics in guidelines to encourage manufacturers and regulators to prioritize their development. For diagnostic recommendations, emphasis is often placed on FDA-approved tests and not on laboratory developed tests. Although the intention may be to focus recommendations to those tests that are more widely available to all laboratories and vetted in a more standardized process (FDA submission), the result may be that a viable diagnostic option is underutilized or carries a high payer denial rate, so clinical needs may go unmet. Even in the absence of commercial tests, guidelines can promote the use of laboratory-developed tests, if appropriate, to address specific clinical needs, thus allowing clinicians earlier access to these critical methods before FDA clearance. This strategy was adopted and resulted in successfully advancing the STI diagnostics field: the 2015 CDC STD Treatment Guidelines promoted the use of NAATs for extragenital detection of GC and CT before their FDA clearance. That recommendation was a crucial factor in driving manufacturers to seek FDA clearance for extragenital NAATs. Furthermore, data generated using laboratory developed tests can provide the necessary clinical and epidemiological data that can justify commercial development of new tests.[20]

Guidelines are a step toward changing the payer landscape for diagnostic tests that could become much more widely available if laboratories are reimbursed for performing these tests. For example, studies have demonstrated a clear impact of MG AMR detection on treatment and patient outcomes.[53s] The newly released 2021 guidelines have made a step forward and suggest NAAT testing as an option for BV diagnosis, but only if conventional methods are not available. Such recommendations, although making BV NAAT testing permissible, do not encourage or support BV NAAT utilization or reimbursement from payers.

Development of clinical practice and diagnostic guidelines and recommendations are important for best practice, but they are not without challenges. One such challenge is striking the appropriate balance between conservative and innovative recommendations. Bacterial vaginosis provides an excellent case in point as the lack of a defined etiological agent for BV, the availability of a cheaper POC alternative like the Amsel's criteria, and the wait time for many of the molecular tests may have led the guidelines committee to decide against placing more emphasis on NAATs. Although BV NAATs are likely to be more sensitive than the Amsel's criteria, it is unclear if that translates to a therapeutic advantage. Further evidence-based discussions are needed to ensure that advances in BV diagnostics are not hindered.

Timeliness of guideline development is another challenge both to those who develop them and those who rely on them for pipeline planning. Guidelines serve the community best as living documents that can be more readily updated in response to changes in the field. Guidelines should reflect current epidemiological data and contemporary management strategies aimed at controlling STIs. The workshop participants suggested that the current practice in the United States of an entirely updated CDC document every 5 (or more) years is impractical and not conducive to optimal patient management. A living document, which is the practice in the EU, may be one possible solution, and the CDC is currently looking into this option.

SOCIAL AND STRUCTURAL FACTORS FUELING THE STI EPIDEMIC

The workshop did not limit discussions to diagnostic technologies, but also discussed the critical issues of structural racism and stigma, which fuel the STI epidemic. We explored several ways in which the resulting sexual health disparities might be addressed through innovation in STI diagnostics. First, understanding which communities bear the largest burden of STIs in the United States is critical. In 2019, more than half of reported STI cases were among adolescents and young adults aged 15 to 24 years.[1] That same year, 31% of all cases of chlamydia, gonorrhea, and primary and secondary syphilis were among non-Hispanic Black people, who account for approximately 13% of the US population.[29] Sexual and gender minorities, including MSM and transgender people, continue to be disproportionately impacted by STIs.[54s,55s] Explanations for high STI rates within these populations are myriad and multifactorial. These include limited access to care, deeply rooted systemic racism, mistrust of the medical establishment, and poverty dynamics in the United States.[56s,57s]

One barrier to STI testing for gender-diverse people is a lack of inclusive and affirming language. In most clinical scenarios, even in sexual health care, cisgender identity is assumed, resulting in potentially dysphoric experiences with providers and staff, especially when anatomically specific STI diagnostics are indicated.[58s–60s] This issue is evident at multiple points on the STI testing continuum, from gendered language in packaging, to binary terminology regarding gender and genitalia used by clinicians, to how anatomic site-specific test results are communicated to patients. Negative experiences at any of these touch points may lead gender-diverse people to forgo STI testing altogether, which contributes to the widening gaps in sexual health care affecting this vulnerable population.[61s] In addition to educating clinicians on using a patient-centered approach while collecting sexual history information, there is space for STI testing materials themselves to be more gender affirming. Currently, graphics and instructions for many of these diagnostics specify "male" or "female" anatomy, which does not represent all patients. Furthermore, many diagnostic assays are not technically cleared for use in transgender persons (e.g., a female vaginal swab indication for use excludes testing the vagina of transgender males). Anatomical designations for site-specific testing should be used, and even then, there should be a limited emphasis on gender when this information is not clinically relevant. To combat these barriers, gender-diverse people should be involved in conversations around product development. Community partnerships when crafting products and associated documents are paramount in making patients and providers feel comfortable when using them.

SUMMARY

Considerable advances have been made in the field of STI diagnostics. However, many challenges to the development and widespread deployment of these technologies remain. The development of new diagnostics technologies far outpaces the updated release of STI diagnostic guidelines, which means that technologies are often dated by the time guidelines are released, creating significant challenges in receiving payer reimbursement for new diagnostic options. Changes in the provision of STI care, such as a transition to telemedicine, testing in nonclinical settings, direct-to-consumer options, and, in the near future, access to OTC tests, require us to carefully consider logistics around STI service provision. The increased prevalence of AMR-NG and AMR-MG requires the development of FDA-approved tests. Lack of understanding around the etiology of certain sexually related infections, such as BV, impedes the development of more accurate diagnostic tests for these infections, and further research is needed in this area. In addition, widespread stigma related to STI testing and the presence of racism, sexism, homophobia, and other forms of discrimination against populations disproportionately burdened by STIs is a significant barrier to STI testing. In this report, we offered suggestions and recommendations that we hope will facilitate improvements to STI diagnostics, and the contexts in which they are delivered, to reduce the rising spread of STIs.

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For further references, please see "Supplemental References," http://links.lww.com/OLQ/A827.