



October 1, 2020

B. Kaye Hayes, MPA

Acting Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP)

Office of the Assistant Secretary for Health (OASH)

U.S. Department of Health and Human Services

200 Independence Avenue, S.W.

Room 715-G

Washington, D.C. 20201

Dear Ms. Hayes:

We are writing on behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) to offer comments on the inaugural Sexually Transmitted Infections (STI) National Strategic Plan. We applaud the development of a national plan for addressing the STI epidemic in the United States. With STI rates increasing at record levels for five consecutive years, a comprehensive national plan with strong federal leadership for responding to the STI epidemic is urgently needed. We appreciate the comprehensive scope of the Strategic Plan, its focus on being data-driven and a recognition of the role that social determinants of health play in fueling the STI epidemic. In addition, as infectious diseases and HIV specialists, we strongly support efforts to integrate and coordinate service delivery across infectious diseases programs, including STI, HIV and viral hepatitis programs.

We appreciate the Strategic Plan's vision for everyone in the U.S. to have access to high-quality STI prevention, care and treatment, specifying that this refers to "all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, disability, geographic location or socioeconomic circumstance." A commitment to ending stigma and discrimination is critical to reducing the impact of all infectious diseases, from COVID-19 to tuberculosis to HIV to STIs.

We offer recommendations below for strengthening the Strategic Plan and hope there will be opportunities to provide additional input as the process advances.

Federal Implementation Plan: The Strategic Plan outlines clear goals and objectives but details on the resources and programs necessary to achieve those goals are needed. Without these, the impact of the Strategic Plan on the ground will be limited. We urge the timely release of a federal implementation plan with clear timelines and metrics to advance the Strategic Plan's goals and objectives.

Investing in Public Health and STI Programs: The COVID-19 pandemic has painfully exposed the fragility of the public health system and the need for a robust investment to rebuild and sustain public health programs and the public health workforce. The proposed plan lacks details on the funding, workforce and other resources necessary to meet the plan's goal and objectives. It will take a collective effort at multiple levels including federal and local governments, policy makers, healthcare systems, researchers, community and professional groups and clinicians to successfully address the epidemic. A strong

investment by the federal government in public health, including in the Centers for Disease Control and Prevention's Division of STD Prevention, will be critical to the success of this and other plans under development or in revision by the U.S. Department of Health and Human Services.

Maintaining and Improving Health Care Access: The Affordable Care Act and the Medicaid program are important sources of coverage for STI prevention and care services and the role of these programs should be highlighted in the content of the Strategic Plan and its implementation.

Timely Surveillance Data: The federal investment also should include funding to strengthen and improve our national surveillance system for STIs to allow for more timely monitoring of STI cases across the country to inform and strengthen our national response. As part of this investment, resources and incentives for clinics and providers to upgrade to electronic reporting will be critical.

Investing in New and Affordable STI Treatment Options: We strongly support the Strategic Plan's recognition that the public health crisis of antimicrobial resistance has limited treatment options for STIs and strongly support the call for an investment in developing innovative diagnostic and treatment options. We also emphasize the need to invest in antimicrobial stewardship programs to ensure optimal use of antimicrobial drugs and preserve their effectiveness. In addition to supporting the development of new diagnostics and treatment options, it is critical that existing and new diagnostics and treatments are affordable to improve and increase their accessibility. As an example, the price of benzathine PCN G (BPG) continues to climb with one private practitioner without access to 340B discount pricing reporting a price of \$450 for a 2.4MU dose. This price poses a significant barrier for many private practices to stock BPG because of the limited shelf life, inventory costs and poor reimbursement. Innovation and affordability must go hand-in-hand when incentivizing drug development for conditions of public health significance. New payment models, such as subscription models, that delink payment for antimicrobial drugs from their use can help ensure innovators receive a predictable return on investment while also supporting access and appropriate use.

Prevent Shortages of Tests and Testing Supplies: In addition to developing new diagnostics, we urge use of the Strategic Plan as a mechanism to strengthen the supply chain in order to ensure continuous access to tests and testing materials during public health emergencies. COVID-19 has resulted in limited access to testing for STIs, HIV and other infectious diseases.

Home-based Specimen Collection and Lab Testing: In-home point-of-care STI testing and in-home collection of lab-based STI tests are innovative ways to reach populations not being reached with current brick and mortar services. These approaches have also provided an important way to continue to deliver essential care and preventive services during COVID-19-related disruptions to in-person care. These testing modalities face multiple challenges from a cost and regulatory standpoint and are not uniformly accessible. These issues must be addressed by improving coverage requirements and providing federal support for home-based testing options for individuals who are uninsured and low income.

Add Transgender Individuals as a Priority Population: There is extensive evidence to support that trans persons are disproportionately affected by STIs and HIV. Leaving this group out when there is strong evidence to support designation as a priority population will further widen the disparities experienced by trans persons while also contributing to the discrimination and stigma that already serves as a major barrier to trans persons accessing health care services.

Integrated Service Delivery: An important component of the Strategic Plan is integrating STI prevention and care into existing HIV programs. HIV prevention programs are quite well-established with networks extending throughout communities. Many HIV patient navigators are well-positioned to expand their client base and assist with linkage to care and preventive STI services.

Expand the Vaccine for Children's (VFC) Program: The VCF program should be expanded to cover all vaccinations for human papillomavirus (HPV) and hepatitis A and B to support increased access and uptake of these important preventive measures.

Other specific recommendations for the text:

- On pages 21 and 23 for the "Box 3 Chlamydia Snapshot" and the "Box 4 Gonorrhea Snapshot" - the "Consequences when left untreated" sections focus only on female complications. This leads one to believe that consequences related to lack of treatment only occur in women or those with female reproductive organs, which is not the case.
- On page 25 and onward in the discussion of syphilis, it is not clear why only primary and secondary syphilis were discussed excluding early latent syphilis. In this discussion of the prevention and elimination of syphilis in the US, all stages that are contagious should be considered. Notably, early syphilis as in the table is usually used to refer to not just primary and secondary syphilis, but also early latent infection.
- On page 26, the discussion on tertiary syphilis and the manifestations of syphilis in various stages is misleading. Ocular and neurosyphilis can occur with secondary syphilis. It is important to recognize this given the clusters/emergence of ocular syphilis and its complications due to lack of recognition and delayed treatment in this country.
- On page 33, paragraph 3 under "Goal 1" - Adolescents who report not being sexually active should still receive counseling on safer sex practices to inform safer sex practices at sexual debut. Additionally, adolescents may not be forthcoming regarding their sexual activity as evidenced by a high prevalence of chlamydia in young women despite their report of no prior sexual activity.

We greatly appreciate the opportunity to comment on the inaugural National STI Strategic Plan and want to again acknowledge the importance of this effort. We look forward to partnering with you on its implementation as it advances. For questions, please contact us through Amanda Jezek, IDSA's Senior Vice President, Public Policy & Government Relations at ajezek@idsociety.org or Andrea Weddle, HIVMA's Executive Director aweddle@hivma.org.

Sincerely,



Thomas M. File, Jr., MD, MSc
President, IDSA



Judith Feinberg, MD
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