

March 29, 2021

SUBMITTED ELECTRONICALLY

USPSTF Coordinator
c/o USPSTF
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

Re: Draft Recommendations on Screening for Chlamydia and Gonorrhea

Dear Sir or Madam:

Whitman-Walker Health (WWH) and the Whitman-Walker Institute (collective known hereinafter as Whitman-Walker) are pleased to submit these comments on the U.S. Preventive Services Task Force (USPSTF) draft recommendations on screening for chlamydia and gonorrhea. The Affordable Care Act embeds the USPSTF recommendations into insurance coverage policies and therefore shapes access to health care for millions of people in the United States. The outcomes of this research have a large impact on our communities and is of utmost concern as a matter of science and public health.

Interest and Expertise of Whitman-Walker: Whitman-Walker Health is a Federally Qualified Health Center serving greater Washington, DC's diverse urban community, including individuals who face barriers to accessing care, and with a special expertise in HIV care and serving lesbian, gay, bisexual, transgender and questioning/queer (LGBTQ) populations. In our mission we empower all persons to live healthy, love openly, and achieve equality and inclusion. In 2019, our health center's more than 300 highly educated and experienced staff provided high quality, affirming health care across five sites to more than 21,000 individuals.

WWH services include primary medical care, HIV and LGBTQ specialty care, oral health, mental health care, addictions treatment services, psychosocial support, medical nutrition therapy, early intervention services, public benefits and insurance navigation, nurse-focused case management, HIV and STI screening, legal services, youth programs, and an onsite pharmacy. The health center has achieved Level 3 Patient Centered Medical Home accreditation with the National Committee for Quality Assurance.

In 2019, Whitman-Walker Health served 25% of the District of Columbia's reported HIV-positive population, many of them low-income or members of otherwise underserved communities. Our patient populations include African Americans; Hispanic individuals; gay and bisexual men; substance users; low-income and homeless individuals; and transgender persons. We have extensive experience in testing and treating STIs. In 2019, our HIV testing program

diagnosed 36% of the new cases of HIV reported in the District. We also diagnosed approximately 10% of the new HCV cases in DC; 52% of the new cases of primary and secondary syphilis; 18% of the new cases of gonorrhea; and 10% of the new cases of chlamydia.

Whitman-Walker has a robust portfolio of high-quality, holistic services to the transgender and gender-nonbinary community in the Washington, DC metropolitan area, and serves a number of such individuals living at greater distances – in Maryland and Virginia, and some residents of Pennsylvania, West Virginia and Delaware. In calendar year 2019 we provided health care to more than 2,100 unique transgender and gender-nonbinary persons.

Whitman-Walker Institute conducts research, advocates for just and inclusive policies, and engages in clinical and community education to advance the health and wellness of our community. Institute researchers, educators and policy advocates work closely with WWH providers to enhance the impact of their work and to ensure that direct health care, research, education and public policy mutually reinforce each other. The Institute also has a large and growing Research Department, which is participating in several studies that include or focus on transgender individuals. We currently have more than 2,500 participants in 40+ active studies. Recent research projects include collaborations with several other large LGBTQ-focused health centers to identify and address the health needs of transgender and gender-nonbinary persons.

Question 1: Based on the evidence presented in this draft Recommendation Statement, do you believe that the USPSTF came to the right conclusions?

Somewhat, I believe that the USPSTF came to the right conclusion in some ways but not in others.

Question 2: Please provide additional evidence or viewpoints that you think should have been considered

We are concerned that, while the recommendations acknowledge the role of chlamydia and gonorrhea as a driver of HIV infection¹, this does not appear to be a consideration that is applied to the recommendation for men and other genders. The data seem most concerned with the risks to infant health and around pregnancy/fertility, but not on the morbidity of individuals infected. The recommendations do not appear to consider sexual orientation and HIV risk. The recommendations are not inclusive of a diversity of gender identities. In Whitman-Walker's practice, we see a high rate of gonorrhea infections in MSM which is a driver of HIV infection, therefore asymptotic screening is important among our MSM patients to reduce HIV infection.

¹ See *Draft Recommendation Statement: Screening for Chlamydia and Gonorrhea*, March 2, 2021. Footnotes 12 & 13 “12. Fleming DT, Wasserheit JN. *From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection*. *SEX TRANSM INFECT*. 1999;75(1):3-17. 13. Kalichman SC, Pellowski J, Turner C. *Prevalence of sexually transmitted co-infections in people living with HIV/AIDS: systematic review with implications for using HIV treatments for prevention*. *SEX TRANSM INFECT*. 2011;87(3):183-190.”

The lack of recommendations for high-risk populations appears bizarre to us in the context of the CDC's recommendations and HHS's commitment to ending the spread of HIV.²

This outcome does not seem to be based in the latest diagnostic science, which are sufficient to inform the CDC's recommendations for MSM, but rather in the constraints of the methods used to determine the studies used in this evaluation.

From the resulting systematic exclusion of men and other sexual and gender diverse (SDG) populations, it appears that the inclusion criteria were too narrowly calibrated. The methods excluded research on many studies which may have relevant information, including SDG populations. This seems to arise because the research protocol excludes studies with:

Patients with symptoms of chlamydial or gonococcal infections; patients with current or recent diagnosis of any acute sexually transmitted infection; patients undergoing management for HIV infection; children (age < 13 years); studies in which the majority of participants is comprised of persons infected with HIV or persons not infected with HIV and currently using pre-exposure prophylaxis.³

These narrow inclusion criteria appear to have resulted in the exclusion of too many studies and the USPSTF's failure to answer their key question number 2 for key populations:

What is the accuracy of risk stratification methods or alternative screening strategies for identifying persons at increased risk of chlamydial and gonococcal infections (such as younger persons or men who have sex with men)? Screening strategies include testing for concurrent infections, including HIV, or using different screening intervals.⁴

As the exclusion criteria and the research question stand in apparent contradiction, it appears that the criteria, or their application, limited the inclusion of relevant information on large swaths of the study population, and reducing the USPSTF's ability to consider relevant evidence.

The apparent contradiction resulted in excluding research conducted primarily on gender minorities and men who have sex with men, leading to the conclusion that the evidence was insufficient to make recommendations for those priority populations. We believe that enough

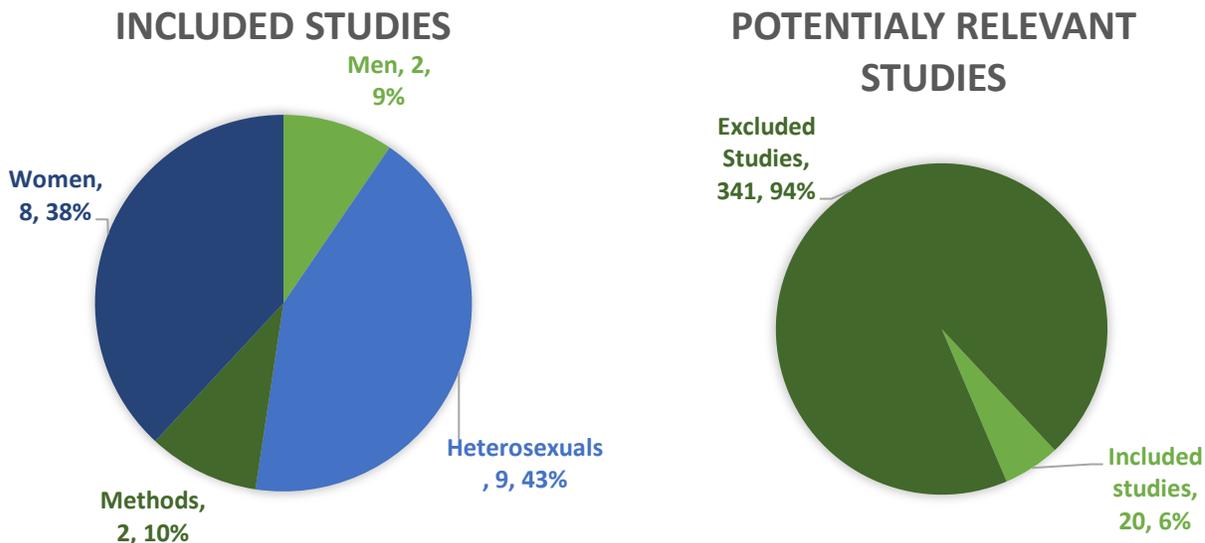
² See, *Gonococcal Infections*, Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Dec. 18, 2020, Accessed via <https://www.cdc.gov/std/tg2015/gonorrhea.htm>; and *Chlamydial Infections*, Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, June 4, 2015, Accessed via <https://www.cdc.gov/std/tg2015/chlamydia.htm>; See also, *Ending the HIV Epidemic : About Ending the HIV Epidemic: Plan for America : Overview*, Office of Infectious Disease and HIV/AIDS Policy, HHS, March 23, 2021, Accessed via <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

³ *Id.*, at pg. 62

⁴ *Id.* at 13

information about chlamydia and gonorrhea testing in MSM and SDG populations is available to produce a recommendation.

A quick overview of the twenty studies⁵ that satisfied the research criteria demonstrate an imbalance in the gender inclusion.



Unfortunately, due to time constraints we are unable to conduct a thorough review of the studies excluded in the USPSTF’s research. However, the 341 potentially relevant studies that were excluded are likely potentially fruitful sources of information on the efficacy and safety of chlamydia and gonorrhea screening in MSM and non-binary people.

We recommend that the USPSTF account for the low rates of rectal screening and higher prevalence rates of rectal *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomati* (CT) among priority populations in their final decision. More research is available here:

- Grov, C., Cain, D., Rendina, H. J., Ventuneac, A., & Parsons, J. T. (2016). Characteristics Associated With Urethral and Rectal Gonorrhea and Chlamydia Diagnoses in a US National Sample of Gay and Bisexual Men: Results From the One Thousand Strong Panel. *Sexually transmitted diseases*, 43(3), 165–171. <https://doi.org/10.1097/OLQ.0000000000000410>
- Mustanski, B., Feinstein, B. A., Madkins, K., Sullivan, P., & Swann, G. (2017). Prevalence and Risk Factors for Rectal and Urethral Sexually Transmitted Infections From Self-Collected Samples Among Young Men Who Have Sex With Men

⁵ See *Draft Evidence Review: Screening for Chlamydia and Gonorrhea*, Appendix A4, pgs. 65,66. March 2, 2021. Accessible at: <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-evidence-review21436/chlamydial-and-gonococcal-infections-screening>

Participating in the Keep It Up! 2.0 Randomized Controlled Trial. Sexually transmitted diseases, 44(8), 483–488. <https://doi.org/10.1097/OLQ.0000000000000636>

We recommend that the USPSTF recommendations account for the research on patient-collected samples vs. clinician-collected samples. The recommendations do not consider the question of the anatomical sites of screening, while there is a long history of research among the populations of interest, namely MSM and transgender and gender non-conforming people. More research is available here:

- Sexton, M. E., Baker, J. J., Nakagawa, K., Li, Y., Perkins, R., Slack, R. S., Baker, D. C., Jucha, B., Arora, S., & Plankey, M. W. (2013). How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men?. *The Journal of family practice*, 62(2), 70–78.
- Baker, J., Plankey, M., Josayma, Y., Elion, R., Chiliade, P., Shahkolahi, A., Menna, M., Minter, K., Slack, R., Yang, Y., Masterman, B., & Margolick, J. B. (2009). The prevalence of rectal, urethral, and pharyngeal *Neisseria gonorrhoeae* and *Chlamydia trachomatis* among asymptomatic men who have sex with men in a prospective cohort in Washington, D.C. *AIDS patient care and STDs*, 23(8), 585–588. <https://doi.org/10.1089/apc.2008.0277>

Question 3: How could the USPSTF make this draft Recommendation Statement clearer?

We recommend the USPSTF review more studies to contribute to the evidence to potentially support a recommendation to conclude “with moderate certainty that screening for chlamydia in all sexually active men who have sex with men age 24 years and younger and in sexually active men who have sex with men age 25 years and older who are at increased risk for infection has moderate net benefit.”

We recommend the USPSTF review more studies to contribute to the evidence to potentially support a recommendation to conclude “with moderate certainty that screening for gonorrhea in all sexually active men who have sex with men age 24 years and younger and in sexually active men who have sex with men age 25 years and older who are at increased risk for infection has moderate net benefit.”

Question 4: What information, if any, did you expect to find in this draft Recommendation Statement that was not included?

We expected to find information on the efficacy and benefits of CT and NG screening in populations of sexually active men.

We expected to find information on the efficacy and benefits of CT and NG screening in populations of sexually active men who have sex with men.

We expected to find information on the efficacy and benefits of CT and NG screening for non-binary people.

We expected to find information on the accuracy of self-collected samples compared to clinician-collected samples for men, women, and non-binary people.

Question 5: What resources or tools could the USPSTF provide that would make this Recommendation Statement more useful to you in its final form?

A recommendation that included or acknowledged the role of self-collecting samples to emphasize how important it is to include extragenital testing using throat and rectal swabs in these recommendations would expand our organization's capacity to test and screen for chlamydia and gonorrhea.

Question 7: Do you have other comments on this draft Recommendation Statement?

Our medical providers and researchers found it surprising that this recommendation failed to include data on priority populations for ending the HIV epidemic. These communities of racial, sexual, and gender minorities historically have been neglected by the medical system, and should be highlighted rather than further neglected in the Task Force's recommendations.

The Prevention Committee of the AIDS United Public Policy Council, co-chaired by Cory Howard, COO of Cempa Community Care, and Amna Osman, CEO of Nashville CARES, express their support for, and join Whitman-Walker's comments on the USPSTF draft recommendation on screenings for chlamydia and gonorrhea.

Respectfully submitted,



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