

January 17, 2023

Carol M. Mangione, MD MSPH  
Chair  
United States Preventive Services Taskforce  
USPSTF Program Office  
5600 Fishers Lane,  
Mail Stop 06E53A,  
Rockville, MD 20857

SUBMITTED ELECTRONICALLY

Dear Dr. Carol M. Mangione, MD MSPH:

Whitman-Walker Health and Whitman-Walker Institute (Whitman-Walker or WW) are pleased to submit these comments in response to the United States Preventive Services Taskforce Grade A Recommendation for pre-exposure prophylaxis (PrEP) for HIV. Whitman-Walker supports the Task Force's recommendation and suggests additional information be included in the recommendation to facilitate the robust and efficient implementation of long-acting injectable and oral PrEP modalities in communities of people at elevated risk for acquiring HIV.

### **Interest and Expertise of Whitman-Walker:**

**Whitman-Walker Health** is a Federally Qualified Health Center (FQHC) 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.

Whitman-Walker has been a nationally recognized leader in LGBTQ+ community health for almost four decades. In calendar year 2021, we provided health care to over 16,000 patients. In 2021, about 50% of our patients identified as Lesbian, Gay, or Bisexual and 14% as Transgender.

Whitman-Walker Health received the National Committee for Quality Assurance's (NQCA) Patient-Centered Medical Home (PCMH) Recognition. This recognition shows Whitman-Walker uses evidence-based and patient-centered processes to serve patients. These practices focus on highly coordinated care and long-term relationships. Whitman-Walker's medical teams are recognized at the highest level of this recognition at all our care center sites.

**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 communities of LGBTQ people and people living with HIV. Institute researchers, educators and policy advocates work closely with the over 200 Whitman-Walker Health providers to enhance the impact

of their healthcare delivery and to ensure that direct health care, research, education, and public policy mutually reinforce each other. The Institute's large and growing Research Department currently has 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 marginalized communities.

### **Comments on the Draft Recommendation Statement**

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

Yes; I believe the USPSTF came to the right conclusions.

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

In our experience, in the practice of FQHC's more generally, and CDC guidelines specifically, PrEP for HIV is a prevention modality that includes other costs aside from those affiliated with medication. These costs include office visits for initiation and monitoring; laboratory tests; affiliated health team support visits, including social workers, peer navigators, pharmacists, and others; and visits in-between routine monitoring and labs for sexually transmitted infections (STI) risk reduction counseling and motivational interviewing.

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

It needs to be clear in the recommendation that routine follow-up visits for monitoring injection site reactions; visits in-between routine monitoring; health team support visits, including those from peer navigators, community health worker, pharmacists; and check-in visits are covered without cost sharing. These should be covered via in-person or telehealth care encounters. It may take multiple visits before the patient is ready to initiate PrEP. However, these costs are a routine part of the practice of preventive medicine and should be covered by the recommendation.

It is essential for the efficient administration of our health care system and PrEP implementation that the recommendations clearly cover associated costs. The lack of clarity in the previous recommendations was a source of uncertainty that delayed PrEP implementation for many patients while providers, insurance carriers, and government regulators negotiated a shared understanding that supported services are covered by USPSTF's recommendation.

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

We expect to find recommendations for helping identify patients at increased risk of HIV acquisition, which should align with the USPSTF recommendations for HIV screening itself.

We expected to find clarity that the additional services that are part of this medication's prevention modality are covered by the recommendation, including; visits for initiation and monitoring;

expenses for labs and follow-up visits; in-between office visits to address issues with reactions at the injection site or other side effects; and support from an individual other than the provider, such as peer navigators, pharmacists, and community health workers. These guidelines clearly cover the medication, and it would be helpful for implementation of the USPSTF recommendations if the guidelines clearly identified that the surrounding supports were included in the recommendation.

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

Clinicians who do not routinely screen for HIV or prescribe PrEP will need support in identifying patients who are at increased risk of HIV acquisition. Evidence-based tools are needed to identify people at increased risk of HIV infection. Many providers need to be educated on their role in screening for HIV risk and ending the HIV epidemic. Visual, graphic-based tools would be helpful for widely and quickly disseminating this information to a wide audience.

Additionally, the following would be helpful:

1. Easy to read dissemination graphic of USPSTF guidelines. The document must be user-friendly for all the stakeholders of PrEP,
2. Billing sheet related to the recommendations with billing codes,
3. Guidance for documentation of provider notes in the health records so that the insurance coverage is effectuated, and providers can avoid sending a patient a bill they are not expecting for a preventive service, and
4. Suggested templates and language for advocating for PrEP coverage when the healthcare system has denied insurance coverage of the service.

**Question 6: The USPSTF is committed to understanding the needs and perspectives of the public it serves. Please share any experiences that you think could further inform the USPSTF on this draft Recommendation Statement.**

It is our experience, in our 40-year history of responding to the HIV epidemic, that everyone should be screened for HIV acquisition risk and that a patient that requests PrEP should be believed that they have identified themselves as a good candidate for PrEP. Clinicians who don't routinely screen for HIV or prescribe PrEP will need support in identifying patients who are at increased risk of HIV acquisition. Evidence based tools are needed to identify people at increased risk of HIV infection. Many providers need to be educated on their role in screening for HIV risk and ending the HIV epidemic. Visual, graphic-based tools would be helpful for widely and quickly disseminating this information to a wide audience.

There are several Technical Capacity Building fora and learning centers with providers that will benefit targeted outreach. Centers funded by the CDC's 19-1904 grants, NASTAD, and NACHO, for example, are natural partners for disseminating and implementing the updated recommendations. These fora are usually part of the education of HIV care providers, and therefore the natural audience for the guidance materials, such as

1. Easy to read dissemination graphic of USPSTF guidelines. The document must be user-friendly for all the stakeholders of PrEP,

2. Billing sheet related to the recommendations with billing codes,
3. Guidance for documentation of provider notes in the health records so that the insurance coverage is effectuated, and providers can avoid billing a patient for a preventive service, and
4. Suggested templates and language for advocating for PrEP coverage when the healthcare system has denied insurance coverage of the service.

The USPSTF should integrate their resources into existing frameworks of education of the providers and the administration of our health care system, so that the guidelines can be disseminated in a way that the audience can digest and then implement them. This should be an iterative process and the USPSTF should work with these partners to get feedback from them on the tools that are needed for more efficient dissemination to accelerate the implementation of PrEP.

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

To reiterate, it is essential for the efficient administration of our health care system and PrEP implementation that the recommendations clearly cover associated costs. The lack of clarity in the previous recommendations where a source of uncertainty that delayed the implementation of PrEP for many patients while providers, insurance carriers, and government regulators negotiated a shared understanding that supported services are covered by the recommendation.

**CONCLUSION**

Whitman-Walker appreciates this opportunity to provide comment on the research plan. Please feel free to contact us if we can be of assistance in any other way.

Respectfully submitted,



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