



January 17, 2023

Dr. Carol M. Mangione, M.D., M.S.P.H.  
U.S. Preventive Services Task Force  
5600 Fishers Lane  
Rockville, MD 20857

***Re: Draft Recommendation Statement and Draft Evidence Review: Pre-Exposure Prophylaxis for the Prevention of HIV Infection***

Dear Dr. Mangione,

AVAC is pleased to respond to the United States Preventive Services Task Force's (USPSTF) Draft Recommendation Statement and Draft Evidence Review: *Pre-Exposure Prophylaxis for the Prevention of HIV Infection*. Founded in 1995, AVAC is a non-profit organization that uses advocacy, communications, policy analysis, and a network of global collaborations to accelerate the ethical development and global delivery of emerging HIV prevention options as part of a comprehensive and integrated pathway to health equity.

AVAC commends the USPSTF for its unequivocal "A" grade and recommendation that clinicians prescribe pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV infection.

Nearly 400,000 new HIV transmissions have occurred in the United States since PrEP was first approved by the Food and Drug Administration (FDA) on July 16, 2012. Over those ten years, Black, Latino/a/x, and queer communities have continued to bear a disproportionate brunt of this devastating epidemic. Of the 1.2 million individuals estimated by the Centers for Disease Control and Prevention (CDC) to be most in need of PrEP, ***only 9 percent of Black individuals and 16 percent of Latino/a/x people had accessed it by 2020 compared to 66 percent of White individuals.***

The Biden Administration included a proposal to fund a groundbreaking National PrEP Program in the Fiscal Year (FY) 23 budget request and Congress called for the Centers for Disease Control and Prevention (CDC) to expand equitable national PrEP access in order to end the HIV epidemic in the final FY23 spending bill. The "A" grade from the USPSTF for PrEP is a crucial policy measure, combined with political will and fiscal commitment from the federal government, that could also provide a model for other countries as to what it takes to comprehensively expand access to cutting-edge HIV prevention for communities that need it most.

Accelerating ethical development of and global access to HIV prevention options as part of a comprehensive and integrated pathway to global health equity

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This “A” grade is critical to expanding access to communities and scaling up community-centered programs that deliver these products to those that need them most. Additionally, we fully support the inclusion of FDA-approved injectable cabotegravir (CAB) as part of the “A” grade after a review of the evidence. In June 2022, AVAC published [Translating Scientific Advance into Public Health Impact: A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP](#) to provide a comprehensive plan on ways to introduce injectable cabotegravir for PrEP that is more strategic and coordinated with a goal of accelerating impact. USPSTF’s inclusion of injectable CAB for PrEP sends a clear message to governments, health providers and people at risk of HIV that this injectable option is highly effective and should be integrated as part of the growing range of safe and effective HIV prevention options.

Ensuring populations most at-risk for HIV are afforded access to PrEP is essential to ending the epidemic in the US and abroad. Injectable CAB for PrEP studies ([HPTN 083 and 084](#)) have demonstrated safety and efficacy in men who have sex with men, transgender women and cisgender women globally; meanwhile additional research and safety surveillance is being conducted in other key populations such as pregnant and lactating people. [New guidelines](#) from WHO on CAB for PrEP call for countries, including the US, to consider this safe and highly effective prevention option for those at substantial risk of HIV infection, noting that “it is important that women of reproductive potential do not face barriers to uptake of effective HIV prevention options such as CAB-LA”. We encourage PrEP programs in the US to prioritize reaching populations ‘placed’ most at risk with all FDA-approved PrEP modalities.

We suggest the following modifications to the PrEP Recommendation Statement:

- The USPSTF recommends that clinicians offer **FDA-approved** pre-exposure prophylaxis (PrEP) **using** effective antiretrovirals **based on current CDC HIV prevention guidelines along with any necessary programmatic services** to persons who are at high risk of HIV acquisition.

Making the changes above would ensure that:

- 1) Antiretroviral drugs are understood to be the primary PrEP intervention, rather than in addition to PrEP, which some readers have found confusing in the current recommendation.
- 2) Clinical services (counseling and screening) required to prescribe the antiretroviral drugs are clearly understood to be part of the overall recommendation for PrEP.
- 3) The PrEP recommendation remains up to date with CDC clinical practice guidelines.

In summary, we laud the USPSTF for this A grade for PrEP and urge the federal government to continue to build upon this critical momentum generated by this

landmark decision. This includes funding and setting up a National PrEP Program in the US, working with bilateral global health programs such as PEPFAR to increase access to PrEP globally, and robustly funding HIV prevention R&D and the timely reviewing of additional HIV prevention options as they make their way through the pipeline.

Should you have any questions in regards to our comment, please direct inquiries to John Meade, Senior Program Manager: Policy at [john@avac.org](mailto:john@avac.org). Thank you for the opportunity to submit this comment and we look forward to engaging with the USPSTF on this critical issue.

Sincerely,

A handwritten signature in black ink that reads "Mitchell Warren". The signature is written in a cursive style with a long, sweeping underline.

Mitchell Warren  
Executive Director