

December 26, 2018

On behalf of the HIV Medicine Association and Ryan White Medical Providers Coalition, we are pleased to provide public comments on the U.S. Preventive Services Task Force’s recent draft “A” Recommendation for the use of PrEP for HIV prevention. Our organizations represent thousands of healthcare providers and researchers nationwide caring for patients living with HIV and those seeking HIV prevention services, like PrEP.

At this critical time in our national HIV response, where biomedical HIV prevention includes promoting the scientific evidence that a person with HIV’s undetectable viral load prevents them from transmitting the virus and that PrEP works to prevent HIV acquisition if taken as prescribed, every tool must be recognized and made available, especially to those at higher risk for acquiring HIV.

Only 7% of the over 1.1 million people in the U.S. that CDC estimates are candidates for PrEP have been prescribed PrEP.¹ As front-line providers of HIV care, we see the many structural, socioeconomic, and policy barriers that prevent our patients and populations at higher risk for HIV from accessing the care and services they need to stay healthy with HIV or remain HIV-free. We want to highly commend the USPSTF’s thorough review of the current scientific evidence supporting PrEP and note that this Recommendation is an historic milestone in our efforts to expand access to PrEP, educate providers and patients regarding its safety and efficacy and thus, reduce new HIV infections in the U.S. If implemented properly, this Recommendation can have a much-needed and critical impact on expanding access to PrEP nationwide.

As the landscape of biomedical HIV prevention continues to evolve, more effective, more durable and accessible options for PrEP, including new antiretrovirals and delivery modalities, will likely be brought to market.² As a result, changes to clinical guidelines and recommended treatment regimens will occur with some frequency over time. These changes necessitate continuing education for all healthcare providers. For this reason mitigating confusion about the latest recommendations should also be an ongoing priority. Given the strong evidence that the USPSTF considered for this Grade “A” Recommendation and to ensure that the most effective clinical practice is followed as new drug regimens and technologies are approved, we urge that the final Recommendation maintain its scientific relevancy by explicitly recommending that clinicians always refer to the most recent U.S. Public Health Service Guideline for PrEP.

Please see our specific suggestions in response to the questions asked for public comment below:

- 1. Based on the evidence presented in this draft Recommendation Statement, do you believe that the USPSTF came to the right conclusions?** *(Multiple Choice - Yes, Somewhat, No, Unsure, Other)*
Yes
- 2. Please provide additional evidence or viewpoints that you think should have been considered.**
Nothing more to offer. The USPSTF conducted a comprehensive evaluation of this prevention intervention.

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

We strongly urge the USPSTF to clarify that while antiretroviral drugs are the primary “active agents” of a PrEP intervention in the Recommendation Statement, equally important are the associated clinical services (laboratory testing, insurance navigation, adherence support) that are an integral component of a successful PrEP intervention. In addition, the term “therapy” generally refers to treatment so we suggest replacing it with “medications” to avoid confusion.

We recommend revising the Recommendation as follows:

“The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) using effective antiretroviral medications to persons who are at high risk of HIV acquisition and also provide associated clinical services as recommended by the U.S. Public Health Service including regular laboratory screening for HIV, sexually transmitted infections and monitoring of renal functional in addition to adherence counseling.”

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

Specific, evidence-derived data regarding the populations known to be at high risk for HIV acquisition should be included in the “Assessment of Risk” section to strengthen the focus of this Recommendation.

Youth: According to the CDC, youth aged 13 to 24 accounted for 21% of all new HIV diagnoses in the U.S. in 2016. A majority of the new diagnoses occurred among gay and bisexual men and disproportionately among Black and Latino gay and bisexual men.³ The FDA approved PrEP for adolescents in 2018, and it is imperative to educate providers regarding the potential benefit of PrEP for adolescents at higher risk of acquiring HIV, including minors.⁴ Maximizing the use of PrEP among young people at risk is paramount to reduce new infections among our most vulnerable patients as well as reaching those who are underserved by the current paradigm of HIV prevention and treatment.

Transgender people: We recommend revising the paragraph in this section to make a stronger statement about the increased risk of HIV among transgender individuals, especially transgender women of color. CDC estimates that around a quarter (22%-28%) of transgender women in the U.S. are living with HIV and more than half (an estimated 56%) of Black transgender women are living with HIV.⁵ These estimated rates are significantly higher than the rates found among other high risk populations and warrant special recognition in describing the assessment of risk for PrEP.

Patients requesting PrEP: In addition to offering PrEP to populations with documented higher risk for HIV acquisition, we recommend noting that patients who request PrEP at provider visits should be considered as at-risk and prescribed PrEP following medical evaluation. As noted by the USPSTF in “Identification of Risk Status,” specific risk assessment tools have “inadequate evidence” to support them, making risk assessment difficult for many providers and clinics. In addition, chlamydia and gonorrhea screening is not recommended by the USPSTF for men who have sex with men so in some cases, current clinical practice may interfere with early identification of individuals at high risk. In the absence of an effective and efficient tool for assessing risk, we recommend that the final Recommendation specifically state that patients who request PrEP should be assumed to be at higher risk and should be prescribed PrEP if there are no medical contraindications. In addition, individuals receiving care in, living in or who have previously lived in a high prevalence setting should be considered for PrEP in the absence of an effective screening tool. In other words, assessment for HIV risk also should take into account the populations and communities disproportionately impacted by HIV

Serodiscordant couples: The scientific community and federal agencies stand behind the science that individuals with a durably undetectable viral load will not transmit HIV to their sexual partners. This paragraph should be edited to remove the “quite low” language and replaced with a statement that those with durably suppressed viral loads do not transmit HIV to their sexual partners.⁶

Research Needs and Gaps: We recommend noting other research needs and gaps in the final Recommendation. The extent to which integrating STI post-exposure prophylaxis and other STI prevention interventions with PrEP services could have an effect on PrEP use and should be carefully evaluated. Similarly, the integration of PrEP into reproductive health and family planning services could prove impactful if scientifically evaluated. The impact that “on-demand” dosing of PrEP could have on its effectiveness should also be better assessed in all at-risk populations with the noted exception of cis-gender, heterosexual women. An ongoing demonstration study being conducted in France (Prevenir) presented preliminary data at the International AIDS Conference in July 2018 showing that no new HIV infections occurred when participants (gay and bisexual men) chose to only take PrEP immediately before and after having sex.⁷ Because on-demand or “event-based” dosing strategies would not require the level of long-term adherence of the current indication for PrEP, additional U.S.-based studies could show similar effectiveness while mitigating some challenges with daily adherence.

Implementation: We strongly suggest clarifying the wording of the Recommendation to highlight the requirement of additional clinical services to continue PrEP prescription. Within the Implementation Section, the clinical services recommendations are summarized but the focus is on the initial visit with little attention to the need for regular HIV and STI laboratory screening, monitoring of renal function, and adherence support. As providers of PrEP, we have seen firsthand how important these services are for the health of patients taking PrEP. According to the U.S. Public Health Service Guideline, at a minimum the following should be provided when prescribing PrEP: follow-up visits at least every 3 months for HIV testing, medication adherence counseling, behavioral risk reduction support, bacterial STIs testing (every 3 to 6 months depending on risk factors), and for women pregnancy intent should be assessed and pregnancy testing conducted. In addition, renal functioning should be assessed at 3 months and then every 6 months.⁸

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

We urge the final Recommendation to underscore the need for clinicians to follow the most recent U.S. Public Health Service Guidelines for PrEP delivery to stay current with the latest medical evidence and prevention standards.

Health care providers of all specialties, particularly infectious diseases, primary care, reproductive health, adolescent medicine and pediatrics should be aware and comfortable prescribing PrEP, and, thus, the final Recommendation should include resources that can help educate providers. This includes the federally-funded Clinician Consultation Center administered by the University of California San Francisco, which offers a free hotline for providers who need clinical support prescribing PrEP.⁹ The federally-funded National LGBT Health Education Center administered by the Fenway Institute also published a “PrEP Action Kit” resource for providers to successfully discuss PrEP with patients.¹⁰ The final USPSTF Recommendation should include other evidence-based resources for providers that can be found on CDC’s PrEP webpage¹¹ and the most recent CDC Sexually Transmitted Diseases Guidelines.¹²

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.

As previously referenced, currently only a very small percentage (7%) of 1.1 million individuals in the U.S. who could benefit from PrEP had been prescribed PrEP. PrEP is an intervention that can be successfully delivered by primary care providers, and its success relies on awareness and comfort among providers to assess patients, discuss medical and sexual histories, prescribe the medication, and conduct quarterly follow-up. Recent studies suggest however that nearly a quarter of primary care providers have never heard of PrEP, just over a quarter felt familiar with prescribing PrEP, and less than a fifth have prescribed it.¹³

According to the most recent Kaiser Family Foundation survey of young Americans, only 13% knew that PrEP existed at all and only 17% knew that PrEP is very effective in preventing HIV infection. Even among those who had heard of PrEP, the survey suggests that a quarter or more do not believe that PrEP is even somewhat effective in preventing HIV.¹⁴

The populations at higher risk for HIV continue to face significant stigma and discrimination including within healthcare settings. HIV providers and clinics have emerged as major PrEP providers in some communities because primary care providers are uncomfortable prescribing PrEP. We urge the USPSTF to acknowledge the role that stigma and discrimination play in HIV prevention and specifically with increasing information about of PrEP. It is critical for all stakeholders to implement this Recommendation in a non-discriminatory manner.

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

We strongly urge the USPSTF to recommend the U.S. Public Health Service Guidelines on PrEP as setting the standard for clinical care for implementing PrEP to ensure that clinical practice does not fall behind the science. We urge that the final Recommendation advise all stakeholders to appropriately follow the most recent guidelines.

Thank you again for putting forth this important recommendation and for considering our views. Please reach out with any questions to HIVMA's executive director Andrea Weddle at aweddle@idsociety.org.

Sincerely,



W. David Hardy, MD
Chair, HIVMA Board of Directors



Anna K. Person, MD
Co-Chair, Ryan White Medical Providers Coalition

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- ² AVAC. The Future of ARV-Based Prevention and More (October 2018). Available online at: https://www.avac.org/sites/default/files/infographics/AR2018_The_Future_ARV_Based_Prevention.pdf.
- ³ CDC. HIV Among Youth. April 2018. <https://www.cdc.gov/hiv/group/age/youth/index.html>.
- ⁴ Balaji, A et al. 2017. High HIV incidence and prevalence and associated factors among adolescent sexual minority males, 3 cities, 2015. Clinical Infectious Diseases. 66. 10.1093/cid/cix902.
- ⁵ CDC. HIV Among Transgender People. November 2018. <https://www.cdc.gov/hiv/group/gender/transgender/index.html>.
- ⁶ NIH. 10 Things to Know About Viral Suppression. November 2017. <https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression>.
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- ⁹ UCSF Clinician Consultation Center. PrEP: Pre-Exposure Prophylaxis. <https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/>.
- ¹⁰ National LGBT Health Education Center. PrEP Action Kit. June 2017. <https://www.lgbthealtheducation.org/prep-action-kit/>.
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