Comments from the HIV Health Care Access Working Group and the HIV Prevention Action Coalition on the U.S. Preventive Services Task Force (USPSTF) Draft Recommendation Statement -- Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis

December 2018

The Federal AIDS Policy Partnership's HIV Health Care Access Working Group and HIV Prevention Action Coalition are pleased to offer comments in response to the USPSTF's draft recommendation of a Grade A for Pre-Exposure Prophylaxis (PrEP). In the U.S., there are more than a million people living with HIV and nearly 40,000 new cases occur annually. Just over 50 percent of people living with HIV are on effective treatment meaning the virus is suppressed in their bodies to undetectable levels, which allows them to stay healthy and stops their risk of transmitting HIV. Increasing access to HIV treatment and to PrEP is critical to reduce the number of new HIV infections. Currently, a very small percentage (7%) of 1.1 million individuals in the U.S. who could benefit from PrEP had been prescribed PrEP.[i] The USPSTF proposed Grade A for PrEP following a thorough review of the evidence is an important step to make PrEP a prevention tool that will be more widely recognized and accepted within the medical community.

While currently only one antiretroviral drug combination has been approved for PrEP, the HIV biomedical prevention field is rapidly advancing[ii] and likely to yield more options for PrEP that could be even more effective and accessible for some individuals within the higher risk populations. Given the strong evidence considered for the USPSTF to recommend a Grade A for PrEP to prevent HIV, it is critical that clinical practice not fall behind the science if and when new antiretroviral drugs are approved for PrEP by the US Food and Drug Administration (FDA).

We offer comments regarding the details of the recommendation by responding to the questions as requested.

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.**

   We have nothing to offer. The USPSTF conducted a comprehensive evaluation of this prevention intervention and we strongly agree with the Grade A recommendation.

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

We strongly urge the USPSTF to clarify that antiretroviral drugs are the primary PrEP intervention in the Recommendation Statement. The current wording of the recommendation suggests that antiretrovirals are in addition to PrEP rather than antiretrovirals being the primary prevention tool. We also recommend replacing "therapy" with "drugs" since therapy generally refers to treatment of a condition. We suggest clarifying the wording of the recommendation as noted below to also highlight the clinical services that are an integral component of the PrEP intervention.

- The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) ~~with~~ **using** effective antiretroviral ~~therapy~~ drugs to persons who are at high risk of HIV acquisition **and provide associated clinical services including regular screening for HIV and sexually transmitted infections and monitoring of renal functioning in addition to adherence counseling.**

Healthcare providers who are not already familiar with PrEP may not be aware that it refers to prescribing antiretrovirals to prevent HIV acquisition and are likely to rely on the USPSTF recommendation and rationale as their primary information source. In addition, providers should be aware of and offer the clinical services recommended in the U.S. Public Health Services Guidelines on PrEP for HIV Prevention in the U.S. when prescribing antiretrovirals for PrEP.[iii] It is important for the recommendation and supporting information to be clear and specific.

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

Assessment of Risk Section

We urge that the additions described below be added to this section.

Adolescents:

We recommend including more robust data on new HIV cases among adolescents highlighting the disproportionate impact on young men of color who have sex with men. According to the Centers for Disease Control and Prevention (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 bi-sexual men and disproportionately among black/African American and Hispanic/Latino gay and bisexually men.[iv]

Transgender Individuals:

We recommend revising the paragraph in this section to make a stronger statement about the increased risk of HIV among transgender individuals. The 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/African American transgender women are living with HIV.[v] These estimated rates are significantly higher than the rates found among other populations even those at higher risk and warrant being recognized in describing the assessment of risk for PrEP.

Serodiscordant Couples:

We urge a revision to the paragraph describing the risk of HIV transmission within serodiscordant couples to reflect the scientific evidence that individuals living with HIV who are virally suppressed and sustain suppression do not transmit HIV. This critical information has been endorsed and promoted widely by many in the medical community including the Director of the National Institute of Allergy and Infectious Diseases Anthony Fauci, MD.[vi]

Patient Requests for PrEP:

In addition to offering PrEP to populations at higher risk, we recommend noting that patients who request PrEP should be considered as at risk and prescribed PrEP. As noted by the USPSTF in the Identification of Risk Status Section, 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[vii] so in some cases 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 urge USPSTF to note that patients who request PrEP should be assumed to be at higher risk and should be prescribed PrEP. 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.

Other Considerations - Implementation:

The clinical services recommended in the 2017 U.S. Public Health Services' Clinical Practice Guideline for PrEP[viii] are integral components of the PrEP intervention, ensuring the effectiveness of PrEP and monitoring for potential seroconversion while also reducing the risk of STIs among PrEP users. 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, STI screening, monitoring of renal function, and adherence support. We strongly recommend including details regarding the accompanying clinical services and highlighting the importance of these services to the effectiveness of PrEP. This is particularly important given the finding in the "estimate of net benefit" section that adherence to PrEP is central to realizing its benefit. In addition, the implementation section should note that accompanying services should be modified as appropriate when updates are made to the U.S. Public Health Service Guideline. 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 STI testing (every 3 to 6 months depending on risk factors). n addition, renal functioning should be assessed at 3 months and then every 6 months. For women, pregnancy intent should be assessed and pregnancy testing conducted.

Research Needs and Gaps

Additional research is needed on the integration of STI prevention such as post-exposure prophylaxis and pregnancy prevention with PrEP. Modalities that have multiple uses are more likely to be used, which can increase uptake and adherence in addition to reducing the stigma associated with HIV or STI prevention.

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

As previously noted the HIV biomedical prevention landscape is rapidly evolving with the potential for new tools that could significantly benefit individuals who are at higher risk for acquiring HIV. We strongly recommend that the Task Force emphasize the importance of the most recent U.S. Public Health Service Guideline for PrEP and indicate that the Grade A recommendation is given to antiretrovirals and clinical services recommendations for PrEP consistent with the most recent version of the U.S. Public Health Service Clinical Practice Guideline on PrEP.

Because PrEP is currently being prescribed in a number of public health settings, we recommend that the Task Force consider resources and dissemination strategies that ensure provider types outside of primary care clinicians are aware of and adhering to the Grade A recommendation for PrEP. Public health providers – including STI clinics, state and local health departments, and family planning clinics – are an important part of the PrEP delivery system and should be included in the Task Force recommendations.

We also recommend including the following resources:

The University of California, San Francisco's Clinical Consultation Center – PrEPline (855-448-7737) which offers clinical support to healthcare providers prescribing PrEP. Service hours are Monday to Friday from 9 am to 8 pm ET. More information is available online at https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/.

The most recent version of the CDC's Sexually Transmitted Disease guidelines, which currently are the 2015 Sexually Transmitted Diseases Treatment Guidelines available at: https://www.cdc.gov/std/tg2015/default.htm.

CDC: Preexposure Prophylaxis – clinical tools and educational resources for clinicians available online at: https://www.cdc.gov/hiv/risk/prep/index.html.

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.

Populations at higher risk for HIV infection experience significant stigma and discrimination including within the healthcare field and by some healthcare providers.[ix] [x] [xi] While the USPSTF endorsement of PrEP with a Grade A should help to reduce stigma and discrimination for some, we strongly recommend noting that stigma and discrimination is a barrier to individuals accessing and receiving PrEP with potentially harmful consequences for their health. With this in mind, it is important for PrEP to be implemented by all sectors of the healthcare system in a non-discriminatory manner.

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

We strongly agree with the USPSTF approach to offering a general recommendation for clinicians to offer PrEP using antiretroviral drugs without referring to the only antiretroviral combination currently approved by the FDA for PrEP (TDF-FTC). As previously stated, biomedical HIV prevention is a rapidly evolving field and new oral antiretrovirals options are on the horizon in addition to new modalities for administering antiretrovirals for prevention that could help to improve adherence and better meet the prevention needs of some populations. We strongly urge that the USPSTF's recommendation regarding the effectiveness of antiretroviral drugs as a highly effective prevention intervention for populations at higher risk apply to antiretrovirals approved by the FDA for PrEP and as recommended in the U.S. Public Health Service Guideline for PrEP.

Thank you for the opportunity to comment on the USPSTF's Grade A recommendation for PrEP. Please contact the HHCAWG co-chairs Amy Killelea with the National Alliance of State and Territorial AIDS Directors (NASTAD) at akillelea@nastad.org, Andrea Weddle at aweddle@hivma.org with the HIV Medicine Association, or Robert Greenwald at rgreenwa@law.harvard.edu with the Center for Health Law and Policy Innovation or the HPAC co-chairs Mike Weir with NASTAD at mweir@NASTAD.org or Nick Armstrong with The AIDS Institute at narmstrong@theaidsinstitute.org questions regarding our comments.

Submitted on behalf of the undersigned organizations,

ADAP Educational Initiative | AIDS Alabama | AIDS Action Baltimore | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Research Consortium of Atlanta | AIDS United | American Academy of HIV Medicine | APLA Health | AIDS Resource Center of Wisconsin | Careteam Plus Family Health and Specialty Care | Children's Hospital Los Angeles |Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | Fair Pricing Coalition |Georgia AIDS Coalition | Georgia Equality | Harm Reduction Coalition | HealthHIV | HIV Medicine Association| Housing Works | Human

Rights Campaign | John Snow, Inc. (JSI) |Legal Council for Health Justice | Los Angeles LGBT Center |Michigan Positive Action Coalition | Minnesota AIDS Project | National Alliance of State and Territorial AIDS Directors | Nashville CARES | National Latino AIDS Action Network | NMAC | Positive Women's Network - USA| Project Inform | Rocky Mountain CARES | San Francisco AIDS Foundation | SisterLove | Southern AIDS Coalition | Southern HIV/AIDS Strategy Initiative | The AIDS Institute | Treatment Access Expansion Project | Treatment Action Group

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[i] Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV Preexposure Prophylaxis, by Race and Ethnicity - United States, 2014-2016. MMRW. 2018 Oct 19:67(41):1147-1150.

[ii] 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

[iii] U.S. Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States. Accessed online at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

[iv] CDC. HIV Among Youth. Online at: https://www.cdc.gov/hiv/group/age/youth/index.html.

[v] CDC. HIV Among Transgender People. Online at: https://www.cdc.gov/hiv/group/gender/transgender/index.html.

[vi] Remarks delivered by NIAID Director Anthony S. Fauci, MD. Science Validates Undetectable = Untransmittable HIV Prevention Message. NIAID Now. July 2018. Online at: https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable.

[vii] U.S. Preventive Health Services Task Force. Chlamydia and Gonorrhea: Screening (Sept. 2014).

[viii] U.S. Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States. Accessed online at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

[ix]Bauermeister JA, et al. Stigma Diminishes the Protective Effect of Social Support on Psychological Distress Among Young Black Men Who Have Sex With Men. AIDS Educ Prev. 2018 Oct; 30(5):406-418.

[x] Baugher AR[1], et al. Discrimination in healthcare settings among adults with recent HIV diagnoses. AIDS Care. 2018. Nov 15:1-6.

[xi] Hatzenbuehler ML, Pachankis JE. Stigma and Minority Stress as Social Determinants of Health Among Lesbian, Gay, Bisexual, and Transgender Youth: Research Evidence and Clinical Implications. Pediatr Clin North Am. 2016 Dec;63(6):985-997.