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Position paper

# HIV Pre-Exposure Prophylaxis Medication for Adolescents and Young Adults: A Position Paper of the Society for Adolescent Health and Medicine

Society for Adolescent Health and Medicine




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**A B S T R A C T**

Pre-exposure prophylaxis (PrEP) is a biomedical prevention intervention that has demonstrated high efficacy in reducing human immunodeficiency virus (HIV) transmission. While an increasing number of jurisdictions have endorsed the use of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for PrEP, access to PrEP varies widely. Adolescents and young adults (AYAs), especially those at high risk of HIV acquisition, such as young gay, bisexual, and other men having sex with men (YGBMSM) and individuals living in countries where HIV is endemic, face multiple barriers that limit their access to PrEP. This position paper provides context and recommendations for the promotion and use of PrEP among AYAs.

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**Summary of Positions**

SAHM recommends the following positions:

- (1) Investigators and policy advocates should promote increased access to PrEP for AYAs through research and advocacy focused on minors' consenting ability and confidentiality
- (2) Developmentally-appropriate educational programs and screening tools should be developed alongside skills-building interventions to increase adherence to PrEP regimens by AYA
- (3) Investigators and health professionals should develop culturally sensitive and accessible PrEP delivery models as part of routine care offered to AYAs at risk of HIV infection.

**Statement of the Problem**
*Global burden of HIV disease among AYA*

Nearly 4 million young people ages 15–24 are living with human immunodeficiency virus (HIV), and new infections among this age group increased nearly 30% in the last decade [1]. The majority of youth with HIV live in low and middle-income countries in sub-Saharan Africa (85%) and South Asia (6%) [1].

Adolescents and young adults (AYA) at greatest risk for HIV acquisition live in HIV prevalent communities with overlapping vulnerabilities that expose them to HIV. The subgroups with the

greatest vulnerabilities and largest burden of disease are heterosexually active young women and young gay, bisexual, and other men who have sex with men (YGBMSM). Other at-risk AYAs include youth who inject drugs, youth engaged in sex work or who are sexually exploited, and young transgender women who have sex with men. In the US, a model based on current average incidence rates among black YGBMSM predicts 40% of these AYA will acquire HIV by age 30 unless prevention efforts improve [2].

*FTC/TDF for HIV PrEP*

Clinical trials of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for HIV prophylaxis have demonstrated risk reductions of 75% in heterosexuals with serodiscordant partners and 92% in men having sex with men and transgender women when taken daily. Recent Centers for Disease Control and Prevention (CDC) data suggest that current HIV prevention efforts including HIV testing, treatment, and PrEP have resulted in an 18% decrease in new HIV infections [3]. A systematic review and meta-analysis of PrEP trials also demonstrated the level of protection was similar across age, gender, antiretroviral regimen (FTC/TDF or TDF alone), or mode of acquisition (rectal or penile/vaginal exposure) [4]. These studies have also demonstrated a high safety profile and minimal risk compensation. Citing this evidence, the US Food and Drug Administration (FDA) approved FTC/TDF for PrEP for adults 18 years and older in 2012. Since then, several developed and developing countries have endorsed FTC/TDF for HIV prophylaxis in adults [5].

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In May 2018, the FDA extended approval of FTC/TDF for PrEP to include all patients weighing 35 kilograms or more. Thus far, only the US has approved PrEP for use among minors.

Two studies evaluated the acceptability and adherence of PrEP in adolescents- Project PrEPare in YGBMSM aged 15–17 years old and Project PrEPare 2 in YGBMSM aged 18–22 years old. These studies described high acceptability of PrEP in AYAs. However, results from both studies demonstrated decreased use of FTC/TDF over time, particularly as visits moved from monthly to quarterly [6, 7].

Despite limited evidence for use in adolescents, the World Health Organization announced in 2014 its recommendation for offering PrEP to all MSM [4]. In 2015, this recommendation was extended using a cost-effectiveness argument to include population groups with an HIV incidence of three per 100 person-years or higher, such as young women in high HIV prevalence countries [5]. The US Public Health Service also endorses the use of PrEP in adult populations, with special emphasis on high-risk groups: sero-discordant couples, transgender women, MSM, female sex workers, and people who inject drugs [5,8].

Research shows important disparities in the use and awareness of PrEP. For instance, uptake has been slow in AYAs, and even more so in the youth of color [9,10]. Data shows that young black men were least likely to fill a prescription for FTC/TDF, with significantly lower rates than white women or black men of all ages [9]. According to US retail pharmacy data from 2012–2015, most prescriptions for PrEP were filled by white men; only 7.6% of prescriptions were filled by youth under 25, of whom 76% were white and 11.5% were black [9]. Low uptake rates among young black men were reflected in a recent study of YGBMSM, which showed only 8% PrEP utilization, despite 67% reporting condomless anal sex [10].

#### *Approval, Access, Safety, and Adherence*

Interested and eligible AYAs face many obstacles to accessing PrEP, even with regulatory approval. In many countries, same-sex behavior is illegal, stigmatized, or hidden, which may impede health-seeking behaviors and disclosure of risks to healthcare providers. Further, US state laws create a patchwork of regulations that affect minors' ability to confidentially access HIV care and PrEP; some states allow minors to consent to HIV testing but not prevention (including PrEP), while others allow consent for both. As such, insurers may not cover the costs of FTC/TDF for minors, making PrEP cost-prohibitive. Providers may also hesitate to prescribe PrEP to minors because of potential adverse effects, such as decreased bone mineral density (BMD). The largest decrease typically occurred in the first 12 months of FTC/TDF use and is not associated with increased fractures, but there are no data on long-term effects [11].

Medication adherence is another concern. TDF levels greater than 700 fmol/punch, equivalent to at least 4 doses per week, are protective against HIV acquisition [6]. However, in two open-label studies of YGBMSM aged 15–17 and 18–22, protective TDF levels began to decline at week 12 and only 35% of participants aged 18–22 and 28.2% aged 15–17 had protective TDF levels at the end of the study (48 weeks) [6]. As such, interventions to support adherence are needed to increase the effectiveness of PrEP as a prevention tool [12].

#### **Positions and Recommendations**

Globally, PrEP frameworks call for robust approaches to increase use among priority populations, including AYAs. This

approach includes policy reform and advocacy, ongoing research for new medications and delivery devices, educational campaigns, and service delivery systems that include readiness assessments, linkages to care, and sustainable financing models. Based on these frameworks, SAHM endorses the following positions and recommendations regarding PrEP for AYAs. Positions and recommendations are delineated by age in recognition of current PrEP research among AYAs, differing developmental capacities between adolescents and young adults, and legal constraints limiting confidentiality and consent for care. For the purposes of these proposals, we define AYA as 15–24 years old, which reflects the age group in which PrEP for youth has been studied [5]. This definition may vary across countries and a lower age limit may be more appropriate to define the AYA population in different settings. We use 18 years as the general age of majority in the following recommendations, but they are applicable to minors and young adults as defined by local statutes.

#### **1. Advocacy and Research: Clinical investigators and policy advocates should promote increased access to PrEP for AYAs through youth-focused PrEP research and legislative advocacy regarding minors' consent, confidentiality, and healthcare financing.**

Exclusion of minors from initial PrEP studies has delayed regulatory approval of FTC/TDF for adolescents and created policy barriers that limit access to PrEP. Additionally, safety data for FTC/TDF use among HIV-uninfected adolescents is considerably limited compared to safety data for HIV-uninfected adults. This may leave many providers uncomfortable prescribing PrEP to minors, even though FTC/TDF is now FDA approved for both prevention and treatment of HIV, based on weight, among minors.

The lack of AYA-specific analysis in original PrEP studies represents a missed opportunity to examine outcomes unique to this age group, such as acceptability, adherence patterns, and behavioral disinhibition. Such data are necessary for achieving wider regulatory approval, provider practice change, and effective implementation. Planned inclusion of AYAs in initial safety and efficacy trials, as well as demonstration projects for new PrEP medications and novel delivery devices, can result in timely drug regulatory approval for this age group, ultimately leading to earlier access and uptake [13].

Minor consent laws and threats to confidentiality are additional barriers to PrEP research trials and clinical services for AYAs. Minor consent legislation lags behind advances in PrEP and has resulted in murky and inconsistent laws regarding consent for services to prevent sexually transmitted infections [14]. These barriers exist despite clear developmental science supporting AYAs' maturity to consent for preventive medical services and research participation when done in consultation with adult professionals. Similarly, documents that disclose AYAs' confidential health information to policyholders represent further obstacles to AYAs' uptake of PrEP and access to preventive care.

Medication costs, associated laboratory tests, and office visit fees limit AYA access to PrEP, even in the presence of regulatory approval for minors and consent and confidentiality assurances. These financial and time costs can potentially reduce AYA access to PrEP, particularly for key HIV prevention populations, likely increasing HIV burden among youth who engage in sex work, inject drugs, are MSM or are transgender. Patient assistance programs are available in jurisdictions without national health programs to assist with lowering costs, however, providers will need to have the skills to access them.

## Recommendations

- a) Applicable to all AYA: Investigators should increase clinical trials among AYAs, including minors, to demonstrate the safety of current and future PrEP medications. Such trials should explore potential barriers and facilitators of PrEP uptake and adherence, evaluate PrEP delivery models for all AYAs regardless of age, and examine the impact of PrEP on sexual health behavior, healthcare engagement, and other health outcomes.
- b) Youth less than 18 years: Youth policy advocates should support uniform minor consent laws that allow youth less than 18 years to consent for healthcare including the prevention and treatment of HIV and other sexually transmitted infections. Advocates should focus on privacy protections within legal statutes and third-party payer contractual agreements for preventive services. These include mechanisms for states to allow providers to provide preventive services to minor adolescents and for suppression of explanation of benefits (EOB) statements and/or other health insurance communications that threaten confidentiality for AYAs insured as dependents (e.g., New York and California laws allow for suppression of EOB).
- c) Applicable to all AYA: Policy advocates should determine sustainable financing models that cover access to PrEP, necessary laboratory testing, and clinical visits to avoid perpetuating existing HIV disparities among vulnerable youth populations. Additionally, policies should be developed for suppression of EOB statements and/or other health insurance communications that threaten confidentiality for AYAs insured as dependents (e.g., New York and California).

## 2. Health Education and Promotion: PrEP information should be incorporated into comprehensive sexual health educational and screening tools for AYA. Developmentally-appropriate, skills-building interventions should be developed to increase AYA adherence to PrEP regimens.

Limited provider confidence and capacity with HIV risk assessment results in missed opportunities to discuss PrEP and other HIV prevention strategies. Providers report less comfort addressing the sexual health needs of sexual and gender minorities compared to heterosexual and cisgender patients [15]. Providers also often lack the training to assess substance use, including injection drug use, which significantly affects HIV risk. Yet gathering comprehensive sexual and substance use histories is an imperative first step for providing PrEP and other prevention services. Youth who discussed their sexual history prior to counseling about PrEP reported significantly greater comprehension of PrEP effectiveness and proper use [16]. Moreover, providers must address institutional, social, and historical factors that influence patients' sense of safety in medical settings and disclosure of stigmatized behavior, which can ultimately impede PrEP uptake [10,16].

PrEP education is also an important yet often lacking a component of HIV prevention strategies among youth [5]. Incorporating biomedical prevention strategies in sexual health education curricula is essential to increasing AYAs' knowledge and awareness of PrEP as part of the continuum of HIV prevention.

The World Health Organization suggests that additional research is needed to determine effective strategies to assess adherence skills in adolescents and to guide the implementation of PrEP services. Little research has been conducted on more generalized adolescent

populations. AYA adherence may improve in youth-friendly settings providing tailored adherence support, including case management or increased frequency of clinic visits [5].

## Recommendations

Applicable to all AYA:

- a) Professional training and continuing education should support AYA healthcare providers to incorporate best practices for obtaining comprehensive social histories into all medical visits to identify youth at increased risk of HIV. Providers should be aware of barriers to disclosure of high-risk behaviors that result from medical mistrust and stigma.
- b) PrEP information should be included in school, community, and parent-based sexual health education curricula. PrEP education campaigns should be inclusive of, and applicable to, youth populations at highest risk for HIV as determined by local epidemiology.
- c) Federal and state funding agencies should support research to validate AYA-specific tools to assess PrEP knowledge, readiness, and adherence skills among AYAs that can inform educational and skills-based interventions to support optimal PrEP use as part of HIV prevention care.

## 3. PrEP delivery: Investigators and adolescent health professionals should develop evidence-based, developmentally appropriate, culturally sensitive, and accessible PrEP service delivery models as part of routine care offered to AYAs.

Age disparities exist in PrEP uptake. AYA account for less than 10% of PrEP prescriptions despite comprising 40% of new US HIV infections [6]. Additionally, research with young adults who have started PrEP show concerning patterns of low or nonadherence shortly after initiation of PrEP [6]. Two decades of HIV prevention research offer promising guidance on intervention strategies and program services that may support improved PrEP uptake and adherence: rapid initiation of treatment; peer support; care navigators and case management; and technology-enhanced support services [12].

AYA experience unique barriers in accessing and adhering to PrEP. Existing PrEP guidelines primarily focus on clinical monitoring protocols and do not address the impact of mental health and social stigma on youth willingness or ability to access, initiate, and adhere to PrEP. Furthermore, young adults at highest risk for HIV are disproportionately impacted by factors that limit access and adherence to PrEP [5,10]. Comprehensive PrEP guidelines for youth must include strategies to combat discrimination and stigma.

Integration of PrEP into routine care for at-risk adults 18 years and older already is widely recommended. Despite the existence of compelling efficacy data and comprehensive clinical guidelines, however, providers working in settings where AYAs are likely to be seen report low PrEP knowledge, familiarity with PrEP clinical guidelines, and willingness to prescribe PrEP [5,17].

## Recommendations

Applicable to all AYA:

- a) Researchers and AYA health professionals should develop, implement, and evaluate novel approaches for supporting PrEP uptake and adherence among youth, including the use of same-day PrEP, peer-to-peer social support, case manager

- involvement, and mobile technologies to enhance linkage, adherence, and retention in care.
- b) Researchers and AYA direct service professionals should develop comprehensive PrEP clinical guidelines that address psychosocial issues affecting PrEP uptake and adherence that are specific to youth at greatest risk for HIV.
- c) Healthcare providers should counsel patients about PrEP, describing it as a safe and effective HIV prevention strategy in combination with condoms, and refer patients to available providers for initiation and monitoring of PrEP.

### Summary/Conclusion

AYAs, worldwide, are heavily impacted by the HIV/AIDS epidemic. PrEP has demonstrated high efficacy in reducing HIV transmission and is a potential tool to reduce HIV burden globally among adolescents. However, AYAs face many obstacles to accessing and adhering to PrEP. We must promote increased access to PrEP for AYAs by addressing confidentiality and minors' consenting ability, expanding research among adolescents under 18 years, and incorporating PrEP into comprehensive sexual health education services. AYA professionals should also develop screening tools and culturally-sensitive and accessible PrEP service delivery and adherence models as part of routine care offered to AYAs at increased risk of HIV infection.

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