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Navigating the long road forward for maximizing PrEP impact among adolescent men who have sex with men

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Abstract

Preexposure prophylaxis (PrEP) has tremendous potential to decrease new HIV infections among populations at high risk, such as men who have sex with men (MSM). That potential is already becoming realized among adult MSM, where PrEP uptake has increased rapidly in the past several years. However, expanding PrEP access to adolescent MSM (AMSM) will be more challenging. This paper reviews the existing scientific literature relevant to PrEP use for AMSM, and highlights critical areas in need of further attention before PrEP is likely to impact the HIV epidemic among adolescents. We highlight concerns that need to be addressed in the areas of (a) achieving adequate coverage of PrEP in the adolescent population, (b) increasing awareness and access, (c) supporting adherence and maintenance, and (d) ensuring that PrEP does not perpetuate existing disparities. Across all of these domains, we highlight the central roles of parents and healthcare providers in supporting AMSM PrEP utilization. Finally, we suggest a number of areas of future research that must be addressed before PrEP is likely to see wide implementation among AMSM.

Preexposure prophylaxis (PrEP) for HIV prevention involves prescribing antiretroviral medications to people who are *HIV-uninfected* as a means of preventing future infection. Clinical trials have shown significant reductions in HIV incidence among adults prescribed a daily oral dose of combined tenofovir and emtricibine (Truvada) (Spinner et al., 2016), and as a result, in 2012 the FDA first approved PrEP for adults. Based on a study demonstrating safety of PrEP in adolescent men who have sex with men (AMSM) (Hosek et al., 2017), in 2018 the FDA expanded its approval to include adolescents over 35kg (approximately 77 lbs). This is an important advance for the field, as we urgently need new tools to combat HIV infection among adolescents. Every week nine adolescents ages 13–17 are diagnosed with HIV in the United States (Ocfemia, Dunville, Zhang, Barrios, & Oster, 2018) and HIV incidence has been found to be alarming high in this group (Balaji et al., 2018). The majority of these teens are young gay and bisexual men, particularly young men of color (Ocfemia et al., 2018).

Despite PrEP's promise as an HIV prevention tool, the field must confront multiple critical challenges before it will begin to have an impact on the adolescent HIV epidemic. These include expanding access to achieve adequate coverage through the population, particularly

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those at highest-risk, maintaining high levels of adherence to the medication and sustaining those levels of adherence over time, and attending closely to existing racial/ethnic disparities within the HIV epidemic that have the potential to be exacerbated by uneven access to PrEP. Moreover, given adolescents' unique developmental and social position, each of these challenges require careful consideration of the roles of parents and adolescent healthcare providers.

Coverage

Recent modeling work on the HIV epidemic among AMSM ages 13–18 suggests that PrEP has the potential to avert approximately 28% of new HIV infections in the population if it is distributed to 40% of AMSM ages 16–18 within six months after they first initiate anal intercourse (Goodreau et al., 2018). Among the various parameters the authors manipulated in their models (e.g., adherence, age of PreP initiation), those with the most direct impact on number of infections averted were degree of coverage across the population and the background HIV prevalence of the setting. For example, reducing PrEP coverage to 20% averted just 18% of new infections. Thus, ensuring adequate distribution of PrEP to the population, particularly in higher-prevalence locations, is critical to its success. Unfortunately, lessons learned from other HIV prevention technologies make clear that getting 20–40% of AMSM onto PrEP will pose a significant challenge. Currently, only 25% of sexually active AMSM have ever even received an HIV test (Phillips, Ybarra, Prescott, Parsons, & Mustanski, 2015). Obviously, obtaining a one-time HIV test is much simpler than accessing, adhering to, and maintaining an expensive, daily medication regimen. Achieving comparable coverage with PrEP will require far more resources and intensive intervention.

Awareness and Access

The first steps to increasing adolescent coverage with PrEP is raising awareness and improving access. Awareness of PrEP is low among AMSM. One recent study of AMSM ages 14–18 recruited nationally online indicated that only 16% had ever heard of PrEP (Thoma & Huebner, 2018). Perhaps reassuringly, awareness of other reproductive and preventive healthcare services (e.g., HPV vaccination) is also typically low among adolescents (Fishman, Taylor, & Frank, 2016; Patel, Jeve, Sherman, & Moss, 2016), given that most rely on their providers and parents to initiate conversations about these services and to direct their healthcare decision-making. However, providers and parents likely pose their own barriers to PrEP access among AMSM. Up to half of general pediatric providers have never heard of PrEP (Chenault, Waddell, & Tepper, 2018). Providers specializing in adolescent healthcare may be more aware of PrEP. In a recent report, 93% of adolescent providers had heard of PrEP; however only 65% were willing to prescribe it to patients under age 18 (Hart-Cooper, Allen, Irwin, & Scott, 2018). While these numbers might increase following recent FDA approval for use with adolescents, providers who were unwilling to prescribe more commonly cited concerns regarding adolescent adherence, and FDA approval is unlikely to alleviate these concerns. Moreover, CDC guidelines state that PrEP is indicated for individuals "at substantial risk" for HIV infection. Providers are commonly unaware of a child's sexual orientation, leaving them unable to adequately assess

that risk and provide adequate clinical guidance (Fisher, Fried, Macapagal, & Mustanski, 2018; Luk, Gilman, Haynie, & Simons-Morton, 2017).

Emerging research suggests many AMSM are concerned about taking to their parents about using PrEP (Fisher, Fried, Macapagal, & Mustanski, 2018). Presently, access to PrEP is virtually impossible without parental awareness and assistance. State laws govern adolescents' independent access to healthcare, and currently in many states there is lack of clarity about adolescent autonomous access to PrEP (e.g., debates if laws allowing adolescent autonomous consent to STI or HIV treatment apply to PrEP). However, even if AMSM have a provider willing to prescribe PrEP without parental permission, financing the medication poses a challenge. While public and most private health insurance will cover PrEP for adolescents, accessing those sources of coverage is difficult to do independently and without parental awareness. Similarly, financial assistance with PrEP co-pays is currently only available to adolescents who receive explicit parental consent (Gilead, 2018).

We are aware of only one study that has examined parent perspectives on their sons' use of PrEP with or without their involvement—the study interviewed parents of gay/bisexual and heterosexual sons on their attitudes towards their sons participating in studies of PrEP adherence (Mustanski, Macapagal, et al., 2018). Parents identified several health and educational benefits of such research and expressed that waiving parental permission would help overcome barriers to PrEP access, particularly for teens who need it most. Among parent concerns were medication non-adherence and risk compensation. Given that parental engagement is a critical consideration for PrEP access for adolescents, this is an area urgently in need of research.

Adherence and Maintenance

After initiating PrEP, adolescents will only benefit if they adhere to the medication and sustain their use throughout the times that their HIV risk is the greatest. Ironically, the same demonstration trial that supported the safety of PrEP for adolescents and facilitated FDA approval also revealed that AMSM faced considerable barriers to using it. Six months after PrEP initiation, only 28% of AMSM who initiated PrEP had therapeutic levels of drug in their system, and annualized HIV incidence in the cohort was extremely high at 6.1% (Hosek et al., 2017). Another study of adolescent and young adult MSM found high rates of PrEP discontinuation, with the most common reasons being trouble attending doctors' appointments and loss of insurance coverage (Morgan, Ryan, Newcomb, & Mustanski, 2018). Clearly, we need more research and intervention focused on the challenges AMSM face in adhering to and maintaining on PrEP. More frequent and better facilitated engagement with providers might provide some assistance, as participants in the PrEP demonstration trial had better adherence during the early portions of the trial when study visits were more frequent (Hosek et al., 2017). Parents can also be a source of support here. Research with other daily medical regimens indicates adolescents have higher adherence when they communicate effectively with their parents (Dashiff, Hardeman, & McLain, 2008), and one recent study found that adolescents who reported higher quality communication with their parents about HIV also feel greater self-efficacy to adhere to a daily PrEP regimen (Thoma & Huebner, 2018).

Perpetuating Existing HIV Disparities

From the beginning of the epidemic to the present day, HIV has disproportionately impacted communities with fewer social and economic resources. In 2016, 81% of new HIV infections among youth ages 13–24 occurred among young MSM. The majority of those occurred among young men who were African American (54%) and Latino (25%) (Centers for Disease Control and Prevention, 2018). Research examining disparities in PrEP access has been limited to adults and has revealed generally low levels of PrEP use among participants of all ethnicities. In one cohort of young MSM from Chicago, 7% of men reported PrEP use in the past 6 months, with no evidence of racial or ethnic differences (Morgan, Moran, Ryan, Mustanski, & Newcomb, 2018). Another large study of young MSM from California found that approximately 7% were current PrEP users, and this also did not vary by race or ethnicity (Holloway et al., 2017). Historically, people of color in the United States have seldom had equal access to healthcare of any kind, including HIV care. It would be surprising if PrEP access did not follow similar trends, both among adults and adolescents. This is particularly likely as PrEP use moves from research trials and demonstration projects to delivery through established medical systems, given that the early research-focused delivery systems required enrollment of people of color. An initiative to provide PrEP to a cohort of young Black MSM in Atlanta is illustrative. Researchers attempted to alleviate prominent structural barriers to PrEP uptake by offering free provider visits and laboratory tests, as well as navigation of insurance to ensure that drug costs and copays would be covered (Rolle et al., 2017). Sixty-three percent of men indicated interest in initiating PrEP, but only about half of the interested men attended the initial provider appointment, and only one third actually initiated PrEP. Clearly we will not bend the curve on new HIV infections if PrEP is only accessible to adults with disposable income. However expanding access to PrEP for some communities will require identifying and addressing social-structural barriers to healthcare engagement that go beyond provision of free services. Any implementation strategy that fails to focus primary planning on communities most effected by the epidemic will increase rather than decrease disparities.

Future Directions for Research and Implementation

Given the immediate landscape, we are frankly more pessimistic than optimistic about the short-term potential for PrEP to be widely accessed and maintained among AMSM. This means that in the near term, controlling the HIV epidemic among AMSM will require doubling down on proven HIV prevention approaches, such as comprehensive and inclusive sexuality education, increasing condom use, facilitating testing, and reducing community viral load through increasing HIV-infected individuals' engagement in clinical care. We are far from maximizing the impact of these strategies among AMSM. Indeed, we are 35 years into the HIV epidemic and a recent analysis of the 93 HIV risk reduction programs in the Centers for Disease Control and Prevention's Compendium of Evidence-Based Interventions for HIV Prevention (2017) identified only four that were evaluated with samples that were mostly or exclusively young MSM aged older than 18 years (i.e., CLEAR and Together Learning Choices for young people living with HIV; Mpowerment and Young Men's Health Project for young MSM who are HIV-negative), and none that were evaluated primarily or exclusively with MSM under age 18 years (Mustanski & Fisher, 2016). New interventions

for young adult MSM have recently been found to be efficacious (Mustanski, Parsons, et al., 2018) and there is preliminary evidence for the first comprehensive sexual health education program for LGBTQ teens (Mustanski, Greene, Ryan, & Whitton, 2015) (which is currently being studied for scale up nationally in English and Spanish with 13–18 year old MSM). Although these recent advances represent enormous steps forward, the paucity of interventions for AMSM clearly indicates that we still have much work to be done, both in the development and dissemination of interventions focused on condoms, testing, and treatment.

This is not to suggest that we give up on the potential of PrEP. However, for PrEP to have a meaningful impact on HIV among AMSM, we suggest a number of considerations for both clinicians and scientists.

Clinical Guidelines.

First, it is necessary to consider whether current clinical indications for PrEP are appropriate for adolescents. CDC-issued guidance to providers currently states that the indications for PrEP are the same for adult and adolescent MSM. Specifically, PrEP is indicated for any HIV-negative man who is not in a monogamous relationship with another HIV-negative individual, and who has had any condomless anal intercourse or sexually transmitted infection in the past six months (US Public Health Service, 2017). However, adolescent sexual behavior is more intermittent and less predictable than adult behavior, which makes the applicability of these indications less clear for AMSM. For example, the current indications would not recommend PrEP for an adolescent prior to sexual debut, an adolescent who is newly sexually active but who happened to successfully utilize a condom in their first encounter, or an adolescent who is engaging in regular condomless sex with his first boyfriend that he believes to be HIV negative. Whether those recommendations are truly appropriate are unclear, as we simply do not have enough research to understand how early sexual behaviors unfold for AMSM and what implications that has for their evolving HIV risk. Until such a research base is established, we recommend adopting more liberal indications for AMSM. This approach would more appropriately account for the fact that AMSM have less well-established patterns of sexual behavior, and that only an adolescent, in collaboration with his healthcare provider and other trusted adults in his life, can begin to appreciate the trajectory his sexual behaviors are likely to take.

In addition to considering whether clinical guidelines adequately address the needs of AMSM initiating PrEP, we should also consider guidance regarding termination. Few AMSM will remain on PrEP for their entire lives. Even among adults, we know little about how or why people naturally initiate and terminate PrEP use over time (Morgan, Ryan, et al., 2018; Whitfield, John, Rendina, Grov, & Parsons, 2018), and what patterns of intermittent use are most effective for protecting individuals from HIV over the lifespan. As we initiate PrEP use at younger ages, the need to understand these patterns will become even more important.

Family and Ethical Considerations.

With appropriate clinical indications in place, we will also need to create a motivated market for PrEP among AMSM and their parents. We see parent involvement in PrEP access as crucial (although not necessary or sufficient). It is a unique adolescent that could access and fund an expensive medication, and then to adhere to the daily pill regimen and accompanying quarterly medical appointments, all without parent awareness and/or engagement. Studies of parent and adolescent perspectives on PrEP will support development of messaging and education campaigns to help young men and their parents appreciate PrEP's value, and to understand how they might access, fund, and adhere to the regimen. Moreover, it is possible that certain subgroups of AMSM (and families) will have greater challenges in accessing and adhering to PrEP, and research to identify these individuals and support them will be critical to preventing disparities from evolving.

Policy analysis and ethics research can also help guide the path forward when parents may not be involved in adolescent PrEP use by helping to describe (and possibly change) the legal landscape and identify protections and supports needed by adolescents self-consenting to PrEP. For example, legal and policy analyses have helped describe if state laws that allow adolescents to consent to medical care, including HIV testing and treatment, relate to the provision of PrEP for prevention of HIV infection (Culp & Caucci, 2013). Ethics research can help inform policies and principals that promote adolescent access to sexual healthcare, including PrEP, while recognizing that some adolescents may lack supportive families. For example, research can help create developmentally-informed tools that facilitate adolescent informed consent for PrEP use and that support adherence and sustained use.

Alternate PrEP Formuations.

Research on alternate delivery systems for PrEP is already well underway. Longer-acting formulations (i.e., injectables or implants) have the potential to reduce challenges for adherence, and might in some cases make it more feasible for AMSM to utilize PrEP outside of parent awareness. However, as these technologies are developed and studied, it is imperative that adolescent needs be considered. Differences among the various technologies will likely exist with respect to methods of administration (an injection for the long-acting shot vs. a very minor surgical procedure for the implant), duration of effect (long-acting shots typically last a few months, whereas implants might last up to a year or longer), and profiles of side effects. In considering these factors, lessons learned from dissemination of hormonal contraception in adolescent girls might be useful. For example, recent research suggests that despite clinical guidance and public health messaging urging use of longer-acting forms of hormonal contraception in adolescents, girls ages 15–19 are still far more likely to have ever tried daily oral contraception (55.5%) than a long-acting injection (17.2%), and only a small proportion have ever utilized an implant (3.0%) (Itriyeva, 2018). Barriers to utilization of longer-acting forms of contraception among adolescents include greater cost, more difficult access, patient misperceptions about the technologies, and provider concerns about the appropriateness of the method for adolescents, all of which are likely to be at play when these formulations become available for PrEP (Itriyeva, 2018). Additionally, different PrEP formulations require different behaviors to support their utilization, and those behaviors must also be considered from the perspective of adolescents.

As an example, the long-acting injectable formulations of PrEP currently wash out of the body slowly, such that after drug levels have dropped below the therapeutic level necessary to provide protection from HIV, a sub-therapeutic level remains (Landovitz, Kofron, & McCauley, 2016). While the clinical implications of this are still being studied, it is possible that individuals who get infected during the wash-out period vulnerable to developing resistant virus. Thus, daily, oral PrEP has been suggested to cover individuals during this window. However, if injectable PrEP is meant to reduce concerns we have about AMSM adhering to daily oral PrEP in the first place, we must consider whether it is feasible to expect them to be adherent to oral medication for the amount of time necessary for safe termination of an injectable.

Implementation Science.

Finally, implementation science methods should be used to create generalizable knowledge about the characteristics of stakeholders, organizations, communities, and individuals that impact effective PrEP utilization among AMSM, as well as the strategies that can help close the gap between what is learned in research and routine practice in healthcare settings (Odeny et al., 2015). As researchers are contemplating research studies to improve effective AMSM PrEP utilization, we encourage consideration of hybrid, rather than classic, trial designs. Hybrid effectiveness-implementation trials range from type 1 (focus on effectiveness while gathering information on context for implementation) to type 3 (tests of implementation strategies while gathering information on effectiveness) (Curran, Bauer, Mittman, Pyne, & Stetler, 2012). Such designs could help accelerate the pace of PrEP implementation among AMSM more rapidly than beginning with traditional trial designs focused initially only on efficacy. Simulation modeling is also a form of implementation science that can help inform AMSM PrEP implementation. For example, some may wonder if resources should be expended on PrEP implementation among AMSM, or if coverage among young adult MSM is sufficient (i.e., a form of “herd immunity”). For this to be the case, the sexual networks of AMSM and young adult MSM would need to be sufficiently interconnected that reducing HIV transmission rates in young adults would be sufficient to impact transmissions in AMSM. To date there is very little research on ages of sexual partners among AMSM, but the data that do exist suggest that age differences tend to be small (i.e., 1–2 years on average) (Mustanski, Newcomb, & Clerkin, 2011; Newcomb, Ryan, Garofalo, & Mustanski, 2014). Early simulations designed to address this question have found that adult focused PrEP program would likely reduce HIV prevalence among AMSM, but that PrEP uptake in 16–18 year old MSM would lead to further reductions among AMSM (Hamilton et al., 2019). These data and models suggest the added prevention value of PrEP among AMSM, and also speak to the value of observational and simulation studies to help inform implementation strategies.

Conclusions

The U.S. National HIV/AIDS Strategy recommends providing HIV risk populations access to effective prevention, such as pre-exposure prophylaxis (PrEP), which was recently FDA approved for adolescents. However, this strategy will fail if the field has no evidence-based interventions to offer AMSM, and it is disturbing to note the relative dearth of studies on the

efficacy of PrEP and other behavioral and combination strategies for AMSM under age 18 years. Differences in neurodevelopmental, psychosocial, and familial characteristics between adolescents and adults mean that prevention strategies tested on older MSM may be ineffective in younger populations (e.g., more rapid discontinuation of PrEP) or even iatrogenic (e.g., condomless sex with poor PrEP adherence). As PrEP becomes more of a priority for HIV prevention initiatives, we must address the lack of scientifically informed and adolescent-appropriate approaches to implement HIV prevention strategies. Only then will we see PrEP begin to prove its value among AMSM.

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