



HRC POLICY PAPER ON

# PRE-EXPOSURE PROPHYLAXIS (PrEP)

According to the Centers for Disease Control and Prevention (CDC), there are over 1.1 million Americans currently living with HIV and approximately 50,000 new infections every year.<sup>1</sup> While HIV affects Americans from all walks of life, the virus continues to disproportionately impact members of the lesbian, gay, bisexual, and transgender (LGBT) community. For example, almost two-thirds of new HIV infections are among gay and bisexual men.<sup>2</sup> Black men, in particular, bear the biggest burden of these new infections, as they are six times more likely to contract HIV in a given year than white men.<sup>3</sup> Additionally, recent studies suggest that transgender women are 34 to 49 times more likely to have HIV than the general population.<sup>14</sup> These data indicate the need for additional HIV prevention strategies, as those rates of infection are hugely disproportionate to the actual size of these populations. Fortunately, there are now more ways than ever to prevent HIV, including the use of Truvada for Pre-Exposure Prophylaxis (PrEP). PrEP is any medical or public health tool used to prevent the spread of a disease or infection prior to exposure.<sup>5</sup> Truvada is the only brand name anti-HIV drug combination currently approved for PrEP. In this context, PrEP is an HIV prevention strategy that includes taking Truvada before exposure to reduce the risk of becoming HIV-positive.

## OUR POSITION

HRC explicitly endorses the use of Truvada for PrEP as a key aspect of a comprehensive preventive care regimen. We believe that PrEP is a critically important tool that must be part of any and all efforts to end the HIV/AIDS epidemic in the United States. We join the growing number of LGBT and allied organizations calling for increased PrEP implementation, access and education. With someone becoming newly infected with HIV every 9-1/2 minutes<sup>6</sup> and PrEP's efficacy and safety becoming increasingly understood, we feel a responsibility to make sure everyone has the opportunity to discuss PrEP with a knowledgeable healthcare provider and the ability to access PrEP if it is recommended for them. It is important to note that HRC's recommendation applies especially to populations deemed most vulnerable to HIV infection. Truvada is not right for all individuals, and any medical decision should be made in concert with a knowledgeable healthcare provider.

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1 While few studies have been done to assess HIV infection rates among transgender men and gender-variant people, we believe these communities may also be at greater risk.



## OUR REASONING

HRC has carefully weighed the evidence, and we believe PrEP's potential to help end the HIV/AIDS epidemic in the United States far outweighs any remaining uncertainties about it. We support increased PrEP implementation, access and education for the following reasons:

### 1. PrEP is effective.

CDC notes that, "when taken consistently, PrEP has been shown to reduce the risk of HIV infection in people who are at high risk by up to 92 percent."<sup>7</sup> Several clinical trials have demonstrated the effectiveness of PrEP among gay and bisexual men, transgender women who have sex with men, heterosexual women, and couples where one person is HIV-positive and the other is HIV-negative. The largest study to date of PrEP's effectiveness among gay and bisexual men and transgender women is the [iPrEx study, which randomly assigned 2,499 HIV-negative gay and bisexual men and transgender women to receive Truvada – the only brand name anti-HIV medication currently approved for PrEP – or a placebo. The study showed an overall efficacy rate of 42 percent when comparing the 'Truvada group' to the 'placebo group.'](#)<sup>8</sup> However, the 'Truvada group' included people who were offered Truvada but did not take it. [When researchers looked at data only from people who took the drug regularly, they found that transmissions dropped by as much as 92 percent.](#)<sup>9</sup> Further analyses indicate those individuals who took Truvada every day were protected against HIV by as much as 99 percent.<sup>10</sup> Similar findings from the [iPrEx OLE, Partners PrEP, TDF2 and Bangkok Tenofovir](#) strongly suggest PrEP works when taken as prescribed.<sup>11</sup>

### 2. PrEP is safe and generally well tolerated.

According to the Food and Drug Administration (FDA), Truvada's safety for PrEP was demonstrated in two large, randomized, double-blind, placebo-controlled clinical trials (i.e. iPrEx and Partners PrEP).<sup>12</sup> Some people who participated in the trials experienced early side effects such as transient nausea or loss of appetite, but these were mild and usually went away within the first month.<sup>13</sup> Truvada sometimes adversely affects the kidney, but that, too, is uncommon and rarely becomes a serious health issue.<sup>14</sup>

### 3. PrEP promotes sexual health and wellness.

Contrary to popular belief, PrEP is more than just a pill. It is a comprehensive HIV prevention strategy that should also include routine testing for sexual transmitted diseases (STDs), risk-reduction counseling, and other forms of HIV prevention such as consistent condom use. In this way, PrEP promotes sexual health and wellness by giving those at substantial risk for contracting HIV a reason to think proactively about their sexual behavior. Qualitative data presented by Kim Koester at the 20<sup>th</sup> International AIDS Conference in July 2014 seems to support this claim. In-depth interviews with a purposeful sample of participants in the iPrEx OLE study found that, "People on PrEP seem to be more mindful about sex."<sup>15</sup> PrEP users seem to have a greater awareness of their sexual behaviors and recognize the need for increased HIV prevention practices.<sup>16</sup> In other words, PrEP is an important tool for those at substantial risk of contracting HIV to enhance the protection already afforded to them by condoms and other HIV prevention strategies. PrEP further enables people to lead sexually healthy and fulfilling lives, including those in relationships where one partner is HIV-negative and the other is HIV-positive.



## OUR RESPONSIBILITY

HRC does not take this position lightly. We recognize there is still ongoing debate about PrEP, and that there are those out there who will disagree with our stance. However, HRC does not believe this is reason enough to justify denying people the opportunity to make an informed decision about PrEP with a knowledgeable healthcare provider. Nor does it justify stigmatizing those who may ultimately decide to use PrEP. HRC is aware of many of the concerns surrounding PrEP, including:

- 1. Adherence** – Adherence has been, and continues to be, a major concern related to PrEP, as failure to regularly take the medication can significantly diminish its efficacy. According to the CDC, “Data from the published studies of daily oral PrEP indicate that medication adherence is critical to achieving the maximum prevention benefit and reducing the risk of selecting for a drug-resistant virus if non-adherence leads to HIV acquisition.”<sup>17</sup> Rather than dismiss the viability of PrEP because of issues with adherence, HRC believes we should invest in the various approaches that have been shown to help people take their medication. These approaches include “educating patients about their medications; helping them anticipate and manage side effects; helping them establish dosing routines that mesh with their work and social schedules; providing reminder systems and tools; addressing financial, substance abuse, or mental health needs that may impede adherence; and facilitating social support.”<sup>18</sup> HRC is encouraged by the PrEP demonstration projects happening across the country, which suggest a high level of PrEP adherence is attainable.<sup>19</sup>
- 2. Cost** – On average, Truvada costs approximately \$1,300 per month, which can be prohibitively expensive for many of the individuals who need it the most.<sup>20</sup> Gilead – the manufacturer of Truvada – offers payment assistance programs to those with and without insurance. However, high copays and deductibles can still be a burden to people with suboptimal insurance plans. HRC believes more can be done – in the public and private sector – to bring down the cost of Truvada for consumers, such as the PrEP Drug Assistance Program recently launched in the State of Washington<sup>21</sup> and Gilead’s recent decision to expand their payment assistance program to include those earning less than \$58,000 per year<sup>22</sup>.
- 3. Access** – Most private insurance providers and Medicaid cover Truvada, which can also be used alongside other medications to treat people living with HIV. However, there is reason to believe some insurance providers are generally unaware of the fact that Truvada has been approved for PrEP, as some HIV-negative men have had their requests for Truvada initially denied. Furthermore, some insurance providers have placed difficult-to-understand pre-authorization restrictions on Truvada for PrEP, which may inadvertently deter people from beginning the regimen. HRC believes some of these barriers to PrEP can – and should – be lowered alongside increased consumer education.
- 4. Risk compensation** – There is a concern that PrEP will encourage people to engage in riskier sexual behavior, such as increased condomless anal or vaginal sex. But researchers have yet to see this behavior occur en masse in any of the clinical trials that have been done to date.<sup>23</sup> In fact, they have seen evidence to the contrary – that PrEP users may engage in less risky sexual behavior over time.<sup>24</sup> In iPrEX OLE, for example, “self-reported sexual risk behavior declined during the study: at the start, 34 percent of those allocated PrEP reported receptive anal sex without a condom and this dropped to 25 percent during the study; in those not taking allocated PrEP, it started at 27 percent and ended at 20 percent, in other words being allocated PrEP made no difference to risk behavior.”<sup>25</sup> Even so, HRC strongly supports federal guidelines, which recommend continued condom use while on PrEP.<sup>26</sup> It is important to note that Truvada does not provide protection against other sexually transmitted



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diseases. With STDs such as syphilis on the rise, and with their capacity to lead to life-threatening conditions if untreated, it is important for sexually active individuals to protect themselves by engaging in safer sex practices and getting tested regularly.

5. **Resistance** – There is a concern that those taking Truvada may become resistant to the medication in the event they become HIV-positive. While research suggests this is not a significant cause for concern, there is reason to believe drug resistance may occur if someone is in the early stages of recently acquired HIV infection and unknowingly begins to take PrEP.<sup>27</sup> PrEP is only intended for those individuals with a recent HIV-negative test result.
6. **Interaction with other drugs** – Although there is some evidence to support PrEP's efficacy among transgender women who have sex with men<sup>28</sup>, more research should be done to determine what effect, if any, PrEP has on transgender men and women utilizing hormone replacement therapy. These types of population-specific concerns are important to keep in mind when discussing PrEP and underscore the need for research specifically designed to address the concerns of transgender people.

## OUR CALLS TO ACTION

It would be wrong to advocate for the use of a proprietary pharmaceutical without taking aggressive steps to help guarantee affordable access to the drug in question. After all, people of all backgrounds can contract HIV, and those who are least empowered to access or afford treatment are also most at risk. That is why HRC is also targeting five key audiences with campaigns to expand access, improve affordability, and expand education about the benefits of a PrEP regimen.

HRC makes the following requests of stakeholders:

1. **Centers for Medicare and Medicaid Services:** HRC calls on the Centers for Medicare and Medicaid Services (CMS) to accelerate dissemination of expanded guidance and support about PrEP and its administration to all agencies and providers.
2. **Gilead Sciences:** HRC acknowledges Gilead Sciences, the manufacturer of Truvada, for their efforts to increase access and co-pay assistance for low-income individuals. HRC urges Gilead to reduce the staggering cost of the drug in furtherance of expanded access. Furthermore, we urge Gilead to undertake a public awareness campaign to increase consumer knowledge of these affordability options.
3. **State Officials:** HRC calls on the directors of state Medicaid programs to investigate best practices for increasing access to PrEP for individuals within their jurisdictions. Importantly, those states that have yet to expand Medicaid should do so swiftly in order to ensure low-income Americans have access to PrEP. Additionally, we call on states to look to the Washington State Department of Health in their creation of a PrEP Drug Assistance Program as a potential model.
4. **Chief Insurance Regulators in all 50 states:** HRC calls on each state's chief insurance regulator to aggressively disseminate formulary and co-pay best practice information to all insurers—and to pursue all insurers who deny legitimate claims for HIV-negative patients who, with the blessing of their provider, seek to utilize PrEP.
5. **Top 25 Insurance Companies in the United States:** HRC calls on the nation's leading



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insurance companies to undertake a stem-to-stern revision of their formulary and co-pay standards as they relate to PrEP. In all cases, access standards should be consistent across state lines, co-pays should be lowered, and full access to PrEP for those who qualify should be prioritized. In addition, insurance companies should further educate subscribers and providers on PrEP eligibility.

## CONCLUSION

PrEP is not a universal solution. But the evidence is clear – when taken as prescribed, PrEP is a safe and effective tool to prevent HIV infection. Furthermore, implementation studies currently underway are helping us better understand how to solve some of PrEP's operational challenges. As we continue our efforts to support HIV-positive people in connecting to and staying in care, we must also educate those who are HIV-negative about the many prevention options available to them, encourage routine testing, and combat stigma, which often keeps so many in the LGBT community from getting tested or treated for HIV in the first place.

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