

Globally, HIV continues to be a major public health problem. There are 36.9 (31.1- 43.9) million people living with HIV (PLWH) in the world.¹ The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) is a global initiative dedicated to preventing new HIV infections and ensuring that PLWH have consistent access to HIV treatment and care. Prevention, treatment, and care are key to reducing the number of new HIV infections globally. HIV treatment, specifically antiretroviral therapy (ART), has improved the quality of life and life expectancy of PLWH and has transformed HIV into a manageable chronic disease<sup>2, 3, 4</sup>. Research conducted during the last decade has also demonstrated the impact of HIV treatment in preventing the sexual transmission of HIV, referred to as "Treatment as Prevention" (TasP).<sup>5, 6, 7,8,9,10,11</sup>

To promote the public's understanding of TasP, the Prevention Access Campaign developed the Undetectable = Untransmittable (referred to as U=U) campaign. The goal of the U=U campaign is to increase awareness about the relationship between viral suppression and the sexual transmission of HIV. Specifically, that PLWH who take their ART medicine daily as prescribed and achieve and maintain an undetectable viral load cannot sexually transmit HIV to their partners. According to the Prevention Access Campaign, the U=U message improves the lives of PLWH by reducing the fear of sexual transmission, decreasing HIV stigma, encouraging medication adherence, and strengthening advocacy efforts for universal access to HIV treatment. Approximately 850 organizations from 97 countries have shared the U=U message to-date and the campaign has been translated into more than 25 languages, including K=K in Vietnamese, N=N in Dutch, B=B in Turkish, and I=I in Spanish, Italian, and Portuguese . 13

This technical brief aims to: 1) describe the scientific evidence that supports the TasP strategy and U=U campaign; 2) examine factors associated with the implementation of the U=U campaign; and 3) explain the importance of the TasP strategy and U=U campaign for HIV programs supported by the Division of Global HIV and Tuberculosis (DGHT).



### **SCIENTIFIC EVIDENCE**

In 2011, the interim results of the HIV Prevention Trials Network (HPTN) 052 randomized controlled trial among 1,763 HIV serodiscordant couples revealed that PLWH who started ART immediately had a 96% reduction in HIV transmission risk to their HIV-negative partner versus those who delayed ART initiation.<sup>5,6</sup> Similarly, the final results released in 2016 indicated no sexual HIV transmissions within couples where the HIV-positive partner had a suppressed viral load. A suppressed viral load was defined as having a viral load of less than 400 copies of HIV RNA per milliliter.<sup>6</sup> There were eight genetically linked HIV infections among couples where the HIV-positive partner was taking ART but had not achieved and maintained viral suppression.

Comparable results were reported in the Partners of People on ART—A New Evaluation of the Risks (PARTNER) <sup>7</sup>, Opposites Attract<sup>8</sup>, and PARTNER2 studies. <sup>9</sup> The PARTNER2 study was an extension of the PARTNER study conducted among HIV-discordant MSM couples. None of the aforementioned observational studies reported new genetically linked HIV infections among couples who engaged in condomless sex when the HIV-positive partner was virally suppressed. Of note, the HIV-negative partners were not taking pre-exposure prophylaxis (PrEP). While viral suppression was defined as less than 200 copies of HIV RNA per milliliter of blood for all three studies, 94% of HIV-positive participants in the PARTNER study had less than 50 copies of HIV RNA per milliliter of blood. <sup>7</sup> Collectively, the three studies were comprised of more than 500 HIV-discordant heterosexual couples and more than 1,300 HIV-discordant MSM couples. Couples in the studies engaged in over 125,000 sex acts without PrEP or a condom. <sup>7,8,9</sup> . The scientific evidence demonstrates that the TasP strategy may reduce new HIV infections and lead to epidemic control of HIV.

# **FACTORS TO CONSIDER**

The success of the TasP strategy and U=U campaign is contingent upon PLWH achieving and maintaining viral suppression. As of 2017, 75% of people living with HIV were aware of their status, 79% were accessing HIV treatment, and 81% were virally suppressed. Health care workers, PLWH, and others affected by HIV need clear and concise information about factors at each level of influence (i.e., intrapersonal, interpersonal, community, institutional, and structural) that may impede the achievement and maintenance of viral suppression for PLWH. Before discussing the U=U campaign in global settings, health care workers should be aware of the following factors:



### **FACTORS TO CONSIDER**

**Lack of awareness and knowledge about viral suppression:** Awareness and knowledge of the importance of viral suppression to prevent transmission of HIV and improve their own health may motivate PLWH to consistently take their ART. However, research demonstrates that some PLWH either do not know or do not believe that viral suppression is a HIV prevention strategy. <sup>15, 16, 17</sup>

**Duration of ART prior to achieving viral suppression:** Most people will achieve an undetectable viral load within 6 months of starting ART. The HPTN 052 trial found no HIV transmissions at both 3 and 6 months since ART initiation. <sup>6</sup>

**Knowledge of viral load level:** Research findings indicate a discordance between study participants self-report of their viral load level and laboratory testing. <sup>18</sup> It is important for PLWH to know and understand their viral load level.

**Monitoring of viral load:** The World Health Organization recommends regular viral load monitoring to confirm that a person living with HIV has achieved and maintained viral suppression. <sup>19</sup> Yet, large gaps exist in global access to viral load monitoring in low- and middle-income countries and rural areas.

**Medication adherence:** Taking ART daily as prescribed will help PLWH achieve and maintain an undetectable viral load. If a person living with HIV misses multiple doses or stops taking their HIV medication this will result in an increased viral load and a risk of transmitting HIV sexually. People who are having a difficult time taking ART daily as prescribed should speak with their health care providers to improve their medication adherence and discuss other prevention strategies to prevent sexual transmission of HIV.

**People Who Inject Drugs:** Currently, there is limited evidence on whether taking ART and achieving and maintaining viral suppression prevents HIV transmission among people who share needles, syringes, and other injection drug equipment. In the HPTN 052 trial and PARTNER studies, only 2% or fewer of the study participants reported injection drug use.<sup>6, 7</sup>

**Prevention of mother-to-child transmission:** There is insufficient evidence to know if a woman living with HIV who is virally suppressed can transmit HIV to her baby through breastfeeding. However, if a woman living with HIV takes ART daily as prescribed throughout pregnancy and childbirth, and ART drugs are administered to the baby for 4-6 weeks after delivery, the risk of HIV transmission can be reduced to  $\leq 1\%$ .<sup>20</sup>

**Protection against Sexually Transmitted Infections (STIs):** Taking ART and achieving and maintaining viral suppression will not protect either partner from acquiring other STIs. Condoms can be used to provide protection from STIs and unintended pregnancies. However, the PARTNER 1 and 2 and Opposites Attract studies found that among serodiscordant couples where the PLWH was virally suppressed, when one of the partners had a STI and the couple engaged in condomless sex the STI was not transmitted to the other partner.<sup>7,8,9</sup>



### **CURRENT DGHT EFFORTS**

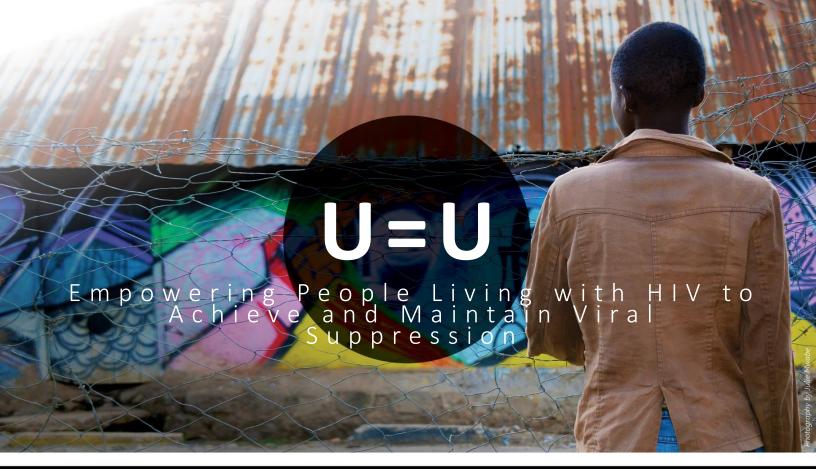
Within the U.S. Centers for Disease Control and Prevention (CDC), DGHT continues to work with policy makers, health care providers, civil society organizations, and other partners across the globe to educate and increase the awareness and impact of the TasP strategy and U=U campaign. The CDC is supporting HIV prevention efforts across Africa, Asia, Eastern Europe, Central America, and Caribbean regions through five prevention pillars:

- Supporting PLWH to know their status and receive ART through HIV case-finding, testing, and linkage of PLWH to treatment and care services;
- Providing HIV prevention, treatment, and care services for key populations<sup>21</sup> (i.e., people who inject drugs, sex workers, men who have sex with men, transgender persons, and people in prisons and other closed settings) and other populations (e.g., adolescent girls and young women);
- Preventing primary HIV infection through Voluntary Medical Male Circumcision (VMMC), condom promotion and distribution, and parent-child interventions (e.g., Families Matter!) and other youth programs and interventions:
- Introducing and accelerating HIV prevention interventions, such as PrEP and HIV self-testing; and
- Strengthening the usage and availability of data to inform prevention program improvements, including routine monitoring and evaluations, and prevention research and evaluations.

# **FUTURE DGHT EFFORTS**

DGHT will continue to provide technical assistance to partners and evaluate programmatic efforts focused on the TasP strategy and U=U messaging to increase awareness, knowledge, motivation, and behavior change among PLWH. Simultaneously, DGHT will effectively communicate and disseminate resources on all HIV prevention options to assist countries, PLWH, and those affected by HIV. It is vital that PLWH who cannot achieve viral suppression are not stigmatized and receive support as well as access to multiple prevention options. DGHT will continue to provide support for PLWH to have increased access to regular viral load monitoring. Additionally, it will be critical for DGHT to integrate TasP and U=U communication messages into existing PEPFAR programs and materials. DGHT will strive to engage and empower PLWH and their partners and representatives, field officers, health care workers, civil society organizations, faith-based organizations, and all international and national implementing partners to incorporate U=U messages into HIV treatment and care practices.





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