



## Department of Health

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Dear Colleagues:

Though I usually cover two topics each month, I have chosen to focus on just one for my September letter. The reason for this decision is to ensure that all practitioners are aware of recent significant scientific developments and publications which have a direct impact on one of our most important initiatives: ending the AIDS epidemic in New York State. These developments address the concept of Treatment as Prevention (TasP), which the broader HIV-affected community refers to as Undetectable=Untransmittable, or U=U. There is now evidence-based confirmation that the risk of HIV transmission from a person living with HIV who is on Antiretroviral Therapy (ART), and has achieved an undetectable viral load in their blood for at least 6 months, is negligible. (Negligible is defined as: *so small or unimportant as to be not worth considering; insignificant.*)<sup>1</sup>

As many of you know, for more than a decade clinical trials and cohort studies have indicated that adherence to effective ART reduces the risk of HIV transmission. Today, with immediate ART treatment recommended for all individuals living with HIV, TasP has become the accepted strategy for reducing new infections. Cumulative, evidence-based scientific data supporting the concept of U=U has confirmed the previous epidemiological conclusion posited in 2008: effective antiretroviral therapy blocks HIV sexual transmission.<sup>2</sup>

In 2011, *The New England Journal of Medicine* published the interim results of the HIV Prevention Treatment Network (HPTN) 052 study, in which more than 1700 sero-discordant heterosexual couples were randomly assigned to either having the HIV positive partner immediately start ART or delay the start of ART.<sup>3</sup> The randomized phase of the study was stopped early because of the overwhelming evidence demonstrating that of the 28 HIV transmissions linked to the HIV partner, 27 occurred in those randomized to delay treatment until the WHO CD4 count based criteria were met. The single linked HIV transmission in the immediate antiretroviral therapy group occurred within the early weeks of therapy prior to full viral suppression.<sup>3</sup> In 2016, *The New England Journal of Medicine* published the final results of the study which showed eight linked transmissions with four prior to viral suppression and four due to treatment failure.<sup>4</sup> Over time, results showed no linked transmissions when the index (HIV+) partner's viral load was fully suppressed; and the study also showed that initiating ART early reduces transmission. The evidence for suppressive antiretroviral therapy in curtailing HIV heterosexual transmission has been effectively and definitely established.

The evidence for fully suppressive antiretroviral therapy curtailing HIV transmission in heterosexual couples, as well as in same sex male couples engaging in anal sex, was demonstrated in the observational cohort PARTNER study published in JAMA in 2016.<sup>5</sup> Approximately a third of the nearly 900 couples in the PARTNER Study were gay men; in more than 58,000 condomless sexual acts there were no reported linked HIV transmissions when viral load was undetectable (defined as less than 200 copies/mL).<sup>5</sup> This summer, at the International AIDS Conference in Paris, the results of the Opposites Attract study were presented, which also found no linked HIV transmissions in nearly 17,000 condomless sexual acts by 358 gay male couples. HIV negative partners were taking PrEP for about 5,000 of those sexual acts, which equates to roughly 12,000 sexual acts with only viral suppression as the HIV prevention method.<sup>6</sup>

The robust results from these clinical trials have led global authorities on AIDS research and policy to support the broader community message that individuals with a durable undetectable viral load will not sexually transmit HIV, or "Undetectable equals Untransmittable" (U=U). The cumulative scientific evidence is

clear: the risk of sexual transmission of HIV from someone with a fully suppressed HIV viral load is negligible.

The findings from these three large-scale studies have definitively demonstrated that not only does effective antiretroviral therapy improve the individual health of each person with HIV, it also prevents the transmission of HIV to their sexual partners. This evidence affirms the second goal in Governor Cuomo's Ending the Epidemic Blueprint: 'Link and retain persons diagnosed with HIV in care to maximize HIV virus suppression so they remain healthy and prevent further transmission'. The goal for us as clinicians will be to support patients in maintaining successful HIV treatment.

New York State has always been committed to and will continue to support efforts to improve patient health and well-being; the evidence affirming Treatment as Prevention provides another pillar in our progress toward ending the epidemic by the end of 2020.

U=U opens a new and hopeful chapter in the HIV epidemic. Therefore, based on the current scientific evidence, the unprecedented opportunity U=U brings to improving the lives of people living with HIV and our work to dismantle HIV stigma and discrimination, the Department has signed onto the Prevention Access Campaign Consensus statement that the *risk of sexual transmission of HIV from a person living with HIV who has an undetectable viral load is negligible*<sup>1</sup>. The New York State Department is the first state health department to endorse the Prevention Access Campaign Consensus Statement. Working together we can provide clear messaging in New York State about the benefits of sustained viral load suppression.

Thank you for all your work in our goal to End the Epidemic! Lastly, please remember to get your flu shot.

Sincerely,

Howard A. Zucker, M.D., J.D.  
Commissioner of Health

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