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PERSPECTIVES

Redefining Prevention and Care: A Status-Neutral Approach to HIV

Julie E. Myers,[1,2] Sarah L. Braunstein,[1] Qiang Xia,[1] Kathleen Scanlin,[1] Zoe Edelstein,[1] Graham Harriman,[1] Benjamin Tsoi,[1] Adriana Andaluz,[1] Estella Yu,[1] and Demetre Daskalakis[1]

[1]Bureau of HIV/AIDS Prevention and Control, New York City Department of Health and Mental Hygiene, New York, New York; [2]Division of Infectious Diseases, Department of Medicine, Columbia University College of Physicians and Surgeons, New York, New York

Recent biomedical advances inspire hope that an end to the epidemic of HIV is in sight. Adopting new approaches and paradigms for treatment and prevention in terms of both messaging and programming is a priority to accelerate progress. Defining the key sequential steps that comprise engagement in HIV care has provided a useful framework for clinical programs and motivated quality improvement initiatives. Recently, the same approach has been applied to use of pre-exposure prophylaxis for HIV prevention. Building on the various prevention and care continua previously proposed, we present a novel schematic that incorporates both people living with HIV and people at risk, making it effectively "status-neutral" in that it proposes the same approach for engagement, regardless of one's HIV status. This multidirectional continuum begins with an HIV test and offers 2 divergent paths depending on the results; these paths end at a common final state. To illustrate how this continuum can be utilized for program planning as well as for monitoring, we provide an example using data for New York City men who have sex with men, a population with high HIV incidence and prevalence.

Keywords. antiretrovirals; continuum; HIV; prevention; pre-exposure prophylaxis.

The HIV epidemic has evolved over the past 3 decades; its end is now in sight. Yet, despite major progress and the existence of epidemic-ending technology, HIV continues to spread, with at least 37 000 new diagnoses in the United States in 2014 [1]. These new diagnoses add to the more than 1.1 million persons living with HIV (PLWH) in the United States [1]. Given these staggering numbers, adopting new approaches and paradigms for treatment and prevention messaging and programming is critical. This is especially true in the era of "treatment as prevention," where it is now empirically clear that achievement of viral load suppression has implications for both individual and public health [2–4], and where pre-exposure prophylaxis (PrEP) represents a viable, highly effective biomedical intervention for HIV prevention [5–8].

Building on earlier innovative HIV prevention and care continua [9–17] following the original care continuum proposed by Gardner [9] and colleagues, we present a novel schematic of the current care environment that incorporates both PLWH and people at risk of HIV exposure (Figure 1). This multidirectional continuum begins with an HIV test and proposes 2 dynamic, divergent paths depending on the test results ("HIV Primary Prevention Engagement" on the left for those testing negative; "HIV Treatment Engagement" on the right for those testing positive) that end at a common final state: engaged in clinical care, with either sustained viral load suppression (VLS) or taking daily PrEP, reflecting that the risk of either HIV transmission or acquisition is negligible in this state. Such a continuum is effectively "HIV status-neutral" in that it proposes the same approach for engagement, regardless of one's HIV status.

A key characteristic of this "cycle" is its nonlinearity. Continuous preventive and quality care services are highlighted as part of an ongoing effort by patient and provider to maintain engagement in clinical preventive care or treatment. The end point is not a final state but a dynamic one requiring continued attention by all parties. The figure emphasizes the consistent return among the uninfected to HIV testing, with a resultant trajectory into and through the continuum, as appropriate, depending on test results (and on the appropriateness of PrEP for those testing negative).

We illustrate how this continuum can be utilized by applying data for men who have sex with men (MSM) aged 18–40 years from NYC, a population known to have both a high incidence and prevalence of HIV infection attributed to sexual transmission. For the HIV Treatment Engagement cohort (Figure 1), we use NYC surveillance data on MSM, drawing on 2015 data from the NYC Department of Health and Mental Hygiene (DOHMH) surveillance registry and 2014 data from NYC's Centers for Disease Control and Prevention (CDC) Medical Monitoring Project (MMP) limited to respondents from NYC

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Correspondence: J. E. Myers, MD, MPH, 42-09 28th Street, Queens, NY 11101 (jmyers@health.nyc.gov).

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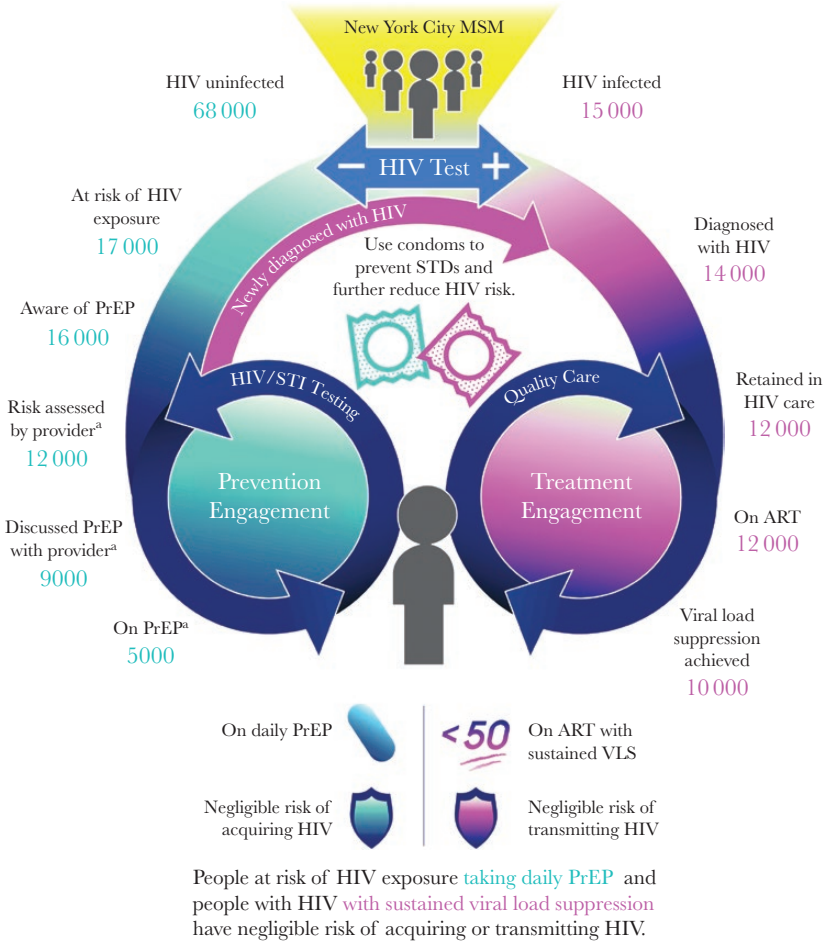

Figure 1. New York City's HIV status-neutral prevention and treatment cycle with estimates derived from HIV surveillance and local surveys. Data for the HIV-positive side of the continuum are derived from NYC surveillance data on men who have sex with men (MSM) aged 18–40 years, combining 2015 data from the surveillance registry with 2014 data from the NYC Medical Monitoring Project; data for the HIV-negative side of the continuum are derived from the Sexual Health Survey, conducted in Spring 2016 among NYC MSM aged 18–40 years who report anal sex with another man in the past six months and any of the following in previous 6 months, rendering them potentially at risk of HIV exposure and eligible for pre-exposure prophylaxis: condomless anal sex, stimulant or injection drug use, transactional sex, PEP use, HIV-positive sexual partner, or STI diagnosis in the past year. Numbers are rounded to the thousands. [a]Past 6 months. Abbreviations: ART, antiretroviral therapy; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; STD, sexually transmitted disease; VLS, viral load suppression.

[18, 19]. The "denominator" for all continuum steps is the number of cisgender MSM aged 18–40 years in NYC who are estimated to be HIV-infected (n = 15 000). Subsequent steps in the continuum are well described and defined when using population-based data: those who are diagnosed with HIV, followed by those retained in care, those prescribed antiretroviral therapy, and, finally, those achieving VLS [9, 20, 21]. The largest drop-off (33% relative decrease) is between those who are prescribed antiretrovirals and those who achieve VLS, highlighting the importance of medical and social interventions focused on maintenance of care and adherence.

For the HIV-negative Primary Prevention Engagement cohort, to derive the "denominator" of all cisgender MSM aged 18–40 years in NYC who are estimated to be HIV-uninfected (n = 68 000), we used data from the 2015 and 2016 Community Health Surveys [22], creating a weighted average estimate of all cisgender MSM aged 18–40 years (n = 83 000; 95% CI, 66 000–100 000), and subtracted the cisgender MSM aged 18–40 years estimated to be HIV-infected (n = 15 000). For most subsequent steps, we used data from the NYC DOHMH Sexual Health Survey (SHS), conducted semiannually online and annually in-person among NYC MSM aged 18–40 years who report anal sex with another man in the past 6 months [23–25]. The figure includes data from the Spring 2016 survey among respondents who reported any of the following in the previous 6 months, rendering them potentially at risk of HIV exposure and eligible for PrEP: condomless anal sex, stimulant or injection drug use, transactional sex, postexposure prophylaxis (PEP) use, HIV-positive sexual partner, or sexually transmitted infection (STI) diagnosis in past year.

For this HIV-negative cohort, the steps in the continuum are derived from NYC DOHMH work, as well as steps set forth

by other colleagues [10–13]. We begin with those who report behavior consistent with PrEP "candidacy," defined according to alignment with NYS PrEP prescribing guidance [26]; it has been previously estimated that approximately 25% of HIV-negative MSM have indications for PrEP [27] (n = 17 000, or 25% of the "denominator" for the HIV-negative cohort). From there, the steps include both client- and intervention-centric approaches; each is actionable from a public health perspective [15]; and estimates are derived using SHS.

This approach defines an arc from individual awareness to engagement in health care to taking daily PrEP. Further, we disaggregated critical aspects of PrEP-related clinical engagement, separating risk assessment conducted by a provider (operationalized as having had a provider visit at which a sexual history was taken) and discussing PrEP with a provider (regardless of who initiated the conversation). Awareness of PrEP is the only step that is not time bound; other steps refer to the past 6 months. Clearly, the steps for the HIV-negative cohort lack the inexorable, rigid progression that is characteristic of the HIV-positive side of the continuum. Specifically, individuals may become aware of PrEP from their provider. But awareness is often a recognized precursor to subsequent clinical engagement, so we present it as such herein.

The 2 largest drop-offs in the HIV-negative Primary Prevention Continuum are between having a sexual history taken and having a PrEP discussion with a provider (25% relative decrease), and from having a PrEP discussion with a provider to having initiated PrEP (44% relative decrease). There are any number of explanations for each of these substantial drop-offs, including both provider and patient factors that require elucidation through additional investigation. Importantly, in terms of patient factors, we expect that patient choice will play a critical role; PrEP will not be right for every person who meets existing criteria. One limitation of these data is that they are not population-based (as the HIV surveillance data are) or a representative sample of all NYC MSM.

This extension of the continuum framework to visualize treatment as prevention has several key implications. First, the continuum makes clear that HIV testing is the ultimate gateway to prevention and care. Any HIV test result spurs action. Clinical protocols in settings that provide care to vulnerable, high-incidence populations can build this philosophy into workflows by following HIV testing with the offer of antiretrovirals as treatment or as either PrEP or PEP depending on the HIV test result and the recentness of any possible exposure to HIV.

This "status-neutral" continuum also serves as a reminder that the same approaches used for achieving VLS for treatment will be necessary for HIV prevention, supporting more integrated prevention and care programs. The cyclic aspect of this visualization emphasizes that PrEP and other prevention engagement must provide a seamless entrée into the care system in the event that individuals engaged in primary prevention are newly diagnosed with HIV. The new continuum also highlights that approaches to serving people taking prophylaxis and people taking treatment are virtually indistinguishable both clinically and programmatically. The "double cycle" equates the person living with HIV who is consistently virally suppressed to the individual taking PrEP daily, thereby supporting a vision in which the clinical and social HIV "divide" is nonexistent. Normalizing both treatment and prevention serves to destigmatize both.

In our own Health Department, the continuum has engendered status-neutral messaging, starting with a sex-positive HIV prevention social marketing campaign, PlaySure [28], which was simultaneously geared toward those living with HIV and those at risk [28]; a subsequent campaign, StaySure [29], explicitly promoted treatment as prevention. The Health Department's #PlaySure Kit physically embodies that message, providing discrete transport for safer sex supplies, such as a "prevention" pill (HIV treatment or PrEP), condoms, and lubricant [30].

Extensive status-neutral programming followed, including the transformation of publicly funded sexually transmitted diseases clinics into more culturally competent sexual health clinics [31] that offer more comprehensive HIV services, including immediate antiretroviral therapy for those testing HIV-positive and pre-exposure prophylaxis for those testing HIV-negative, with navigation to clinical sites in the community for ongoing care or prevention [32]. And new programs were also developed citywide to offer navigation services through a robust referral network, sharing a name with the PlaySure campaign, for all persons regardless of HIV status at a combination of community-based organizations and clinical sites [33]. Additional programs, paid for with city funding, have been built on the Ryan White Care Coordination model to expand services to HIV-negative persons for engagement in PrEP, mental health, and substance use services. We recently rebid our portfolio of HIV testing contracts to align them with this approach and formally incorporate them into the PlaySure Network. A status-neutral, Health Department–convened community collaborative to improve testing and navigation services to black and Latino MSM in Brooklyn was also launched as part of a CDC-supported demonstration project (THRIVE) [34]. Further, New York Knows, the large-scale HIV testing initiative borne out of an earlier Bronx-specific campaign [35, 36], already focused on HIV testing and linkage to care, was expanded to provide technical assistance with PrEP implementation among 266 partner organizations [37]. A hands-on workshop to support diverse clinical sites to incorporate PrEP into existing workflows has been successful in supporting the development of PrEP-related protocols, including sites formerly focused on HIV care provision [38]. Future plans include developing protocols to initiate immediate, field-based antiretroviral therapy (as treatment or prevention) through partner services.

In the context of the ambitious goals for HIV prevention and care both locally [39] and nationally [40], tools are needed that

stimulate and guide thought and action and measure progress on a range of outcomes. We believe the synergies and dynamism inherent in our new status-neutral continuum help bring us closer to our critical goals: "virtually eliminating new HIV infections, effectively supporting all people with HIV to lead long and healthy lives, and eliminating the disparities that persist among some populations." [40]

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