

A Multicomponent Approach to Evaluating a Pre-exposure Prophylaxis (PrEP) Implementation Program in Five Agencies in New York

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Research has shown that pre-exposure prophylaxis (PrEP) is effective for preventing HIV infection. We developed the Targeted PrEP Implementation Program (TPIP), an 18-month project that involved five statewide agencies, to assess the extent to which PrEP could be implemented in “real world” clinical settings. The target population was men who have sex with men at high risk for HIV infection. Data were collected from a variety of sources. Implementing PrEP statewide required facilitating provider capacity, developing resources, and identifying/addressing potential barriers. TPIP focused on three key questions: (a) Can providers identify and retain appropriate candidates for PrEP? (b) Can PrEP participants adhere to daily medication? (c) Can PrEP be delivered as part of a comprehensive/integrated plan? There were 171 participating clients, most of whom successfully incorporated PrEP into their daily routines. After addressing initial barriers, we found that PrEP could be routinely delivered as part of a comprehensive prevention plan.

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The absence of an effective vaccine against HIV creates a need for alternative, high-impact HIV prevention tools to reduce the incidence of HIV infection

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(GroV, Whitfield, Rendina, Ventuneac, & Parsons, 2015). In 2009, studies were underway in the United States and other countries to determine if pre-exposure prophylaxis (PrEP) would be a safe and effective prevention method (Marcus et al., 2013). The New York State Department of Health AIDS Institute created an internal workgroup in 2009 to consider the benefits and challenges of implementing PrEP statewide.

Once the results of PrEP studies demonstrated effectiveness, the AIDS Institute began a small project to identify needed resources for statewide implementation of PrEP in real-world settings. AIDS Institute staff considered models of care, which persons would most benefit from PrEP, and how to integrate risk-reduction counseling, condom distribution, and adherence counseling with clinical visits. Of the many questions to be addressed were those related to payment for PrEP, which providers would be involved in PrEP services provision, and how to increase client awareness and staff knowledge of PrEP.

Epidemiologic data were reviewed to identify the project's target population. Data indicated that gay, bisexual, and other men who have sex with men (MSM) had been disproportionately affected by HIV, representing approximately 65% of new HIV infections in the United States, while representing just 2% to 5% of the total population (GroV et al., 2015; Daughtridge, Conyngham, Ramirez, & Koenig, 2014). In 2011, in the United States, MSM accounted for 79% of the 49,273 estimated HIV diagnoses in all men ages 13 years and older; (Centers for Disease Control and Prevention, 2012). During the same year in New York State, MSM accounted for 49.1% of newly diagnosed HIV infections. Based on these data, MSM were set as the target population for the implementation project.

We based the implementation project on established federal guidance and approval. The Centers for Disease Control and Prevention (2011) issued interim guidance for the use of PrEP with MSM in January 2011. In July 2012, the U.S. Food and Drug Administration approved tenofovir disoproxil fumarate/emtricitabine (TDF + FTC) for PrEP use (U.S. Food and Drug Administration, 2012), and in January 2014, the AIDS Institute released *Guidance for the Use of PrEP to Prevent HIV Transmission* (New York State Department of Health AIDS Institute Clinical Guidelines, 2014).

The Project

The Targeted PrEP Implementation Program (TPIP) was an 18-month project designed by the AIDS Institute to assess the extent to which PrEP could be implemented in “real world” clinical settings. The AIDS Institute invited five agencies (three located in New York City and two in upstate New York), which were already providing services to large numbers of MSM, to collaborate and participate in TPIP. These five agencies (a) had strong linkages to relevant community-based organizations (CBOs); (b) worked extensively with the lesbian, gay, bisexual, transgender, and questioning (LGBTQ) community and individuals living with and affected by HIV; and (c) were willing to participate in TPIP without additional funding. Prior to initiation of the project, a 3-hour webinar training was held with the involved health care agencies to discuss PrEP clinical guidance and the TPIP project. CBOs also participated in the project to serve as recruitment venues for clients interested in participating and to provide support services.

Payment for PrEP medications, clinic visits, and lab tests were not provided by the AIDS Institute. Payment options for clinic visits and lab testing included private insurance; Medicaid, if eligible; and the PrEP Assistance Program (PrEP-AP), if uninsured or underinsured. PrEP-AP was implemented in January 2015 in response to some clients needing coverage for clinic visits and lab testing. Medication assistance programs were available to clients, including the Gilead Co-Pay Coupon Card or Gilead Truvada for PrEP Medication Assistance Program (New York State Department of Health AIDS Institute, 2016).

The primary objective of the project was to determine the practicality of using PrEP as an HIV prevention intervention for adult MSM who were at high risk for acquiring HIV infection. Key evaluation questions included: (a) Can medical providers, in collaboration with CBOs, successfully identify, recruit, and retain appropriate candidates for PrEP? (b) Can TPIP participants adhere to a PrEP regimen with sufficient rigor to adequately protect them from contracting HIV? (c) Can PrEP be delivered as part of a comprehensive and integrated prevention plan?

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