

TARGETED PREP IMPLEMENTATION PROGRAM FINAL REPORT 2016



**Department
of Health**

**AIDS
Institute**

ACKNOWLEDGEMENTS

The Targeted PrEP Implementation Project was made possible through the collaboration among the following contributors:

AIDS Institute:

Office of the Medical Director
Division of HIV/STD Epidemiology, Evaluation and Partner Services
Division of HIV and Hepatitis Health Care

Participating Agencies:

APICHA
Evergreen Health Services
SUNY Downstate/HEAT Program
Trillium Health
William F. Ryan CHC

TABLE OF CONTENTS

	Page
Targeted PrEP Implementation Program (TPIP) Final Report	
Background	1
Program Participation	1
Activities and Timeline	2
Program Evaluation Activities	3
Human Subjects Considerations	4
Evaluation Findings	4
<i>Findings from Medical Visits</i>	4
<i>Lessons Learned from Clients</i>	5
<i>Lessons Learned from TPIP Providers</i>	6
Furthering PrEP Implementation by the AIDS Institute	7
Appendices	
A. Targeted PrEP Program - Implementation Protocol	A
B. Medical Visit Forms	B
C. PrEP Implementation Program Client Survey	C
D. Targeted PrEP Implementation Program (TPIP) Agency “Table Talk”..	D
E. Data Brief #1 – Targeted PrEP Implementation Program	E
F. Data Brief #2 – TPIP Clients Exit Survey	F
G. Data Brief #3 – TPIP “Table Talk”	G

New York State Department of Health/AIDS Institute
Targeted PrEP Implementation Program
Final Report

BACKGROUND

The efficacy of pre-exposure prophylaxis (PrEP) using Truvada as a biomedical HIV prevention intervention had already been established at the clinical trial level. The Targeted PrEP Implementation Program (TPIP) was an 18-month project designed to assess the extent to which PrEP could be implemented in “real world” clinical settings. The goals of TPIP were to assist the AIDS Institute in identifying needed resources to enable routine use of PrEP and lay the foundation for statewide program implementation, where PrEP is delivered as part of a comprehensive prevention plan.

Although PrEP was approved for several populations, it has the most potential to assist in reducing HIV transmission among gay men/men who have sex with men (MSM). Thus, a decision was made to assess the practicality of implementing TPIP in clinical settings serving a significant number of MSM adults. Key implementation questions included:

- What program elements facilitate the ability of medical providers, in collaboration with community-based organizations (CBOs), to successfully identify, recruit and retain appropriate candidates for PrEP?
- What program activities are needed to assist PrEP clients in adhering to their medications with sufficient rigor to adequately protect them from contracting HIV?
- What key program elements are needed to enable PrEP to be delivered as part of a comprehensive and integrated prevention plan that minimally includes:
 - regular attendance at medical appointments
 - regular testing for HIV and sexually transmitted illnesses (STIs)
 - consistent and correct condom use
 - safer-sex practices and risk reduction counseling?

PROGRAM PARTICIPATION

The AIDS Institute invited five medical providers to participate in TPIP. These providers were being funded by the AIDS Institute for other initiatives, were already providing services to large numbers of MSM, had strong linkages with relevant CBOs and were willing to participate in TPIP without additional funding. Three of the agencies were located in New York City: APICHA, William F. Ryan Community Health Center and the HEAT Program at SUNY-Downstate Medical Center. Two agencies were in upstate New York: Evergreen Health Services in Buffalo and Trillium Health in Rochester.

Total client enrollment in TPIP was projected to be at least 150 individuals among the 5 clinical sites. TPIP's client eligibility was focused on MSM and transgender women who met the following criteria:

- male sex at birth
- aged 18 or older
- HIV-seronegative status
- evidenced high-risk behavior for acquisition of HIV infection
- willing to provide contact information
- informed about program requirements and willing to participate as indicated.

ACTIVITIES AND TIMELINE

The five medical providers and their CBO partners were expected to work together to:

- utilize internal and external resources to identify potential clients for PrEP
- screen potential clients for eligibility and enroll eligible/willing clients in TPIP
- prescribe PrEP to clients
- provide supportive services as part of a comprehensive prevention plan that included routine HIV and STI testing, adherence counseling, education on condom use and safer sex practices
- participate in twice monthly calls with the other TPIP providers and AIDS Institute staff to discuss program activities, identify best practices and troubleshoot problems
- participate in data collection, monitoring and evaluation activities.

Prior to initiation of TPIP, a three hour training was provided by webinar in January 2014 to discuss the PrEP clinical guidance and TPIP protocol, including data collection.

The intent was for the partnering CBOs to serve as recruitment venues for clients to participate in TPIP and provide some or all of the comprehensive HIV prevention services key to the PrEP package. The partnering CBOs could be either onsite or within close proximity of the medical provider.

The recruitment period for TPIP was a 12 month period, beginning February 1, 2014 and ending January 31, 2015. There was a 12-month follow-up period for clients enrolled during the first 6 months and shorter follow-up period for clients enrolled in the second six months. TPIP ended on July 31, 2015, and data were collected on clients until that date.

All clinically related activities (e.g., determining clinical eligibility, provision of PrEP, clinical visit schedules, assessment activities, testing for HIV and STIs, etc.) were conducted according to the AIDS Institute's "Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission", dated January 2014. For a summary of TPIP clinical activities and timeframes, see: "Table 1: Summary of PrEP Visits and Assessments, from Appendix A: "Targeted PrEP Program – Implementation Protocol".

PROGRAM EVALUATION ACTIVITIES

The PrEP program evaluation focused on activities necessary to assess the following general questions:

- What program elements were needed to facilitate the ability of medical providers and CBOs to successfully identify, recruit and retain appropriate clients for PrEP?
- What program activities were needed to assist PrEP clients in adhering to their medication with sufficient rigor to adequately protect them from contracting HIV?
- What key program elements were needed to enable PrEP to be delivered as part of a comprehensive prevention plan which minimally includes:
 - consistent and correct condom use
 - safer-sex practices and risk-reduction counseling
 - HIV testing and screening for other STIs that can facilitate transmission?

Specific questions that were assessed during TPIP included:

- What percent of recruited clients were deemed eligible and agreed to participate?
- What percent of providers were able to recruit the targeted number of PrEP clients?
- What program activities assisted providers in recruiting PrEP clients?
- What percent of clients were adherent enough to their medication to remain on PrEP, and what program activities assisted them in doing so?
- What percent of clients dropped out of the program and for what reasons (such as: seroconversion, lack of adherence, medical indications, self-removal, lost to follow-up, other reason)?
- What percent of clients completed the 12-month program period?
- What were the most effective prevention messages and interventions to assist with behavior change?
 - Did the self-reported risk behaviors of clients change during the program and, if so, how?
 - What percent of clients tested positive for STIs during the program period?
 - What percent of clients reported condom use and did this change during the program?

Data were collected using several methods:

- *Medical Visit Forms*: Providers completed one of two forms at each medical visit: 1) PrEP Client Intake and Eligibility Form (completed at the initial baseline medical visit and the follow-up visit at 2-4 days) and 2) PrEP Client Medical Visit Form (completed at all other medical visits). The client's ID number on the data collection forms was their AIRS Tc_Id number. See Appendix B: medical visit forms.
- *AIDS Institute Reporting System (AIRS)*: In addition to these brief data collection forms, demographic and key service-related information (such as HIV testing and STI assessment/testing) was entered directly into AIRS by the provider.
- *Client Exit Surveys*: All clients were asked to complete a Client Exit Survey after participating in TPIP for 12 months or, if the client had not completed a full year in TPIP, at the end of TPIP which was July 31, 2015. The client exit survey captured:
 - clients' experiences while being on PrEP
 - insurance issues experienced by clients
 - program activities that assisted PrEP adherence
 - clients' ratings of key program elements.

See Appendix C: “The PrEP Implementation Program Client Survey”.

- *Agency “Table Talk”*: This was a guided discussions by each participating agency among their own TPIP staff to:
 - reflect on their partnership with the AIDS Institute in promoting and implementing PrEP
 - share best practices and challenges they faced
 - provide recommendations for future program implementation.

See Appendix D: “Targeted PrEP Implementation Program (TPIP) Agency ‘Table Talk’”.

HUMAN SUBJECTS CONSIDERATIONS

The NYS Department of Health’s Institutional Review Board (IRB) reviewed the project’s protocol and determined that it represented program evaluation and therefore did not constitute “research” and was not subject to IRB review. All clients were fully informed about the program and agreed to participate. Data associated with the program were reported to the AIDS Institute in a de-identified manner, using a unique ID linkable back to clients only at the provider level.

EVALUATION FINDINGS

One hundred ninety-eight (198) individuals were assessed for TPIP, of which 27 (13.6%) did not meet TPIP’s eligibility criteria. One hundred seventy-one (171) clients met TPIP’s eligibility criteria and were enrolled in the program. Thus, total enrollment exceeded the projected target of 150 clients.

Findings from Medical Visits:

For the 27 clients who did not meet TPIP’s eligibility, the most frequently reported reasons were: tested HIV-positive at baseline, had acute HIV at assessment, were less than 60 days after completing a PEP regimen, or had insurance issues.

Among the 171 clients enrolled in TPIP, the majority were white (60.2%), aged 25-34 years (46.2%), male (93.6%) and privately insured (66.7%). Clients reported good adherence with taking Truvada; from 91.0% to 94.1% of the clients during the program reported taking 4 or more doses the week prior to their medical visits. Clients with unstable housing were more likely to miss at least one dose of PrEP in the week prior to their medical visit (OR=4.72, 95% CI= (1.33-16.7)).

Side effects from Truvada were reported among a small group of clients, and diminished over time. The side effects clients reported at their first medical visit after starting Truvada were gastrointestinal problems (21.8%), fatigue/drowsiness (5.9%), headaches (2.4%) and loss of appetite (1.8%).

HIV testing was conducted at each 3-month medical visit. None of the clients who had been on PrEP for any significant length of time acquired HIV infection during the program. One client, HIV-negative on his initial assessment, tested positive at one month. This client likely was in the window period at the time of his initial assessment, which was not identified by HIV testing done at that time.

Clients were tested for STIs at enrollment into TPIP and at their 6 and 12 month medical visits. Screening for STIs was conducted at other medical visits, and testing was done if indicated by the screening. Overall, 13 clients (7.6%) had at least one STI at baseline. Few new positive STI cases were identified during the follow-up.

Among the 171 clients enrolled in TPIP, 41 (24.0%) clients discontinued PrEP before TPIP was concluded. The most frequently reported reason for discontinuing PrEP was client's request to stop due to changes in behavior. The majority of clients who discontinued PrEP did so within the first 6 months.

See Appendix E: "Data Brief #1 – Targeted PrEP Implementation Program" for additional data obtained from the medical visit forms.

Lessons Learned from Clients:

TPIP clients were asked to complete a client exit survey at the end of their participation in the program. The client exit survey captured their experiences while being on PrEP, issues they encountered while in TPIP and program activities that helped them remain in the program. Eighty-three clients completed the survey. The majority of survey respondents had positive comments about their experiences with TPIP.

The majority of survey respondents found it easy to attend medical visits every three months, regularly test for HIV and STIs, take a pill every day and manage any side effects experienced. They also reported that, since being on PrEP, they had no change in the number of sexual partners, condomless sex practices or feelings of stigma because they were on PrEP. The majority of respondents reported having few insurance issues or problems getting their prescriptions filled. Those who did have insurance issues had difficulties related to lack of coverage for lab tests and medical visits, and high deductibles or co-pays.

Among the things that helped respondents remain on PrEP was having someone available to answer their questions and to provide HIV prevention and risk reduction education. Most of the clients said they would recommend PrEP to their friends. The majority of respondents reported that since being on PrEP they worried less about becoming HIV-positive. For the majority of TPIP participants, feelings of stigmatization remained unchanged, but increased stigma concerns lingered among a small group of clients (n=8).

See Appendix F: "Data Brief # 2 – TPIP Client Exit Survey" for additional data obtained from the client surveys.

Lessons Learned from TPIP Providers:

During the implementation period, staff at the five agencies provided the AIDS Institute with a wealth of programmatic information regarding activities and resources needed to effectively and efficiently provide PrEP services, as well as barriers that hindered provision of PrEP or impeded the ability of clients to access and remain on PrEP. Each agency also completed an agency-specific “Table Talk” document which provided additional qualitative information on their experiences implementing PrEP.

It became evident fairly quickly that most of the agencies were encountering start-up issues that needed to be addressed prior to their being able to effectively incorporate PrEP activities into clinical services provided by the agency. One agency, already providing PrEP to some degree, had an existing infrastructure that facilitated provision of PrEP and related services. Over the period that TPIP was operational, the providers developed innovative ways to address many of the barriers/issues they encountered. As a result, their ability to effectively and efficiently provide a “comprehensive PrEP package” increased over time.

Among the activities/resources identified as a need by the TPIP providers were:

- administrative buy-in from agency executive staff to support the developing program and provide the necessary resources to successfully integrate the program into their clinical and programmatic operations
- a “PrEP Champion”/coordinator, dedicated to raising community awareness about PrEP and assist in recruitment, retention and data management for the program
- training for all staff, both clinical and non-clinical, regarding PrEP itself as well as cultural and diversity training regarding the populations most likely to benefit from PrEP
- PrEP-related materials for both providers and consumers to raise awareness of PrEP and provide them with the tools they needed to either provide or receive PrEP services
- infrastructure development, such as PrEP-related policies and procedures
- networking/collaboration with CBOs serving high risk populations for recruitment as possible PrEP candidates and provision of supportive services needed as part of the “PrEP package”
- identifying staff roles and responsibilities, so that PrEP-related activities are divided among appropriate staff and not falling on just the prescribing provider
- managing a more intense upfront period where the PrEP-related assessments, insurance navigation, client readiness education, etc. need to be completed
- staff navigator who was knowledgeable regarding the patient drug assistance programs for PrEP, and able to navigate PrEP clients through the maze of insurances and drug assistance programs
- coverage for medical visits and lab tests, such as a resource similar to ADAP that could assist eligible clients with payment for PrEP related medical visits and lab expenses (many clients on PrEP were healthy younger adults who had insurance through the Affordable Care Act with deductibles and co-pays so high it prevented them from accessing PrEP-related services)
- a process and clinical guidance for transitioning patients on post-exposure prophylaxis (PEP) to PrEP
- development of PrEP templates in electronic health records (EHRs) to facilitate provision of services, documentation, monitoring and data reporting

- streamlined data collection requirements in AIRS
- routine, ongoing quality assurance activities for data collection
- marketing resources, inclusive of social media used by clients
- capacity building to accommodate an increasing caseload of healthy adults on PrEP who require routine medical visits and lab work.

See Appendix G: “Data Brief #3 – TPIP Table Talk” for additional information obtained from the agencies’ “Table Talk” discussions.

FURTHERING PrEP IMPLEMENTATION BY THE AIDS INSTITUTE

In response to the needs identified by the TPIP agencies, the AIDS Institute began addressing those needs that had statewide programmatic or policy implications. For example, the AIDS Institute developed a statewide PrEP Assistance Program (PrEP AP) to cover the costs of doctor’s visits and lab testing for uninsured and underinsured individuals who met financial eligibility (435% of the Federal Poverty Level). PrEP AP was implemented January 2015. The AIDS Institute received additional funding for PrEP that enhanced health care contracts to enable provision of PrEP. A key funded position on these contracts was a “PrEP Specialist” who acted as a PrEP Champion/Coordinator.

In late 2015, the AIDS Institute released a Request for Applications (RFA) focused on “Pre-Exposure Prophylaxis (PrEP) Services in General and HIV Primary Care Settings”. The intent of the RFA was to “fund community driven solutions aimed to raise awareness of and reduce barriers to the access of PrEP as a critically important prevention tool for people with substantial risk of HIV infection”. The six key elements of these PrEP services programs reflect some of the lessons learned from TPIP. These elements include: education and outreach, patient identification and screening, administrative and organizational transition to establish services in a clinical setting, assessment and services consistent with the PrEP clinical guidance, PrEP insurance navigation and assistance, and adherence support.

The AIDS Institute’s PrEP Clinical Guidance document was revised in October 2015 to include “Appendix D: PrEP Payment Options”. The 2015 guidance also provided updated information about prescribing PrEP for adolescents, as well as information about managing patients on PrEP who present with a positive HIV screening test or symptoms suggestive of acute HIV infection.

Additional activities are underway, many of which were informed by lessons learned from the TPIP clients and providers.

**New York State Department of Health
AIDS Institute
Targeted PrEP Program - Implementation Protocol**

INTRODUCTION

HIV prevention through pre-exposure prophylaxis (PrEP) involves the use of antiretroviral medications by non HIV-infected individuals who wish to reduce their risk of HIV acquisition. In July 2012, the Food and Drug Administration (FDA) approved the use of tenofovir + emtricitabine for HIV PrEP in adults who are at high risk for acquiring HIV infection.

Use of tenofovir alone and tenofovir + emtricitabine as PrEP have been studied in clinical trials in several populations including men who have sex with men (MSM),¹ transgender women, heterosexual discordant couples,² heterosexual men and women and injecting drug users.³ Almost all of the trials found PrEP to be safe and effective for preventing HIV infection. Two studies did not show a benefit, likely due to poor adherence to the daily PrEP regimen.⁴

Studies of other antiretroviral agents for use as PrEP, such as maraviroc, rilpivirine, and dapivirine, are underway. PrEP has not been studied in individuals younger than 18 years of age.

RATIONALE FOR A TARGETED IMPLEMENTATION of PrEP in NYS

The efficacy of PrEP as an HIV prevention intervention has been established at the clinical trial level, and PrEP is now approved as a standard of medical care. However the extent to which PrEP can be implemented in real world settings is unknown. A targeted program implementation will assist the AIDS Institute in identifying needed resources to enable routine use of PrEP and lay the foundation for statewide program implementation, where PrEP is delivered as part of a comprehensive prevention plan. Key considerations include assisting medical providers to identify appropriate candidates for PrEP and assessing the willingness, motivation and ability of those candidates to participate (e.g., adhere to their medication schedule, adhere to their HIV and STD testing schedule, participate in safer sex and risk reduction counseling, etc.).

Although PrEP has been approved for many populations, this intervention has the most potential to assist with reducing HIV transmissions among gay men/MSM. In 2011, in the United States, MSM accounted for 79% of 38,825 estimated HIV diagnoses among all males aged 13 years and older and 62% of 49,273 estimated diagnoses among all persons receiving an HIV diagnosis that year.⁵ In the NYS, MSM accounted for 49.1% of newly diagnosed HIV infections during 2011.⁶

TARGETED PrEP PROGRAM IMPLEMENTATION OBJECTIVES

The primary objective of a targeted PrEP program implementation is to assess the practicality of using PrEP as an HIV prevention intervention for MSM adults who are at high risk for acquiring HIV infection. Key implementation questions include:

- What program elements facilitate the ability of medical providers, in collaboration with community based organizations, to successfully identify, recruit and retain appropriate candidates for PrEP;
- What program activities are needed to assist PrEP clients in adhering to their medication with sufficient rigor to adequately protect them from contracting HIV;
- What key program elements are needed to enable PrEP to be delivered as part of a comprehensive and integrated prevention plan that minimally includes:
 - regular attendance of medical appointments;
 - regular testing for HIV and STDs;
 - consistent and correct condom use, and
 - safer-sex practices and risk-reduction counseling.

PrEP PROVIDERS AND FUNDING

The AIDS Institute will invite selected medical providers to participate in this targeted PrEP program implementation. Medical providers currently funded by the AIDS Institute and already providing services to large numbers of the target population will be asked to participate. Although there is no new funding associated with this targeted program implementation, the AIDS Institute is offering flexibility with existing contracts to permit project activities to occur within existing funding structures. AIDS Institute contract managers have been briefed about the targeted PrEP implementation and are ready to assist agencies with modifying existing contract workplans as necessary.

Community based organizations will be integral to the success of this targeted PrEP program implementation. Serving as key partners with medical providers, community based organizations and other AI funded providers (e.g., STD clinics) will help identify clients appropriate for the PrEP programs, as well as provide key supportive HIV prevention services. The AI will offer, as necessary, similar contract flexibility to community based providers in order for them to accommodate the PrEP recruitment and prevention activities.

PROGRAM PARTICIPATION

As detailed above, this targeted PrEP program implementation will focus on MSM/transgender women. In order to be eligible to participate, prospective clients must:

- be male sex at birth;
- be the age of 18 years or older;
- be a gay man or MSM/transgender woman;
- have an HIV-seronegative status;
- exhibit evidence of high-risk behavior for acquisition of HIV infection;
- be willing to provide contact information, and
- be informed about program requirements and be willing to participate as indicated.

For purposes of this targeted program implementation, **high risk behavior** is defined as one or more of the following in the **past six months**:

- condomless anal sex with a partner who is HIV infected or unknown infection status;

- anal sex with 2 or more male partners;
- a diagnosis of a sexually transmitted infection;
- a history of transactional sex activity.

Mental health issues, use of stimulant drugs, alcohol use (e.g., greater than 5 drinks per day), sharing drug injection equipment, injecting one or more times per day, injecting cocaine or methamphetamine, in combination with any factor above, represent additional considerations for administering PrEP and participating in this targeted program.

The following represent exclusion criterion from the targeted program:

- documented HIV infection;
- lack of readiness to adhere to a daily PrEP regimen;
- active and clinically significant medical problems including renal insufficiency (Creatinine Clearance <60mL/min), current treatment for Hepatitis B or C infections, individuals with pre-existing risk factors for and/or demonstrated osteoporosis/osteomalacia/osteopenia;
- medical therapy with agents known to have drug-drug interactions with tenofovir and/or emtricitabine, or use of concomitant nephrotoxic drugs (excluding valacyclovir and acyclovir);
- individuals less than 60 days after completing an HIV PEP regimen; if very high risk (i.e., repeated high-risk behavior or have repeated courses of nPEP), consider the individual a candidate for PrEP, refer to intensified education and prevention services for the interim and reschedule for PrEP assessment in 60 days;
- anti-HIV vaccine recipients;
- acute HIV - febrile, “flu”-, or “mono”-like illness in last 6 weeks or patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month, and
- acute Hepatitis A, B or C infection at study entry or prior to receiving the first dose of PrEP.

In addition to the exclusion criteria above, clients deemed initially eligible for PrEP may be discontinued at the discretion of the PrEP provider. Reasons for discontinuing a participant from the PrEP medications (but continuing to evaluate) would include:

- becoming HIV positive;
- developing renal disease;
- being non-adherent to medication or appointments (after attempts to improve adherence have failed);
- using medication for purposes other than intended;
- reducing risk behaviors to the extent that PrEP is no longer needed, and
- client decision to discontinue PrEP medications.

To facilitate assessing the effectiveness of program implementation activities, it will be important to document the reason(s) for discontinuing clients from PrEP.

ACTIVITIES

Because this is a targeted program implementation to assess the practicality of using PrEP as an HIV prevention intervention for high risk MSM/transgender women, certain requirements are being established for both providers and clients. Clients will receive PrEP as part of a comprehensive program that includes medical visits, adherence support, condom distribution and risk reduction counseling. Clients will be expected to participate in the targeted program, be adherent to their medication regimens, and attend all clinical and non-clinical program activities as recommended by their medical and HIV prevention providers. Providers (medical providers and community based HIV prevention providers) participating in this program are expected to work together to:

- utilize internal and external resources to identify potential clients for PrEP;
- screen potential clients for eligibility and enroll eligible and willing clients into the project;
- prescribe PrEP to clients;
- provide supportive services as part of a comprehensive prevention plan that includes routine HIV and STD testing, adherence counseling, education on condom use and safer sex practices;
- participate in twice monthly calls with other providers and the AI to discuss program activities, identify best practices, and troubleshoot problems, and
- participate in data collection/monitoring and evaluation activities as detailed below.

PARTNERSHIP WITH COMMUNITY BASED ORGANIZATIONS

This program is a partnership between selected medical providers and community based organizations serving the target population either located on site or within close proximity. These partnering sites will serve as recruitment venues for participation in the program, and will also provide, as needed, some or all of the comprehensive HIV prevention services that must accompany the administration of PrEP. Medical providers may also choose to accept referrals and services from other local community based organizations serving MSM/transgender women. The AI will also work, as necessary, to assist medical providers with recruitment, by reaching out to its provider network serving the target population. Each agency is encouraged to serve as many PrEP clients as possible. It is hoped that the total PrEP client enrollment for the project will be at least 150 individuals.

PrEP PROJECT TIMELINE

The enrollment period for the PrEP pilot will be for 12 months, beginning February 1, 2014. There will be a 12-month follow-up period on clients enrolled during the first 6 months, and a shorter follow-up period for those clients enrolled in the second 6 months. The pilot will end on July 31, 2015, and data will be collected on clients until that date.

RECRUITMENT AND ELIGIBILITY DETERMINATION

There will be a baseline screening for each potential client at the initial medical visit. This initial visit will include educating clients about the PrEP program and its requirements (including the signs and symptoms of acute HIV infection), obtaining agreement from clients to participate, assessing risk factors to verify eligibility, obtaining a current medication list, determining how PrEP will be paid for, conducting a substance use and mental health screening, obtaining partner risk information, and performing a physical examination and pre-prescription laboratory tests including a baseline HIV test (4th generation strongly recommended), basic metabolic panel, urinalysis, screening for sexually transmitted infections and serology for Hepatitis A, B and C. Standard primary care services should also be provided if the client is new to the medical practice.

As soon as possible after the baseline medical visit, preferably within 2-4 days when test results are available, there will be a follow-up visit where clients will receive their HIV and STD test results and will be prescribed a 30-day prescription for PrEP if they are eligible. It is imperative that a negative HIV test is confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given. Adherence counseling and commitment should be provided at this visit. Risk reduction counseling and condoms should also be provided. Mental health and/or substance use screening, STD assessment and, if indicated, STD treatment should be provided at this and all subsequent visits as indicated.

There should be a check in with program clients (by phone or in-person) two weeks after their initial prescription for PrEP. This will be an opportunity to verify contact information and to troubleshoot any initial problems being experienced by clients.

CLINICAL VISIT SCHEDULE AND ASSESSMENT ACTIVITIES

The next clinical visit should occur approximately 30 days after the client has been prescribed PrEP (but soon enough to avoid treatment interruption). At this visit, clients will be assessed for adherence and commitment, and provided counseling as necessary. Risk reduction counseling and condoms should be provided and a 60 day prescription for PrEP issued. HIV and, if indicated, STD testing should also be performed. Any side effects of the PrEP should be assessed. Serum creatinine and calculated creatinine clearance should be measured for clients with borderline renal function or at increased risk for kidney disease. The next visit should be scheduled 60 days from the 30 day visit. At this 60 day visit, in addition to laboratory tests, the following should be done: an adherence and commitment assessment with counseling as indicated, risk assessment and risk reduction counseling including condom distribution, an HIV test (preferably 4th generation), STD assessment, with STD testing and treatment as needed, and a 90 day prescription for PrEP.

For the participants who are adherent, future visits after the above visits should be scheduled quarterly. Each quarterly visit should include many of the same elements as described for the 60 day visit. Refer to Table 1 for what elements are recommended to be done at specific visits.

For clients who report poor adherence at any clinical visit, adherence counseling should be delivered and a future adherence support visit scheduled for 30 days to reinforce adherence or sooner if needed. For purposes of this program, poor adherence is defined as reporting missing doses of medication “daily,” “more than once a week,” or “once a week” on two consecutive visits.⁷ If adherence does not improve by the subsequent clinical visit, PrEP should be discontinued, the client disenrolled from the program, and tailored risk-reduction messages and HIV prevention referral provided to the client.

At the last visit, all clients should have screening for STDs, a physical examination, laboratory tests, and an HIV test (preferably 4th generation). An exit interview to assess any behavior changes from the baseline assessment form and satisfaction with the program should be done. Staff from OPER will work with the participating agencies to develop an exit interview tool. **Table 1** provides a summary of PrEP activities and time frames.

Table 1: Summary of PrEP Visits and Assessments

	Baseline Visit (Day 1)	Follow-up * (Day 2-4)	Visit 1 30 day (1 mo)	Visit 2 60 day (3 mo)	Visit 3 90 day (6 mo)	Visit 4 90 day (9 mo)	Visit 5 90 day (12 mo)
Pre-prescription education	X						
Agreement to participate	X						
Insurance/payment plan	X						
Hepatitis A, B screening	X						
Hepatitis C screening	X						X
Basic metabolic panel	X						
Serum creatinine; calculated creatinine clearance			X*	X		X	
Urinalysis	X						X
Physical examination	X						X
Assessment for STDs	X		X	X	X	X	X
Screening for STDs	X				X		X
HIV test (preferably 4 th generation)	X			X	X	X	X
Verify program eligibility***	X	X	X	X	X	X	X
Adherence assessment and counseling****		X	X	X	X	X	X
Risk Assessment	X		X	X	X	X	X
Risk reduction counseling and condom distribution	X	X	X	X	X	X	X
PrEP Prescription-30 day supply*****		X					
PrEP Prescription-60 day supply			X				
PrEP Prescription-90 day supply				X	X	X	AS NEEDED
STD treatment		AS NEEDED					
Mental health/substance use screening	X	AS NEEDED					
Exit Interview							X

* As soon as possible after the baseline visit, preferably within 2-4 days when test results are available; it is imperative that a negative HIV test is confirmed as close to initiation of PrEP as possible.

**Only for clients with borderline renal failure or at increased risk for kidney disease (>65 years of age, black race, hypertension or diabetes).

**Initially eligible clients who no longer wish to continue with PrEP and/or those who cannot be adherent to their medication should be disenrolled from the project.

***Adherence assessments and support for non-adherent clients should occur at 30 day intervals or more frequently as needed throughout the program.

****Medication “check in” assessment by phone or in person should be done two weeks after the initial prescription for PrEP.

PROGRAM EVALUATION ACTIVITIES

The PrEP program evaluation will focus on activities necessary to assess the following general questions:

- What program elements are needed to facilitate the ability of medical providers and community based organizations to successfully identify, recruit and retain appropriate clients for PrEP?
- What program activities are needed to assist PrEP clients in adhering to their medication with sufficient rigor to adequately protect them from contracting HIV?
- What key program elements are needed to enable PrEP to be delivered as part of a comprehensive prevention plan which minimally includes:
 - Consistent and correct condom use;
 - Safer-sex practices and risk-reduction counseling, and
 - HIV testing and screening for other STIs that can facilitate transmission?

Specific questions to be assessed during the program period include:

- What percent of recruited clients were deemed eligible and agreed to participate?
- What percent of providers were able to recruit the targeted number of PrEP clients? What program activities assisted providers in recruiting PrEP clients?
- What percent of clients were adherent enough to their medication to remain on PrEP, and what program activities assisted them in doing so?
- What percent of clients dropped out of the program and for what reasons (seroconversion, lack of adherence, medical indications, self-removal, lost to follow-up, other reason)?
- What percent of clients completed the 1-year program period?
- What were the most effective prevention messages and interventions to assist with behavior change?
 - Did the self-reported risk behaviors of clients change during the program and, if so, how?
 - What percent of clients tested positive for STDs during the program period?
 - What percent of clients reported condom use and did this change during the program?

Providers participating in the PrEP program will collect data using two forms: 1) PrEP Client Intake and Eligibility Form (completed at the initial baseline medical and the follow-up visit at 2-4 days) and 2) PrEP Client Medical Visit Form (completed at all other medical visits). The client's ID number on the data collection forms will be their AIRS Tc_Id number.

Completed forms should be submitted Donna Parisi in the AI's Office of Program Evaluation and Research (OPER) on a monthly basis. The data collection forms may be submitted by one of three methods: fax to OPER (518.402.6813); mail copies of the forms to OPER at P.O. Box 2067, Empire State Plaza Station, Albany, NY, 12237; or scanned and submitted electronically via the Health Commerce System at <https://commerce.health.state.ny.us>.

In addition to these brief data collection forms, demographic and key service-oriented information (i.e., HIV testing, STD assessment/testing, adherence assessment and counseling, HIV risk assessment, HIV risk reduction counseling, condom provision, etc) will be entered directly into the AIDS Institute Reporting System (AIRS) by the provider. Participating agencies will be asked to add a program (similar to their exiting prevention program) and be provided a service mapping to collect the above data. Staff from the AI will work with the agencies to assure the AIRS setup is complete. Clients participating in PrEP will have all of their prevention services recorded in this designated (PrEP) program in AIRS.

HUMAN SUBJECTS CONSIDERATIONS

The NYS Department of Health's Institutional Review Board (IRB) has reviewed the pilot protocol and determined that this pilot evaluative program does not constitute "research" and is therefore not subject to IRB review. All clients will be fully informed about the program and agree to participate. Data associated with the program will be reported to the AIDS Institute in a de-identified manner, using a unique ID linkable back to clients only at the provider level.

¹ Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363:2587-2599. [[PubMed](#)]

² Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012;367:399-410. [[PubMed](#)]

³ Choopanya K, Martin M, Suntharasamai U, et al. Antiretroviral prophylaxis for HIV-infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): A randomized, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013;381:2083-2090. [[PubMed](#)]

⁴ Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med* 2012;367:411-422. [[PubMed](#)] and
Marrazzo J et al. *Pre-exposure prophylaxis for HIV in women: daily oral tenofovir, oral tenofovir/emtricitabine or vaginal tenofovir gel in the VOICE study (MTN 003)*. 20th Conference on Retroviruses and Opportunistic Infections, Atlanta, abstract 26LB, 2013.

⁵ CDC. Estimated HIV incidence in the United States, 2007–2010. *HIV Surveillance Supplemental Report* 2012;17(No. 4). <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/#supplemental>. Published December 2012. 3. CDC. *HIV Surveillance Report*, 2011; vol. 23. <http://www.cdc.gov/hiv/topics/surveillance/>

⁶ New York State Department of Health AIDS Institute. New York State HIV/AIDS Epidemiologic Profile 2012. Albany, NY: New York State Department of Health.

⁷ Glass T, Rotger, M, Telenti A, et al. *Determinants of Sustained Viral Suppression in HIV-Infected Patients with Self-Reported Poor Adherence to Antiretroviral Therapy*. *PLoS One* 2012; 7(1):e29186. [determinants of sustained viral suppression in HIV-Infected patients - PubMed - NCBI](#)

PrEP Client Intake and Eligibility Form (Complete at Initial Medical and Follow-up Visits)

CLIENT "Tc_Id" NUMBER* _____ AGENCY NAME _____ DATE of VISIT _____

Section 1 Client Risk Factors - Complete at Initial Medical Visit (Check all that apply)

High risk behavior is defined as one or more of the following activities the client has been involved in the past six months:

- condomless anal sex with a partner who is HIV infected or unknown status
 anal sex with 2 or more male partners
 a diagnosis of a sexually transmitted infection
 Chlamydia Gonorrhea Syphilis Other _____
 a history of transactional sex activity.

In combination with any factor above does the client also:

- share drug injection equipment, injecting one or more times per day, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors?
 have mental health issues?
 use stimulant drugs, or alcohol (e.g., greater than 5 drinks per day)?

Section 2 PrEP Eligibility* - Complete at Initial Medical Visit

- Male sex at birth Yes No
 Age of 18 years or older Yes No
 A gay man or MSM/transgender woman Yes No
 Have an HIV-seronegative status Yes No
 Exhibit evidence of high-risk behavior for acquisition of HIV infection (See Section 1) Yes No
 Willing to provide contact information Yes No
 Informed about project requirements and be willing to participate as indicated. Yes No

***All items must be "Yes" for participation, if any items are checked "No," the client is not eligible for participation. Stop filling out the form and go to page 2 for instructions on how to submit the form.**

Section 3 PrEP Visits and Assessments Checklist - Complete at Initial Medical and Follow-up Visit

	Initial Medical Visit	Follow-up Visit	Action
Verify project eligibility	<input type="checkbox"/>	N/A	
Pre-prescription education	<input type="checkbox"/>	N/A	
Agreement to participate	<input type="checkbox"/>	N/A	
Insurance/payment plan	<input type="checkbox"/> Private <input type="checkbox"/> Medicaid <input type="checkbox"/> Uninsured	N/A	
Physical examination	<input type="checkbox"/>	N/A	
Risk Assessment	<input type="checkbox"/>	N/A	Entered in AIRS at baseline
Hepatitis A, B, C screening	<input type="checkbox"/>	<input type="checkbox"/>	Review results with client; Enter in AIRS
Laboratory tests: Basic metabolic panel, urinalysis	<input type="checkbox"/>	<input type="checkbox"/>	Review results with client
Screening for STDs	<input type="checkbox"/>	<input type="checkbox"/>	Review results with client; Enter in AIRS
HIV test (preferably 4th generation)	<input type="checkbox"/>	<input type="checkbox"/>	Review results with client; Enter in AIRS
Adherence assessment and counseling	N/A	<input type="checkbox"/>	Enter in AIRS
Risk reduction counseling and condom distribution	<input type="checkbox"/>	<input type="checkbox"/>	Enter in AIRS
PrEP Prescription-30 day supply	N/A	<input type="checkbox"/>	
STD treatment	N/A	<input type="checkbox"/>	As needed
Mental health/substance use screening	<input type="checkbox"/>	<input type="checkbox"/>	As needed

*Tc_Id is the AIRS generated ID found in the status box in the lower left corner when the client is selected in the "Client Information and Services" screen. It consists of two letters+8 numbers (e.g.: "JP00002355") and is created upon saving entry of a client intake.

PrEP Client Intake and Eligibility Form (Complete at Initial Medical and Follow-up Visits)

CLIENT "Tc_Id" NUMBER _____ AGENCY NAME _____ DATE of VISIT _____

Section 4 Medication "Check-in" Assessment – Complete 14 days after the first PrEP medication prescription

Medication "check-in" assessment was performed roughly 14 days after PrEP initiation:

 by phone in person no**Section 5 PrEP Project Ineligible (check all boxes that pertain to why the client was excluded from the project)***Client tested HIV positive at baseline Yes NoLack of adherence to a daily PrEP regimen Yes NoAcute HIV-febrile "flu", or "mono" – like illness in last 6 weeks or patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month Yes NoActive and clinically significant medical problems including renal insufficiency (Creatinine Clearance <60mL/min), current treatment for Hepatitis B or C infections, individuals with pre-existing risk factors for and/or demonstrated osteoporosis/osteomalacia/ osteopenia; Yes NoMedical therapy with agents known to have drug-drug interactions with tenofovir and/or emtricitabine, or use of concomitant nephrotoxic drugs (excluding valacyclovir and acyclovir); Yes NoIndividuals less than 60 days after completing an HIV PEP regimen Yes NoAnti-HIV vaccine recipients Yes NoAcute Hepatitis A, B or C infection at study entry or prior to receiving the first dose of PrEP. Yes No

Other:

If any items are checked "Yes," the client is not eligible for participation. Follow the instructions below on how to submit the form.*Data Submission Instructions**

Please submit client medical visit data forms by the 30th of the following month to: Donna Parisi, Office of Program Evaluation and Research::

FAX to: 518-402-6813

Mail to: Empire State Plaza P.O. Box 2067
Albany NY 12237

Electronic Submission:

<https://commerce.health.state.ny.us>

Name of person completing the form _____

*Tc_Id is the AIRS generated ID found in the status box in the lower left corner when the client is selected in the "Client Information and Services" screen. It consists of two letters+8 numbers (e.g.: "JP00002355") and is created upon saving entry of a client intake.

PrEP Client Medical Visit Form (Complete at Visits in Months 1-12)

CLIENT "Tc_Id" NUMBER* _____ AGENCY NAME _____ DATE of VISIT _____

Section 1 Client Risk Factors

Has the client engaged in high risk behaviors since his last visit?

- condomless anal sex with a partner who is HIV infected or unknown status
 anal sex with 2 or more male partners
 a diagnosis of a sexually transmitted infection
 Chlamydia Gonorrhea Syphilis Other _____
 a history of transactional sex activity

In combination with any factors above, does the client also:

- share drug injection equipment, injecting one or more times per day, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors?
 have mental health issues?
 use of stimulant drugs or alcohol (e.g., greater than 5 drinks per day)?

Section 2 Adherence – Questions (ask client during visit 1-5)

1. How many doses of PrEP medications did the client miss in the past week?

- 0 1 2 3 4 5 6 7

Additional Comments Including Side Effects

Is the client experiencing any side effects from PrEP? Please describe:

Any Additional Comments:

Name of person completing the form _____

CLIENT "Tc_Id" NUMBER* _____ AGENCY NAME _____ DATE of VISIT _____

*Tc_Id is the AIRS generated ID found in the status box in the lower left corner when the client is selected in the "Client Information and Services" screen. It consists of two letters+8 numbers (e.g.: "JP00002355") and is created upon saving entry of a client intake.

PrEP Client Medical Visit Form (Complete at Visits in Months 1-12)

Section 3 Checklist for PrEP

Visit⇒	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Action
	1mo	3mo	6mo	9mo	12mo	
Serum creatinine; calculated creatinine clearance	<input type="checkbox"/> 1mo*		<input type="checkbox"/> 6mo		<input type="checkbox"/> 12mo	
Urinalysis			<input type="checkbox"/> 12mo			
Physical examination			<input type="checkbox"/> all visits			
Risk Assessment			<input type="checkbox"/> all visits			Enter in AIRS
Assessment for STDs			<input type="checkbox"/> all visits			
Hepatitis C screening			<input type="checkbox"/> 12mo			Enter in AIRS
Screening for STDs		<input type="checkbox"/> 6mo	<input type="checkbox"/> 12mo			Enter in AIRS
HIV test (preferably 4th generation)	<input type="checkbox"/> 3mo	<input type="checkbox"/> 6mo	<input type="checkbox"/> 9mo	<input type="checkbox"/> 12mo		Enter in AIRS
Verify project eligibility**			<input type="checkbox"/> all visits			
Adherence assessment and counseling***			<input type="checkbox"/> all visits			Enter in AIRS
Risk reduction counseling and condom distribution			<input type="checkbox"/> all visits			Enter in AIRS
PrEP Prescription	<input type="checkbox"/> 1mo	<input type="checkbox"/> 3mo	<input type="checkbox"/> 6mo	<input type="checkbox"/> 9mo	<input type="checkbox"/> 12mo	
STD treatment			<input type="checkbox"/> as needed			
Mental health/substance use screening			<input type="checkbox"/> as needed			
Exit Interview			<input type="checkbox"/> 12mo			At last visit only
*Only for clients with borderline renal failure or at increased risk for kidney disease (>65 years of age, black race, hypertension or diabetes)						
**Initially eligible participants who no longer wish to continue with PrEP and/or those who cannot be adherent to their medication will be disenrolled from the project.						
***Adherence assessments and support for non-adherent participants occurs at 90 day intervals or as needed throughout the project.						

Section 4 Continuation of PrEP**Based on findings from today's visit, will the client continue with the PrEP Project?**

- Yes (Skip to Data Submission Instructions section below) No (Continue to Section 5)

Section 5 Discontinuation from the PrEP Project (Only for clients discontinued at the discretion of the PrEP provider)

Why is the client discontinuing the PrEP Project?

- Participant became HIV-positive
- Participant is non-adherent to medication or appointments (after attempts to improve adherence have failed)
- Participant reduced risk behaviors to the extent that PrEP is no longer needed
- Participant is using medication for purposes other than intended
- Participant requested to discontinue PrEP
- Participant developed renal disease
- Other, specify: _____

Data Submission Instructions

Please submit client medical visit data forms by the 30th of the following month to: Donna Parisi, Office of Program Evaluation and Research:

FAX to: 518-402-6813

Mail to: Empire State Plaza P.O. Box 2067
Albany NY 12237

Electronic Submission:

<https://commerce.health.state.ny.us>

*Tc_Id is the AIRS generated ID found in the status box in the lower left corner when the client is selected in the "Client Information and Services" screen. It consists of two letters+8 numbers (e.g.: "JP00002355") and is created upon saving entry of a client intake.

Targeted PrEP Implementation Project (TPIP) Client Exit Survey Instructions

Dear TPIP Providers,

All clients who are enrolled in the implementation project are encouraged to respond to the Client Exit Survey during their last TPIP medical visit. Any client enrolled from February 1, 2014 through July 31, 2014, will complete the survey at their 12-month visit. Any client enrolled in TPIP on or after August 1, 2014 will complete their exit survey on July 31, 2015; this is the last day of data collection. We understand that the client exit survey dates will not be exact.

You will be provided with a list of approximate exit survey dates by TC_ID number to assist you in knowing when to have the client complete the survey. The list provides a place for you to check off when the client does complete their survey. If the approximate exit survey date has already passed, please have the client complete the survey during their next visit.

Please remember that the client should continue taking PrEP as appropriate after TPIP ends. However, we will no longer be collecting data on clients after their 12-month mark or July 31, 2015, whichever comes first.

When you send in your monthly medical visit forms, please also send in any completed client exit surveys.

Thank you very much for your assistance with collecting this information! Please contact me if you have any questions about these procedures.

Donna Parisi
NYSDOH AIDS Institute, Office of Program Evaluation and Research
Donna.paris@health.ny.gov
518.402.6814

The Targeted PrEP Implementation Project Client Survey

Introduction

As a client who takes PrEP we would like to know about your experiences with taking PrEP. Your personal opinion is very important to us. The attached survey will take about 5 minutes to complete. Participation in this confidential survey is voluntary. Your responses will be summarized with those of other PrEP program clients, and they will be used to improve services for you and others. You may skip any questions that you don't want to answer.

After you fill out the survey, please return it to the person who gave it to you. There is no need to write your name on the survey. If you have any questions, please ask your PrEP provider.

Thank you for your participation in this important survey.

1. What is today's date?

MM DD YYYY

Today's date: / /

2. What is the agency name where you receive PrEP?

- | | |
|---|---|
| <input type="radio"/> APICHA | <input type="radio"/> Trillium Health |
| <input type="radio"/> Evergreen Health Services | <input type="radio"/> William F. Ryan NENA |
| <input type="radio"/> Harlem United | <input type="radio"/> William F. Ryan Chelsea-Clinton |
| <input type="radio"/> SUNY Downstate | <input type="radio"/> William F. Ryan Upper Westside |

3. How old are you?

4. Are you Hispanic or Latino?

- Yes No

5. Which one or more of these groups would you say best describes your race? (Please check all that apply)

- | | |
|--------------------------------|---|
| <input type="checkbox"/> White | <input type="checkbox"/> American Indian/Alaska Native |
| <input type="checkbox"/> Black | <input type="checkbox"/> Asian |
| <input type="checkbox"/> Other | <input type="checkbox"/> Pacific Islander/Native Hawaiian |

Other (please specify)

The Targeted PrEP Implementation Project Client Survey

6. How long have you been taking PrEP?

- Less than 3 months
- 3 - 5 months
- 6 - 9 months
- 10 - 12 months
- more than 12 months

7. Where did you learn about PrEP? (Please check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Friends | <input type="checkbox"/> Newspaper/TV/Magazine |
| <input type="checkbox"/> Sexual Partner | <input type="checkbox"/> Poster/Pamphlet/Palm card |
| <input type="checkbox"/> Family/Relatives | <input type="checkbox"/> Medical Provider |
| <input type="checkbox"/> Social Media/Internet | <input type="checkbox"/> Community Based Organization (CBO) |

Name of CBO

8. How did you decide to start using PrEP? (Please check all that apply)

- | | |
|---|---|
| <input type="checkbox"/> A sexual partner encouraged me to take PrEP | <input type="checkbox"/> A Community based organization (CBO) suggested I take PrEP |
| <input type="checkbox"/> My primary care provider recommended I take PrEP | <input type="checkbox"/> A friend suggested I take PrEP |
| <input type="checkbox"/> HIV counseling center suggested I take PrEP | <input type="checkbox"/> My family members suggested I take PrEP |
| <input type="checkbox"/> STD clinic suggested I take PrEP | <input type="checkbox"/> I decided on my own to take PrEP |

Other (please specify)

The Targeted PrEP Implementation Project Client Survey

9. How would you rate the following activities associated with being on PrEP ?

(Please check only one box per each statement)

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Need for medical visits every 3 months	<input type="radio"/>				
Testing for HIV every 3 months	<input type="radio"/>				
Testing for STDs at least every 6 months	<input type="radio"/>				
Taking a pill everyday	<input type="radio"/>				
Side effects from the medication	<input type="radio"/>				

Other (please specify)

10. Since being on PrEP,

	Less	No change	More
I worry about becoming HIV positive	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I worry about getting an STD	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My number of my sexual partners is	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I have condomless sex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel stigmatized for being on PrEP	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If feel more stigmatized, please explain:

The Targeted PrEP Implementation Project Client Survey

11. What helped you remain on PrEP? (Please check only one box for each statement)

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Someone available to answer my questions	<input type="radio"/>				
Someone to talk with me about condom use	<input type="radio"/>				
HIV prevention education /risk reduction activities	<input type="radio"/>				
Community support groups	<input type="radio"/>				
Other (please specify)	<input type="text"/>				

12. Did you receive PrEP medication adherence counseling?

- Yes
 No

13. Did any of the following tools help you remember to take your PrEP medication everyday? (Please check all that apply)

	No help at all	Slightly helpful	Neutral	Fairly helpful	Very helpful	N/A
Pill Box	<input type="checkbox"/>					
Electronic device (beeper, alarms etc.)	<input type="checkbox"/>					
Friend reminding me	<input type="checkbox"/>					
Telephone reminder	<input type="checkbox"/>					
Pill chart	<input type="checkbox"/>					
Text messaging	<input type="checkbox"/>					
Other	<input type="checkbox"/>					
Other (please specify)	<input type="text"/>					

The Targeted PrEP Implementation Project Client Survey

14. Have you had problems getting your PrEP prescriptions filled?

- Yes No

If yes, please explain;

15. What types of insurance issues have you experienced? (Please check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> high deductible | <input type="checkbox"/> income too high for assistance programs |
| <input type="checkbox"/> high co-pay | <input type="checkbox"/> inability to change insurance plans during the year to one with broader coverage |
| <input type="checkbox"/> lack of coverage for lab tests/medical visits | <input type="checkbox"/> insurance will not pay for PrEP |
| <input type="checkbox"/> delay with prior authorization | <input type="checkbox"/> I have not experienced any insurance issues |

Other (please specify)

16. Are you receiving your PrEP medication from your primary care provider?

- Yes No

17. Based on your experience, how likely would you be to recommend PrEP to your friends?

- Very unlikely Unlikely Neutral Likely Very likely

18. Did you tell your sexual partners you are on PrEP?

- Yes No

If yes, how did they react?

19. Did you tell people other than your sexual partners you are on PrEP?

- Yes No

If yes, how did they react?

The Targeted PrEP Implementation Project Client Survey

20. Please provide any other comments about your experiences being on PrEP

Targeted PrEP Implementation Project (TPIP) Agency “Table Talk”

Dear TPIP Providers,

The AIDS Institute would like to thank you for partnering with us on implementing TPIP. We recognize how daunting it must have been for you to initiate, persevere, and complete the pilot project amid your many other priority programs and objectives. Your diligence, patience and tenacity in collecting and sharing client-level data with us did not go unnoticed. Furthermore, thoughtful comments exchanged through monthly meetings and emails have greatly enhanced our understanding of many practical issues associated with PrEP implementation. I certainly hope that valuable knowledge gained from TPIP will benefit you as much as it benefited us.

As TPIP is drawing to a close, we would like to hear from you one more time as you and your staff reflect on our partnership in promoting and implementing PrEP. We thought a “Table Talk,” conducted with staff involved with TPIP would be a great way to reflect on lessons learned in an informal and stress-free manner. Attached is a collection of questions that could be used to jump start this important conversation among your staff. We would like to know what you consider to be best practices and what challenges you faced when implementing TPIP. You don’t have to follow the suggested questions and if other topics or ideas come up in your Table Talk, please include them in your discussion.

We hope the key ideas of your conversation could be captured and committed on paper, arranged by the suggested topics provided. If possible, please share the outcomes of your reflections on TPIP by June 30, 2015.

Thank you very much for your assistance with gathering this information! Please contact me if you have any questions.

PrEP Implementation Project (TPIP) "Table Talk" Guidance Questions

Agency name: _____ Number of people participating: _____

Contact person: _____

1. Please describe which components worked well and did not work well when implementing TPIP.
What worked well:
What did not work well:
2. What part of TPIP would you do differently?
3. What part of TPIP will you continue?
4. As a service provider, what do you perceive as the biggest issues TPIP clients encountered when accessing PrEP services? (e.g., insurance, routine testing for Hepatitis, STIs, and HIV, and adherence)?
5. Do you have any comments about the data collection process (e.g., Intake form, Medical visit form, AIRS) and the TPIP Protocol?
6. What, if anything, should change in the PrEP Clinical Guidance document?
7. What would you recommend to others who are interested in starting a PrEP program?
8. Do you have any additional comments?

Targeted PrEP Implementation Program

Data Brief #1 May, 2016

What is Pre-Exposure Prophylaxis (PrEP)?



PrEP is a new HIV prevention method in which people who do not have HIV infection take a pill daily to reduce their risk of becoming infected.



Only people who are HIV-negative should use PrEP. An HIV test is required before starting PrEP and then every 3 months while taking PrEP.



PrEP can only be prescribed by a health care provider and must be taken as directed to work.

Targeted PrEP Implementation Program (TPIP)

In 2013, the New York State Department of Health (NYSDOH) AIDS Institute (AI) initiated a pilot PrEP program targeting HIV-negative men who have sex with men (MSM) and transgender females at high risk for HIV infection. The one-year program was a collaboration between NYSDOH and five community medical providers* designed to gain practical knowledge and understanding of the opportunities and challenges associated with implementing PrEP in the community. This data brief is the first of a series of three that highlights the key findings from a multiple-component evaluation of TPIP.

*Trillium Health, APICHA, Evergreen Health Services, William F. Ryan CHC, SUNY Downstate.



PURPOSE

- Determine the extent to which PrEP can be implemented in “real world” settings
- Assist the AI in identifying needed resources to enable routine use of PrEP
- Lay the foundation for statewide program implementation, where PrEP is delivered as part of a comprehensive prevention plan



PROGRAM ELIGIBILITY

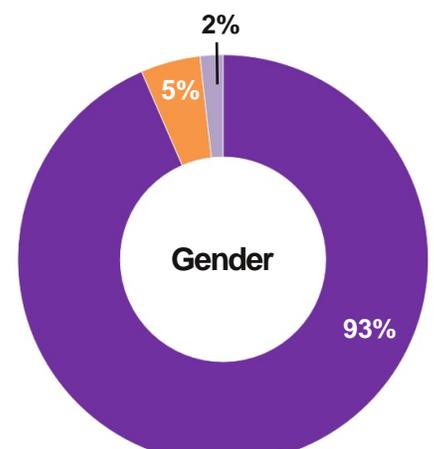
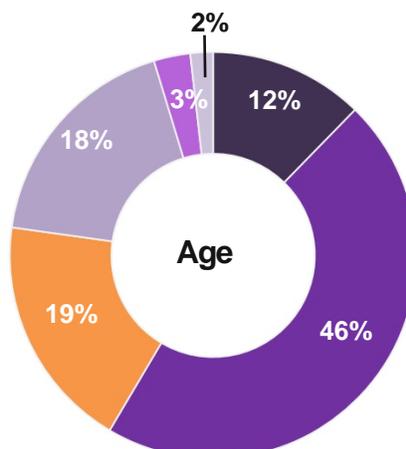
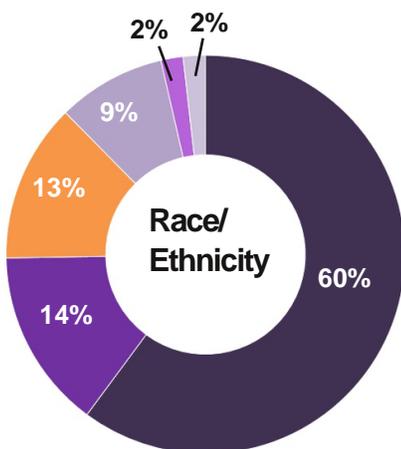
- Be male sex at birth
- Be the age of 18 years or older
- Be a gay man or MSM/transgender woman
- Have an HIV-seronegative status
- Exhibit evidence of high-risk behavior for acquisition of HIV infection
- Be willing to provide contact information
- Be informed about program requirements and be willing to participate as indicated



DATA COLLECTION

- Intake, eligibility, and medical visit:**
- Assess and determine client’s eligibility at intake
 - Collect client medical visit data at 1st, 3rd, 6th, 9th, and 12th month visit
- Demographic and STI testing data:**
- Match TPIP clients records to AIDS Institute Reporting System for demographic and STI results

Client Demographics (N=171)



White Black Hispanic
Asian Other Unknown

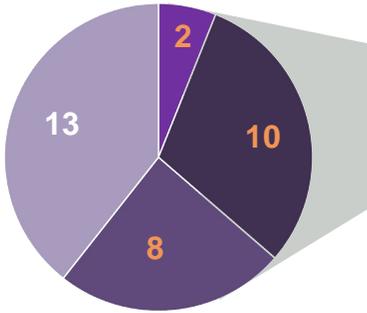
18-24 25-34 35-44
45-54 55+ Unknown

Male Transgender woman
Unknown

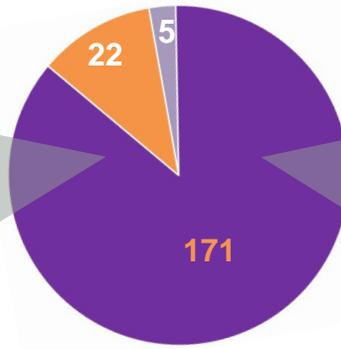
Client Enrollment

198 Assessed for TPIP

33 Lost to follow up

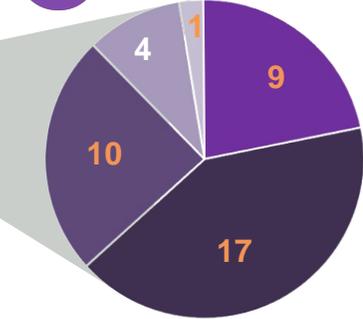


2 at 1st month
10 at 3rd month
8 at 6th month
13 at 9th month



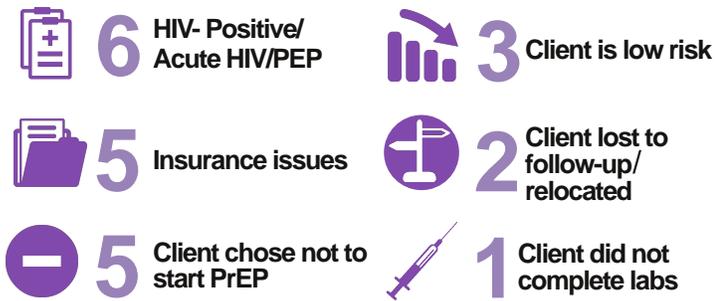
171 enrolled in TPIP
22 ineligible/chose not to start
5 did not return after intake

41 Discontinued



9 at 1st month
17 at 3rd month
10 at 6th month
4 at 9th month
1 at 12th month

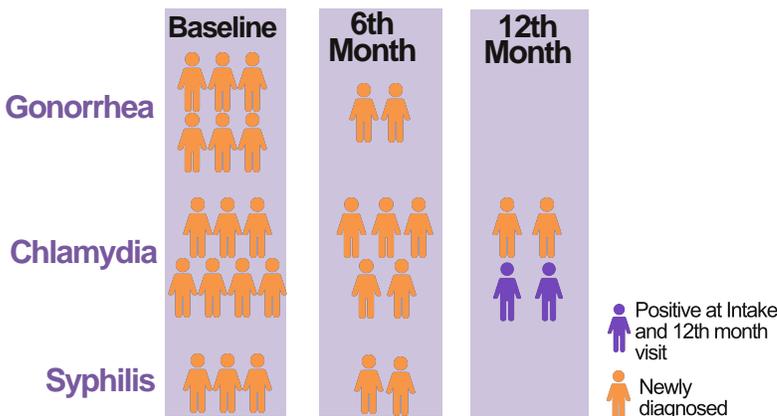
Reasons Why Clients Were Not Enrolled in TPIP (N=22)



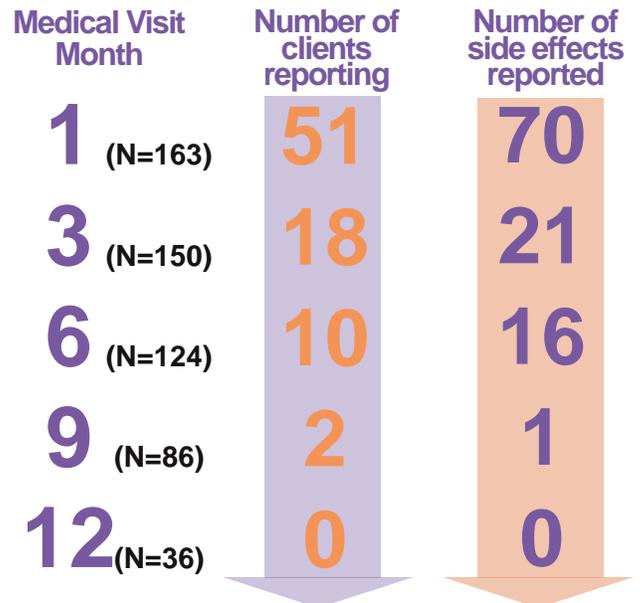
Reasons Why Clients Stopped Taking PrEP (N=41)



STI Diagnosis



Reported Side Effects by Month



Adherence* rate during the program ranged from 91.0% - 94.1%

* Taking 4 or more doses of PrEP medication in the week prior to medical visit



Department of Health

AIDS Institute
Office of Program Evaluation and Research

1-800-541-AIDS
www.health.ny.gov/diseases/aids/

Targeted PrEP Implementation Program (TPIP) Client Exit Survey

Data Brief #2 May, 2016

Purpose

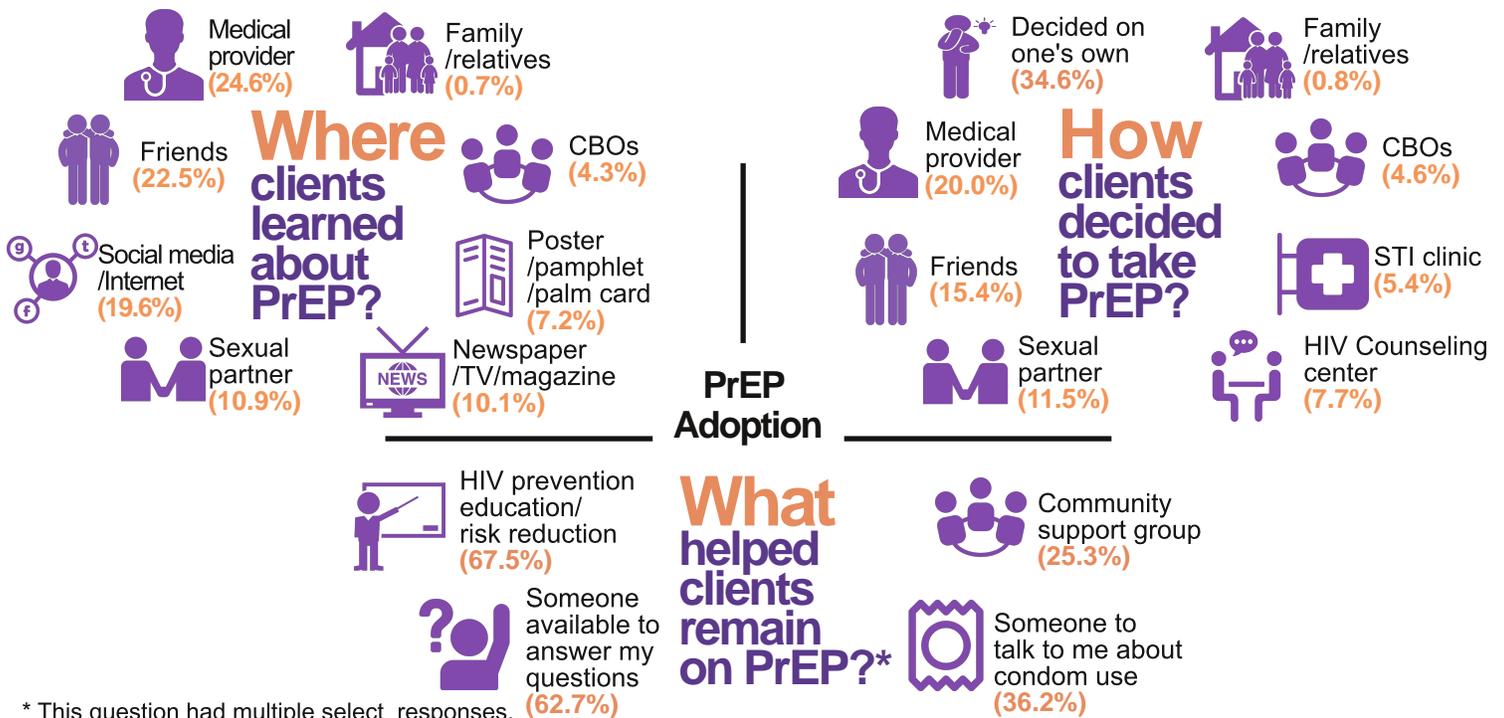
- Assess client experience with taking PrEP
- Help TPIP agencies and the AIDS Institute (AI) with improving services
 - Identify gaps and barriers
 - Address program barriers
 - Render solutions to problems

Survey Topics

- Learning about PrEP
- Decisions to start and remain on PrEP
- Rating experiences associated with being in TPIP
- Perceptions of clients and their partner(s) about being on PrEP
- Insurance issues and barriers to filling PrEP prescriptions

Methodology

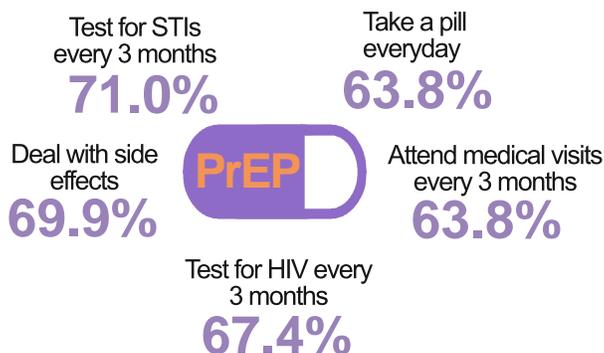
- Survey created by AI TPIP team
- Administered by TPIP agencies
- Consisted of 20 questions
- Completed at clients' last TPIP visit
- 151 clients qualified to take survey
- Response rate was 55% (N=83)



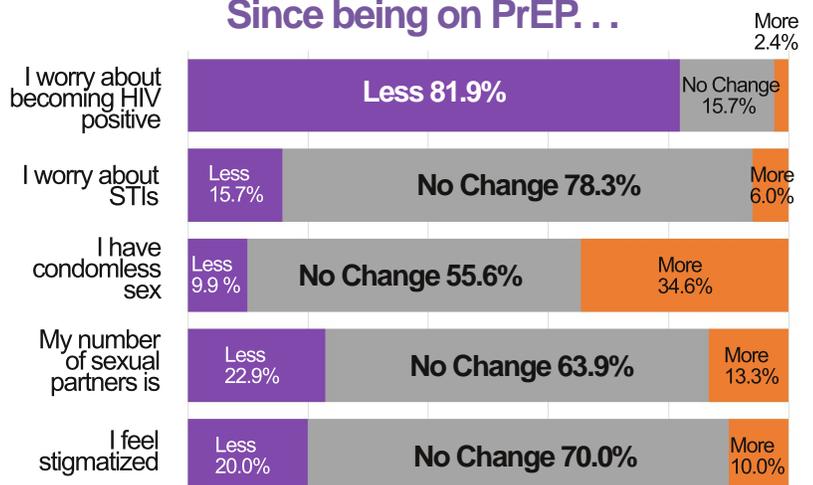
* This question had multiple select responses.

Client experiences associated with being in TPIP

Respondents found it easy to:



Since being on PrEP...



Types of insurance issues experienced by clients

77% (N=64) of clients did not have any insurance issues

Financial issues

- High deductible / High co-pay
- Lack of coverage for lab tests/ medical visits
- Insurance will not pay for PrEP
- Income too high for assistance programs

Administrative issues

- Delay with prior authorization
- Inability to change insurance plans during the year to one with broader coverage

Few clients experienced problems getting PrEP

82% (N=68) of clients did not have a problem getting their scripts filled

Insurance issues



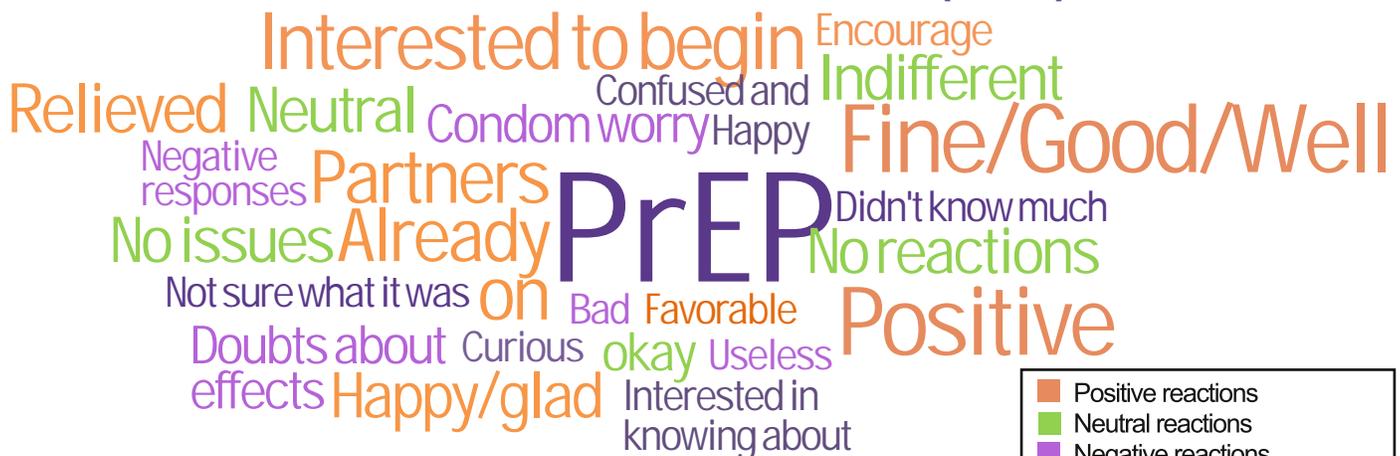
- Insurance required medication to be mail order
- Insurance was cancelled
- Need to switch to insurance provider that would cover medication

Refill issues



- Only 30-day script at a time and needed doctor to call in
- Did not time the refill correctly
- Limited number of pharmacies stocking medication
- Need to have blood drawn before could get a refill script
- Did not receive the medication during the switch to mail order
- Wrong medication sent

Reactions of Sexual Partners (N=64)*



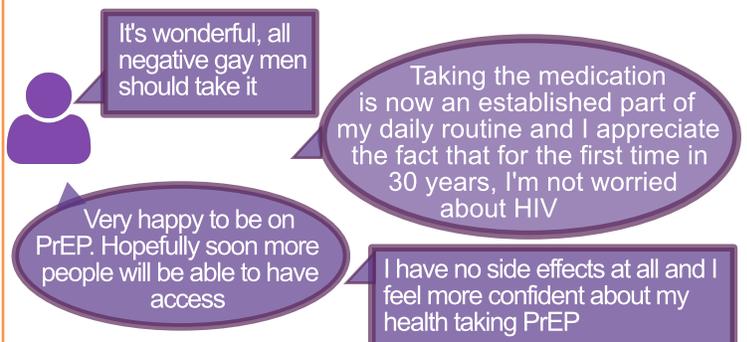
* 64 of the 83 survey respondents told their sexual partners that they were on PrEP.

Other Key Findings

94.0% (N=78) of clients were likely to recommend PrEP to their friends, 6% not likely to recommend.

- For the majority of TPIP participants, feelings of stigmatization remain unchanged, but increased concern lingered among a small group of clients.
- The role of CBOs in promoting PrEP and assisting the client in the decision making process should be enhanced.

Comments from TPIP clients



Department of Health

AIDS Institute
Office of Program Evaluation and Research

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Targeted PrEP Implementation Program (TPIP) Table Talk

Data Brief #3 May, 2016



Purpose

- A guided discussion by PrEP staff from each participating agency to:
- Reflect on their partnership with the AIDS Institute (AI) in promoting and implementing PrEP
 - Share best practices and challenges faced during TPIP
 - Provide recommendations for future program implementation



Topics of Interest

- Infrastructure
- Medical visits
- Support services
 - Risk reduction
 - Medication adherence
- Quality assurance (QA)
- Data collection



Methodology

- AI and agency staff determined key topics to address during guided discussions
- Staff at each agency convened for roughly one hour to discuss key topics
- Round table discussion results were provided to AI staff
- AI staff identified patterns and themes from guided discussions and shared with agency staff

Infrastructure



- Ensure adequate resources
- Clear roles and responsibilities
- Routine meetings of PrEP team
- Deliver PrEP within integrated system of prevention/care
- Introduce PEP patients to PrEP
- Initiate process for insurance, payment options as soon as possible
- Maintain a list of resources for assistance with paying for medications, medical visits, lab testing

Medical Visits

- Allow staff, Primary Care Physician (PCP) more discretion for scheduling of risk assessments, patient visits, HIV/STI screening
- Provide PrEP in conjunction with Primary Care
- Retention issues with healthy persons attending routine medical visits
- Scheduling challenges as number of patients increases
- Follow-up visits at less frequent intervals for adherent clients



Quality Assurance



- Routine, ongoing quality assurance activities for monitoring, linkage, retention, data collection and reporting
- Use QA visual aids, “at a glance” tools, spreadsheets to review patient needs
- Institutional feedback and support
 - AI technical assistance, reports, calls, QA

Support Services

- Develop/use information packet with medication information, adherence education, side effects management
- Adherence especially difficult for youth
- Provide additional support for youth and other subgroups
- Provide risk reduction and condom use counseling



Data Collection



- Lessons learned from data collection will be used for future implementation projects
- Streamline data collection requirements for AIDS Institute Reporting System (AIRS)
- Integrate EMR system with PrEP data requirements, labs, follow-up visits, assessment of risk

Lessons Learned: Activities and Resources for PrEP Providers

Program Resources, Infrastructure and Support

- Conduct trainings regarding the basics of PrEP, tracking patients' medical visits, cultural and diversity issues, and available resources for payment of medications for patients without health insurance or limited medication payment or reimbursement options
- Gain buy-in from agency executive and administrative staff to foster support and obtain the necessary resources to deliver PrEP services
- Identify a PrEP "Champion" whose role is to raise community awareness about PrEP, and to bolster recruitment and retention in the program
- Develop or obtain PrEP-related educational materials and resources for providers and consumers
- Integrate PrEP-related policies and procedures within the agency's overall activities
- Prepare for a more intense initial phase, when client eligibility, readiness, and insurance/payment options will be assessed
- Ensure that staff are aware of available drug assistance programs and insurance provider options for payment of PrEP medications and services
- Identify or develop PrEP-related marketing resources, including internet and social media
- Promote capacity building to accommodate the increase in patient caseloads due to enrollment of healthy adults on PrEP who require routine medical visits and lab work

TPIP Implementation

- Ensure that PrEP eligibility criteria is not overly restrictive
- Develop procedures and clinical guidance for transitioning patients who repeatedly seek post-exposure prophylaxis (PEP) to PrEP
- Clearly define roles and responsibilities of clinical and non-clinical staff, so that PrEP-related activities are divided among staff and not the sole responsibility of the prescribing clinician
- Collaborate with community-based agencies and organizations serving high risk populations to facilitate recruitment of candidates for PrEP and provision of supportive services not available on-site.
- Be prepared and educate staff about limited/lack of insurance coverage, potentially high deductibles and co-pays, and obtaining prior authorization for PrEP medications
- Identify options for payment of medication (Truvada), medical visits and lab tests, including through pharmaceutical companies, private institutions, and publicly available funds such as Medicaid and PrEP-AP

Data Collection, Reporting, and Quality Assurance

- Develop organizational tools for data collection, data management, monitoring, reporting, patient scheduling, and service delivery
- Integrate PrEP templates and data reporting requirements within the existing EMR system, including labs, follow-up visits, and risk assessments
- Conduct routine, ongoing quality assurance activities for data collection, management, monitoring, and reporting



