

Phase 1 Pre-Implementation	Description of Activity
Stage 1: Engagement	
Initiate program development process	• Date the site initiates program development process • Organization or clinic decides that they want to initiate a new or enhance/standardize an existing PrEP program • Site may have proactively sought out information • Information may have been purposefully disseminated to site • Please indicate in the notes section whether the process began in response to grant or agency funding
Relevant parties identified	• Site identifies relevant parties within the clinic or organization (e.g., leadership, providers, other supporting staff, pharmacy) to determine if they would support program development or enhanced standardization to meet reach or equity goals • Relevant parties consider developing new or standardized program for PrEP; specify in notes PrEP type (daily only; new protocol for event-driven PrEP; 2-month injectable; 6-month injectable)
Cost and resource information gathered	• General cost and resource information (e.g., medication cost, insurance coverage, storage requirement) is requested by the site (not necessarily specific to site structure) • If there is a RFP for PrEP program implementation, site may gather cost and resource information by attending an information session about the RFP
Stage 2: Feasibility Assessment	
First site planning meeting	• Date of first discussion of program development or standardization process • Date of first discussion where implementation is outlined, including negotiations to fit biomedical HIV prevention modality into organization or clinic flow • Participants might include director of nursing, director of social work, front desk / manager, medical director, pharmacy, other leadership
Senior leadership endorsement of program	• This refers to senior administration such as CEO, CFO, ED communicating to the program team that they support program development or enhanced standardization process
Key external stakeholders identified	• This includes stakeholders who might facilitate program implementation (e.g., pharmacy, referral sites) and stakeholders who may help with demand generation or referral to PrEP program (e.g. CBOs)
Stakeholder meeting #1	• Date of first meeting with external stakeholders whose services or contributions could facilitate implementation • Meetings may occur with multiple stakeholders or individually with each stakeholder. Use date when clinic finishes first meetings with each key stakeholder identified • Meetings are most often in person, but can also occur via video conference or teleconference • Concrete information is provided about the program development or standardization to external stakeholders; potential contributions are discussed • Key steps necessary to achieve positive outcomes are described
Program lead identified	• Clinic employee or team member responsible for taking the lead on implementation efforts is identified • Program Lead is defined - must have a degree of decision-making power • Please specify the level and expertise of the identified program lead in the notes section
Stage 3: Readiness Planning	
Cost calculator / funding plan review	• Clinic estimates cost or cost implications of program development or enhanced standardization • Cost calculator / funding plan categories may include staffing, staff training time, system changes (e.g., to EMR, updates to billing system), infrastructure changes, marketing and materials.
Program components identified	• This includes components related to engagement (e.g., education and counseling), initiation (labs and prescription), and retention (e.g., follow up, repeat labs, and prescriptions), generating an enterprise formulary request to introduce new drug into clinic
Internal program review meeting	• This meeting should include all stakeholders (and external if necessary for program implementation) involved in service delivery to review and revise program components, i.e. how the PrEP program components will be implemented at the clinic
Program model is finalized	• Program components are finalized based on feedback from internal stakeholders (could also involve external stakeholders)

Training needs and resources identified	Program coordinator identifies list of training needs for relevant staff. This might include clinical/skills training (e.g., how to take a sexual history, how to help a patient self swab), content area training (e.g., what is PrEP, labs required), and specific protocols
Written implementation plan completed	Finalized written plan establishing protocols, goals, policies, and timelines for implementation
Staffing plan finalized	- Site finalizes plan on staffing for PrEP program. This should include staffing, percentage of effort, qualifications, roles and responsibilities, and sequence of staff assignment - Clinic provides a staffing timeline to make sure roles are filled in an efficient manner (e.g., navigator hired prior to but close to training)
Staffing plan approved	- Staffing plan is approved by agency leadership - Coordinator is given green light to advertise the position
Program goals defined	- Clinic defines goals for program implementation (e.g., service reach, equity, quality) that will be assessed using the metrics - Could be: number of people offered PrEP; % increase of certain client characteristics offered PrEP; retention goal - In defining these Program Goals, programs may need to review and revise metrics to make sure all the necessary data are being collected. For example, if health equity is a specific goal, then disaggregation by key populations will be needed.
Phase 2: Implementation	Description of Activity
Stage 4: Staff Hired and Trained	
First PrEP care team staff hired/assigned	- Occurs either when the first clinical staff member is hired, reassigned or identified as being part of the implementation of new biomedical HIV prevention modalities - In many cases this may be when existing clinic staff are informed that they should incorporate PrEP-related services into their existing work (eg registration, clinic visits, stocking materials)
Data collection and evaluation point of contact person assigned/identified	- Date site identifies a person to be in charge of data collection and management and providing technical support for using the data system at site level - This person should also be able to create reports from the data system and present data to the PrEP Care team to inform review of service delivery outcomes.
Relevant staff trained on standard operating procedures	- Date when the clinical and non-clinical staff start training or when the first clinical staff member receives training. - Please document the following information in the notes section: training participants, whether they were trained together, date of training initiation, date of completion.
Relevant staff receive clinical / skills / supplemental training	Please document the following information in the notes section: content of training participants, whether they were trained together, date of training initiation, date of completion.
Stage 5: Data System for Monitoring Program Performance	
Monitoring and evaluation metrics are agreed upon	- Program agrees on metrics they will collect to monitor PrEP program performance - This may include QA measures, service delivery measures, and/or patient reported outcomes.
Date program data capture tool is finalized	- Clinic agrees on what to collect and how to track metrics identified in 5a. - The system tracks key indicators and process measures of PrEP service delivery; This could include creation of spreadsheet, code for extraction from EMR, etc.
Date program data capture training held	- Clinic is trained on data collection and management system. The system tracks key indicators and process measures of PrEP service delivery - This involves entering information into an online database or spreadsheet or EMR
Process for data utilization is finalized	A program should have a formal process for review of program data with key internal stakeholders to inform program fidelity, equity, and improvement
Stage 6: Services Introduction	
Medication available for PrEP implementation	Document date when site first makes a new PrEP modality available to PrEP clients, either on-site (e.g., injectable CAB or a starter pack for oral PrEP) or pharmacy has new PrEP modality in stock

Awareness & engagement plan initiated	• Date site first starts to implement PrEP awareness and engagement plan; This includes education and counseling • This is the date that signals "Program Start Up" • If multiple modalities available, includes discussion of best PrEP option
First client received PrEP decision-making counseling	• Date first client receives PrEP Decision-Making Counseling to determine whether they could benefit from using PrEP • If multiple modalities available, includes discussion of best PrEP option
First client received PrEP financial navigation	• Date first client receives PrEP Financial Navigation • If introducing new PrEP modalities, includes discussion of coverage for each type of PrEP
First client has PrEP initiation visit	• If the clinic has never implemented PrEP, use the date when the first PrEP prescription is written • If introducing new PrEP modalities, use the date the first prescription for that new modality is written
First client received PrEP adherence and sustainment support	• This might include an on-schedule visit, outreach by navigator for visit reminder, or refill • If introducing new PrEP modalities, this would be the first time that there is an Adherence service for the new modality
First client received PrEP follow up visit	• Date first PrEP user receives follow-up clinical visit; this might include an on-schedule visit, outreach by navigator for visit reminder, or refill.
Stage 7: Delivery with Feedback and Assistance	
First meeting after service introduction to review program	• Date of first meeting to review / discuss status of program after service introduction • Mark as complete only when all parties involved in PrEP care (e.g., physicians, nurses, benefit navigators, pharmacists [if applicable], etc.) attend the meeting
First data review meeting	• This is a meeting where metrics identified in Stage 5 are presented and reviewed by team to identify areas for improvement • Requires sufficient number of patients to allow for assessment • Should involve review of engagement, initiation, and retention components of the program
First discussion of potential modifications to service delivery and patient flow	• Date when PrEP care team first reviews how PrEP is being delivered at site, whether implementation plan is followed, and patient flow. • The purpose of the meeting is to identify modifiable bottlenecks and strategies to improve service delivery.
First implementation plan for service improvement created	• Date when PrEP care team creates first plan to implement strategies to improve service delivery
First improvement strategy implemented	• Date when site first implements strategies for improvement
Second review of service delivery and patient flow	• This activity includes (1) review of M&E metrics data to identify areas for improvement; and (2) review of how PrEP is being delivered in the clinic to identify modifiable bottlenecks and strategies to improve service delivery
Second implementation plan for service improvement created	• Date PrEP care team creates a second plan to implement strategies to improve service delivery
Second improvement strategy implemented	• Date when site implements strategies for improvement
Program reaches first goal	• Date when site's first / one goal articulated in Stage 5 is reached
Phase 3: Sustainment	
Stage 8: Development of Competency and Sustainment	
PrEP is fully integrated into clinical services (Sustainment)	• PrEP services are fully integrated into clinic flow. PrEP services have graduated from a "program" to routine part of care at the site
Delivery of PrEP is embedded into clinic policies and procedures	• PrEP services are embedded in policies and procedures manuals of the clinic that allow PrEP to be sustained through staffing turn over and shortages.
PrEP services increase health equity	• PrEP services intentionally designed and refined to reach groups with high unmet PrEP need in the catchment area