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# A case study of the co-creation of the PrEP-SIC: a roadmap to support introduction of pre-exposure prophylaxis into new settings

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## Abstract

**Background** Pre-exposure prophylaxis (PrEP) is an effective biomedical intervention to prevent HIV, however uptake of PrEP across the United States has been slow and uneven. Understanding "what it takes" to implement PrEP so that it reaches those groups with the highest rates of new diagnoses is a critically important and understudied question. This descriptive case study details the development of an implementation science tool to guide the introduction of PrEP into new settings.

**Methods** The Universal Stages of Implementation Completion (U-SIC) was customized for the provision of PrEP services (PrEP-SIC) by using subject matter expert recommendations to operationalize PrEP implementation processes into discreet activities. Six clinical sites used the PrEP-SIC retrospectively and prospectively to assess the extent to which the PrEP-SIC activities mapped onto their experience of introducing oral daily, event-driven, and injectable PrEP into their clinical settings. Interviews with site champions and PrEP-SIC data, including proportion of activities completed, were analyzed to refine the PrEP-SIC and identify patterns of implementation behavior.

**Results** Five themes emerged about the accuracy of the PrEP-SIC to capture real world implementation processes: (1) Some PrEP-SIC activities, such as generating a costing plan, are not reflected in real-world implementation; (2) Sites do not define sustainment as achieving a set of quantitative program goals, but rather as being able to continue a program through staffing turnovers and shortages; (3) Written protocols and reviewing clinic data for program improvement were identified as two key factors that differentiate sites that reached sustainment from sites that did not; (4) The PrEP-SIC is assessed as somewhat useful to guide introduction of PrEP, but pairing the tool with technical assistance or coaching would optimize its utility; (5) Implementation is cyclical and recursive and pre-implementation activities may need to be revisited over time to ensure sustainment.

**Conclusions** The case study has resulted in a PrEP-SIC that accurately captures an idealized implementation process. Using a well-defined set of implementation activities as a roadmap with supportive services to clinics, like technical assistance or implementation coaching, could direct implementation efforts and facilitate the integration of PrEP into new clinical settings that reach the people who need PrEP the most.

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## Background

The effectiveness of multiple formulations of biomedical HIV prevention has been established in clinical trials, demonstration projects, and real world use [1–3]. The number of pre-exposure prophylaxis (PrEP) users in the United States continues to increase, growing by 17% between 2022 and 2023 [4], however, uptake of PrEP overall has been slow and uneven, widening disparities in HIV incidence by region, race/ethnicity, and gender [5, 6]. The South, which accounted for 53% of new HIV diagnoses in 2023, only comprised 39% of PrEP prescriptions [4]. In the same year, Black people represented 39% of all new HIV diagnoses, but only received 14% of PrEP prescriptions, while cisgender women made up 18% of new HIV diagnoses but only 8% of PrEP prescriptions [4]. For PrEP to maximize its potential public health impact in the United States, it will need to be adopted by many more people, particularly by non-white, gay, bisexual, and other men who have sex with men and cisgender and transgender women of color. This is true for formulations that are already FDA approved and for newer, longer-acting formulations, like the highly effective, every-six-months injectable medication, lenacapavir [7], that was submitted to the FDA for review in early 2025. Understanding "what it takes" to implement PrEP so that it reaches those groups with the highest rates of new diagnoses (e.g., who could benefit from PrEP the most) is a critically important and understudied question.

A primary strategy to achieve growth in uptake is to increase the number and types of clinical settings that provide access to PrEP, including reproductive health clinics and primary care practices, but also locations such as pharmacies and school-based health centers that serve diverse populations and are located in geographies with the highest rates of incident HIV [8]. However, access at pharmacies and within school-based health centers is limited by state laws and regulations, with generally more permissive environments in Western and Northeastern states and more restrictive regulation in the South, further contributing to disparities in access. To date, beyond clinical guidance from the Centers for Disease Control (CDC) [9], there has been scant implementation guidance for how to introduce PrEP into clinical services. Instead, studies on PrEP implementation have focused on patient- and provider-level behaviors and cognitive constructs such as knowledge, awareness of, and willingness to use PrEP, and they have largely ignored the planning activities and structural processes required for successful PrEP implementation in clinical settings.

The Universal Stages of Implementation Completion® (U-SIC) originally was created as a research tool to specify and measure, and thereby generate scientific understanding of, common and necessary steps that agencies take when introducing evidence-based interventions (EBIs) into their service settings. The tool distills introduction of an intervention into a set of 46 action steps or activities that are common for a wide range of EBIs across diverse settings, including mental health centers, school-based initiatives, community-based pharmacies, child welfare programs, primary care clinics and substance use disorder treatment centers [10–13]. These 46 action steps are distributed across the eight stages of implementation: from engagement with the decision to implement to delivering with competency. The U-SIC assesses how many (proportion score) and how quickly (duration score) a site completes implementation activities, by capturing the date an implementation activity is first completed. Since its creation, U-SIC has been adapted or customized for over 85 EBIs [10, 13–16]. Studies show that proportion and duration scores, as measured by the SIC, are a strong predictor of implementation success [16]. From these data, universal benchmarks have been developed and programmed into the SIC's web-based dashboard to guide optimal implementation performance. Identifying sites performing below benchmarks can help agencies plan the provision of targeted technical assistance or coaching for sites at risk of implementation failure. The current study reports on the customization of the U-SIC for PrEP, resulting in the PrEP-SIC.

As a biomedical intervention, PrEP for HIV — prescribed as a pill, vaginal ring, intra-muscular injection or soon a sub-cutaneous injection – may appear to be different than the more behavioral EBIs from which the SIC was developed. However, the challenge with PrEP implementation has not been related to its biomedical characteristics but instead to the complex provider-, clinic- and systems-level work of implementation. Effective PrEP implementation requires that providers routinely discuss or present PrEP as an option to their patients, support them in their decision-making process to determine whether PrEP would be beneficial to them and which option to choose, and provide them with the services to support sustained use, switching, or discontinuation as appropriate to their changing sexual and social lives. To date, few studies have offered concrete guidance on activities that program planners and healthcare teams need to undertake to effectively implement a holistic PrEP program that reaches populations in need.

We sought to investigate whether the U-SIC could be customized for PrEP provision and efficiently guide introduction of current and future formulations of PrEP into new clinical settings. Theoretically, by customizing the U-SIC activities across the eight stages of implementation defined for measurement, we could develop a prescriptive roadmap to guide a facilitation process for introducing PrEP into new settings. We provide a descriptive account of the co-creation process of the PrEP-SIC through a partnership between leaders and administrators of PrEP programs and academic researchers. This research occurred within the context of a collaborative research project called BLUPrInt (R01MH123262). BLUPrInt is designed to develop the biobehavioral infrastructure (i.e., knowledge, guidelines, tools) needed to support the integration of PrEP services into new clinical settings and accelerate the expansion of existing service delivery to include emerging PrEP formulations.

## Methods

This descriptive case study reports on the development and real-world use of an implementation science tool to guide clinical sites in the provision of PrEP services. The case study methodology lends itself to explaining, describing or exploring events or phenomena in the everyday contexts in which they occur [17]. With the introduction of PrEP services as the 'event', we used a deductive approach to describe the series of activities necessary for any clinical site to begin offering PrEP services. Following the standardized adaptation protocol for the U-SIC, we first operationalized PrEP implementation processes and derived a draft PrEP-SIC [14]. We then partnered with six clinical sites in the northeast, south, and midwest regions of the US to assess the extent to which the PrEP-SIC activities mapped onto their experience of introducing oral daily, event-driven, and injectable PrEP into their clinical settings (Table 1). Our study did not intervene on the introduction of PrEP services, rather sought to document the process retrospectively and prospectively. Finally, we refined the PrEP-SIC to more accurately reflect these real-world implementation processes.

1. *Operationalization of the PrEP Implementation Process.* A panel of five subject matter experts, selected due to their experience implementing PrEP, independently reviewed the U-SIC. The panel included an infectious disease clinician who championed the introduction of PrEP into a sexual health clinic at an academic medical center (JZ), a social psychologist who designed and supported implementation of one of the earliest PrEP services in the US at a community health center (SAG), an HIV Prevention Program Director from a large urban health department responsible for contracting and monitoring implementation of PrEP at funded agencies, a social scientist studying the introduction of PrEP into a public health system (KM), and a PrEP project coordinator and trainer (YW). First, the panel discussed the fit of the overall framework of the eight stages of implementation (Fig. 1). Next, each panel member assessed the relevance of each

**Table 1** Clinical partner site and PrEP program description

| Program Number | PrEP Modality Introduction Measured by PrEP-SIC | Clinic Type | State | Approximate Number of Patients Served Annually | PrEP Modality Pre-Implementation Start Date | PrEP-SIC Data Collection Start Date | Status of Implementation as of Jan- 24 |
|---|---|---|---|---|---|---|---|
| P1 | Daily oral (teleprep) | Sexual health clinic (Telehealth) | CO | 10,000 | Jan-19 | Sep-21 | Sustainment |
| P8 | Daily oral | Department of Health-affiliated clinic | VA | 1,000 | Feb-22 | Feb-22 | |
| P7 | Daily oral | Academic medical center-affiliated school-based health center | NY | 7000 | Jun-17 | Dec-23 | |
| P6 | Daily oral | Hospital-based infectious disease clinic | NY | 250 | Oct-20 | Dec-22 | |
| P2 | Event-driven oral | Sexual health clinic | CO | 10,000 | Feb-21 | Sep-21 | Sustainment |
| P9 | Long-acting injectable | Department of Health-affiliated clinic | VA | 850 | Jun-22 | Jan-23 | |
| P4 | Long-acting injectable | Academic medical center- affiliated sexual health clinic | FL | 1,600 | Jan-22 | Oct-22 | Sustainment |
| P3 | Long-acting injectable | Academic medical center-affiliated sexual health clinic | NY | 550 | Nov-20 | Dec-22 | Sustainment |
| P5 | Long-acting injectable | Sexual health clinic | CO | 12,000 | Dec-21 | Apr-23 | |

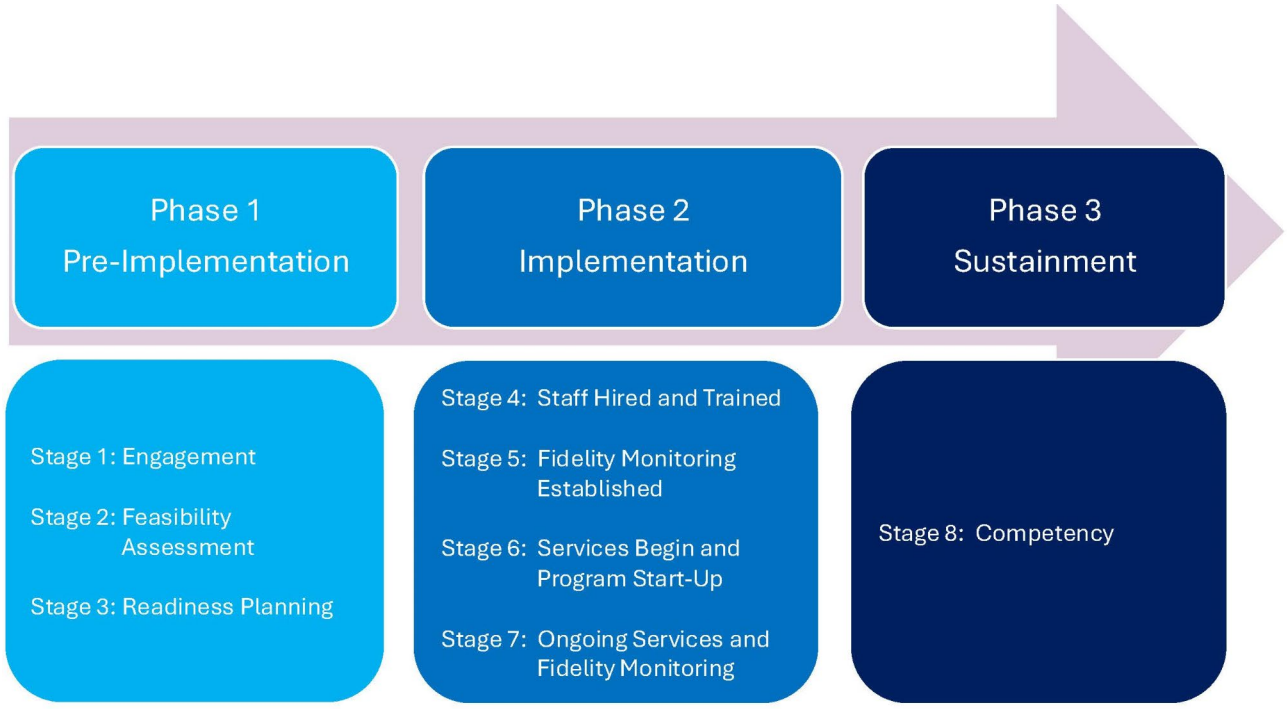


**Fig. 1** Universal Stages of Implementation Completion® (U-SIC)

U-SIC activity to the implementation of PrEP in their setting or agencies. Members also were queried about gaps in the U-SIC activities and asked to identify additional activities needed to implement PrEP that were not represented. The project lead (KM) synthesized suggested changes, accepted suggestions that captured common themes across the panel, and engaged in further discussions on items that were inconsistent across members of the panel.

2. *Customization and iterative refinement.* The project lead (KM) met with the U-SIC primary developer (LS) to explain the suggested changes and discuss whether the changes hued closely enough to the spirit of the U-SIC to allow for the U-SIC to be used or whether customization was necessary. Determining that customization was necessary, the project lead and SIC developer reviewed each SIC stage and ensured that the activities and their definitions accurately captured the implementation processes described by the panel of PrEP implementors. The threshold for activity completion, decision rules for validity checks, and scoring protocol were clearly defined. A "skeletal" PrEP-SIC was outlined for programming, iteratively refined, and confirmed with the expert PrEP panel. Through this process, 47 activities were delineated in the customized PrEP-SIC. Finally, the customized PrEP-SIC was programmed into the web-based SIC tool for use.
3. *Accuracy of the PrEP-SIC Activities.* We conducted a workshop introducing the PrEP-SIC at the Biomedical HIV Prevention Summit in Chicago in 2022. Six clinical settings with nine distinct PrEP programs were identified through these dissemination efforts and recruited to partner in assessing the PrEP-SIC. The six sites were purposively chosen for their diversity in geography, clinic type, and PrEP formulation being introduced (Table 1). They included a school-based health center program ($n = 1$), a teleprep program ($n = 1$); sexual health clinics ($n = 2$), health department-affiliated clinics ($n = 3$), and private hospitals ($n = 2$). One site completed the PrEP-SIC for three programs: tele-PrEP, long-acting injectable PrEP, and event-driven PrEP. Another site completed the PrEP-SIC for oral and long-acting injectable PrEP. The remaining sites completed the PrEP-SIC for either oral or long-acting injectable PrEP.

### Data collection

An excel version of the PrEP-SIC, listing activity names and their definitions, was sent to the PrEP champion at each partner site between June and December 2022. PrEP champions, identified as individuals who played a key role in designing and implementing the agency's PrEP services, were diverse across sites and included a state

PrEP coordinator, infectious disease physician, school-based health center medical director, HIV prevention program director, clinical pharmacist and nurse practitioner. The PrEP champion completed the excel sheet retrospectively for PrEP introductions that had already taken place and prospectively for introduction of new PrEP programs (e.g., introduction of long-acting injectable PrEP). Retrospective data was gathered using email histories and calendar and through discussion with other team members. Prospective data was collected in real-time and reported to the study team bimonthly through email and on Zoom calls to clarify any details as needed.

For each activity listed in the PrEP-SIC, the PrEP champion noted whether their implementation process included it, whether the activity was not yet started, in progress, completed (if completed, the completion date), or assessed as not relevant to their setting. If an activity had already occurred in a prior implementation (e.g., stakeholder engagement), then the activity was coded as "existing" and included in the proportion score. Similarly, if an activity was known to have occurred but the date on which it was completed was unknown, it was also included in the proportion score as having occurred.

In addition, each PrEP champion was asked to annotate the PrEP-SIC with written comments about the salience of the activities and their definitions and suggestions for edits to further clarify or match their experience implementing a specific PrEP formulation. These annotations were treated as primary data and included in the analysis. Following the conclusion of the PrEP-SIC data collection, we conducted 60-minute debriefing interviews to assess the usefulness of the tool to monitor and guide the implementation process. The interview guide (See Supplementary Materials) was designed to clarify information collected in the written document about the implementation process. Data collection took place between June 2022 and December 2023.

### Positionality statement

This study was conducted as a partnership between academic researchers, clinicians delivering PrEP services, and administrators of PrEP programs. The academic researchers included individuals with training in public health, psychology, and implementation science. The clinicians included pharmacists, medical doctors, and nurse practitioners. The administrators included individuals with training in public health and at least five years of experience implementing PrEP programs. The multi-disciplinary composition of the team had the benefit that no single epistemology was dominant. Instead, the team was unified in our primary intention to generate a tool that would be useful to the field.

Unique to this study, the project champions who were the source of the mixed-methods data presented are included as co-authors as their intellectual input was central to the co-creation process. A key threat to this approach was the possibility that the project champions would feel uncomfortable expressing negative feedback towards the PrEP-SIC. The researchers took this concern seriously and used two strategies to mitigate this threat. First, we asked for written annotations of the PrEP-SIC and in our instructions for the annotations encouraged criticism by noting that only by relying on their critiques would we be able to generate an accurate and useful tool. We thought providing written feedback through email would provide space for honest expression of enthusiasm or reservations. Second, when conducting interviews to elicit further feedback from the PrEP champions, interviewers included statements that the PrEP-SIC was an experiment and that most experiments fail and need to be tweaked and that only through failure can knowledge be generated -- further giving opportunity for interviewees to share negative assessments of the tool. We assess that these strategies were successful as PrEP champions provided pointed negative feedback that led to refinements throughout the PrEP-SIC and the wholesale revision of activities in stage eight. This experience further provides confidence that while a power dynamic among the co-authors exists, all members of the research team and the PrEP champions felt comfortable providing extensive feedback and edits throughout the analytic and writing process.

Beyond these threats noted above, we did not feel there were any ethical considerations that influenced the research process.

### Ethics

City University of New York Human Research Protections Program reviewed and approved all research procedures under Protocol number 2019-1122-Hunter. Interviewees reviewed an information sheet and indicated consent verbally. Interviewees were compensated with $100 gift cards.

### Analysis

While the U-SIC measures the proportion of activities completed and duration for completion of each stage of implementation, in this study the focus was on whether the correct activities were included and not on the actual measurement of the implementation process. Therefore, analyses included the proportion score only to provide evidence that the items included defined activities that were both completed by sites and were relevant to the PrEP implementation process experienced at chosen sites.

Two researchers (BL and KM) familiarized themselves with the interview audio recordings, interview debriefing notes, and annotations on the PrEP-SIC to identify themes explaining patterns of activity completion across the 47 PrEP-SIC activities and accuracy with which the PrEP-SIC mapped each site's real world implementation process. They created a matrix of activities marked not completed and not accurate and combined with any notes and quotes from interviews that added context to why an activity was marked as not completed or not accurate. If an activity was reported as not accurate by over half the sites, it was removed or revised. In addition, if written comments or interviews suggested the need for new activities, they were added.

The research team presented initial analyses to PrEP champions in April-May 2024. PrEP champions provided feedback and endorsed revisions to the PrEP-SIC. They also reviewed, clarified, and endorsed the identified themes.

## Results

The PrEP-SIC was applied to nine PrEP programs, providing data on the completion of pre-specified activities (Fig. 2). The results are presented in two parts. First, we present three findings related to key characteristics of PrEP that informed the customization of the PrEP-SIC. Then, we report on five themes that assess the extent to which the PrEP-SIC captured the implementation process and patterns of implementation behavior.

### Customization

The PrEP-SIC retained the original structure of the U-SIC's eight stages of implementation across pre-implementation, implementation, and sustainment. The customization process revealed three salient differences between PrEP and other EBIs that have used the U-SIC.

#### *Theme 1– PrEP service delivery is not driven by external purveyor*

The U-SIC includes activities that are facilitated by an external purveyor or technical assistance provider that introduces the EBI to a clinical setting. The purveyor is defined as an entity representing a program or practice that works with an institution to implement that practice or program with fidelity and good effect [18]. In the case of PrEP, the purveyor could be conceived of as the drug manufacturer of oral and injectable forms of PrEP that is marketing their drugs to HIV prevention programs. However, implementing the different components of PrEP service delivery (increasing awareness and educating patients, providing benefits navigation, adherence support, and retention in care) remains outside the purview of a drug manufacturer. There are also significant ethical concerns about the potential role of a for-profit pharmaceutical company acting in the purveyor role in this context.

#### *Theme 2– comprehensive PrEP service delivery has no evidence-based implementation package*

While oral and injectable PrEP *medication* have strong evidence of their clinical efficacy and real-world effectiveness, there is a limited evidence-base that delineates what constitutes best practice in the creation and delivery of a PrEP *program*. Over the last 5 years there has been a proliferation of strategies focusing on specific patient-level PrEP outcomes (initiation, adherence, linkage to care), however the target population for these strategies is mostly limited to MSM and lack the external validity needed for greater population coverage and overall equitable uptake of PrEP across diverse populations [19–22]. Furthermore, best practice for PrEP service delivery remains a moving target as the multi-component strategies and interventions must adapt to new biomedical innovations and emerging HIV prevention formulations that all require unique clinical guidelines and protocols and in turn, unique healthcare team and health system behaviors to implement. For example, factors that influence new program implementation not considered in patient-level interactions include clinic-wide awareness that the innovation is available at a site and development of standardized protocols to coordinate across multiple members of a healthcare team needed to deliver a biomedical innovation.

#### *Theme 3– without a purveyor and unified evidence-based practice, there is no "certification" and fidelity monitoring*

In the U-SIC the purveyor monitors fidelity of the intervention and approves a site's competency to carry out the intervention as intended. The absence of both a purveyor and best practices for PrEP service delivery requires modification of the SIC stages and activities including how a clinical setting gathers resources to assess intervention feasibility (stage 3), creates workflows and trains staff (stage 4), monitors and improves program performance (stage 5 and 7) and defines competency (stage 8). We made two significant changes between the U-SIC and the PrEP-SIC at the level of the stage. Stage 5, called "Fidelity Monitoring Process in Place" in the U-SIC was renamed "Data System for Monitoring Program Performance in Place." We made this change because "Fidelity Monitoring" suggests that the fidelity of program implementation is being monitored against an established and evidence-based best-practice.

CDC PrEP clinical guidance specifies clinical and laboratory components that constitute a minimum package of care to support delivery of PrEP, and this fidelity to the specific clinical and laboratory requirements could be measured. However, this differs from fidelity to a best

| Phase 1 Pre-Implementation | Reached Sustainment in Study Period | | | | Did Not Reach Sustainment in Study Period | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Stage 1: Engagement** | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 |
| Initiate program development process | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Relevant parties identified | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Cost and resource information gathered | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| **Stage 2: Feasibility Assessment** | | | | | | | | | |
| First site planning meeting | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Senior leadership endorsement of program | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Key external stakeholders identified | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Stakeholder meeting #1 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Program lead identified | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| **Stage 3: Readiness Planning** | | | | | | | | | |
| Cost calculator / funding plan review | ■ | ■ | ☒ | ☒ | | | | | ■ |
| Program components identified | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ |
| Internal program review meeting | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ |
| Program model is finalized | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| Training needs and resources identified | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | |
| Written implementation plan completed | ■ | ■ | ■ | ■ | ■ | | | | |
| Staffing plan finalized | ■ | ■ | ■ | * | ■ | ■ | ■ | ■ | ■ |
| Staffing plan approved | ■ | ■ | ■ | * | ■ | ■ | ■ | ■ | ■ |
| Program goals defined | ■ | ■ | ☒ | ☒ | | | | ■ | ■ |
| Proportion of Activities Completed in Pre-Implementation Phase | 100% | 100% | 81% | 88% | 88% | 81% | 81% | 75% | 88% |

| Phase 2: Implementation | Reached Sustainment in Study Period | | | | Did Not Reach Sustainment in Study Period | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Stage 4: Staff Hired and Trained** | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 |
| First PrEP care team staff hired / assigned | ■ | ■ | * | ■ | ■ | ■ | ■ | ■ | ■ |
| Data collection and evaluation staff assigned / identified | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Relevant staff trained on standard operating procedures | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | |
| Relevant staff receive clinical / skills / supplemental training | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| **Stage 5: Data System for Monitoring Program Performance** | | | | | | | | | |
| Monitoring and evaluation metrics are agreed upon | ■ | ■ | ☒ | ■ | ■ | | | ■ | ■ |
| Date program data capture tool is finalized | ■ | ■ | ■ | ■ | ■ | | | ■ | ■ |
| Date program data capture training held | ■ | ■ | ■ | * | ■ | | | ■ | ■ |
| Process for data utilization is finalized | ■ | ■ | ■ | * | ■ | | | | ■ |
| **Stage 6: Services Introduction** | | | | | | | | | |
| Medication available for PrEP implementation | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Awareness and engagement plan initiated | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| First client received PrEP decision-making counseling | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| First client received PrEP financial navigation | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| First client has PrEP initiation visit | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| First client received PrEP adherence and sustainment support | * | * | ■ | ■ | ■ | ■ | ■ | | |
| First client received PrEP follow up visit | ■ | * | ■ | ■ | ■ | ■ | ■ | | |
| **Stage 7: Delivery with Feedback and Assistance** | | | | | | | | | |
| First meeting after service introduction to review program | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| First data review meeting | ■ | ■ | ■ | ■ | ■ | ■ | | | |
| First discussion of modifications to service delivery and patient flow | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| First implementation plan for service improvement created | ■ | ■ | ■ | ■ | ■ | | | | |
| First improvement strategy implemented | ■ | ■ | ■ | ■ | ■ | | | | |
| Second review of service delivery and patient flow | ■ | ☒ | ■ | ☒ | ■ | | | | |
| Second implementation plan for service improvement created | ■ | ☒ | ■ | ☒ | ■ | | | | |
| Second improvement strategy implemented | ■ | ■ | ■ | ☒ | ■ | | | | |
| Program reaches first goal | ■ | ■ | ☒ | ☒ | ☒ | ☒ | | | |
| Proportion of Activities Completed in Implementation Phase | 100% | 92% | 92% | 82% | 95% | 55% | 50% | 41% | 41% |

| Phase 3: Sustainment | Reached Sustainment in Study Period | | | | Did Not Reach Sustainment in Study Period | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Stage 8: Development of Competency and Sustainment** | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 |
| 50% program goals achieved | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ |
| All program goals achieved | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ |
| At least 50% Program Goals sustained for 12 months | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ |
| All Program Goals sustained for 12 months | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ | ☒ |
| Program review meetings occur regularly for 12 months | ☒ | ■ | ☒ | ■ | ■ | ☒ | ☒ | ☒ | ☒ |
| PrEP is fully integrated into clinical services (Sustainment) | ■ | ■ | ■ | ■ | | | | | |
| Proportion of Activities Completed in Sustainment Phase | 17% | 33% | 17% | 33% | 17% | 0% | 0% | 0% | 0% |

**Acronyms: P1=Program 1, P2=Program 2; PrEP=Pre-exposure prophylaxis**

**Figure Legend**

Activity completed ■
Activity completed with prior implementation (e.g. oral PrEP) *
Activity not completed
Activity not applicable to PrEP implementation process ☒

**Fig. 2** Completion and relevance of PrEP-SIC activities

practice because it primarily focuses on laboratory components rather than the broader range of clinical care that make PrEP programs serve their clients well; for example, ensuring that care is sex-positive and making gender-affirming services available, is likely a best practice even though it is not part of clinical guidance. Furthermore, the guidelines rely heavily on expert opinion and observational data and make recommendations for costly elements like HIV RNA testing that may not be strictly necessary or implementable.

In the case of a PrEP program, while evidence of efficacy of the biomedical intervention is strong, there is no established best practice for the necessary components of a PrEP program and therefore monitoring fidelity was not the appropriate nomenclature. Instead, a broader name for this stage was chosen that captured the need for a system to be in place to monitor program performance. By the same logic, stage 7, originally called "Ongoing Services and Fidelity Monitoring" was renamed "Delivery with Feedback and Assistance" to better capture how sites described using or aspiring to use data.

### Assessment of accuracy and refinement of the PrEP SIC

PrEP-SIC activities in Phase 1 (Pre-Implementation) and Phase 2 (Implementation) were largely assessed to appropriately reflect the implementation process, however phase 3 activities (Sustainment) did not. The refinement process produced a final version of the PrEP-SIC with 44 activities (Table S1). Below we report on five themes from analyses of the annotations and interviews that elaborate on activities in the PrEP-SIC that diverge from real world implementation processes.

#### *Theme 1 - some PrEP-SIC activities are not reflected in real-world implementation processes*

67% (6/9) of sites did not complete a costing plan (stage 3), including two that reached sustainment, suggesting that for some clinical site in real world settings, the cost implications of program development were not integral to PrEP service implementation initially. However, one site that did not complete a costing plan suspended offer of LAI PrEP for a time because the clinic lost money for every person whom they initiated on LAI PrEP due to insurance coverage issues. The clinical site was later able to resume their program, but limited services initially to clients with a certain insurance type as they developed new strategies to address this issue across payor types. Reflecting on this later, the clinic leadership team remarked that a costing plan would have potentially avoided this misstep, however, she also noted that because of the complexities of navigating coverage for LAI PrEP, she was unsure whether a costing plan derived before service introduction could have been realistic given all the intricacies learned through implementation.

Although some activities were coded as not needing to be repeated as they were already completed for oral PrEP implementation, one champion noted that in retrospect, they might have benefitted from revisiting some activities for the implementation of a new PrEP formulation:

> *"We talked about how we didn't think we would go back through all the stages, but maybe we should have gone back to community engagement. So we had a lot of curiosity around where do you enter the SIC after starting a new modality."* -Provider.

This suggests the salience of the implementation activities (stages 4–7) may depend on the PrEP formulation being implemented and whether the clinical site has pre-existing PrEP services into which new formulations are being integrated.

#### *Theme 2 - stage 8 activities did not reflect sustainment for pilot sites*

The original definition of sustainment was operationalized as completing program goals and sustaining those goals over 12 months, however 56% (5/9) of sites did not set quantitative program goals, including two sites that reached sustainment.

> *"Everyone wants a lot of people to be on PrEP, but with Cab-LA we want as many people who want it, to get it. We would never set, for example, an n of 200 to benchmark that. It's setting yourself up for failure. This is not an HIV med. We want people to go on and off. We want people to feel flexible."* -Nurse Practitioner.

> *"For sustainability conversations, we don't talk about program goals. We want sites to think about using data to look at gaps for continuous quality assurance both from clinical delivery and population uptake [of PrEP]; [and also] getting feedback from clinical staff or patients served. There's so many clinics that don't have a way to look at data, but if they aren't continuously monitoring, they can't change course and improve their program."* -Program Director.

Among sites that did set goals, they were qualitative in nature, such as creating a standardized approach to discussing and prescribing new PrEP formulations. Sustainment was instead described more broadly as being able to continue a program through staffing turnovers and shortages.

#### *Theme 3 - difference makers that led to sustainment*

Out of nine PrEP programs, 44% (4/9) reached sustainment during the data collection period. All sites that reached sustainment had written protocols (stage 3), while 80% (4/5) of sites that did not reach sustainment did not have written protocols. This suggests that protocolization of PrEP workflows is integral to sustaining long term delivery of PrEP services. Among sites that did not reach sustainment, 60% (3/5) did not have a process for data utilization (stage 5) and 80% (4/5) did not complete most of stage 7, program improvement. Without a culture and process for integrating review of data into programmatic decision making, it is more difficult to complete stage 7, which focuses on program improvement. The data suggests there needs to be opportunity to reflect on implementation delivery and identify, either qualitatively or quantitatively, service delivery components that could benefit from continuous quality improvement efforts.

#### *Theme 4 - PrEP-SIC is useful but insufficient to guide introduction without TA support for activities or coaching to overcoming implementation barriers*

Even though the PrEP-SIC was originally developed as an observational tool to monitor implementation process, many sites assessed the complete list of implementation activities as useful for clinics implementing PrEP for the first time or integrating a new PrEP formulation into existing services.

> *"It would be very useful for someone wanting to start a program. Like, 'if you are at this point [in the SIC] with 5 patients, you are ready to start this [stage or activity].' You want to start on a small scale and take on more and more people. For example, my list was open from May to July and I got 62 patients [interested in LAI PrEP]. It was just me working on it. I should have set a quota and learned how things work versus being overloaded and not knowing where to start."* -Pharmacist, Florida.

However, two teams remarked how, although they thought the PrEP-SIC would be useful for first time implementors, the number of implementation activities could be overwhelming. To rectify this, one respondent suggested:

> *"TA providers could use the SIC in the moment, walking sites through it and then come up with a TA plan. We have clinics who come to us and say "this isn't working, how do we fix it?" It would also be useful to go through the SIC as a checklist to figure out what's not working. Using the SIC retrospectively could help fill in any gaps and figure out what was missed."* -Program Director, Colorado.

A few sites noted that a limitation of the PrEP-SIC is that it does not tell you how to complete the activities or overcome barriers to activity completion.

#### *Theme 5– implementation is cyclical and recursive, and some pre-implementation activities need to be revisited over time*

Although all sites marked the stage 2 activity "senior leadership endorsement of program" as complete, external context shifted prioritization of clinic resources impeding PrEP service delivery for some sites. Debriefing interviews with sites revealed the complex and recursive process of implementing an intervention where some activities previously marked as completed must be revisited to meet the needs of a changing implementation landscape.

> *"PrEP is not a mandate, so we had to sell the concept of an injectable to leadership. There was some buy in initially but then waffling as COVID and then [mpox] ramped up. So we spent a lot of time getting buy in and then cementing buy in. As an example [of needing to cement buy in], we have two sites that have been providing PrEP for years, and they have just stopped providing PrEP entirely just because of staff vacancies"* -PrEP Coordinator, Virginia.

The often cyclical and repetitive nature of implementation is challenging to capture with a date-based measurement tool. The SIC captures the date an implementation activity was first completed; however, implementation plans change over time depending on external forces and shifting contexts.

## Discussion

Previous research in PrEP implementation in the Unites States has largely focused on patient-level determinants impacting PrEP uptake and adherence, with little attention given to studying the process of introducing or scaling up PrEP services into clinical practice. Limited research addressing structural and clinic level factors has identified salient clinic level determinants to successful PrEP implementation including: designating a champion to advocate for PrEP service integration, increasing staff knowledge of and willingness to prescribe PrEP, identifying strategies to cover costs (personnel, professional development training, care coordination services, medications, and laboratory tests), obtaining administrative buy-in from executive staff, integrating PrEP into the electronic health record, and clearly defining roles of clinical and non-clinical staff [23, 24]. Our study develops these observational findings into a tool to facilitate introduction of PrEP services and better understand what implementation activities are necessary for sustainment of PrEP programs. This operationalized set of strategies

provides a blueprint for routinizing new practices, similar to processes described in Normalisation Process Theory, where ideal implementation becomes so standard that it is undistinguishable from normal service delivery [25, 26].

Through the process of adapting the U-SIC to PrEP implementation and assessing this tool in nine US-based PrEP programs, we found the eight stages of implementation captured an idealized PrEP implementation process. The sites that completed 100% of pre-implementation activities also reached sustainment; notably the completion of stage 3 activities, including writing an implementation plan and finalizing the program model, differentiated sites who reached sustainment and sites that did not. While all PrEP Program teams endorsed the importance of costing and goal setting, it was rarely done in practice in our small sample. Sites also considered stage 7 (Delivery with Feedback and Assistance) to be a particularly important and often overlooked component of implementation. The most significant change to our defined implementation process was our original articulation of Stage 8 activities as related to program goal achievement was not appropriate to capture sustainment. As a result, we removed five of the six original activities in stage 8 and added two new activities that better map to sites' experience of having reached "sustainment."

Key informants from sites reported that the PrEP-SIC was useful as a roadmap and high-level checklist, however, to optimize its utility, they noted the need for a complement of tools and resources to support conduct of activities. The PrEP-SIC alone may not be enough to support clinical sites in the routinization of their implementation efforts, however, it could be used in conjunction with resources, technical assistance, and implementation coaching to help direct and facilitate the implementation process. Further development of the U-SIC and the PrEP-SIC could therefore include tools to support these activities.

Over the last five years, there has been a large wave of research dedicated to incorporating equity into implementations science frameworks, with calls to action encouraging researchers and practitioners to be more intentional in their use of implementation science to reduce health disparities [27–30]. Following debriefing interviews which revealed strong recognition that current implementation efforts are failing to reach non-white gay, bisexual, and other men who have sex with men and cisgender and transgender women of color, resulting in increased disparities in incident HIV, we articulated an additional, aspirational activity to mark a program as having entered equity-enhancing sustainment: "PrEP services intentionally designed and refined to reach groups with high unmet need in the catchment area." This dovetails with an injectable treatment-focused project, the ALAI UP Project, for which we have also developed and are piloting the SIC tool. In that project, we encourage sites to ensure that their data monitoring plans established in Stage 5 capture data that will allow for assessment of whether implementation of injectable treatment is equity-enhancing or disparity-generating. Similarly, by adding an equity-focused activity in Stage 8, we refined the definition of data monitoring activities in Stage 5 and 7 to ensure that their data systems allow them to monitor the extent to which populations with the highest HIV incidence are being offered and provided PrEP. If there are disparities in offer and uptake across race, ethnicity, and gender, we urge refinement of implementation strategies to address such disparities in real time.

While adapting the PrEP-SIC we were aware that future PrEP formulations would continue to be developed and therefore we purposefully chose to assess the PrEP-SIC across programs offering different formulations. This forced us to design universal PrEP SIC activities that consider unique service components of different PrEP formulations. Sites implementing LAI PrEP expanded many of their implementation activities (staffing plans, data monitoring systems) from their oral PrEP services, while many pre-implementation activities (stakeholder meetings, identifying staff training needs, senior leadership endorsement) were either skipped or repeated for the new formulation. In planning for introduction of new formulations of PrEP, it is imperative that implementation efforts plan for the unique structural and logistical requirements of different PrEP formulations. For example, clinical sites planning to offer LAI PrEP in addition to oral PrEP must consider expanding client-facing educational materials to describe new PrEP formulations, training providers in giving gluteal injections, developing job aids for discussing the pharmacokinetic tail, and increasing clinical capacity to accommodate more frequent patient visits due to the bimonthly dosing schedule of cab-LA [31]. For clinical sites preparing to introduce lenacapavir, many similar considerations apply; in addition, protocols will need to consider the frequency of STI testing and clinic administrators will need to consider the impact of less frequent visits on potential revenue.

### Limitations

While 44% (4/9) of our sites did reach sustainment in the reporting period, not enough time has passed to see whether any sites were at risk for discontinuing. In addition, closing data collection in January 2024 was somewhat arbitrary and it is likely that some of the programs have reached sustainment since then. Previous research on the SIC suggests the higher proportion of activities completed is associated with higher likelihood of implementation success. While we did observe this pattern in our data, our sample size was not large enough to analyze

predictive power. Second, while participating clinics varied in their geographic location, size, type of agency, and patients served, they are not representative of clinics across the United States and therefore findings may not be generalizable to all settings. Similarly, research was conducted in a small sample of agencies in the United States, therefore its utility to clinics outside the US context is unknown. However, the U-SIC has been utilized to study implementation process in numerous global settings, suggesting that the PrEP-SIC could have applicability outside the United States. Third, we did not have any power to assess whether reaching sustainment was clustered, e.g., that multiple PrEP programs within one clinical setting were more likely to reach sustainment. Lastly, the SIC provides no information on why activities were skipped or why sites choose to perform activities in a given order. Debriefing interviews with staff provided valuable information on implementation context and reasons for not completing activities, however more systematic methods will need to be developed to better understand the recursive process of completing activities articulated in the PrEP-SIC and whether order of completion impacts sustainment.

## Conclusion

The current study has resulted in a PrEP-SIC that accurately captures an idealized implementation process. For PrEP to have a population-level impact it needs to be offered in a wider array of healthcare settings. Using a well-defined set of implementation activities as a roadmap with supportive services to clinics, like technical assistance or implementation coaching, could direct implementation efforts and facilitate the integration of PrEP into clinical services in clinical and community settings that reach people where they access services.

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-025-12670-4.

Supplementary Material 1.

Supplementary Material 2: Table S1. Finalized PrEP-SIC with Activities and Definitions. The Stages of Implementation Completion ® is trademarked and copyrighted by the Oregon Social Learning Center. To request use of the SIC, contact the 11th author.

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**Authors' contributions**
Authors' contributions. KM, YW, LS designed the study. KM, JZ, YW, SAG developed the initial PrEP-SIC. KM, YW, and LS refined the PrEP-SIC. CC, HB, SR, EM, GN, MAG, KM completed the PrEP-SIC. KM and BL conducted interviews. KM and BL analyzed the data and wrote the manuscript. All authors reviewed, revised, and approved the manuscript.

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**Data availability**
The datasets analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

**Ethics approval and consent to participate**
The Institutional Review Board of the City University of New York Human Research Protections Program reviewed and approved all research procedures under Protocol number 2019-1122-Hunter. Participants reviewed an information sheet about the study and provided oral informed consent. All study procedures were performed in accordance with the protocol. The study adhered to the principles of the Helsinki Declaration.

**Consent for publication**
N/A.

**Competing interests**
The authors declare no competing interests.

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**References**

1. Donnell D, Baeten JM, Bumpus NN, Brantley J, Bangsberg DR, Haberer JE, et al. HIV protective efficacy and correlates of Tenofovir blood concentrations in a clinical trial of PrEP for HIV prevention. JAIDS J Acquir Immune Defic Syndr. 2014;66(3):340–8.
2. Landovitz RJ, Hanscom BS, Clement ME, Tran HV, Kallas EG, Magnus M, et al. Efficacy and safety of long-acting cabotegravir compared with daily oral Tenofovir disoproxil fumarate plus emtricitabine to prevent HIV infection in cisgender men and transgender women who have sex with men 1 year after study unblinding: a secondary analysis of the phase 2b and 3 HPTN 083 randomised controlled trial. Lancet HIV. 2023;10(12):e767–78.
3. Molina J-M, Capitant C, Spire B, Pialoux G, Cotte L, Charreau I, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. N Engl J Med. 2015;373(23):2237–46.
4. AIDSVu PEPVU. Understanding PrEP in the US. 2023. Available from: https://prepvu.org/.
5. Bunting SR, Hunt B, Boshara A, Jacobs J, Johnson AK, Hazra A, et al. Examining the correlation between PrEP use and black: white disparities in HIV incidence in the ending the HIV epidemic priority jurisdictions. J Gen Intern Med. 2023;38(2):382–9.

6. Odii IO, Vance DE, Patrician PA, Dick TK, Wise J, Corcoran JL, et al. HIV PrEP coverage among black adults: A concept analysis of the inequities, disparities, and implications. Health Equity. 2024;8(1):314–24.
7. Bekker LG, Das M, Abdool Karim Q, Ahmed K, Batting J, Brumskine W, et al. Twice-Yearly Lenacapavir or daily F/TAF for HIV prevention in cisgender women. N Engl J Med. 2024;391(13):1179–92.
8. Calabrese SK, Krakower DS, Mayer KH. Integrating HIV preexposure prophylaxis (PrEP) into routine preventive health care to avoid exacerbating disparities. Am J Public Health. 2017;107(12):1883–9.
9. CDC. Clinical Guidance for PrEP. 2024. updated August 20, 2024. Available from: https://www.cdc.gov/hivnexus/hcp/prep/index.html.
10. Chamberlain P, Feldman SW, Wulczyn F, Saldana L, Forgatch M. Implementation and evaluation of linked parenting models in a large urban child welfare system. Child Abuse Negl. 2016;53:27–39.
11. Goswami S, Rosenthal M, Nair S, Inguva S, Al Hamarneh Y, Tsuyuki R. Applying the stages of implementation completion (SIC) framework retrospectively to a community pharmacy clinical intervention implementation project for scaling up future success. Value Health. 2021;24:S82.
12. Nadeem E, Saldana L, Chapman J, Schaper H. A mixed methods study of the stages of implementation for an evidence-based trauma intervention in schools. Behav Ther. 2018;49(4):509–24.
13. Saldana L, Bennett I, Powers D, Vredevoogd M, Grover T, Schaper H, et al. Scaling implementation of collaborative care for depression: adaptation of the stages of implementation completion (SIC). Adm Policy Ment Health. 2020;47(2):188–96.
14. Saldana L. The stages of implementation completion for evidence-based practice: protocol for a mixed methods study. Implement Sci. 2014;9:1–11.
15. Saldana L, Alley Z, Chapman J, Schaper H, editors. Coaching to competency: Reducing implementation discontinuance and improving rates of success. 14 th Annual Conference on the Science of Dissemination and Implementation; 2021: AcademyHealth.
16. Saldana L, Chamberlain P, Wang W, Hendricks Brown C. Predicting program start-up using the stages of implementation measure. Adm Policy Ment Health. 2012;39:419–25.
17. Yin R. Case study research: design and methods. Sage; 2009.
18. Fixsen D, Naoom S, Blase K, Friedman R, Wallace F. Implementation research: A synthesis of the literature. National Implementation Research Network; 2005.
19. Kamitani E, Higa DH, Crepaz N, Wichser M, Mullins MM. Identifying best practices for increasing HIV Pre-exposure prophylaxis (PrEP) use and persistence in the united States: A systematic review. AIDS Behav. 2024;28(7):2340–9.
20. Weitzman PF, Zhou Y, Kogelman L, Rodarte S, Vicente SR, Levkoff SE. mHealth for pre-exposure prophylaxis adherence by young adult men who have sex with men. mHealth. 2020;7:44.
21. Mitchell JT, LeGrand S, Hightow-Weidman LB, McKellar MS, Kashuba AD, Cottrell M, et al. Smartphone-Based contingency management intervention to improve Pre-Exposure prophylaxis adherence: pilot trial. JMIR Mhealth Uhealth. 2018;6(9):e10456.
22. Desrosiers A, Levy M, Dright A, Zumer M, Jallah N, Kuo I, et al. A randomized controlled pilot study of a Culturally-Tailored counseling intervention to increase uptake of HIV Pre-exposure prophylaxis among young black men who have sex with men in Washington, DC. AIDS Behav. 2019;23(1):105–15.
23. Faro EZ, Mantell JE, Gonzalez-Argoti T, Hoffman S, Edelstein Z, Tsoi B, et al. Implementing PrEP services in diverse health care settings. JAIDS J Acquir Immune Defic Syndr. 2022;90(S1):S114–28.
24. Parisi D, Warren B, Leung SJ, Akkaya-Hocagil T, Qin Q, Hahn I, et al. A multicomponent approach to evaluating a pre-exposure prophylaxis (PrEP) implementation program in five agencies in New York. J Assoc Nurses AIDS Care. 2018;29(1):10–9.
25. Huddlestone L, Turner J, Eborall H, Hudson N, Davies M, Martin G. Application of normalisation process theory in Understanding implementation processes in primary care settings in the UK: a systematic review. BMC Fam Pract. 2020;21(1):52.
26. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med. 2010;8:63.
27. Baumann AA, Shelton RC, Kumanyika S, Haire-Joshu D. Advancing healthcare equity through dissemination and implementation science. Health Serv Res. 2023;58:327–44.
28. Shelton RC, Brownson RC. Enhancing impact: a call to action for equitable implementation science. Prev Sci. 2024;25(Suppl 1):174–89.
29. Snell-Rood C, Jaramillo ET, Hamilton AB, Raskin SE, Nicosia FM, Willging C. Advancing health equity through a theoretically critical implementation science. Transl Behav Med. 2021;11(8):1617–25.
30. Woodward EN, Singh RS, Ndebele-Ngwenya P, Melgar Castillo A, Dickson KS, Kirchner JE. A more practical guide to incorporating health equity domains in implementation determinant frameworks. Implement Sci Commun. 2021;2(1):61.
31. Celum C, Grinsztejn B, Ngure K. Preparing for long-acting Prep delivery: Building on lessons from oral Prep. J Int AIDS Soc. 2023;26:e26103.


## Publisher's Note