

The Women's PrEP Project (W-PrEP): development of a clinic-based, socio-structural intervention to improve provision of pre-exposure prophylaxis (PrEP) for cisgender women using the ADAPT-ITT framework

Rachel Katherine Scott, Shawnika J Hull, Deanna Kerrigan, Mandi Pratt-Chapman, Tara Mathias-Prabhu, Jennifer Zack, Michelle Xu, Marisa Saduskas, Patricia L Moriarty, Tranessa L Hanson, Hannah Arem

Submitted to: JMIR Formative Research
on: April 13, 2025

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
---------------------------------	----------

Preprint
JMIR Publications

The Women's PrEP Project (W-PrEP): development of a clinic-based, socio-structural intervention to improve provision of pre-exposure prophylaxis (PrEP) for cisgender women using the ADAPT-ITT framework

Rachel Katherine Scott^{1,2} MD, MPH; Shawnika J Hull³ PhD; Deanna Kerrigan⁴ PhD; Mandi Pratt-Chapman⁴ PhD; Tara Mathias-Prabhu²; Jennifer Zack²; Michelle Xu² MD; Marisa Saduskas⁵; Patricia L Moriarty⁶; Tranessa L Hanson⁶; Hannah Arem⁶ PhD

¹110 Irving St NW MedStar Health Research Institute and MedStar Washington Hospital Center MedStar Health Washington US

²School of Medicine Georgetown University Washington US

³Rutgers, The State University of New Jersey New Brunswick US

⁴George Washington University Washington US

⁵School of Medicine Saint Louis University St. Louis US

⁶110 Irving St NW MedStar Health Research Institute MedStar Health Washington US

Corresponding Author:

Rachel Katherine Scott MD, MPH

110 Irving St NW

MedStar Health Research Institute and MedStar Washington Hospital Center

MedStar Health

East Building 5108

110 Irving Street, NW

Washington

US

Abstract

Background: Cisgender women (subsequently referred to as women) account for 23% of new HIV diagnoses in the United States (US), but there are significant socio-structural barriers to engagement and retention in the PrEP cascade, particularly for women of color.

Objective: In response to the lack of evidence-based interventions to improve PrEP initiation, adherence, and persistence among women in the United States, we set out to develop a clinic-based, socio-structural intervention focused on engagement and retention in the PrEP cascade among women.

Methods: We utilized the ADAPT-ITT (Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, Testing) model to create a culturally-appropriate, evidence-based intervention responsive to Black women's HIV prevention needs. In this manuscript we focus on the first six steps of iterative adaptation in preparation for pilot testing. We conducted semi-structured interviews and focus group discussions with key populations to inform and guide intervention development and employed Theater Testing to evaluate the mock-up of the prototype. We conducted rapid qualitative analysis (RQA) to identify key themes around delivering PrEP to the intended population, and engaged subject matter experts to refine the prototype.

Results: Assessment: We conducted n=10 in-depth interviews with key informants from community-based and HIV-prevention organizations, and led n=7 focus group discussions (participant n range 4 to 8) to guide intervention development among medical providers (n=2 groups), PrEP navigators and educators (n=1 group), and female patients (n=4 groups). Key themes included population specific barriers to PrEP utilization, namely accessibility/availability, perceived risk, and stigma. Additionally, participants advised on model adaptation specific to PrEP navigation, clinic-level training and social support. Decision: We selected two evidence based-interventions from the Centers for Disease Control Compendium of Best Practices in HIV Prevention. Adaptation: We adapted and theater tested a preliminary intervention for feedback. Production: Using feedback from theater testing, we created a prototype of "the Women's PrEP Project (W-PrEP)" designed to address patient-, provider-, and clinic-level barriers to provision of PrEP for women through a clinic-wide intervention delivering education, resources, and support (including PrEP navigation). Topical Experts & Integration: We collected iterative feedback from our advisory board and subject matter experts and integrated feedback into the final prototype.

Conclusions: The adaptation of the W-PrEP program integrated key elements of the local context for cisgender women with potential exposure to HIV, as well as medical providers, clinic-staff, and PrEP navigators. Next steps include training clinic staff in a real-world setting to pilot test the acceptability, feasibility, and preliminary effectiveness of the intervention. Clinical Trial: N/A

(JMIR Preprints 13/04/2025:75922)

DOI: <https://doi.org/10.2196/preprints.75922>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in a JMIR publication, my accepted manuscript PDF will be visible to all users.

No. Please do not make my accepted manuscript PDF available to anyone.

Original Manuscript

TITLE PAGE

Title: The Women's PrEP Project (W-PrEP): development of a clinic-based, socio-structural intervention to improve provision of pre-exposure prophylaxis (PrEP) for cisgender women using the ADAPT-ITT framework

Authors:

Scott, Rachel K^{*1,2,3}; Hull, Shawnika⁴; Kerrigan, Deanna⁵; Pratt-Chapman, Mandi⁵; Mathias-Prabhu, Tara³; Zack, Jennifer³; Xu, Michelle³; Sadauskas, Marisa⁶; Moriarty, Patricia¹; Hanson, Tranessa¹; Arem, Hannah⁷

¹MedStar Health Research Institute, Women's Health Research Division, Columbia, MD, USA

²MedStar Washington Hospital Center, Women's and Infants' Services Department, Washington, DC, USA

³Georgetown University School of Medicine, Washington, DC, USA

⁴Rutgers University, New Brunswick, NJ, USA

⁵George Washington University, Washington, DC, USA

⁶Saint Louis University School of Medicine, Saint Louis, MO, USA

⁷MedStar Health Research Institute, Healthcare Delivery Research, Columbia, MD, USA

*Corresponding author. Email address(es): rachel.k.scott@medstar.net; rachelkscott@gmail.com

Abstract

Background: Cisgender women (subsequently referred to as women) account for 23% of new HIV diagnoses in the United States (US), but there are significant socio-structural barriers to engagement and retention in the PrEP cascade, particularly for women of color.

Objective: In response to the lack of evidence-based interventions to improve PrEP initiation, adherence, and persistence among women in the United States, we set out to develop a clinic-based, socio-structural intervention focused on engagement and retention in the PrEP cascade among women.

Methods: We utilized the *ADAPT-ITT* (*Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, Testing*) model to create a culturally-appropriate, evidence-based intervention responsive to Black women's HIV prevention needs. In this manuscript we focus on the first six steps of iterative adaptation in preparation for pilot testing. We conducted semi-structured interviews and focus group discussions with key populations to inform and guide intervention development and employed Theater Testing to evaluate the mock-up of the prototype. We conducted rapid qualitative analysis (RQA) to identify key themes around delivering PrEP to the intended population, and engaged subject matter experts to refine the prototype.

Results: *Assessment:* We conducted n=10 in-depth interviews with key informants from community-based and HIV-prevention organizations, and led n=7 focus group discussions (participant n range 4 to 8) to guide intervention development among medical providers (n=2 groups), PrEP navigators and educators (n=1 group), and female patients (n=4 groups). Key themes included population specific barriers to PrEP utilization, namely accessibility/availability, perceived risk, and stigma. Additionally, participants advised on model adaptation specific to PrEP navigation, clinic-level training and social support. *Decision:* We selected two evidence based-interventions from the Centers for Disease Control Compendium of *Best Practices in HIV Prevention*. *Adaptation:* We adapted and theater tested a preliminary intervention for feedback. *Production:* Using feedback from theater testing, we created a prototype of "the Women's PrEP Project (W-PrEP)" designed to address patient-, provider-, and clinic-level barriers to provision of PrEP for women through a clinic-wide intervention delivering education, resources, and support (including PrEP navigation). *Topical Experts & Integration:* We collected iterative feedback from our advisory board and subject matter experts and integrated feedback into the final prototype.

Conclusions: The adaptation of the W-PrEP program integrated key elements of the local context for cisgender women with potential exposure to HIV, as well as medical providers, clinic-staff, and PrEP navigators. Next steps include training clinic staff in a real-world setting to pilot test the acceptability, feasibility, and preliminary effectiveness of the intervention.

Keywords

Pre-Exposure Prophylaxis, Female, HIV infections, Ambulatory Care Facilities, Primary Prevention, Education

INTRODUCTION

Cisgender Women (subsequently referred to as “women”) account for 23% of new Human Immunodeficiency Virus (HIV) diagnoses in the United States (US),^[1] highlighting the unrealized opportunity for tailored HIV prevention programs in this population. The HIV epidemic in the US disproportionately affects Black and reproductive-age women.^[1–3] Among women, HIV transmission occurs primarily through heterosexual transmission (84%), principally receptive vaginal sex.^[4,5] HIV is preventable through consistent use of barrier contraception and HIV pre-exposure prophylaxis (PrEP).^[6–12] Barrier contraception, specifically male condom use, is notably limited by partner power discordance and is implicitly dependent upon partner cooperation.^[13]

Both daily oral and long-acting injectable formulations of PrEP offer women-controlled options for HIV prevention prior to risk exposure, circumventing the need for cooperation from sex partners. Pharmacoprevention with either daily oral tenofovir disoproxil fumarate/emtricitabine or injectable bi-monthly cabotegravir decreases HIV transmission by up to 99% in women.^[7–11] Despite the efficacy of PrEP, the number of prescriptions of PrEP to women in the US remains dwarfed by the number of women with indications for PrEP,^[14] highlighting the considerable unmet need for biomedical HIV prevention among women, especially Black women.^[15–19]

There are significant socio-structural barriers to engagement and retention in the PrEP cascade for women, including medical mistrust, cost, stigma, and lack of access.^[20–28] Our prior work with reproductive-age, majority-Black women with demonstrable potential exposure to HIV^[29–32] highlights the critical importance of medical provider^[20,23,25,26,28,33–38] and community/peer support^[20,25,26,28,35–37] in engagement and retention in the PrEP cascade. The Centers for Disease Control and Prevention (CDC) further highlighted the importance of medical providers as PrEP educators with their 2021 guidance that providers should educate all sexually active adults and adolescents about PrEP.^[39] Despite their pivotal role, medical provider knowledge of and comfort with prescribing PrEP continues to lag across medical specialties,^[22,40–45] and despite

the synergy of offering integrated PrEP services as part of routine women's health care, the majority of women's health clinics do not routinely educate about or prescribe PrEP.[23,44–46] Both our formative work and the existing literature indicates the socio-structural nature of the factors influencing women's engagement in the PrEP cascade, thus we utilized the *Socio-Ecological Model* as our guiding theoretical framework for intervention adaptation.

The *Socio-Ecological Model* theorizes that an individual's decisions and behaviors result from reciprocal interactions within and between the individual and their social, cultural, and structural environments,[47]. Although health decisions or behaviors occur at the individual level, they are influenced by individual (i.e., psychological), interpersonal (e.g., relationship power, relationship commitment), community (i.e., cultural norms, stigma), institutional (e.g., equitable provision of care, appropriate services), and structural factors (e.g., public policy, infrastructure).[48] As applied to the PrEP cascade for women, our previously published survey of 1437 women found intention to initiate PrEP was associated with different factors by level: on the individual level positive attitudes toward PrEP (odds ratio [OR], 1.56; 95% confidence interval [CI], 1.13-2.15) and higher self-efficacy (OR, 1.32; 95% CI, 1.02-1.72); on the community level perceived acceptability of PrEP among peers and low fear of shame/stigma (OR, 1.65; 95% CI, 1.33-2.04); and on the institutional level having discussed PrEP with a medical provider (OR, 2.39; 95% CI, 1.20-4.75).[29] Our findings underscore the importance of multilevel, clinic-based interventions for women, with education and tools to support for women's health providers as well as PrEP navigation to destigmatize PrEP and break down logistical barriers to PrEP initiation and continuation.

Given the critical role of providers as both PrEP educators and gatekeepers, we previously developed and tested a *Clinic-level Educational Intervention*, which utilized a clinic-level training and a provider toolkit to promote provision of universal PrEP services. The intervention significantly improved provision of PrEP services and PrEP uptake among women at a sexual health center in Washington D.C. compared to baseline and was cited as a CDC PrEP Best Practice *evidence-informed intervention* (EII).[49,50] While the *Clinic-level Educational* EII significantly improved the

provision of PrEP by providers and PrEP uptake among reproductive age women of color, it did not actively address the social barriers of stigma, lack of community/peer support, and medical mistrust that the literature indicated were critical to engagement and retention in the PrEP cascade.

In contrast, *Project Shikamana* was a socio-structural intervention, also developed by a member of our research team, which showed decreased HIV acquisition among female sex workers in Tanzania and was designated by the CDC as an *evidence-based intervention* (EBI) for HIV prevention.[50–52] *Project Shikamana's* strengths include its community-driven, multi-level approach to HIV prevention, involving provider sensitivity training, peer education/navigation and support, community mobilization to address socio-structural factors such as stigma and discrimination, and a focus on reproductive age women. Given notable differences between the intended populations and the medical infrastructure and medical culture in Tanzania compared to the United States, we chose an evidence-based framework to adapt *Project Shikamana* while retaining its core strengths.

In response to the lack of EBI to improve PrEP initiation, adherence, and persistence among women in the US, we adapted these two CDC Best Practices for HIV Prevention for women—and developed “the Women’s PrEP Project (W-PrEP)”, a clinic-level, socio-structural intervention. We set out to modify these two existing evidence based interventions into a single intervention titled “W-PrEP”. We designed W-PrEP to provide education, resources, and support to empower and enable sexual and reproductive health clinics to provide high-quality, non-stigmatizing, universal PrEP services to women who may have increased exposure to HIV, in particular Black women of reproductive age. This manuscript describes the iterative process of refining the W-PrEP intervention.

METHODS

We received Institutional Review Board (IRB) Approval from the MedStar Health Research Institute IRB (#0006908). We conducted the formative work for the intervention adaptation from November 2021 to October 2023, including marked expansion of existing training materials and toolkits.

Intervention Development Process Model

We utilized *ADAPT-ITT* (*Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, Testing*) model as a framework to develop a culturally appropriate and tailored EBI.[53] *ADAPT-ITT* has been utilized to successfully adapt a host of diverse HIV prevention interventions to meet the needs of a new intended population or setting.[54–57] We used the *Project Shikamana* EBI and the *Clinic-level Educational* EII as the base cases from which to initiate the intervention development process (**Table 1**). We focused on socio-structural factors that women in the region indicated were barriers and facilitators of engagement in the PrEP cascade (i.e., stigma and discrimination related to HIV and PrEP within healthcare settings, the role of provider sensitization, PrEP navigation and support). Using *ADAPT-ITT*, we built upon those findings and employed multiple qualitative methods such as in-depth interviews and focus group discussions to refine the existing interventions (**Table 2**). This manuscript describes the first six steps in the model in preparation for pilot testing.

[Table 1. “Base case Interventions” here]

[Table 2. “Study Activities and Measures” here]

Study Setting

Washington D.C. (DC) is an epicenter of the US HIV epidemic. At the time of the intervention refinement, the prevalence of HIV among women in DC was 1,209 per 100,000, nearly seven-fold the national average (170 per 100,000);[58] the prevalence among all women was 0.9%, but nearly double (1.7%) among Black women.[58] At the time of this work, Black women represented one in four new HIV diagnoses in DC and 90% of new diagnoses among women.[58]

Qualitative Tools and Data Collection

We conducted semi-structured in-depth interviews with key informants as part of the **Assessment** phase. We identified key informants from local community based-organization, hospitals, clinics, and HIV prevention organizations through referrals from the Washington D.C. Center for AIDS

Research, our joint community and scientific advisory board, and clinical and community professional relationships of the research team; key informants were invited via email to participate. Target recruitment was 10 key informant interviews. Interview questions focused on (1) socio-structural barriers to and facilitators of PrEP utilization among reproductive age women of color and (2) assessment of the model components for adaptation. Salient themes and questions arising from the key informant interviews informed the focus group discussion guides.

We also conducted 7 focus group discussions, separating participants into groups of (1) medical providers with experience prescribing PrEP; (2) medical providers without experience prescribing PrEP; (3) PrEP clinical navigators, peer navigators, and educators; (4) Black women of reproductive age with experience taking PrEP (n= 2 groups) and (5) Black women of reproductive age without previous experience taking PrEP (n=2 groups). Providers, navigators/educators, and patients were recruited from medical establishments (e.g., hospital-based clinics, community health centers) throughout DC. We invited women's health providers from varying fields (e.g., obstetrics and gynecology, family medicine, pediatrics), institution types (e.g., free standing reproductive health center, government-sponsored sexual health center, tertiary care center, federally qualified community health center), and medical training types (i.e., doctor, nurse practitioner, physician's assistant) to participate via email. PrEP navigators/educators from differing institution types were also invited to participate via email. Patient-participants were identified from the women's health clinics and the electronic health record (EHR) and were recruited via phone.

Health care provider focus group guides concentrated on the proposed PrEP training materials and format, identification of key toolkit resources to provide PrEP services and integration of PrEP into sexual and reproductive health care, and inclusion of a PrEP navigator/educator in the clinic setting. Navigator/educator focus group guides centered on the role(s) and characteristics of the PrEP navigator, as well as training and resources. Patient focus group guides explored women's health priorities and barriers to preventative health, such as PrEP, ideal provision of PrEP services, including education and access, PrEP navigation and the key characteristics and roles of a PrEP navigator/educator, and social support.

We conducted **theater testing** of a mock-up of the adapted training and planned intervention and implementation flowchart among these same health care providers in two follow-up focus group discussions. Providers offered feedback on the content and delivery of PowerPoint training modules and the multi-pronged intervention.

Given the timing during the COVID pandemic and to increase access for participants who would be unable to attend in-person, all qualitative research was conducted remotely via a secure platform.

Qualitative Analysis

We audio-recorded interviews and focus groups with the consent of participants, which were then transcribed verbatim. We applied Rapid Qualitative Analysis (RQA)[59–61] to systematically utilize qualitative feedback from the interviews and focus groups to refine the intervention. To this end, we developed summary templates to identify the coder, respondent role and coding domain (i.e., strengths, information gaps, actionable improvements). We conducted analyses of a subset of interviews (i.e., one from each respondent type) in order to ensure adequate fit of the template to the data, then we coded the remaining transcripts. For the formative *ADAPT-ITT* phases (i.e., *Assessment through Integration*), we developed and populated matrices to identify salient themes that represent topics, information, or activities to include in the adapted intervention. For the *Training and Testing ADAPT-ITT* phases, we developed and populated matrices to align with germane components of the *PRISM* implementation framework. These summaries guided team discussions and W-PrEP intervention refinement.

RESULTS

Assessment

Joint Community and Scientific Advisory Committee. In this first phase of *ADAPT-ITT*, we convened a joint Community and Scientific Advisory Committee (see **Table 2**). In the committee's initial meeting, the research team provided an overview of the existing research and evidence-based interventions for women as the basis for discussion of the gaps in HIV prevention for women and opportunities for HIV prevention interventions. The committee discussion supported the focus of

the key informant interview guide on socio-structural barriers to PrEP and facilitators of PrEP for women and assessment of base case components for adaptation.

Key Informant Interviews. We completed 10 semi-structured interviews with community based-organization leadership, clinic and HIV prevention operations managers and leadership, medical providers, social workers, and educators/coordinators. Illustrative quotations from the key informant interviews (and from the subsequent qualitative portions of the study) are found in **Table 3**. Key informants identified several key barriers to PrEP utilization among reproductive age women of color. The most commonly cited barrier was lack of availability and accessibility of PrEP education and services for women, including lack of integrated HIV prevention and PrEP services into primary women's health care, the challenging logistics of navigating PrEP care in light of competing priorities and social determinants of health, and lack of culturally appropriate PrEP marketing and educational materials for women. Suggested opportunities included increased provider education, integration of PrEP into women's primary and reproductive/sexual health care, and utilization of the full clinical team, including PrEP navigators, serving as PrEP educators and ambassadors. Key informants additionally identified low perceived risk of HIV acquisition and low awareness of PrEP as critical barriers for women. Many referenced the dearth of public health and industry marketing campaigns focused upon women (compared to men-who-have-sex-with-men (MSM)). Multiple key informants noted continued stigma related to taking a medication associated with sexual "promiscuity," MSM, and HIV, and barriers around disclosure of PrEP use to support networks, including partners and family members.

We queried key informants about adaptation of *Project Shikamana* and the *Clinic Level Educational Intervention* as well as key components to retain. There was universal enthusiasm for inclusion of a PrEP navigator. Many expressed that PrEP navigators should be from the community and reflect the intended demographic (i.e., reproductive age women of color). There was a sentiment that PrEP navigators should serve as representatives of the community in the clinical setting as a means of combating medical mistrust and misconceptions surrounding PrEP. Participants suggested that PrEP navigators could also identify community needs and assets surrounding PrEP and HIV

prevention. Many participants also identified the importance of the navigators in PrEP education and in navigation of PrEP services, including insurance prior authorization, appointments, and prescription assistance programs for uninsured/under-insured patients.

In terms of PrEP training for the clinic team, key themes included centering the community/patient voice in the training, promoting sex-positive language (vs. risk-based language) as a non-stigmatizing way of conversing about PrEP and HIV prevention, and the importance of bias training (to reduce racial, sex, and gender biases).

Although key informants underscored the importance of community support in engagement and retention in the PrEP cascade for women, they emphasized harnessing the power of existing community-based organizations and referring to these organizations—while utilizing intervention resources to create a supportive, safe, stigma-free environment in which to learn about PrEP and access PrEP within the clinic.

Focus Group Discussions. Through the key informant interviews, we identified tools, strategies and experiences that the intervention should address. In the next phase we conducted focus groups to gain insight into how to develop the program content. We conducted three sets of focus group discussions separately with providers, PrEP navigators/educators, and patients, specifically Black women of reproductive age (n range 4 to 8 participants per group).

Focus Group Discussions: Medical Providers. A total of n=10 medical providers participated in two focus groups discussions; one group with six providers with experience providing PrEP and one group with four providers without PrEP experience. Providers across both groups agreed upon the utility of workflow aids such as EHR order sets, PrEP reference “cheat” sheets, and badge cards or “badge buddies” to facilitate incorporation of PrEP care into their clinical practices. There was also suggestion of a clinic PrEP champion as a resource to assist with complicated clinical scenarios. Providers agreed that telehealth was helpful for PrEP continuation, especially for patients with competing priorities or social determinants of health (e.g. transportation, limited time off of work) that may limit frequent in person visits. Providers were enthusiastic about the potential for a PrEP

navigator. There was consensus that PrEP clinical navigation (e.g., obtaining insurance prior authorization, assisting with rescheduling appointments) was logistically key to integrating PrEP into a bustling clinical practice with overstretched providers. They additionally supported a PrEP navigator serving to introduce PrEP to patients and to provide additional education about PrEP to alleviate some of the logistical time constraints on patient visits. Providers prioritized clinical navigation and education services (over social support) in order to operably integrate PrEP services into their clinical practice. Several providers reasoned that social support issues outside of the scope of the clinical PrEP navigator could be referred to the outpatient social worker team.

Providers preferred in-person trainings (to virtual or hybrid), with an asynchronous alternative for rotating learners or review at a later time point. Multiple participants emphasized the importance of refresher trainings several months after the initial training. There was a call for interactive training activities (e.g., role playing) both to keep participants engaged and to enact new skills. In addition to education on HIV prevention and PrEP, providers requested inclusion of practical tips and logistics and sample scripts for incorporation of PrEP services into their clinical practice in a non-stigmatizing way. Providers additionally requested incorporation of the epidemiologic context for HIV prevention among women and specifically requested centering the community/patient voice and perspective throughout the trainings.

Focus Group Discussions: Navigators/educators. PrEP peer and clinical navigators and educators (n=4) participated in the focus group. The group agreed that the ability to connect quickly with patients was more important than shared background or personal experience with PrEP. They emphasized the importance of the navigation to find room in a patient's lifestyle for PrEP (in the face of competing priorities)—but also mentioned the importance of social and emotional support and referral to social services.

The group preferred in-person training and supported a supplemental asynchronous option. They shared the providers preference for interactive trainings with role playing. In addition to the basics of HIV prevention and PrEP, navigators/educators identified key training topics of social and structural determinants of health, advocacy skills, and sexual and reproductive health.

Focus Group Discussions: Patients. A total of 16 patients (8 with and 8 without experience taking PrEP) participated in four focus groups discussions, divided by previous PrEP experience. Preventative health (e.g., nutrition, physical activity, mental health, routine health screenings) was identified as a common health goal. Patients described provider bias surrounding sexual health, costs associated with navigating the health system and with accessing healthy foods/fitness options, and competing priorities as barriers to meeting their personal health goals.

Nearly all patient participants were enthusiastic about culturally appropriate educational videos about PrEP to increase PrEP awareness in the waiting room; there was also interest in women-centered PrEP pamphlets, posters, and links to websites with additional information about PrEP. Although there was no consensus around who (e.g., nurse, medical provider, PrEP navigator) should introduce PrEP, there was agreement that what mattered most was that PrEP was introduced in a universal, non-stigmatizing manner.

There was agreement that the PrEP navigator should be a cisgender woman who shares their cultural/community background (i.e., Black and familiar with or from the locality)—ideally someone who is currently taking PrEP or has taken it in the past. There was strong appeal in being able to discuss PrEP with a trusted individual with similar life experiences and first-hand experience with PrEP, yet outside of the medical field. Participants voiced that the roles of educator, prevention navigator, and supportive ally in the process were all important.

There was little consensus around the ideal setting or mechanism for social support, given that participants accessed and utilized social support systems in different ways. Preferences were split between in-person and virtual support mechanisms. Several supported a virtual option that could provide flexibility and continuity for women with competing priorities. Those who preferred a in-person support setting were divided between pop-up events vs. a permanent community support setting; those who favored a permanent space were further conflicted on whether the space should be associated with the hospital or embedded in the community.

Decision

In preparation for the *Decision* phase, the research team reviewed the findings of the key informant interview and focus group discussion RQAs, met with with joint advisory board, and with five additional national HIV prevention intervention experts to discuss existing resources and planned intervention strategies. The research team also updated a scoping review of the contemporary, relevant literature. The research team reaffirmed the plan to adapt and build upon two base cases (**Table 2**), utilizing the multi-pronged, socio-structural approach of *Project Shikamana* and the clinic-centered intervention setting and educational focus of the *Clinic Level Educational Intervention*. Notably, given the feedback from the key informant interviews on harnessing existing community support resources and the lack of consensus on social/community support mechanisms, the research team decided to focus on the “Provider Sensitivity Training” and “Education/Navigation and Support” components of *Project Shikamana*, specifically creating a non-stigmatizing, supportive and safe environment for provision of HIV prevention education and services within the clinic setting (with referrals to outside organizations), rather than creating an intervention-specific community support component. Based on our extensive background research and our findings in this formative work, the research team affirmed the decision to use the *Socio-Ecological Model* given the multi-pronged and multi-level approach of the intervention. [29,62,63]

Adaptation

Provider focus group participants were invited back for theater testing of the planned intervention flowchart and a mock-up of the adapted trainings and toolkits, expanding on the *Clinic-level Educational Intervention* and *Project Shikamana*’s Provider Sensitivity Training, incorporating lessons learned from the *Assessment* phase. We elicited topic-specific feedback on length, level of detail, and preferred formats and mediums for learning and skill enactment within the training modules, as well as feedback on specific slides. We additionally prompted suggestions to improve and or refine the toolkits and intervention flowchart. Participants emphasized overall approval of the intervention mock-up and provided detail-oriented feedback to improve clarity and incorporate additional resources or tools, such as a badge card with reminders about prescribing requirements.

Production

Incorporating the theater testing feedback, we fleshed out a prototype for each of the components of the multi-pronged intervention; **Table 4** outlines the intervention components. We adapted and expanded upon the clinic-wide trainings, incorporating more role play, segments with the patient perspective taken from prior qualitative work,[30] as well as identified key topics such as how to incorporate of PrEP care into clinical practice. We curated a PrEP clinical navigator training program using materials from the Please PrEP Me navigator training while incorporating feedback from qualitative data collection.[64–66] Additionally, we collated educational resources for the clinic team, PrEP navigators, and patients, including a patient-facing educational website. We updated and developed a variety of toolkits for clinic level roll out of W-PrEP, roll out of long-acting injectable PrEP, as well as role-specific toolkits for the clinic team members and the PrEP navigator. We also created a PrEP clinical navigation clinical flowchart, with multiple options for modification/adaptation depending on availability of clinical space and when patients had downtime between clinical activities (e.g., triage by medical assistant, evaluation by medical provider).

Topical experts and Integration

We engaged the community and scientific advisory committee as *Topical Experts* to review the prototypes developed in the *Production* phase, (i.e., the intervention flowchart, toolkits, training modules, educational resources). The committee expressed enthusiastic support for the adapted intervention and offered minimal feedback to incorporate into the intervention components.

DISCUSSION

Principal Results: Using the ADAPT-ITT model, we iteratively adapted two CDC Best Practices in HIV prevention, utilizing the socio-structural approach of *Project Shikamana* and building from the training model from the *Clinic Level Educational Intervention*. We found that while the core elements of provider sensitivity training, navigation, and support of *Project Shikamana* were maintained, the urban Mid-Atlantic context better lent itself to a clinic-based approach. We thus focused on a supportive, trauma-informed clinical environment, without a separate community support venue. Additionally, the navigation model shifted from a community peer support model to a PrEP navigator

supporting clinic workflows to meet the needs of a bustling urban women's health clinic with a high patient volume. The training from the *Clinic Level Educational Intervention* was significantly expanded to center the patient-voice and prioritize shared decision making throughout the modules. We incorporated group activities, discussions, and role-plays to the training to make it more interactive. Added content included a focus on SSDOH, TIC, and incorporation of PrEP counseling into clinical practice. The adapted W-PrEP intervention features clinic-level modular trainings, a toolkit and resources for clinic-level implementation of PrEP services, toolkits and resources for provider and clinic team members, a clinical PrEP navigation program—including training and resources, and patient-facing, woman centric educational and support resources, including a website focused on PrEP for women—all to be tested in the pilot *Testing* phase.

Comparison with Prior Work: At the time of intervention development, *Project Shikamana* and the *Clinic-level Educational Intervention* were the only two *Best Practices* in the CDC compendium addressing HIV prevention for women. W-PrEP is now among a growing number of interventions published in the last several years intended to increase engagement and retention in the PrEP cascade among women, several specifically responsive to Black women.[67–71] Like the POWER Up intervention[70] developed in parallel to W-PrEP and currently under evaluation, W-PrEP utilizes a socio-structural approach. As a clinic-level intervention, W-PrEP expands upon our prior work[49,72] to more fully address identified patient-, provider-, and clinic-level socio-ecological barriers, such as low awareness among patients, low knowledge/confidence of how to provide PrEP among providers, and clinic-level challenges of systems/logistics for obtaining prior authorization and tracking patient follow-up.

Limitations: W-PrEP was adapted in an urban, mid-Atlantic setting and is specifically responsive to the barriers to PrEP for Black women. Although we posit that our developed intervention is likely generalizable to Black women with increased potential exposure to HIV throughout the United States, we recognize that there may be cultural differences specific to geographic region. We catered the intervention development to sexual and reproductive health providers, given the natural synergy between HIV prevention and sexual and reproductive health and the patient populations

that these providers care for. We again recognize that this intervention may need additional adaptation for implementation into the primary care setting, including additional modules for providers who also care for patients assigned male at birth.

Conclusions: This paper details the adaptation process of two evidence-based interventions to create a program that is responsive to the needs and experiences of the various groups involved in its delivery. We provide such detail, because the practicalities and logistics of adaptation are often unarticulated and completed behind a curtain, so to speak. We sought to provide insight into the adaptation process from the ground level. The adaptation of the W-PrEP program integrated key elements of the local context for cisgender women with potential exposure to HIV, as well as medical providers, clinic-staff, and PrEP navigators. Next steps include piloting the adapted intervention in a real-world setting for feasibility, acceptability, and preliminary efficacy, prior to launching a multi-site trial to assess impact on the PrEP cascade.

Acknowledgements Research reported in this publication was supported by National Institute of Mental Health of the National Institutes of Health under award number R34MH128046. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The authors would like to thank the “Women’s PrEP Project” joint community and scientific advisory board and the participants in the pilot, both patients and clinic staff members. The authors would additionally like to thank Drs. Jonathan Fuchs, Alan McCord, Dominica Seidman, Rachel Logan, and Anisha Ghandi for their consultations during the adaptation.

Conflicts of Interest RKS has received investigator-sponsored research funding (managed by MHRI and the IMPAACT Network) from ViiV Healthcare and participated in ViiV Healthcare advisory meetings. DK has received investigator-sponsored research funding (managed by GW) from ViiV Healthcare.

Abbreviations:

CDC: Centers for Disease Control and Prevention

CI: confidence intervals

DC: Washington D.C.

EBI: evidence-based intervention

EII: evidence-informed intervention

HIV: human immunodeficiency virus

MSM: men-who-have-sex-with-men

PrEP: pre-exposure prophylaxis

Rapid Qualitative Analysis

SSDOH: Social and structural determinants of health

TIC: Trauma informed care

US: United States

W-PrEP: Women’s PrEP Project

Data Availability: data are available upon request

REFERENCES

1. AtlasPlus - Charts. Available from: <https://gis.cdc.gov/grasp/nchhstpatlas/charts.html> [accessed Dec 27, 2024]
2. Hess KL, Hu X, Lansky A, Mermin J, Hall HI. Lifetime risk of a diagnosis of HIV infection in the United States. *Annals of Epidemiology Elsevier Inc.*; 2017. p. 238–243. PMID:28325538
3. CDC. HIV Diagnoses, Deaths, and Prevalence. HIV Data. 2024. Available from: <https://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html> [accessed Dec 27, 2024]
4. CDC. Fast Facts: HIV and Women. HIV. 2024. Available from: <https://www.cdc.gov/hiv/data-research/facts-stats/women.html> [accessed Dec 27, 2024]
5. Abdool Karim Q, Sibeko S, Baxter C. Preventing HIV Infection in Women: A Global Health Imperative. *Clinical Infectious Diseases Oxford Academic*; 2010 May;50(s3):S122–S129. doi: 10.1086/651483
6. Beksinska M, Wong R, Smit J. Male and female condoms: Their key role in pregnancy and STI/HIV prevention. *Best Practice and Research: Clinical Obstetrics and Gynaecology*. Bailliere Tindall Ltd; 2020. PMID:32007451
7. Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, Tappero JW, Bukusi EA, Cohen CR, Katabira E, Ronald A, Tumwesigye E, Were E, Fife KH, Kiarie J, Farquhar C, John-Stewart G, Kakia A, Odoyo J, Mucunguzi A, Nakku-Joloba E, Twesigye R, Ngunjiri K, Apaka C, Tamoooh H, Gabona F, Mujugira A, Panteleeff D, Thomas KK, Kidoguchi L, Krows M, Revall J, Morrison S, Haugen H, Emmanuel-Ogier M, Ondrejcek L, Coombs RW, Frenkel L, Hendrix C, Bumpus NN, Bangsberg D, Haberer JE, Stevens WS, Lingappa JR, Celum C. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *New England Journal of Medicine Massachusetts Medical Society*; 2012 Aug;367(5):399–410. doi: 10.1056/NEJMoa1108524
8. Thigpen MC, Kebaabetswe PM, Paxton LA, Smith DK, Rose CE, Segolodi TM, Henderson FL, Pathak SR, Soud FA, Chillag KL, Mutanhaurwa R, Chirwa LI, Kasonde M, Abebe D, Buliva E, Gvetadze RJ, Johnson S, Sukalac T, Thomas VT, Hart C, Johnson JA, Malotte CK, Hendrix CW, Brooks JT. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *New England Journal of Medicine Massachusetts Medical Society*; 2012 Aug;367(5):423–434. PMID:22784038
9. Murnane PM, Celum C, Mugo N, Campbell JD, Donnell D, Bukusi E, Mujugira A, Tappero J, Kahle EM, Thomas KK, Baeten JM, Partners PrEP Study Team. Efficacy of preexposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: subgroup analyses from a randomized trial. *AIDS (London, England)* 2013 Aug;27(13):2155–60. PMID:24384592
10. Marrazzo J, Tao L, Becker M, Leech AA, Taylor AW, Ussery F, Kiragu M, Reza-Paul S, Myers J, Bekker L-G, Yang J, Carter C, de Boer M, Das M, Baeten JM, Celum C. HIV Preexposure Prophylaxis With Emtricitabine and Tenofovir Disoproxil Fumarate Among Cisgender Women. *JAMA* 2024 Mar 19;331(11):930–937. doi: 10.1001/jama.2024.0464

11. Delany-Moretlwe S, Hughes JP, Bock P, Ouma SG, Hunidzarira P, Kalonji D, Kayange N, Makhema J, Mandima P, Mathew C, Spooner E, Mpendo J, Mukwekwerere P, Mgodini N, Ntege PN, Nair G, Nakabiito C, Nuwagaba-Biribonwoha H, Panchia R, Singh N, Siziba B, Farrior J, Rose S, Anderson PL, Eshleman SH, Marzinke MA, Hendrix CW, Beigel-Orme S, Hosek S, Tolley E, Sista N, Adeyeye A, Rooney JF, Rinehart A, Spreen WR, Smith K, Hanscom B, Cohen MS, Hosseinipour MC, Asmelash A, Sehurutshi A, Baguma A, Marais A, Kawoozo B, Malinga BP, Mirembe BG, Okech B, Esterhuizen B, Murombedzi C, Gadama D, Hwengwere E, Roos E, Magada ES, Shava E, Piwowar-Manning E, Tahuringana E, Muhlanga FG, Conradie F, Angira F, Nanyonjo G, Kistnasami G, Mvula H, Naidoo I, Horak J, Jere J, Moodley J, Shin K, Nel K, Bokoch K, Birungi L, Emel L, Monametsi M, Sibanda M, Mutambanengwe M, Chitukuta M, Matimbira M, Bhondai-Mhuri M, Sibisi N, Morar N, Mudzonga N, Natureeba P, Richardson P, Musara P, Macdonald P, Nkambule R, Mosime R, White R, Berhanu R, Ncube-Sihlongonyane R, Sekabira R, Siva S, Pillay S, Govender S, Bamweyana S, Nzimande S, Innes S, Dadabhai S, Samandari T, Tembo T, Mabedi TL, Chirenda T, Chidemo T, Mudhune V, Naidoo V, Samaneka W, Agyei Y, Musodza Y, Fourie Y, Gaffoor Z. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. *The Lancet Elsevier*; 2022 May 7;399(10337):1779–1789. PMID:35378077
12. Bekker L-G, Das M, Karim QA, Ahmed K, Batting J, Brumskine W, Gill K, Harkoo I, Jaggernath M, Kigozi G, Kiwanuka N, Kotze P, Lebina L, Louw CE, Malahleha M, Manentsa M, Mansoor LE, Moodley D, Naicker V, Naidoo L, Naidoo M, Nair G, Ndlovu N, Palanee-Phillips T, Panchia R, Pillay S, Potloane D, Selepe P, Singh N, Singh Y, Spooner E, Ward AM, Zwane Z, Ebrahimi R, Zhao Y, Kintu A, Deaton C, Carter CC, Baeten JM, Kiweewa FM. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *New England Journal of Medicine Massachusetts Medical Society*; 0(0). doi: 10.1056/NEJMoa2407001
13. Sarkar NN. Barriers to condom use. *European Journal of Contraception and Reproductive Health Care*. Taylor & Francis; 2008. p. 114–122. PMID:18465472
14. Siegler AJ, Mouhanna F, Giler RM, Weiss K, Pembleton E, Guest J, Jones J, Castel A, Yeung H, Kramer M, McCallister S, Sullivan PS. The prevalence of pre-exposure prophylaxis use and the pre-exposure prophylaxis-to-need ratio in the fourth quarter of 2017, United States. *Annals of Epidemiology Elsevier Inc.*; 2018 Dec;28(12):841–849. PMID:29983236
15. Smith DK, Van Handel M, Grey J. Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015. *Annals of epidemiology* 2018;28(12):850-857.e9. PMID:29941379
16. Huang YLA, Zhu W, Smith DK, Harris N, Hoover KW. Hiv preexposure prophylaxis, by race and ethnicity — United States, 2014–2016. *Morbidity and Mortality Weekly Report*. Department of Health and Human Services; 2018. p. 1147–1150. doi: 10.15585/MMWR.MM6741A3
17. Mapping PrEP: First Ever Data on PrEP Users Across the U.S. - AIDSVu. Available from: <https://aidsvu.org/prep/> [accessed Nov 6, 2019]
18. Bush S, Ng L, Magnuson D, Piontkowsky D, Mera Giler R. Significant uptake of Truvada for preexposure prophylaxis (PrEP) utilization in the US in late 2014 - 1Q2015. 2015. Available from: https://www.iapac.org/AdherenceConference/presentations/ADH10_OA74.pdf

19. Bush S, Magnuson D, Rawlings M, Hawkins T, McCallister S, Mera Giler R. ASM/ICAAC: Racial Characteristics of FTC/TDF for Pre-exposure Prophylaxis (PrEP) Users in the US. Racial characteristics of FTC/TDF for pre-exposure prophylaxis (PrEP) users in the US Boston; 2016. Available from: http://www.natap.org/2016/HIV/062216_02.htm
20. Kwakwa HA, Bessias S, Sturgis D, Walton G, Wahome R, Gaye O, Jackson M. Engaging United States Black Communities in HIV Pre-exposure Prophylaxis: Analysis of a PrEP Engagement Cascade. *Journal of the National Medical Association National Medical Association*; 2018 Oct;110(5):480–485. PMID:30129509
21. Kwakwa HA, Bessias S, Sturgis D, Mvula N, Wahome R, Coyle C, Flanigan TP. Attitudes Toward HIV Pre-Exposure Prophylaxis in a United States Urban Clinic Population. *AIDS and behavior* 2016;20(7):1443–50. PMID:27115399
22. Bradley E, Forsberg K, Betts JE, DeLuca JB, Kamitani E, Porter SE, Sipe TA, Hoover KW. Factors Affecting Pre-Exposure Prophylaxis Implementation for Women in the United States: A Systematic Review. *Journal of women's health* (2002) 2019 Sep;28(9):1272–1285. PMID:31180253
23. Aaron E, Blum C, Seidman D, Hoyt MJ, Simone J, Sullivan M, Smith DK. Optimizing Delivery of HIV Preexposure Prophylaxis for Women in the United States. *AIDS Patient Care and STDs Mary Ann Liebert Inc.*; 2018 Jan;32(1):16–23. doi: 10.1089/apc.2017.0201
24. Ojikutu BO, Bogart LM, Higgins-Biddle M, Dale SK, Allen W, Dominique T, Mayer KH. Facilitators and Barriers to Pre-Exposure Prophylaxis (PrEP) Use Among Black Individuals in the United States: Results from the National Survey on HIV in the Black Community (NSHBC). *AIDS and behavior* 2018 Nov;22(11):3576–3587. PMID:29468493
25. Wingood GM, Dunkle K, Camp C, Patel S, Painter JE, Rubtsova A, DiClemente RJ. Racial Differences and Correlates of Potential Adoption of Preexposure Prophylaxis. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2013 Jun;63:S95–S101. PMID:23673895
26. Flash CA, Dale SK, Krakower DS. Pre-exposure prophylaxis for HIV prevention in women: Current perspectives. *International Journal of Women's Health*. Dove Medical Press Ltd; 2017. p. 391–401. PMID:28615975
27. Goparaju L, Experton LS, Praschan NC. Women want Pre-Exposure Prophylaxis but are Advised Against it by Their HIV-positive Counterparts. *Journal of AIDS & Clinical Research OMICS Publishing Group*; 2015;6(11):1. doi: 10.4172/2155-6113.1000522
28. Goparaju L, Praschan NC, Jeanpiere LW, Experton LS, Young MA, Kassaye S. Stigma, Partners, Providers and Costs: Potential Barriers to PrEP Uptake among US Women. *Journal of AIDS & Clinical Research OMICS Publishing Group*; 2017;08(09). doi: 10.4172/2155-6113.1000730
29. Scott RK, Hull SJ, Huang JC, Ye PP, Lotke P, Beverley J, Moriarty P, Balaji D, Ward A, Holiday J, Brant AR, Elion R, Visconti AJ, Coleman M. Intention to Initiate HIV Pre-exposure Prophylaxis Among Cisgender Women in a High HIV Prevalence U.S. City. *Womens Health Issues Elsevier*; 2023 Sep 1;33(5):541–550. PMID:37479630
30. Burns JA, Hull SJ, Inuwa A, Moriarty P, Scott RK. Understanding Retention in the HIV Pre-Exposure Prophylaxis Cascade Among Cisgender Women. *AIDS Patient Care and STDs Mary*

Ann Liebert, Inc., publishers; 2023 Apr;37(4):205–211. doi: 10.1089/apc.2023.0009

31. Scott RK, Hull SJ, Huang JC, Coleman M, Ye P, Lotke P, Beverley J, Moriarty P, Balaji D, Ward A, Holiday J, Brant AR, Cameron M, Elion R, Visconti A. Factors Associated with Intention to Initiate Pre-exposure Prophylaxis in Cisgender Women at High Behavioral Risk for HIV in Washington, D.C. *Arch Sex Behav* 2022 Jul 1;51(5):2613–2624. doi: 10.1007/s10508-021-02274-4
32. Hull SJ, Duan X, Brant AR, Peng Ye P, Lotke PS, Huang JC, Coleman ME, Nalls P, Scott RK. Understanding Psychosocial Determinants of PrEP Uptake Among Cisgender Women Experiencing Heightened HIV Risk: Implications for Multi-Level Communication Intervention. *Health Communication Routledge*; 2023 Dec 6;38(14):3264–3275. PMID:36398676
33. Johnson LM, Green HD, Koch B, Stockman JK, Felsher M, Roth AM, Wagner KD. Role of Social Networks and Social Norms in Future PrEP Use in a Racially Diverse Sample of At-Risk Women and Members of Their Social Networks. *J Acquir Immune Defic Syndr* 2021 Apr 1;86(4):422–429. PMID:33196549
34. Jackson GY, Darlington CK, Van Tieu H, Brawner BM, Flores DD, Bannon JA, Davis A, Frye V, Chittamuru D, Gugerty P, Koblin BA, Teitelman AM. Women's views on communication with health care providers about pre-exposure prophylaxis (PrEP) for HIV prevention. *Cult Health Sex* 2022 May;24(5):642–656. PMID:33535887
35. Garfinkel DB, Alexander KA, McDonald-Mosley R, Willie TC, Decker MR. Predictors of HIV-related risk perception and PrEP acceptability among young adult female family planning patients. *AIDS Care* 2016 Sep;29:1–8. doi: 10.1080/09540121.2016.1234679
36. Willie TC, Stockman JK, Keene DE, Calabrese SK, Alexander KA, Kershaw TS. Social networks and its impact on women's awareness, interest, and uptake of HIV Pre-exposure Prophylaxis (PrEP): Implications for women experiencing intimate partner violence. *Journal of Acquired Immune Deficiency Syndromes Lippincott Williams and Wilkins*; 2019 Apr;80(4):386–393. PMID:30570528
37. Auerbach JD, Kinsky S, Brown G, Charles V. Knowledge, Attitudes, and Likelihood of Pre-Exposure Prophylaxis (PrEP) Use Among US Women at Risk of Acquiring HIV. *AIDS Patient Care and STDs* 2015 Feb;29(2):102–110. PMID:25513954
38. Roth A, Felsher M, Tran N, Bellamy S, Martinez-Donate A, Krakower D, Szep Z. Drawing from the Theory of Planned Behaviour to examine pre-exposure prophylaxis uptake intentions among heterosexuals in high HIV prevalence neighbourhoods in Philadelphia, Pennsylvania, USA: an observational study. *Sexual Health CSIRO*; 2019;16(3):218–224. doi: 10.1071/SH18081
39. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.
40. OJ Blackstock SJ VV Patel, U Felsen, C Park. Pre-exposure prophylaxis prescribing and retention in care among heterosexual women at a community-based comprehensive sexual health clinic. *AIDS Care Routledge*; 2017 Jul;29(7):866–869. doi: 10.1080/09540121.2017.1286287

41. Devlin SA, Ridgway JP, Dawdani A, Enaholo OE, Liegeon G, Kasal N, Pyra M, Hirschhorn LR, Simon J, Haider S, Ducheny K, Johnson AK. Adapting Provider Training and Pre-Exposure Prophylaxis Advertising to Increase Pre-Exposure Prophylaxis Awareness and Uptake Among Black Cisgender Women. *AIDS Patient Care and STDs* Mary Ann Liebert, Inc., publishers; 2023 Dec;37(12):574–582. doi: 10.1089/apc.2023.0188
42. Petroll AE, Walsh JL, Owczarzak JL, McAuliffe TL, Bogart LM, Kelly JA. PrEP Awareness, Familiarity, Comfort, and Prescribing Experience among US Primary Care Providers and HIV Specialists. *AIDS and Behavior* 2017 May;21(5):1256–1267. PMID:27885552
43. Castel AD, Feaster DJ, Tang W, Willis S, Jordan H, Villamizar K, Kharfen M, Kolber MA, Rodriguez A, Metsch LR. Understanding HIV care provider attitudes regarding intentions to prescribe PrEP. *Journal of Acquired Immune Deficiency Syndromes* Lippincott Williams and Wilkins; 2015;70(5):520–528. PMID:26247895
44. Seidman D, Weber S, Carlson K, Witt J. Family planning providers' role in offering PrEP to women. *Contraception*. Elsevier USA; 2018. p. 467–470. PMID:29408284
45. Seidman D, Carlson K, Weber S, Witt J, Kelly PJ. United States family planning providers' knowledge of and attitudes towards preexposure prophylaxis for HIV prevention: A national survey. *Contraception* Elsevier Inc.; 2016;93(5):463–469. PMID:26772906
46. Sales JM, Escoffery C, Hussen SA, Haddad LB, Phillips A, Filipowicz T, Sanchez M, McCumber M, Rupp B, Kwiatkowski E, Psioda MA, Sheth AN. Pre-exposure prophylaxis integration into family planning services at title X clinics in the southeastern United States: A geographically-targeted mixed methods study (Phase 1 ATN 155). *JMIR Research Protocols* JMIR Res Protoc; 2019 Jun;8(6). doi: 10.2196/12774
47. Bronfenbrenner U. *The ecology of human development: Experiments by Nature and Design*. Harvard University Press; 1979. Available from: <https://books.google.mu/books?hl=en&lr=&id=ISBN:978-0-674-22457-5>
48. Kaufman MR, Cornish F, Zimmerman RS, Johnson BT. Health behavior change models for HIV prevention and AIDS care: Practical recommendations for a multi-level approach. *Journal of Acquired Immune Deficiency Syndromes* Lippincott Williams and Wilkins; 2014 Aug;66(SUPPL.3). PMID:25007194
49. Scott RK, Deyarmond M, Marwitz S, Huang JC, Moriarty P, Visconti AJ, Beverley J, Elion R, Coleman M, Hull SJ. Implementation of an Educational Intervention to Improve HIV Pre-Exposure Prophylaxis Services for Women in an Urban Sexual Health Clinic. *AIDS Patient Care and STDs* Mary Ann Liebert, Inc., publishers; 2023 Sep;37(9):447–457. doi: 10.1089/apc.2023.0107
50. Compendium | Intervention Research | Research | HIV | CDC. 2024. Available from: <https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html> [accessed Aug 1, 2024]
51. Kerrigan D, Mbwambo J, Likindikoki S, Beckham S, Mwampashi A, Shembilu C, Mantsios A, Leddy A, Davis W, Galai N. Project Shikamana: Baseline findings from a community empowerment-based combination HIV prevention trial among female sex workers in iringa, tanzania. *Journal of Acquired Immune Deficiency Syndromes* Lippincott Williams and Wilkins;

2017 Jan;74(Suppl 1):S60–S68. PMID:27930613

52. Kerrigan D, Mbwapbo J, Likindikoki S, Davis W, Mantsios A, Beckham SW, Leddy A, Shembilu C, Mwampashi A, Aboud S, Galai N. Project Shikamana: Community Empowerment-Based Combination HIV Prevention Significantly Impacts HIV Incidence and Care Continuum Outcomes among Female Sex Workers in Iringa, Tanzania. *Journal of Acquired Immune Deficiency Syndromes* Lippincott Williams and Wilkins; 2019 Oct;82(2):141–148. PMID:31513552
53. Wingood GM, Diclemente RJ. The ADAPT-ITT model: A novel method of adapting evidence-based HIV interventions. *Journal of Acquired Immune Deficiency Syndromes J Acquir Immune Defic Syndr*; 2008. PMID:18301133
54. Crooks N, Debra A, Coleman D, Sosina W, Singer R, Jeremiah R, Green B, Johnson W, Caldwell C, Patil C, Matthews AK, Donenberg G. Application of ADAPT-ITT: adapting an evidence-based HIV/STI mother-daughter prevention intervention for Black male caregivers and girls. *BMC Public Health* 2023 Jul 26;23(1):1426. doi: 10.1186/s12889-023-16364-6
55. Rotheram-Borus MJ, Tomlinson M, Stewart J, Skiti Z, Rabie S, Wang J, Almirol E, Vogel L, Christodoulou J, Weiss RE. Soccer and Vocational Training are Ineffective Delivery Strategies to Prevent HIV and Substance Abuse by Young, South African Men: A Cluster Randomized Controlled Trial. *AIDS Behav* 2024 Dec 1;28(12):3929–3943. doi: 10.1007/s10461-024-04458-0
56. Davis T, DiClemente RJ, Prietula M. Using ADAPT-ITT to Modify a Telephone-Based HIV Prevention Intervention for SMS Delivery: Formative Study. *JMIR Form Res* 2020 Oct 6;4(10):e22485. PMID:32831178
57. Conserve DF, Abu-Ba'are GR, Janson S, Mhando F, Munisi GV, Drezgic B, Rehani A, Sims W, Ritchwood TD, Choko AT, Mushy SE, Johnson C, Jennings Mayo-Wilson L, Komba A, Urasa P, Nelson LE, Mbita G. Development and feasibility of the peer and nurse-led HIV Self-Testing Education and Promotion (STEP) intervention among social networks of men in Dar es Salaam, Tanzania: application of the ADAPT-ITT model. *BMC Health Serv Res* 2024 Oct 2;24(1):1166. doi: 10.1186/s12913-024-11586-9
58. Bowser M, Young RM, Nesbitt LS, District of Columbia Department of Health, HIV/AIDS H, Administration (HAHSTA). Annual Epidemiology & Surveillance Report: Data Through December 2019. Available from: <https://dchealth.dc.gov/service/hiv-reports-and-publications>
59. Hamilton AB. Qualitative methods in rapid turn-around health services research [Webinar]. HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy, VA Greater Los Angeles Healthcare System 2013;
60. Palinkas LA, Mendon SJ, Hamilton AB. Innovations in Mixed Methods Evaluations. *Annu Rev Public Health* 2019 Apr 1;40:423–442. PMID:30633710
61. Gale RC, Wu J, Erhardt T, Bounthavong M, Reardon CM, Damschroder LJ, Midboe AM. Comparison of rapid vs in-depth qualitative analytic methods from a process evaluation of academic detailing in the Veterans Health Administration. *Implementation Sci* 2019 Feb 1;14(1):11. doi: 10.1186/s13012-019-0853-y

62. Price DM, Unger Z, Wu Y, Meyers K, Golub SA. Clinic-Level Strategies for Mitigating Structural and Interpersonal HIV Pre-Exposure Prophylaxis Stigma. *AIDS Patient Care STDS* 2022 Mar;36(3):115–122. PMID:35289691
63. Ojikutu BO, Mayer K. HIV Prevention Among Black Women in the US—Time for Multimodal Integrated Strategies. *JAMA Network Open* 2021 Apr 9;4(4):e215356. doi: 10.1001/jamanetworkopen.2021.5356
64. PrEP Navigation Manual – Please PrEP Me. Available from: <https://pleaseprepreme.org/prepnavigatormanual/> [accessed Jan 22, 2025]
65. TIO | Intro to Trauma Informed Care Training Modules. Trauma Informed Oregon. Available from: <https://traumainformedoregon.org/resources/training/tic-intro-training-modules/> [accessed Aug 2, 2024]
66. Implicit Bias: A Practical Guide for Healthcare Settings | The George Washington University School of Medicine and Health Sciences. Available from: <https://cme.smhs.gwu.edu/www.dcrxce.com/content/implicit-bias-practical-guide-healthcare-settings#group-tabs-node-course-default1> [accessed Aug 2, 2024]
67. Johnson AK, Haider S, Nikolajuk K, Kuhns LM, Ott E, Motley D, Hill B, Hirschhorn L. An mHealth Intervention to Improve Pre-Exposure Prophylaxis Knowledge Among Young Black Women in Family Planning Clinics: Development and Usability Study. *JMIR Form Res* 2022 Jul 28;6(7):e37738. PMID:35900830
68. Randolph SD, Johnson R. A Salon-Based Intervention to Improve PrEP Uptake among Black Women. *New England Journal of Medicine Massachusetts Medical Society*; 2024 Feb 28;390(9):776–777. doi: 10.1056/NEJMp2313708
69. Blumenthal J, Jain S, He F, Amico KR, Kofron R, Ellorin E, Stockman JK, Psaros C, Ntim GM, Chow K, Anderson PL, Haubrich R, Corado K, Moore DJ, Morris S, Landovitz RJ. Results from a Pre-exposure Prophylaxis Demonstration Project for At-risk Cisgender Women in the United States. *Clinical Infectious Diseases* 2021 Oct 1;73(7):1149–1156. doi: 10.1093/cid/ciab328
70. Ridgway JP, Devlin SA, Friedman EE, Enaholo OE, Pyra M, Hirschhorn LR, Haider S, Ducheny K, Johnson AK. POWER Up—Improving pre-exposure prophylaxis (PrEP) uptake among Black cisgender women in the Southern United States: Protocol for a stepped-wedge cluster randomized trial (SW-CRT). *PLoS One* 2023 May 17;18(5):e0285858. PMID:37196008
71. Teitelman AM, Koblin BA, Brawner BM, Davis A, Darlington C, Lipsky RK, Iwu E, Bond KT, Westover J, Fiore D, Tieu H-V. Just4Us: Development of a Counselor-Navigator and Text Message Intervention to Promote PrEP Uptake Among Cisgender Women at Elevated Risk for HIV. *Journal of the Association of Nurses in AIDS Care* 2021 Apr;32(2):188. doi: 10.1097/JNC.0000000000000233
72. Brant AR, Dhillon P, Hull S, Coleman M, Ye PP, Lotke PS, Folan J, Scott RK. Integrating HIV Pre-Exposure Prophylaxis into Family Planning Care: A RE-AIM Framework Evaluation. *AIDS Patient Care and STDs NLM (Medline)*; 2020 Jun;34(6):259–266. doi: 10.1089/apc.2020.0004



Tables:**Table 1.** Base case Interventions

Project EBI [50–52]	Shikamana Peer navigation and education: <i>Shikamana</i> offered both venue-based peer education, which included condom distribution and HIV counseling and testing, and peer service navigation for women living with HIV, including social support to promote HIV treatment access and adherence. Provider sensitivity training: Trainings for HIV medical providers promoted non-stigmatizing, quality health services, and were conducted in coordination with peer navigators. Community-led drop-in center: The drop-in center was designed to stimulate social cohesion and mobilization activities and offered HIV counseling, testing, and condoms. The center hosted support groups for community members and convened seminars on topics such as stigma, gender-based violence, income generation and savings groups, and HIV prevention.
Clinic-level EII [49,50]	Educational Structured clinic-wide training and refresher training(s): Trainings emphasized universal provision of PrEP education/counseling, prescribing PrEP, including screening laboratory analyses, techniques to encourage PrEP adherence and persistence. Trainings include sample language for counseling and role-plays. Provider toolkit: The toolkit featured an EHR PrEP screening prompt, which inquired if patients were interested in discussing starting PrEP as part of their visit, along with screening questions regarding indications for PrEP. The toolkit also offered identification badge card-sized reference “cheat” sheets and work station reference sheets with indicated laboratory testing, dosing, and follow-up for PrEP and nPEP initiation. Looped patient-facing PrEP educational videos: The intervention offered looping, short educational videos about PrEP and sexual health in the waiting room, with the goal of increasing PrEP awareness and normalizing PrEP in order to facilitate conversations with medical providers.

Table 2. Study Activities and Measures by ADAPT-ITT phase

ADAPT-ITT Phase[53]	Activities and Measures
Assessment <i>Obtain a comprehensive understanding of the target population</i>	Formation and initial meeting with joint Community and Scientific Advisory Committee, consisting of a social justice advocate, an HIV and HIV prevention advocate, and the founder of a non-profit focused on HIV and faith communities, a family planning specialist and reproductive rights advocate, a family physician with expertise in provider education and HIV prevention, and a nurse practitioner with expertise in HIV prevention and implementation science. Key informant interviews with an executive director of the national office of an international women's HIV organization, an executive director of a local women's HIV and HIV prevention community-based organization, a director of clinical services of a local branch of a national reproductive health care service provider, a director of a government sponsored sexual health clinic, a director of women's health at a local HIV health center, a coordinator of a government-sponsored PrEP campaign for women, a HIV prevention coordinator at a local federally-qualified community health center, a family medicine provider with a focus on HIV and STI prevention, a family-nurse practitioner working in HIV treatment and prevention, a social worker at a preventative health clinic focused on female sex workers (n=10). Focus group discussions with medical providers with (n=1 group) and without (n=1 group) experience prescribing PrEP, PrEP navigators and educators (n=1 group), and Black women of reproductive age with (n=2 groups) and without (n=2 groups) previous PrEP experience.
Decision <i>Select interventions and decided whether to adopt or adapt</i>	Review of CDC Best Practice base cases (i.e., <i>Project Shikamana EBI</i> and the <i>Clinic-level Educational EII</i>) Review of current literature on PrEP and HIV prevention related interventions for women
Adaptation <i>Use a pretested methodology to better understand how to adapt</i>	Theater testing of a mock-up of the intervention flow, clinic-wide training materials and toolkit with the participants from the medical provider focus groups
Production <i>Create an adaptation plan and determine goals</i>	Production of the initial prototype, including adaptation or development of the following: • Clinic-level PrEP roll-out toolkit, clinical team toolkits, PrEP navigator toolkit • Clinic-wide training and PrEP navigator training • Increased availability and accessibility of PrEP services • PrEP navigation program, including delineation of the role of the navigator • Patient facing PrEP educational resources
Topical Experts <i>Provide substantive content and technical assistance</i>	Engagement of the community and scientific advisory committee to elicit feedback on the intervention prototype
Integration <i>Integrate all forms of information</i>	Reflect feedback from the advisory committee into the refined intervention prototype

Table 3. Exemplary Quotations by ADAPT-ITT phase and activity

ADAPT-ITT Phase Activity Theme	Respondent characteristics	Quotation(s)
Assessment		
Key Informant (KI) Interviews		
<i>Barriers to PrEP: Accessibility & Availability</i>	Prevention coordinator at a community health center Black, cisgender, woman, age 26	"(A) lot of...the providers are not talking about PrEP, they are not well versed in PrEP."
<i>Barriers to PrEP: Accessibility & Availability</i>	Family nurse practitioner working in HIV and HIV prevention. Black, cisgender woman, age 33	"One of the other barriers is just medication access. So, a lot of them, when we send the prescription to the pharmacy, I have to do close follow-up to make sure that they actually pick up the medication. Sometimes, if they go to the pharmacy, if there is an insurance issue, a lot of times it's a deterrent for them continuing with the process of initiating the medication. So, when I see them, I do very close follow-up. I try to stay in touch to make sure that they have picked up the medication, and to check in to make sure that they've started and just to assess if they're having any side effects and things like that."
<i>Barriers to PrEP: health literacy/ perceived risk</i>	Regional leader of an international HIV and HIV prevention advocacy organization. Black, cisgender woman, age 47	"(Women) do not see their lives as at-risk. ...They do not understand... high levels of incarceration in the community, or transactional sex work... as a problem, ...they see that just as regular life in their communities. And then if they were asked by the provider, do you engage in any high-risk activities, they're obviously going to say no, because they don't consider the activities that they do as high risk....Sometimes when you share, or describe some...STDs or things like that that women experience, they will say, oh my gosh, I've had that. Or I've experienced that. And they didn't know what it was."
<i>Barriers to PrEP: health literacy/ perceived risk</i>	Family nurse practitioner working in HIV and HIV prevention. Black, cisgender woman, age 33.	"I think the main barrier is lack of perceived risk. Most women don't believe or know that they're at risk for acquiring HIV. And many of them have not even heard of PrEP before. So, lack of education as well. ... When people hear the word PrEP they think about the (men-who-have-sex-with men (MSM)) community. So, they don't even know that the medication has been approved for female use. So, like I said, the biggest issue is lack of education."
<i>Barriers to PrEP: stigma</i>	Department of Health interim division chief for STD and TB control and sexual health clinic health care provider White (non-Hispanic), cisgender man, age 50	"When we talk to MSM and trans women about PrEP, there is less of a stigma associated with being on PrEP. In some ways, it's socially acceptable and it's socially desirable. So, on dating apps for instance, it's not uncommon for MSM or trans women to say, "HIV-negative, disease-free, on PrEP." It's almost like a badge of honor or something. But with ciswomen, when we talk to them about PrEP, we get a little bit of like, "What are you trying to say? Why do you think I need this medication? What is that saying about me? What are you saying about my partners?" And so, that's also a barrier, the perception of what it means to be on PrEP, and the stigma associated with HIV."
<i>Model Adaptation: PrEP Navigation</i>	Manager of Women's Wellness Programs at a local HIV-focused organization Black, cisgender woman, age 32	"(I)t addresses the medical mistrust piece because you've got a trusted messenger there who's gonna have evidence-based information, but can deliver in a way that maybe will resonate more, so I think that's great. I also think that sometimes, it's helpful to see someone who looks like you, that you feel like you can relate to, and who can also – like I said – take you by the hand to go through that process"
<i>Model Adaptation: Training</i>	Manager of Women's Wellness Programs at a local HIV-focused organization Black, cisgender woman, age 32	"Definitely...history...helping physicians understand the reasons behind medical mistrust in communities of color – the historical context. ...I would definitely want a conversation around taking a sexual history, having these difficult conversations around sexual health, how to have them appropriately, maybe something specific...to the experiences of Black women."
<i>Model Adaptation: Training</i>	Family nurse practitioner working in HIV and HIV prevention. Black, cisgender	"A baseline conversation about what PrEP is, the importance of adherence, how the medication works, that it's important that it's taken every day to be most effective, typical side effects, and maybe a conversation about routine follow-up and how often they would need to be seen and monitored, and lab testing. ... (T)hey definitely should be

	woman, age 33	able to have a conversation with (patients) about just the overall rates of HIV within this area so that they get a better understanding of their risk and why they're even bringing PrEP up as a consideration for them. ... (T)he conversation should definitely lean more towards prevention and holistic care. You're sexually active and taking this medication is a part of ensuring that you're safe and you have safe sexual practices and it can alleviate some of the fear that you may have around acquiring HIV. So, not necessarily saying because you have several partners you're considered high risk, but shifting the conversation towards we know that you're sexually active. You don't always use condoms. As a part of your holistic care, it's a good idea to consider taking this medication as an additional layer of protection for yourself."
<i>Model Adaptation: Community Support</i>	Family medicine practitioner White, cisgender man, age 37	"(T)here (are) a lot of (Community Based Organizations [CBOs]) that are currently out there doing a lot of really, really great work...you (will) have more impact by leveraging existing relationships (with) existing CBOs that already have community buy-in, and (a)re...more grass roots"
Focus Group Discussions (FGD)		
<i>Key Components of the Intervention: PrEP navigation</i>	Provider FGD	"(W)hen we first initiated PrEP at my clinic, we actually had an education coordinator who had reached out to each person after they started PrEP, just to follow up and see were they able to fill their prescription, do they have any issues or anything that we need to assist them with. And so that was really helpful in kind of identifying issues. We don't have that anymore now. And so now we are kind of seeing some challenges where people are paying out of pocket for their medications, you know, things that we didn't realize at their initial appointment that we're learning later on." "I would love for us to have nurses or a navigator, somebody to provide education"
<i>Key Components of the Intervention: Toolkit</i>	Provider FGD	<i>On badge cards & reference sheets:</i> "Something to be able to refer back...that is handy that can either be kept on you ...(or) where people sit and are writing notes. ...(H)aving that sort of quick start PrEP guide...right next to the desk of the attending physician...is really helpful, because otherwise I would forget exactly what I'm supposed to order, what to do, who to screen, how to screen or remember to screen." <i>On sample scripts:</i> "(T)echniques of how to frame the conversation and maybe suggested talking points or, you know, just some like suggested language to use of how to bring up the topic and what are ways to just start the conversation that are recognizing like our patients, backgrounds and experiences and maybe that don't sound judgmental." <i>On EHR tools:</i> "We use...a (EHR quick-text tool) to say...PrEP was discussed with this patient ... what their risk may be and ... what we what was discussed during the visit. So anyone that was at risk or... (had) identified risk factors we would put that (quick-text) in for all the patients and do that use the HIV counseling, ICD 10 code. ...And order sets for initiation of PrEP too, for the labs, can be really helpful and that might take just one step of complexity off the table to make it a little bit easier for providers to have more time to discuss it and less time ordering labs."
<i>Key Components of the Intervention: PrEP Champion</i>	Provider FGD	<i>On a PrEP Champion:</i> "Having a champion...(S)omeone that a new PrEP provider could call...when (the patient's)...labs come back and their LFTs are abnormal. And so (instead of) just giving up on PrEP, which I think a lot of people would do, having someone that they can call."
<i>Key Components of the Intervention: Clinic-wide Training (content & format)</i>	Provider FGD	<i>On training on integration into clinical practice:</i> "(T)his is how a general OBGYN can effectively start prescribing PrEP to their patients and protect them from HIV. It's like very practical. You attend this session; you will be confident to do this. Not like you learned a little bit about it and now you sort of aware this exists and other people do it, but this is how you can do it in your practice." <i>On format:</i> "Some of the most effective and enjoyable trainings are small group sessions...like the simulation lab, where you may work in a small group and have a leader or teacher that presents material, maybe goes through cases or situations and it's interactive or hands on in some way."

		<i>On format:</i> "Case studies, especially in these types of situations, would be really helpful to kind of go through the different patient types that might or might not be candidates for PrEP. Or you know whether there are specific patients with contraindications for PrEP and talking about that. I think as opposed to a list, it's helpful to kind of relate it to a real person or a patient. I think that also, that plus written materials is helpful."
<i>Characteristics and Role of the PrEP Navigator</i>	PrEP Educator & Navigator FGD	<i>On characteristics:</i> "(P)ersonability. Being able to communicate and relate to the patients in the specific area where you work, you know, you want to be able to cater to... the people surrounding you that's going to come into your clinic." <i>On characteristics:</i> "That's not like a big issue, whether it's a woman or man, it's whether or not you are communicating the PrEP information properly." <i>On role:</i> "Informing them about PrEP, addressing any questions that the patient may have about PrEP. Possibly, if the facility does not have a specific person who is responsible for navigating the patient through the insurance process, then that navigator would actually assist the patient with navigating the insurance process and also be that person who kind of like checks up on them to say, hey, how's it going with your PrEP? Have you noticed, like, have you picked up a routine with taking your PrEP? Do you need assistance with figuring out how to make this a part of your lifestyle? I think that's what a PrEP navigator should actually be responsible for."
<i>Barriers to Health Priorities</i>	Patient FGD	<i>On accessibility:</i> "I will agree on financial burdens and accessibility. Like if you live in a certain part of town, you may not have access to different resources that someone else has... If someone doesn't have a form of transportation, things like that. I mean I see that a lot, you know, in my community." <i>On competing priorities:</i> "It's like I have to choose one of the healthy things, but I can't do them all." <i>On competing priorities:</i> "I would say navigating the healthcare system... So if you have different chronic illnesses, you know, if you're gonna see a GI versus your allergist versus your primary care" <i>On medical mistrust:</i> "Well, sometimes, you know, due to certain biases, it doesn't seem like all health providers have the best interest of the patients and mine or they are maybe overworked, too busy and they aren't really taking the time to necessarily treat the patient before them, they're treating like, I guess symptoms of like one person, but, or symptoms of a man that aren't necessarily present in a woman. Umm so it's like when different providers are given different information, it's hard to, to trust it, it's hard to know. Are you actually treating me based on, you know the symptoms I'm showing, are you treating me based on how you see me?"
<i>Preferences for delivery of PrEP education and counseling</i>	Patient FGD	<i>On discussion PrEP as part of a problem-based visit (vs. a follow-up visit):</i> "I kinda just like to do everything at once. I really don't wanna like, you know, come back because I probably had, like, work or school or, you know, just other things. So, if it could be like a one stop shop and get everything you know, done. I would prefer that." <i>On PrEP educational videos:</i> "I think that's good...because (the videos) would like shift your focus off of...whatever you're coming in for and ...it's educational. I like to, like, watch videos. I do think that's better than just, like, reading the sign." <i>On a universal approach:</i> "Definitely just like erase the stigma and then makes the patient feel a lot more like, oh yeah, this is like normal to take and I'm not weird for taking this like, I'm just taking care of my health and I'm doing a positive thing." <i>On PrEP counseling:</i> "I think the doctor should have had a conversation as well, but maybe not up front first. Maybe the peer could be first just to

		give the general and the thought to start thinking of it.” <i>On PrEP counseling:</i> “So I think the single best thing in my opinion is if the providers like hey, like in a no judgment kind of way, you know, there's this thing called PrEP, you know, you're between these ages, I thought, you know, you might be interested in it, you know, what are your thoughts? I think that is the probably the single best thing. And yeah, especially if there was a video before and they already kind of saw and they already kind of knew then they might be already thinking, ooh, that sounds good, but ohh it might be too expensive for me or I'm scared to bring it up. So, if the provider brought it up first and they have the information, I think that would be really good.”
<i>Characteristics and Role of the PrEP Navigator</i>	Patient FGD	<i>On characteristics:</i> “I would be more inclined if the (navigator) was a woman...And I don't know, sometimes I just feel more comfortable talking about certain things.” <i>On characteristic of being a PrEP user:</i> “(I)n a perfect world, I think they'd be like, yes, I use it too. But, you know, it doesn't have to be that way for people to trust it and for people to feel like this is something I need. And this is good for me.” <i>On characteristics:</i> “So I would think necessarily age wouldn't matter to me as much as like college and experience would. Like someone who was very knowledgeable about you know the medicine, somebody that was very knowledgeable about sexual health. They're, the knowledge and experience for me would be a little bit more because I think for particularly as it relates to age, sometimes if a person is kind of much older than the person, I mean the peer educator is much older than the person receiving the information it could come off like preachy and not relational because it's like you know. But I do think, I guess using the medical term like going with the bedside manner and knows how to kind of speak to people who is comfortable kind of engaging with a wide variety of people.” <i>On characteristics:</i> “(C)ommunication skills, being an open listener, so you could, you can build that trust and have that open, you know lone or flow of communication between the patient and them.” <i>On role:</i> “(The) educator is like that person is just giving you that introduction into what this medicine, the medication is about, and then the...navigator is someone that's kind of like helping you throughout the process, making sure you getting appointments and making sure you're getting the medicine, and then the...social support is making sure that you have that extra support to make sure you feel comfortable with any issues that you have in personal or with the partnership, making sure that you're comfortable in yourself and also with the partner that you're with, knowing that you're feeling grounded. So, I think all of them are more important because that introduction is that, that, that breaking that ice and being that middle navigator is making sure you have all the navigation tools to make sure that you getting' the PrEP that you need and then that social support is making sure that you staying constant in that whole process. So, I think all of them are important to keep phoning it, but that last support is making sure that you stand steady in the process as a flow as time goes on and you're not feeling, you know, any kind of you know, guilt or, you know, worries going further or moving forward throughout the journey so to speak.”

Table 4: Adapted W-PrEP Intervention Components

Component	Description
Clinic-level PrEP rollout toolkit	• W-PrEP implementation checklist • Algorithm for universal PrEP counseling and services • Implementation algorithm(s) for roll-out of new PrEP formulations (including prior authorization) • PrEP navigator job description • Identification of a PrEP champion
PrEP Champion	• Medical provider to serve as a PrEP expert and site PrEP champion • Responsibilities include: facilitation of trainings, consultation on clinic-level implementation of PrEP services,

	and advising on complex clinical cases
Clinic-wide Training	Key training topics include: • HIV testing (which test at which time) and STI testing • Taking a patient-centered sexual and social history • Positive re-framing prevention communication/counseling around PrEP • How to incorporate patient-centered PrEP and nPEP provision for women into routine care • PrEP initiation, continuation/persistence, and discontinuation • nPEP initiation and transition to PrEP • Implicit and explicit bias training • Trauma-informed care • Epidemiology of the US HIV epidemic • Social and Structural Determinants of Health related to HIV Key Features: • Synchronous, interactive PowerPoint presentations scripted for reproducibility & scalability • Asynchronous pre-recorded modules to accommodate irregular schedules of medical providers & rotating learners, with activities to engage the asynchronous individual learner • Centering of the patient-voice and experience throughout both modules
Increased availability & accessibility of PrEP follow-up	• Increased availability of telehealth/virtual visits for PrEP follow-up visits. These visits are designed as alternatives to in-person visits for women who were not ready to start PrEP, but want to learn more about PrEP (from providers and/or PrEP navigator) or for women who have been prescribed/started PrEP to follow-up re. issues with prescription pick-up, medication side effects, adherence, or other concerns. • Off-site laboratory referrals: providers will offer referrals to off-site commercial laboratories for follow-up STI and HIV testing if more convenient • PrEP Texting with PrEP navigator: email, text, and telephone follow-up options to address concerns/offer education
Clinic team Toolkit	• EHR PrEP order set (e.g., STI screening lab orders, PrEP injection or prescription orders, HIV testing orders) • EHR PrEP quick-text to facilitate documentation of PrEP education/counseling and prescription &/or EHR PrEP EHR prompts to remind and encourage providers to counsel all patients about PrEP (dependent upon EHR settings) • PrEP/nPEP badge buddy: an identification-badge card sized PrEP/nPEP reference "cheat" sheet with recommended STI and HIV screening, dosing information and follow-up • PrEP/nPEP reference "cheat" sheet and checklists: full-size reference sheet and PrEP start/continuation checklists for quick reference during a busy clinic day (recommended to be posted at the provider work station) • Sample scripts for introduction to PrEP (for medical assistants/nurses) and sample scripts for introduction and counseling for prescribing providers • "Ask me about PrEP!" swag (e.g., pins, lanyards)
PrEP Navigator Training	<i>In addition to the clinic-wide PrEP training</i>, through a combination of tailored one-on-one training from a PrEP education and navigation expert, independent learning, and on-line modules, the PrEP navigator will receive training in: • PrEP navigation through the Please PrEP Me Navigator training[64] • Implicit biases in the health care setting[66] • Trauma Informed Care[65] • Introduction to reproductive/sexual health topics (led by the site PI, topically tailored to the clinical context)
PrEP Navigator Toolkit	<i>In addition to the above clinical tools</i>, the PrEP navigators will have access to: • PrEP quick-text to facilitate documentation of PrEP navigator education/counseling, including assessment of barriers to PrEP • Sample script for introduction to PrEP & counseling about PrEP • Patient-facing educational resources (see below)
PrEP Navigation and support services	Informed by our formative work, PrEP navigators will be cisgender women, ideally from the same community the clinic serves and with first-hand experience with ARVs through PrEP and/or HIV. PrEP navigators will provide: • PrEP educational services: introducing PrEP to patients, combatting misperceptions/myths about PrEP • PrEP social and adherence support: breaking down social barriers to PrEP and mitigating the internalization of PrEP-related stigma; building/encouraging individual agency/self-efficacy to initiate and adhere to PrEP • PrEP navigation services: facilitating access to PrEP appointments; assisting with insurance authorization; referrals to indicated social services (e.g., substance use, gender-based violence, mental health)
Patient-facing PrEP resources	• Videos on PrEP and women's health/sexual health topics (selected by the clinical site) will be spliced and play on loop in the clinic waiting room to increase awareness of PrEP • Inclusive pamphlets on PrEP will be available in the waiting room and exam rooms • Inclusive posters about PrEP and HIV prevention will be displayed in the waiting room and exam rooms • W-PrEP educational website; QR code distributed by the PrEP navigator & available in the waiting area

