

PrEP Protocol Outline

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AURORA Study-A Transformative Approach Utilizing Behavioral Economics, Education, and Data Science to Support Patients Initiating PrEP with Retention-in-care and Medication Persistence

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Protocol Team

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List of Abbreviations

- CAB-LA - Long-Acting Injectable Cabotegravir
- EHR – Electronic Health Record
- FTC – Emtricitabine
- TDF – Tenofovir disoproxil
- TAF - Tenofovir alafenamide
- HCP – Health Care Provider
- HIV – Human Immunodeficiency Virus
- PrEP – Pre-Exposure Prophylaxis
- PROs – Patient Reported Outcomes
- PWID – Persons who inject drugs
- WVHR – West Virginia Health Right

1. PROTOCOL SUMMARY

Title	A Transformative Approach Utilizing Behavioral Economics, Education, and Data Science to Support Patients Initiating PrEP with Retention-in-care and Medication Adherence and Persistence
Funder	ViiV Healthcare
Study Design	Observational Cohort Study
Study Population	Patients >18 y/o who are newly started on PrEP at WVHR and have access to a smart phone with data.
Study Size	n = 105 (70 CAB-LA injection participants and 35 oral PrEP participants)

Study Duration	12 months
Study Site(s)	West Virginia Health Right
Intervention Description	<i>Participants will have been prescribed CAB-LA, daily FTC/TDF, or daily FTC/TAF in accordance with the WVHR standard of care by a licensed HCP prior to enrolling in the study. Those receiving CAB-LA will be in one arm and those receiving oral PrEP will be in the other arm of the study.</i>
Study Aim	To determine the persistence of injectable PrEP compared to oral PrEP
Primary Objectives	To evaluate medication persistence in patients receiving CAB-LA injections vs oral PrEP and who engage with a digital health companion program
Secondary Objective 1	Evaluate retention-in-care in patients receiving CAB-LA vs oral PrEP
Secondary Objective 2	Evaluate PROs (including PrEP medication satisfaction, PrEP acceptance, PrEP-Related Stigma, and reasons for PrEP discontinuation) in patients receiving CAB-LA vs oral PrEP
Secondary Objective 3	Evaluate the acceptability, appropriateness, and helpfulness of a digital health companion program for PrEP
Secondary Objective 4	Evaluate the acceptability, barriers to, and facilitators for implementation of CAB-LA PrEP

2. INTRODUCTION

2.1. Background

2.1.1. Numerous studies have found that medication persistence with oral PrEP (defined as continued use of PrEP over time) tends to be short, with many patients discontinuing oral PrEP within about 6-12 months. Moreover, PrEP persistence has been found to be shorter among underserved populations with health inequities—including Medicaid patients, patients in rural areas, transgender patients, and Black and Latinx patients. The introduction of long-acting, injectable cabotegravir (CAB-LA) for PrEP is viewed by many as an opportunity to overcome adherence

challenges. Moreover, based on its administration by a healthcare professional (HCP) every two months, the implementation for CAB-LA in real-world settings affords HCPs new opportunities to engage with patients, especially those with high unmet needs, which may influence PrEP persistence, retention-in-care, and patient-reported outcomes (PROs). To support adoption of CAB-LA for HIV PrEP, real-world studies are urgently needed to evaluate the impact of CAB-LA on outcomes that are critical to successful HIV prevention, such as adherence, persistence, retention-in-care, and PROs. Additionally, given its mode of administration, studies are needed to elucidate barriers to as well as facilitators for the implementation of CAB-LA PrEP in clinical settings. For people living with HIV, findings from the CUSTOMIZE study shed light on patient and provider perspectives on implementation of CAB+RPV LA for treatment of HIV. These insights from diverse settings of HIV treatment can serve as a springboard for evidence generation on the real-world use of CAB-LA for PrEP. Recognizing the need to support clinics in implementing and streamlining the delivery of PrEP, PRIME recently partnered with West Virginia Health Right (WVHR) in an implementation science initiative. Through this initiative, significant advances were made in overcoming barriers related to PrEP access. Specifically, the initiative directly resulted in a landmark decision by the Director of the West Virginia Medicaid program to remove all prior authorization requirements for CAB-LA for PrEP after attending the PRIME program. Building on this momentum and reduced barriers to CAB-LA access in WV, we propose to evaluate the implementation of CAB-LA supported by a novel PrEP mobile health app among underserved populations receiving care at WVHR. WVHR is a 501(c)3 non-profit, patient-centered, medical home that provides comprehensive primary and specialty care to >40,000 uninsured, underinsured, and underserved adults. Among services provided, WVHR provides HIV prevention care, harm reduction services, behavioral health care, and transgender health care—which is the only transgender health program in the region. Its in-house pharmacy fills >90,000 prescriptions annually,

including access to free medications for uninsured patients. Additionally, WVHR utilizes a mobile health clinic to care for hard-to-reach populations. WVHR is in Kanawha County, which is designated by the CDC as one of the top vulnerable areas of rapid spread of HIV due to injection drug use. Due to its location, services provided, and focus on uninsured/underinsured individuals, the populations cared for by WVHR encompass those with high unmet needs and PrEP-related disparities, including women, persons who inject drugs (PWID), transgender persons, persons in rural areas, and persons with low-income. Importantly, WVHR is committed to sustaining the HIV prevention initiative after the proposed study has concluded, as stated in the letter from Chief Executive Officer, Angie Settle, DNP, APRN, BC, FNP

2.2. Study Rationale

2.2.1. The digital health companion intervention that will be utilized in this research project is based on combining the principles of behavioral health economics, patient education, and data science to drive positive behavior change in PrEP adherence, persistence and retention-in-care. Prior research supports the acceptability and effectiveness of mobile health interventions for adherence to oral PrEP. For example, a PrEP adherence mobile app (“Dot”), which was tailored for culturally-diverse MSM, was found to have high user acceptability and resulted in increased adherence to daily PrEP over the 6-week intervention. Other mobile interventions have similarly been found to be effective in supporting PrEP adherence in key populations, including in MSM (PrEPmate, Viral combat) and cisgender women (AEGiS/iTAB). Importantly, surveys show that 86% of Medicaid beneficiaries own smartphones and that approximately one-quarter to one-half use their smartphone for a variety of health purposes, such as filling prescriptions, measuring health goals, monitoring health issues, and receiving reminders about prescription drugs. Thus, there is an important opportunity to evaluate mobile health interventions for PrEP among low-income, Medicaid populations, and to expand the use of mobile interventions for supporting persistence to long-acting injectable PrEP.

2.3. Hypothesis

2.3.1. This study is designed to test the hypothesis that, compared to oral PrEP, use of CAB-LA in underserved populations in a real-world setting supported by a digital health companion program will be associated with greater medication adherence, persistence, retention-in-care, and improved PROs.

3. STUDY OBJECTIVES

3.1. Study Goal

3.1.1. The study will evaluate the extent to which real-world use of CAB-LA for PrEP in underserved populations impacts PrEP adherence, persistence, retention-in-care, and PROs compared with oral PrEP. Additionally, the study will examine implementation of a digital health companion program that leverages education and behavioral economics to support patients on PrEP, and assess clinician perspectives as well as barriers to, and facilitators for implementation of CAB-LA in a patient-centered medical home.

3.2. Primary Objective

3.2.1. To evaluate medication adherence and persistence in patients receiving CAB-LA vs oral PrEP and who engage with a digital health companion program

3.3. Secondary Objectives

3.3.1. Evaluate retention-in-care in patients receiving CAB-LA vs oral PrEP

3.3.2. Evaluate PROs (including PrEP Medication Satisfaction, PrEP Acceptance, PrEP-Related Stigma, and reasons for PrEP discontinuation) in patients receiving CAB-LA vs oral PrEP

3.3.3. Evaluate the acceptability, appropriateness, and helpfulness of a digital health companion program for PrEP

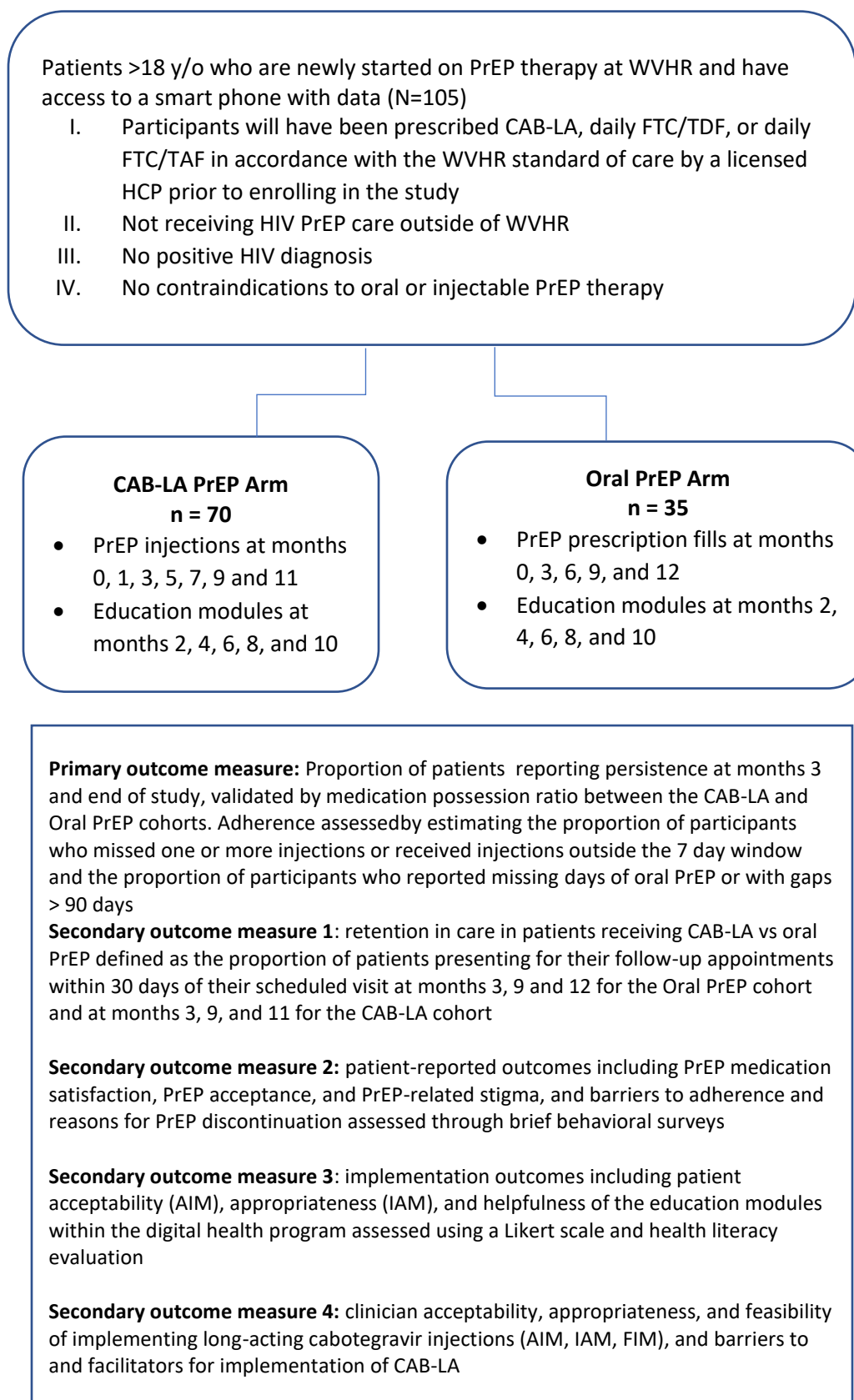
3.3.4. Evaluate the acceptability, barriers to, and facilitators for implementation of CAB-LA

4. STUDY DESIGN

4.1. Study Design

4.1.1. The research project follows a hybrid effectiveness-implementation research design, with the primary aim focused on evaluation of PrEP adherence, persistence and retention-in-care with CAB-LA compared with oral PrEP, and secondary aims focused on evaluating patient-reported outcomes (PROs), implementation of a digital health intervention to support adherence and persistence, and evaluating contextual factors around implementation of CAB-LA. The project is in the initial implementation stage, with CAB-LA beginning to be rolled out at WVHR after the recent state Medicaid decision to drop prior authorization requirements for CAB-LA. The proposed study will utilize a digital health intervention with behavioral health economics and patient education from PRIME and Reciprocity to evaluate the adoption and implementation for PrEP adherence and persistence. The implementation aims of the study will leverage the RE-AIM framework as follows: Assessment of the digital health intervention will focus primarily on individual-level dimensions of RE-AIM, including reach and effectiveness. For example, in assessing reach of the digital health intervention, participant demographics will be compared to the intended audience to evaluate the extent to which populations with high unmet needs were engaged. Conversely, assessment of the implementation of CAB-LA will focus on system-level dimensions of RE-AIM, such as qualitative assessments of barriers to and facilitators for implementation of CAB-LA. Furthermore, evaluation of implementation outcomes will be based on the Proctor et al. conceptual framework, using specific measures developed by Weiner et al. to assess acceptability, appropriateness, and feasibility of the intervention. In addition, evaluation of PROs will be informed by a review of validated instruments, including HIVSTQ (HIV Treatment Satisfaction Questionnaire), SMSQ (Study Medication Satisfaction Questionnaire), I-TAQ (Injection Treatment Acceptance Questionnaire), ACCEPT (Chronic Treatment Acceptance Questionnaire), and the PrEP Stigma Scale, with survey items tailored to evaluate PrEP acceptance, satisfaction, and perceptions of PrEP-related stigma for both the CAB-LA and oral PrEP arms.

4.2. Study Schema



5. STUDY POPULATION

5.1. Inclusion Criteria

5.1.1. >18 y/o

5.1.2. Initiation of PrEP with CAB-LA, daily FTC/TDF, or daily FTC/TAF prescribed in accordance with the WVHR standard of care practices (based practices on CDC PrEP 2021 Clinical Practice Guidelines) by a licensed HCP

5.1.3. PrEP dispensed by WVHR pharmacy

5.1.4. Access to a smart phone

5.2. Exclusion Criteria

5.2.1. <18 y/o

5.2.2. Receiving HIV PrEP care outside of WVHR

5.2.3. Positive HIV diagnosis

5.2.4. Contraindication to oral or injectable PrEP therapy

5.2.5. Receiving oral bridging therapy prior to injectable PrEP therapy

5.2.6. Confirmed pregnancy

5.2.7. Vulnerable populations

5.3. Study Sample

5.3.1. n = 105 (70 CAB-LA intervention participants vs 35 oral PrEP participants)

5.4. Screening and Enrollment

5.4.1. Patients will be enrolled on a rolling basis via HCPs at WVHR. HCPs will verify participant's eligibility for the study.

6. STUDY INTERVENTIONS AND PROCEDURES

6.1. Study Procedures and Interventions Table (Figure 6a)

CAB-LA PrEP Arm (N=70)													
Month 0	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Baseline labs and 1 st PrEP injection Baseline demographic survey	Baseline evaluation and introduction to support group	2 nd PrEP injection Persistence Assessment PRO data collection – Set #1	Education modules and health literacy evaluation	Follow-up labs and 3 rd PrEP injection PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 4 th PrEP injection Persistence Assessment PRO data collection – Set #1	Education modules and health literacy evaluation	Follow-up labs and 5 th PrEP injection Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 6 th PrEP injection PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 7 th PrEP injection Persistence Assessment PRO data collection – Set #1	PRO data collection – Set #2
Oral PrEP Arm (N=35)													
Month 0	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Baseline labs and PrEP prescription filled Baseline demographic survey	Baseline evaluation and introduction to support group	Persistence Assessment PRO data collection – Set #1	Education modules and health literacy evaluation Persistence Assessment	Follow-up labs and PrEP prescription refill PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation Persistence Assessment	Persistence Assessment PRO data collection – Set #1	Follow-up labs and PrEP prescription refill Education modules and health literacy evaluation Persistence Assessment	Persistence Assessment	Education modules and health literacy evaluation Persistence Assessment	Follow-up labs and PrEP prescription refill PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation Persistence Assessment	Persistence Assessment PRO data collection – Set #1	Follow-up labs and PrEP prescription refill PRO data collection – Set #2 Persistence Assessment
Reciprocity App – Education Modules <ul style="list-style-type: none"> Month 2: PrEP Medicines Month 4: Protecting Yourself from HIV, STIs, and other infections Month 6: Building a Support System for HIV Prevention Month 8: Being an Active Participant in Your Own Care Month 10: Overcoming Stigma and Becoming a Health Advocate 						Persistence assessment: patient self-report & barriers/challenges							
						PRO data collection (Set #1): <ul style="list-style-type: none"> PrEP Medication Satisfaction PrEP-Related Stigma AIM 		PRO data collection (Set #2): <ul style="list-style-type: none"> PrEP Acceptance IAM 					

6.2. Description of Study Procedures

Before any screening procedure is performed, informed consent will be obtained. Labs will be taken at baseline and months 3, 5, 7, 9, and 11 for the CAB-LA cohort and at baseline and months 3, 6, 9, and 12 for the Oral PrEP cohort (only collected through standard of care). Participants will complete a baseline evaluation and be introduced to a support group at baseline. Patients will complete assessments within the TheraPay App. Clinicians will complete assessments outside of the app. Patients in both cohorts will complete baseline demographic surveys in month 0, patient reported outcomes (PRO) data collection set 1 in months 1, 5, and 11 and PRO data collection set 2 in months 3, 9, and 12. Patients in the CAB-LA PrEP cohort will complete persistence assessments in months 1, 3, 5, 7, 9, and 11. Patients in the Oral PrEP cohort will complete persistence assessments every month from months 1 through 12. Clinic staff will complete surveys at baseline, month 6, month 12, and at the end of the study. The

schedule of assessments for the CAB-LA PrEP cohort, Oral PrEP cohort, and clinicians is presented in figure 6a. Instruments are in Appendix B for the CAB-LA cohort, in Appendix C for the Oral PrEP cohort, and Appendix D for clinicians. Patient incentives for completing the assessment activities are outlined in Appendix E.

6.2.1. Baseline Patient Demographic Survey

6.2.2. Medication Persistence

6.2.2.1. Definition: Continue to take medicines over time independent of adherence to the PrEP medication regimen.

6.2.3. Persistence Assessment CAB-LA

6.2.3.1. The proportion of participants who received at least one PrEP injection who remained on injectable PrEP or oral bridging at months 3 and 11 measured by the self-report assessment and validated with claims data.

6.2.4. Persistence Assessment Oral PrEP

6.2.4.1. The proportion of participants who initiated oral PrEP who remained on oral PrEP at months 3 and 12 measured by the self-report assessment and validated with claims data period.

6.2.5. Adherence

6.2.5.1. Definition: Taking PrEP in line with medical advice/using PrEP appropriately (critical for efficacy) .

6.2.6. Adherence Assessment CAB-LA

6.2.6.1. Adherence to the dosing schedule will be assessed at month 3 (early adherence) and end of study by:

A) Estimating the number of individuals who missed one or more consecutive injections without taking daily oral bridging PrEP while not on CAB-LA injections and mean and median number of injections missed during a 6- and a 12-month period.

6.2.7. B) Estimating the number of individuals who received the injections seven or more days later than their scheduled injection visit and the mean and median duration of delayed injections. Adherence Assessment Oral PrEP

6.2.7.1. Adherence to the dosing schedule will be assessed at months 3 (early adherence) and 12 by:

A) Estimating the number of individuals who reported three or more days of oral PrEP missed and the mean and median number of days they missed.

B) Estimating the number of individuals who had a gap of >90 days between the end of the days of supply of a dispensing and the start date of the next fill.

6.2.8. Patient Reported Outcomes

6.2.8.1. Patient Reported Outcomes Set 1: PrEP Medication Satisfaction, PrEP-Related Stigma, Acceptability of Intervention Measure (AIM)

6.2.8.2. Patient Reported Outcomes Set 2: PrEP Acceptance, Intervention Appropriateness Measure (IAM)

6.2.8.3. Helpfulness of the education modules and Health Literacy Evaluation

6.2.9. Clinician Instruments

6.2.9.1. Baseline Provider Survey

6.2.9.1.1. Information About You and Your Patients

6.2.9.1.2. Acceptability of Intervention Measure (AIM)

6.2.9.1.3. Intervention Appropriateness Measure (IAM)

6.2.9.1.4. Feasibility of Intervention Measure (FIM)

6.2.9.1.5. Barriers and Facilitators for Implementation of Long-Acting Cabotegravir for PrEP

6.2.9.2. Follow-up Provider Survey

6.2.9.2.1. Information About You and Your Patients

6.2.9.2.2. Acceptability of Intervention Measure (AIM)

6.2.9.2.3. Intervention Appropriateness Measure (IAM)

6.2.9.2.4. Feasibility of Intervention Measure (FIM)

6.2.9.2.5. Barriers and Facilitators for Implementation of Long-Acting Cabotegravir for PrEP

6.3. Standard of Care Visits

6.3.1. The standard of care for patient visits will not be affected. The patients will only be given additional surveys to complete.

6.4. Follow-Up Visits

6.4.1. CAB-LA PrEP cohort: 2nd PrEP injection at month 1; follow-up labs and PrEP injections in months 3, 5, 7, 9, and 11.

6.4.2. Oral PrEP cohort: follow-up labs and prescription refills in months 3, 6, 9, and 12.

6.5. Switching between PrEP regimens

6.5.1. To be included in final data analysis, participants cannot switch between PrEP regimens before 6-months duration of initial PrEP.

6.6. PrEP Discontinuation

6.6.1. Participants will be deemed as having discontinued PrEP if they miss more than 3 consecutive months for PrEP.

6.6.2. Participants will be called, texted and emailed for three consecutive months before considered them as discontinued.

6.7. STI Screening and Management

6.7.1. Participants will receive STI screening at baseline and at every follow up clinic visit. Participants will be screened if they present with any type of symptoms that warrant STI testing. If a participant tests positive for an STI other than HIV, they will receive guideline-directed therapy at the discretion of their HCP at WVHR.

6.8. Suspected or Confirmed HIV Infection

6.8.1. HIV screening will occur a minimum as recommended for every 2 months with CAB-LA (same time as injections) and every 3 months for oral PrEP.

6.9. PrEP Choice Counselling

6.9.1. Patients will be counseled on the benefits and risks of both oral PrEP and PrEP injections. The selection of PrEP option will be done as the standard of care through shared-decision with the patient.

6.10. Possible Participant Pathways

6.10.1. There will only be two observational cohort arms. Patients will either be placed into the injectable PrEP arm or the oral PrEP arm based on their baseline prescription.

6.11. Adherence Strategies

6.11.1. Patients on oral PrEP will be encouraged to set a daily reminder on their smart phone as an alarm at the time their dose is due.

6.11.2. Patients on injectable PrEP will set a monthly calendar reminder on the day/time their injection is due.

6.12. Retention Strategies

6.12.1. Follow-up appointments will be set up and conveyed at each appointment.

6.12.2. Reminder calls will be made by a staff member a few days before the appointment.

6.13. Interventions: PrEP Initiation and Digital Health Companion Program

6.13.1. Participants will be enrolled in the CAB-LA and Oral PrEP cohorts. Participants in the CAB-LA cohort will receive their first dose of the PrEP injection at month 0. Injections will also be administered in months 1, 3, 5, 7, 9, and 11. Participants in the Oral PrEP cohort will have their prescription filled at month 0, 3, 6, 9, and 12. The schedule of dosing is presented in Figure 6a.

6.13.2. Participants in both cohorts will complete education modules and health literacy evaluations in the TheraPay App in months 2, 4, 6, 8, and 10 as presented in Figure 6a. Education Modules include PrEP Medicines (month 2), Protecting Yourself from HIV, STIs, and other infections (month 4), Building a Support System for HIV Prevention Month 6: Being an Active Participant in Your Own Care (month 8), and Overcoming Stigma and Becoming a Health Advocate (month 10).

6.14. STATISTICAL ANALYSIS

6.14.1. Study Endpoints

6.14.1.1. Medication Adherence and Persistence

Medication persistence is defined as continuing to take PrEP over time independent of adherence to the medication regimen. The proportion of

patients reporting receipt of CAB-LA or oral PrEP at months 3 (early) and end of study (late) will be measured through patient questionnaires and validation protocols. Medication adherence is defined as taking PrEP in line with medical advice.

6.14.1.2. Retention-in-Care

Retention-in-care is defined as the proportion of patients presenting for their follow-up appointments within 30 days of their scheduled visit at months 3, 9, and 12 after PrEP initiation in the oral PrEP cohort and months 3, 9, and 11 for the CAB-LA cohort.

6.14.1.3. Patient-reported Outcomes

Patient-reported outcomes will be assessed through surveys. Medication satisfaction will be measured by the HIV Treatment Satisfaction Questionnaire (HIVSTQ) adapted for PrEP and PrEP stigma will be measured by the PrEP Stigma Scale at months 1, 5, and 11. PrEP acceptance will be measured by the Modified Injection Treatment Acceptance Questionnaire (Modified I-TAQ) at months 3, 9, and 12. Barriers to adherence to oral PrEP and reasons for PrEP discontinuation will be assessed through brief behavioral surveys every month after the initiation of PrEP. Barriers to adherence to CAB-LA injections and reasons for PrEP discontinuation will be assessed through brief behavioral surveys at months 1, 3, 5, 7, 9, and 11.

6.14.1.4. Implementation Outcomes for the Mobile App

Acceptability of the mobile app to support patients in taking PrEP will be measured by the Acceptability of Intervention Measure (AIM) at months 1, 5, and 11. Appropriateness of the mobile app to support patients in taking PrEP will be measured by the Intervention Appropriateness Measure (IAM) at months 3, 9, and 12.

6.14.1.5. Clinic Staff Acceptability, Appropriateness, and Feasibility of Providing Long-acting Cabotegravir Injections

Acceptability of the process for providing long-acting cabotegravir injections will be assessed by the Acceptability of Intervention Measure (AIM). Appropriateness of the process for providing long-acting cabotegravir injections will be assessed by the Intervention Appropriateness Measure (IAM). Feasibility of long-term use of cabotegravir injections will be assessed by the Feasibility of Intervention Measure (FIM). Willingness to sustain provision of long-acting cabotegravir injections and barriers to and facilitators for provision of long-acting cabotegravir injections will be assessed through a brief survey. The clinic staff surveys will be administered at baseline, month 6, month 12, and end of study.

7. Statistical Analyses

Baseline analyses will include tabulations of demographic and clinical variables of the study participants. Chi-square tests and t-tests will be used to compare these groups to determine if baseline differences exist. The distribution of each continuous variable will be inspected for outliers to determine whether a parametric or non-parametric approach should be applied. The Wilcoxon ranked sum test will be used for any variable that does not meet the statistical assumptions of the t-test. Variables found to be associated with persistence or adherence following univariate analysis will be included in multivariate models.

To assess the co-primary endpoint of persistence at 3 months and end of study, the proportion of participants reporting continued receipt of injections in the CAB-LA cohort and the proportion of patients reporting continued use of PrEP by mouth in the oral PrEP cohort on the persistence assessment will be compared using chi square tests or Fisher's exact tests. Self-reported persistence will be validated by the medication possession ratio (MPR). MPR is defined as the number of days of medication dispensed during the study period divided by the number of days that the person should have received therapy. The percent of CAB-LA participants with MPRs ≥ 1.0 will be compared to the percent of oral PrEP participants with MPRs ≥ 1.0 using chi square tests or Fisher's exact tests. To assess the co-primary endpoint of adherence, chi square tests or Fisher's

exact tests will be used to compare the percent of CAB-LA participants who reported missing one or more injections during the study period to the percent of oral PrEP participants who reported three or more missed days of oral PrEP. The percent of CAB-LA participants who received any injections seven or more days later than their scheduled injection or oral PrEP participants who had a gap of >90 days between the end of the days of supply of a dispensing and the start date of the next fill will be compared.

Sample Size

Assuming adherence proportions of .90 and .65 and sample sizes of 70 and 35 in the CAB-LA and oral PrEP arms respectively, the 95% confidence interval for the difference between the CAB-LA proportion and the oral PrEP proportion is .0771 to .4229.

8. SAFETY MONITORING AND ADVERSE EVENT REPORTING

- 8.1. An adverse event (AE) is defined as any untoward medical occurrence whether thought to have been caused by the investigational medical product or the Study or not, and a Serious Adverse Event (SAE) shall mean any adverse event which is fatal, life threatening, disabling or incapacitating, requires in-patient treatment or prolongs existing hospitalization, is a congenital anomaly in the off-spring of the patient or which may require intervention to prevent the previously stated outcomes.
- 8.2. All AEs should be reported via FEARS by the health care providers. All SAEs and medical device incidents considered related to CAB-LA should be reported to GSK within 24 hours of awareness. All pregnancies associated with CAB-LA (initial notification followed by outcome of the mother and infant) should be reported to GSK within 1 week of awareness.
- 8.3. Participants will be counselled by HCPs at WVHR on the common ADEs to be aware of and when the participants should contact their HCP. Common ADEs can also be found in the FDA package insert. Participants will be counselled that If they become pregnant or suspect they might be pregnant, they should contact their HCP. All investigators and health care providers are strongly encouraged to report all pregnancies exposed to Cabotegravir to the Antiretroviral Pregnancy Registry (APR) as soon as the pregnancy is

identified. Pregnancies can be reported to the Registry at SM_APR@APRegistry.com via the data forms available at www.APRegistry.com

9. HUMAN PARTICIPANTS AND DATA PROTECTION

9.1. TheraPay App

9.1.1. The TheraPay requires a username and password to access the program and data stored by the application. Only survey completed by enrolled participants will be stored within the application along with name, phone number, and email address.

10. TIMELINES

10.1. Patients will be enrolled until the n value of 105 is met.

2-3 months	3-6 months*	12 months	3 months
<i>Development of study protocol, educational modules and survey instruments</i>	<i>Participant enrollment (rolling basis)</i>	<i>Study period</i>	<i>Data analysis and publication submission</i>

11. PRESENTATION AND PUBLICATION PLANS

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1. PROTOCOL SUMMARY

Title	A Transformative Approach Utilizing Behavioral Economics, Education, and Data Science to Support Patients Initiating PrEP with Retention-in-care and Medication Persistence
Funder	ViiV Healthcare
Study Design	Observational Cohort Study
Study Population	Patients >18 y/o who are newly started on PrEP at WVHR and have access to a smart phone with data.
Study Size	n = 105 (70 CAB-LA intervention participants and 35 oral PrEP participants)
Study Duration	12 months
Study Site(s)	West Virginia Health Right
Intervention Description	<i>Participants will have been prescribed CAB-LA, daily FTC/TDF, or daily FTC/TAF in accordance with the WVHR standard of care by a licensed HCP prior to enrolling in the study. Those receiving CAB-LA will be in one arm and those receiving oral therapy will be in the other arm of the study.</i>
Study Aim	To determine the persistence in injectable PrEP compared to Oral PrEP therapy
Primary Objectives	To evaluate medication persistence in patients receiving CAB-LA vs oral PrEP and who engage with a digital health companion program
Secondary Objective 1	Evaluate Retention-in-care in patients receiving CAB-LA vs oral PrEP
Secondary Objective 2	Evaluate PROs (including PrEP medication satisfaction, PrEP acceptance, stigma, and reasons for PrEP discontinuation) in patients receiving CAB-LA vs oral PrEP
Secondary Objective 3	Evaluate the acceptability, appropriateness, and helpfulness of a digital health companion program for PrEP

Secondary Objective 4	Evaluate the acceptability, barriers to, and facilitators for implementation of CAB-LA
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Study Schema Figure

Figure showing study components and flow – organize by participant cohort (i.e. oral, LA, no PrEP)

Study Outcomes Table

Primary or Secondary Endpoint	Definitions	Type of Endpoint	Assessment Timepoint	Data Source	Intervention or Approach	Tool/Instrument for Endpoint
1. Primary Endpoint: PrEP adherence and Persistence	Proportion of patients reporting receipt of CAB-LA injections or use of oral PrEP at 3 months after PrEP initiation and end of study	Quantitative	M3 and end of study	Participant survey and EHR	Participant survey and EHR	Survey and Medication Retention Ratio
2. Secondary Endpoint: Retention-in-care	The proportion of patients presenting for their follow-up appointments within 30 days of their scheduled visit at months 3, 9 and 12 after PrEP initiation for the Oral PrEP arm and months 3, 9, and 11 for the CAB-LA arm.	Quantitative	M3, M9, M11, M12	Participant survey and EHR	Participant survey and EHR	Survey
3. Secondary Endpoint: PROs	PRO Set #1: PrEP Medication Satisfaction; PrEP-Related Stigma PRO Set #2: PrEP Acceptance ----- Barriers to adherence to CAB-LA injections and	Qualitative	M1, M5, M11 (PRO Set #1), M3, M9, M12 (PRO Set #2) Barriers to adherence in oral PrEP arm: M1, M2, M3, M4, M5,	Participant Survey	Patient questionnaire	Survey

	oral PrEP, and reasons for PrEP discontinuation will be assessed through brief behavioral surveys		M6, M7, M8, M9, M10, M11, M12 Barriers to adherence in CAB-LA PrEP arm: M1, M3, M5, M7, M9, M11			
4. Secondary Endpoint: Implementation Outcomes	Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) Health literacy evaluation and helpfulness of the education modules within the digital health program assessed through a brief survey	Qualitative	M3, M9, M12	Participant Survey	Patient questionnaire	Survey
5. Secondary Endpoint: Clinician Acceptability, Appropriateness, and Feasibility	Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM)	Qualitative	M0, M6, M12, and End of Study	Clinician Survey, Interview	Clinician Survey, Interview	Clinician Survey, Interview

	Willingness to sustain provision of CAB-LA, barriers to and facilitators for provision of CAB-LA assessed through a brief survey					
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Appendix A: Informed Consent

SUMMARY

We are asking you to be in a research study to determine the helpfulness of using a cell phone application in supporting patients wanting to participate in HIV prevention care. TheraPay Rewards is a mobile and web program that tracks the care and rewards patients for doing activities such as participating in education activities and completing surveys about their care. The app provides information on what activities the patient needs to do to earn rewards. It also sends reminders along the way. This will help us understand if the overall patient experience and satisfaction improves when compared to the traditional care and education approaches. This form explains what you need to know to decide whether you want to participate in this program

What will I be expected to do in this study?

You will have to download the TheraPay app. Also, consent to us telling you of when education and surveys will be available for you to complete. In order to receive rewards you would be required to complete the education and surveys during the specified times that they are designated to be completed.

Are there any risks to being in the study?

There is minimal risk. The level of risk you might experience in everyday life, is associated with this study. The risks primarily reside in your personal information being compromised. Payment occurs in the form of rewards added to a reloadable smart rewards card from TheraPay. This reward card will be sent in the mail to you.

Side effects associated with PrEP are possible. To find further information about possible side effects, read the drug label or package insert or talk to your health care provider. If you experience side effects associated with PrEP, contact your healthcare provider. If you become pregnant or suspect that you might be pregnant, contact your healthcare provider.

Will I benefit from being in the study?

You will not benefit directly from the study. We hope to learn how to best communicate and support patients with HIV prevention care activities for patients in the future.

Will my study information be kept safe?

Yes. All your health information is kept private and not shared with anyone. To learn more, go online to: TheraPay's Privacy Policy at www.therapayrewards.com/privacy-policy. The Therapay app will not connect with your contacts or social media.

Is there any cost for me from being in this study?

There is no cost to you for being in the study. You will be responsible for the cost of your regular care. Additionally, there may be costs for data usage relating to the TheraPay application.

Will I get any money or gifts for being in this study?

Participants will be rewarded for completing tasks assigned to them while receiving care for HIV prevention. You will receive your rewards card (similar to a debit card) in the mail in 1 to 2 weeks after registering for TheraPay. You will get information about the activities and rewards you qualify for via the TheraPay Rewards app, emails, and text messages. A \$5-30 credit per task will be issued to your gift card. You will need to complete approximately 20-25 tasks over 12-months. A maximum of \$265 will be loaded onto the card.

Other information

Your information collected as part of this research will not be share with without unique identifiers being removed. You can contact Rhonda Francis, 304-414-5922 if you have questions about this study.

Giving consent

We will ask you to sign this document. By signing this document, you are agreeing participation in this study. Make sure you understand what the study is about before you sign.

HIPAA Authorization - For the Use of Patient Information for Research

The purpose of this section of the form is to give your permission to the research team to obtain and use your Protected Health Information (PHI) or patient information. Your patient information will be used to do the research described earlier in this form. State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form.

You do not have to sign this form. If you do not, you will not be allowed to join the research study. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

“Patient information” means the health information in your medical or other healthcare records. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, and medical record number.

By signing this form, you are giving permission to the following organization(s) to disclose your patient information for this research.

- West Virginia Health Right
- Reciprocity Health, Inc.

Patient information that will be released for research use This permission is for the health care provided to you during the following time period: From the time of enrollment for a duration of approximately 12-months.

The information that will be released and used for this research is described below:

- First Name (You will share this with the app)
- Last Name (You will share this with the app)

- DOB (You will share this with the app)
- Email (You will share this with the app)
- Mobile Number (You will share this with the app)
- Gender (You will share this with the app)
- Address (You will share this with the app)
- Confirmation of tasks (You will share this with the app)
- HIV Prevention Care Information (Will be shared)

How your patient information will be used?

1. Who may get your patient information?

- The group funding the study, known as the sponsor of this research. “Sponsor” includes any persons or companies that are working with or for the sponsor, or that are owned by the sponsor

2. Why your patient information will be used and/or given to others

- To do the research
- To study the results, and
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used. The researcher will use your patient information only in the ways that are described in this research consent form and this HIPAA Authorization. You can ask questions about what the research team will do with your information and how they will protect it.

The privacy laws do not always require the people who get your information to keep your information confidential. After your information has been given to others, there is a risk that it could be shared without your permission. This permission for the researchers to obtain your patient information ends when the research ends and any required monitoring of the study is finished.

Canceling your permission

You may change your mind at any time. To take back your permission, you must send your written request to:

Rhonda Francis
 WV Health Right
 1520 East Washington Street
 Charleston, WV 25311
 Phone: 304-414-5922

If you take back your permission, the research team may still keep and use any patient information about you that they already have. But they can't obtain more health information

about you for this research unless it is required by a federal agency that is monitoring the research.

If you take back your permission, you will need to leave the research study. This means that you would not have any more notifications or rewards. Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans or eligibility for benefits.

Giving permission

By signing this document, you are agreeing to participation in this study. You are also agreeing that your patient information will be used as we described earlier in this form. We will give you a copy of this document for your records. We will keep a copy with the study records.

If you have any questions about the study after you sign this document, you can contact the study team using the information provided above. I have read this consent and HIPAA Authorization form describing the research study and how my patient information will be used. I have had a chance to ask questions and I have received answers to my questions. I agree to be in this study. I also agree to the use of my patient information for this research.

Printed Name of Research Subject

Signature of Research Subject Date of signature

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date of signature

PrEP Digital Health Companion Clinician Survey Informational Sheet

Introduction: You are being invited to volunteer for a research study. You must read each item in this before you agree to take part in this study. This form will give you more information about this study. You should not continue with the survey if you have questions after reading the information sheet.

Purpose of the research: The intent of this study is to gather valuable insights on unmet needs and challenges in PrEP and to gauge Health Care Provider's (HCP's) views on potential solutions for overcoming specific barriers such utilization of a digital health companion. From the information collected and studied, we plan to learn more about the quality of care for patients HIV prevention needs. About 10 clinicians will complete this survey.

What you will do in this research: You are being asked to volunteer as a participant for a short survey. The survey will take approximately 5-10 minutes. You will complete one survey intended to obtain your viewpoint about the healthcare experiences of your patients with influenza.

Risks: There are no foreseeable risks for you because the information being collected will not be linked back to your name or your specific patients.

Benefits: Your answers to questions will help inform future clinical education for providers in HIV prevention care. You will receive a de-identified summary report of aggregate responses through a live virtual continuation education presentation. The de-identified data collected for this project may be published in a peer-reviewed manuscript or presented in a national conference to inform other providers the barriers in care for patients.

Compensation: A \$50 gift card will be offered for completion of this survey

Confidentiality: Your responses will be kept confidential. When research results are reported, responses will be deidentified and aggregated.

Participation and withdrawal: Your participation in this survey is completely voluntary. You may refuse to participate, which will disenroll. At any time during the survey you exit and cease your participation. However, once answers have been submitted, they cannot be retracted as the data is deidentified.

To Contact the Researcher: If you have questions or concerns about this research, please contact: Dr. Jeff Carter: Phone: 954-718-6055 ext 23; Address: 114 5th Ave, 14th Floor New York, NY 10011 Email: j.carter@primeinc.org.

By continuing to complete the online survey form you are consenting to participate in the survey.

Please save a copy of this communication for your records.

Appendix B: CAB-LA PrEP Arm Instruments

Activity Title: Baseline Information About You

Activity Description: Today we'll ask you to answer some questions about yourself. The survey is 17 questions and should take about 10 minutes to complete.

Baseline Demographic Survey

Question	Question #
What year were you born? [Write in]	1
Which of the following best describes your racial/ethnic background? (Select all that apply) <ul style="list-style-type: none"> <input type="checkbox"/> African American/Black <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Caucasian/White <input type="checkbox"/> Hispanic/Latinx <input type="checkbox"/> Native American/Alaska Native <input type="checkbox"/> A race or ethnicity not listed: [Write in] 	2
How do you describe your gender? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Transgender woman <input type="checkbox"/> Transgender man <input type="checkbox"/> Non-binary <input type="checkbox"/> A gender not listed: [Write in] 	3
How do you describe your sexual orientation? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Heterosexual/Straight <input type="checkbox"/> Gay or Lesbian <input type="checkbox"/> Bisexual <input type="checkbox"/> Queer or Sexually Fluid <input type="checkbox"/> Pansexual <input type="checkbox"/> A sexual orientation not listed: [Write in] 	4
What is the highest degree or school level you have completed? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Primary school <input type="checkbox"/> Some high school <input type="checkbox"/> High school diploma or GED <input type="checkbox"/> Some college <input type="checkbox"/> 2-year college degree <input type="checkbox"/> 4-year college degree <input type="checkbox"/> Graduate level degree <input type="checkbox"/> A school level not listed: [Write in] 	5
What health coverage are you currently enrolled with? (Select up to 2) <ul style="list-style-type: none"> <input type="checkbox"/> Medicaid <input type="checkbox"/> Medicare <input type="checkbox"/> Affordable Care Act 	6

<input type="checkbox"/> Uninsured <input type="checkbox"/> Private health insurance <input type="checkbox"/> A health coverage not listed: [Write in]	
<p>Why are you using pre-exposure prophylaxis (PrEP) to prevent HIV? [Select all that apply]</p> <input type="checkbox"/> Reduce acquisition of HIV from sex <input type="checkbox"/> Reduce acquisition of HIV from IV drug use	7
<p>The next 5 questions ask about your food, housing, and transportation routines from the past 12 months. If you have concerns and need support, please check in with your provider at your next visit or call 2-1-1 for immediate support.</p>	
<p>In the last 12 months, was there a time when you were not able to pay the mortgage or rent on time?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	8
<p>In the last 12 months, was there a time when you did not have a steady place to sleep or slept in a shelter (including now)?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes	9
<p>In the last 12 months, have you or the people you live with been unable to get utilities (heat, electricity) when it was really needed?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes	10
<p>Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.</p> <input type="checkbox"/> Never true <input type="checkbox"/> Sometimes true <input type="checkbox"/> Often true	11
<p>Within the past 12 months, has lack of transportation kept you from medical appointments, getting your medicines, non-medical meetings or appointments, work, or from getting things that you need?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes	12
<p>Do you feel physically and emotionally safe where you currently live?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No	13
<p>During the past 30 days, have you used any of the following?</p> <ul style="list-style-type: none"> • An illegal drug (such as by snorting it or injecting it) • Pain killer to get high (like OxyContin, sometimes called Oxy or OC) or Percocet (sometimes called Percs) • Prescription drugs not prescribed to you <input type="checkbox"/> No <input type="checkbox"/> Yes	14
<p>People who experience discrimination may be at higher risk of negative health outcomes. Sharing your experiences with discrimination in everyday life and in healthcare settings may help researchers learn how to reduce negative health outcomes associated with discrimination.</p>	

The next 3 statements describe how others may treat you.	
In your day-to-day life, how often do any of these happen to you?	
You are treated with less respect than other people are. <ul style="list-style-type: none"> <input type="checkbox"/> Never <input type="checkbox"/> Less than once a year <input type="checkbox"/> A few times a year <input type="checkbox"/> A few times a month <input type="checkbox"/> At least once a week <input type="checkbox"/> Almost every day 	15
People act as if they're better than you. <ul style="list-style-type: none"> <input type="checkbox"/> Never <input type="checkbox"/> Less than once a year <input type="checkbox"/> A few times a year <input type="checkbox"/> A few times a month <input type="checkbox"/> At least once a week <input type="checkbox"/> Almost every day 	16
What do you think is the main reason for these experiences? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Your gender <input type="checkbox"/> Your sexual orientation <input type="checkbox"/> Your race <input type="checkbox"/> Your religion <input type="checkbox"/> Some aspect of your physical appearance <input type="checkbox"/> Your education or income level <input type="checkbox"/> Other: [Write in] 	17

End Message: Thank you for completing this survey!

Persistence Assessment

Activity Title: Are You Still Taking PrEP?

Activity Description: In this short survey, we'll ask you some questions about your PrEP journey and any challenges you may have encountered.

Activity:

1. Are you still getting PrEP medicine by an injection from your healthcare provider?

- Yes, I am taking PrEP ([branching logic to question 4](#))
- No, I stopped taking PrEP ([branching logic to question 2](#))

2. If you stopped taking PrEP, which of the following best describes the reason(s) why?

[Select up to 2]

- I no longer feel I needed to take PrEP ([branching logic to question 3 if selected](#))
- It was too difficult to take to take PrEP as prescribed with my lifestyle
- I felt I was being judged by others for taking PrEP
- I experienced side effects from taking PrEP

- I take too many medications
- There were too many appointments as part of my PrEP care
- I tested positive for HIV
- Other: [Fill in the blank]

3. Which of the following best describes why you no longer feel you need to take PrEP?

- I am no longer having sex
- I am in a monogamous relationship
- I am no longer using injectable drugs
- My partners and I are all regularly using condoms and getting tested for HIV
- Other: [Fill in the blank]

4. If you are still taking PrEP, what challenges have you experienced?

- Have not experienced any challenges
- Keeping up with clinical visits and laboratory testing
- Concerns about side effects
- Finding transportation to my appointments
- Stigma or discrimination from family, friends, or partner(s)
- Stigma or discrimination from healthcare professionals
- Other: [Fill in the blank]

5. Did a healthcare provider (for example, a doctor, nurse or pharmacist) or navigator ever ask you what may make it difficult for you to take PrEP? (Month 1 & 11)

- Yes
- No
- Unsure

Activity Type: Patient Reported Outcomes – Set 1

Activity Title: Your Experiences With PrEP

Activity Description: This month we'll ask you to answer questions about your experience using PrEP and your thoughts about PrEP-related stigma. We'll also ask some questions about your experience using this mobile app to support you taking PrEP. The survey is 3 parts with a total of 24 questions. It should take you 10-15 minutes to complete.

Activity:

Part 1. Tell us about your experience using PrEP

The following questions are related to the PrEP medicine you use to protect you from HIV infection and your experience over the **past 4 weeks**. Please answer each question by selecting a number on each of the scales.

1. How satisfied are you with your **current medicine** for PrEP?
 - Very satisfied
 - Satisfied

- Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
2. How **bothered** are you by **any side effects** from the medicine you use for PrEP?
- Very unbothered
 - Unbothered
 - Neither unbothered or bothered
 - Bothered
 - Very bothered
 - I have not experienced any side effects in the last 4 weeks
3. How satisfied are you with the **convenience** of PrEP recently?
- Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
4. How satisfied are you with the **discreetness** of PrEP recently?
- Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
5. How satisfied are you with your **understanding of using PrEP** to prevent HIV?
- Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
6. How satisfied are you with the extent to which PrEP **fits in with your lifestyle**?
- Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
7. Would you recommend this type of PrEP to someone else who wants to protect themselves from HIV?

- Yes, I would **definitely recommend** this type of PrEP
- Yes, I would **recommend** this type of PrEP
- Not sure if I would recommend or not recommend this type of PrEP
- No, I would **not recommend** this type of PrEP
- No, I would **definitely not recommend** this type of PrEP

8. How satisfied would you be to continue your present form of PrEP?

- Very satisfied
- Satisfied
- Neither satisfied or dissatisfied
- Dissatisfied
- Very dissatisfied

Part 2. What are your thoughts about PrEP-related stigma?

Stigma is a negative and unfair belief about someone because of a particular characteristic or attribute. Please answer the following statements to the best of your ability.

Indicate how much you agree with the following:

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
I feel ashamed to go to the doctor for PrEP injections/shots.	()	()	()	()	()
People experience negative judgment because they take PrEP.	()	()	()	()	()
Someone using PrEP should keep their PrEP injection appointments hidden.	()	()	()	()	()

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
Someone taking PrEP would be seen by others as slutty.	()	()	()	()	()

People taking PrEP receive praise for being responsible.	()	()	()	()	()
My friends would be supportive of me taking PrEP.	()	()	()	()	()

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
Someone taking PrEP would be treated unfairly by their doctors.	()	()	()	()	()
People experience problems when they tell their sex partner(s) they are taking PrEP.	()	()	()	()	()
I feel proud to take PrEP.	()	()	()	()	()

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
People on PrEP are taking care of their health.	()	()	()	()	()
My family would be supportive of me taking PrEP.	()	()	()	()	()

Part 3. What is your experience using the TheraPay mobile app?

Please assess your experience using the TheraPay mobile app to support you in your journey using PrEP.

	Completely agree	Agree	Neither agree nor disagree	Disagree	Completely disagree
1. The TheraPay mobile app meets my approval.	1	2	3	4	5
2. The TheraPay mobile app is appealing to me.	1	2	3	4	5
3. I like the TheraPay mobile app.	1	2	3	4	5
4. I welcome the TheraPay mobile app.	1	2	3	4	5

End Message: Thank you for completing this survey! We will ask you these same questions again later to see how your responses have changed.

Patient Reported Outcomes – Set 2

Activity Title: Your Experiences With PrEP

Activity Description: This month we'll ask you to answer questions about your experience using PrEP (pre-exposure prophylaxis). We'll also ask some questions about your experience using this mobile app to support you taking PrEP. The survey is two parts with a total of 16 questions. It should take you 8-12 minutes to complete.

Part 1. Tell us about your experience using PrEP

Question	Question # CAB LA Arm [14]	Sub-concept
Over the past 4 weeks, how confident were you that PrEP prevented you from acquiring HIV ? <input type="checkbox"/> Very confident <input type="checkbox"/> Quite confident <input type="checkbox"/> Somewhat confident <input type="checkbox"/> A little confident <input type="checkbox"/> Not at all confident	1	Perceived efficacy
[CAB-LA arm] Over the past 4 weeks, did you experience any side effects, including injection site side effects (such as redness, bruising, or swelling) from the PrEP injection? <input type="checkbox"/> No (branching logic to question 5) <input type="checkbox"/> Yes (branching logic to show 3)	2	Acceptance of side effects
Over the past 4 weeks, how acceptable or unacceptable did you find the side effects from PrEP? <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	3 (branching logic)	Acceptance of side effects
Over the past 4 weeks, did the side effects of the PrEP medication interfere with your physical activity (such as lifting things, walking, jogging), your leisure or free time activities (such as gardening, reading, dancing, visiting friends), or your daily activities (such as shopping, working, house work, yard work)? <input type="checkbox"/> No, not at all <input type="checkbox"/> Yes, a little <input type="checkbox"/> Yes, somewhat <input type="checkbox"/> Yes, quite a bit <input type="checkbox"/> Yes, very much	4 (branching logic)	Acceptance of side effects
[CAB LA arm] Over the past 4 weeks, did you experience any pain when getting your PrEP injection?	5	Acceptance of side effects

<input type="checkbox"/> No (branching logic to question 7) <input type="checkbox"/> Yes (branching logic to question 6)		
<p>[CAB LA arm] Over the past 4 weeks, how acceptable or unacceptable did you find the pain you experienced when getting your PrEP injection?</p> <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	6 (branching logic)	Acceptance of side effects
<p>[CAB LA arm] Over the past 4 weeks, how acceptable or unacceptable did you find the time it took to get the PrEP injection at your doctor's office?</p> <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	7	Convenience
<p>[CAB LA arm] Over the past 4 weeks, how acceptable or unacceptable did you find the number of times you had to get your PrEP injection?</p> <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	8	Convenience
<p>[CAB LA arm] Over the past 4 weeks, how easy or difficult was it to remember to go to your appointments for your PrEP injection?</p> <input type="checkbox"/> Very easy <input type="checkbox"/> Easy <input type="checkbox"/> Neither easy or difficult <input type="checkbox"/> Difficult <input type="checkbox"/> Very difficult	9	Convenience

<p>[CAB LA arm] Over the past 4 weeks, how easy or difficult was it to fit in getting the PrEP injection into your daily life?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Very easy <input type="checkbox"/> Easy <input type="checkbox"/> Neither easy or difficult <input type="checkbox"/> Difficult <input type="checkbox"/> Very difficult 	10	Convenience
<p>Over the past 4 weeks, did you ever feel like you needed to hide your attendance to PrEP injection appointments so others would not see you?</p> <ul style="list-style-type: none"> <input type="checkbox"/> No, not at all <input type="checkbox"/> Yes, occasionally <input type="checkbox"/> Yes, often <input type="checkbox"/> Yes, quite often <input type="checkbox"/> Yes, all the time 	11	Convenience
<p>Over the past 4 weeks, how convenient or inconvenient did you find taking the PrEP?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Very convenient <input type="checkbox"/> Convenient <input type="checkbox"/> Neither convenient or inconvenient <input type="checkbox"/> Inconvenient <input type="checkbox"/> Very inconvenient 	12	Convenience
<p>[CAB LA arm] In the future, would you choose to continue using the PrEP injection to protect yourself from HIV infection?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Yes definitely <input type="checkbox"/> Yes probably <input type="checkbox"/> I don't know <input type="checkbox"/> Probably not <input type="checkbox"/> Definitely not 	13	Overall Acceptance
<p>[CAB LA arm] In the future, would you choose to switch to using the PrEP pill to protect yourself from HIV infection?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Definitely not <input type="checkbox"/> Probably not <input type="checkbox"/> I don't know <input type="checkbox"/> Yes, probably <input type="checkbox"/> Yes, definitely 	14	Overall Acceptance
<p>Thinking about all aspects of using PrEP over the past 4 weeks, how acceptable or unacceptable did you find the medicine?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable 	15	Overall Acceptance

Overall, over the past 4 weeks, how acceptable or unacceptable did you find taking all of your medicines, including PrEP and any other pills, tablets, or injections ?		
<input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	16	Overall Acceptance

Part 2. What is your experience using this mobile app?

Please assess how **appropriate** the use of a mobile app has been to support you in your journey using PrEP.

	Completely agree	Agree	Neither agree nor disagree	Disagree	Completely disagree
1. Using a mobile app to support me using PrEP seems fitting.	1	2	3	4	5
2. Using a mobile app to support me using PrEP seems suitable.	1	2	3	4	5
3. Using a mobile app seems applicable.	1	2	3	4	5
4. Using a mobile app to support me using PrEP seems like a good match.	1	2	3	4	5

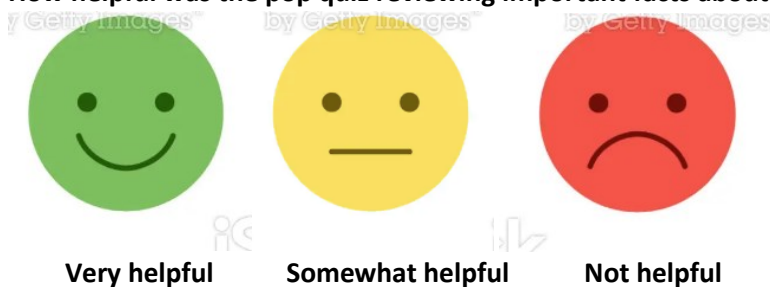
End Message: Thank you for completing this survey! We will ask you these same questions again later to see how your responses have changed.

Health Literacy Evaluation - Month 2

Activity Description: Was the pop quiz on PrEP medicine helpful? What did you learn?

Activity:

1. How helpful was the pop quiz reviewing important facts about PrEP?



2. True/False: A person who takes PrEP will also need to use condoms to prevent other STIs.

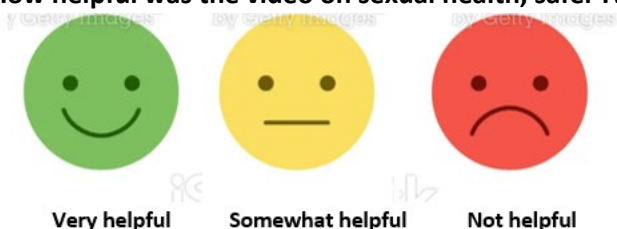
- **True**
 - That's correct! PrEP only protects against HIV. Condoms will protect you against other sexually transmitted infections, such as syphilis, gonorrhea, or chlamydia. Condoms will also protect against unintended pregnancy.
- **False**
 - Not quite. PrEP only protects against HIV. Condoms will protect you against other sexually transmitted infections, such as syphilis, gonorrhea, or chlamydia. Condoms will also protect against unintended pregnancy.

Health Literacy Evaluation – Month 4

Activity Description: Was the video on protecting yourself helpful? What did you learn?

Activity:

1. How helpful was the video on sexual health, safer IV drug use, and protecting yourself?



2. **True/False: All body parts used for sex should be tested for HIV & sexually transmitted infections (STIs).**

- **True**

That's correct! In many cases, this means you should have three body parts tested – (1) the throat; (2) the front (vagina, front hole, penis, urethra); and (3) the back (anus and rectum).
- **False**

Not quite. All body parts used for sex should be tested for STIs. In many cases, this means you should have three body parts tested – (1) the throat; (2) the front (vagina, front hole, penis, urethra); and (3) the butt hole and rectum.

3. **True/False: All sexually transmitted infections (STIs) will cause symptoms.**

- a. **True**

Not quite. Many STIs do not cause any symptoms that you would notice. It is important to get regular testing.
- b. **False**

That's correct! Many STIs do not cause any symptoms that you would notice. It is important to get regular testing.

Health Literacy Evaluation – Month 6

Activity Description: Was the video on “Building a Support System for HIV Prevention” helpful? What did you learn?

Activity:

1. How helpful was the video on building your support system?



2. True/False: West Virginia Health Right has services available if you are facing stressors or challenges.

True

That’s right! There are many services available including telehealth appointments, health education classes, support for alcohol or drug addiction, LGBTQIA+ health, help from social workers, family planning services, dental and vision care, primary health care, behavioral or mental health care, pharmacy, and testing and screening for different health concerns. You can contact WVHR at 304-414-5930 for more information.

False

Not quite. There are many services available including telehealth appointments, health education classes, support for alcohol or drug addiction, LGBTQIA+ health, help from social workers, family planning services, dental and vision care, primary health care, behavioral or mental health care, pharmacy, and testing and screening for different health concerns. You can contact WVHR at 304-414-5930 for more information.

3. True/False: A support person could be a partner, family member, friend, peer navigator, or social worker.

True

That’s correct. Any one of these people could help support you. It’s your choice and completely up to you who you want to bring on your support team.

False

Not quite. Any one of these people could help support you. It’s your choice and completely up to you who you want to bring on your support team.

Health Literacy Evaluation – Month 8

Activity Description: Was the article on “Being an Active Participant in Your Own Care” helpful? What did you learn?

Activity:

1. How helpful was the article on being an active participant in your own care?



2. Which of the following best describes shared decision-making?

- When your doctor makes a decision about your healthcare that they feel is in your best interest**

Not quite. Shared decision-making is a process where you and your healthcare providers work together to make decisions that reflect what's most important to you while making sure your medications are safe and effective.

- When you and your doctor work together to make a decision about your healthcare that considers your values, goals and concerns**

That's right! Shared decision-making is a process where you and your healthcare providers work together to make decisions that reflect what's most important to you while making sure your medications are safe and effective.

- When your doctor works with another member of the care team (such as a nurse or social worker) to make a decision about your healthcare**

Not quite. Shared decision-making is a process where you and your healthcare providers work together to make decisions that reflect what's most important to you while making sure your medications are safe and effective.

3. **True/False: Asking questions during your appointments is an important part of shared decision-making.**

- True**

That's right! By asking your healthcare provider questions, you can get all of the information you need to make decisions about your health.

- False**

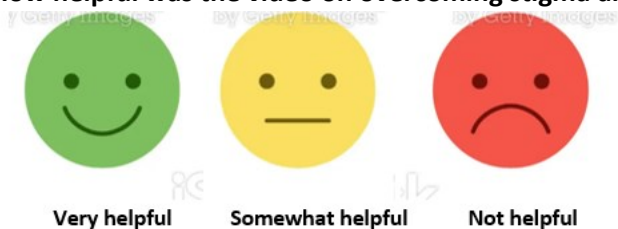
Not quite. By asking your healthcare provider questions, you can get all of the information you need to make decisions about your health.

Health Literacy Evaluation – Month 8

Activity Description: Was the video on “Overcoming Stigma and Becoming a Health Advocate” helpful? What did you learn?

Activity:

1. How helpful was the video on overcoming stigma and becoming a health advocate?



2. True/False: Stigma is when someone views a person or themselves in a negative way because of their unique identity, circumstances, and/or experiences.

True

That's right! Stigma is a negative and unfair belief about someone because of a particular characteristic or attribute.

False

Not quite. Stigma is a negative and unfair belief about someone because of a particular characteristic or attribute.

3. True/False: Sharing your experience with PrEP can help fight stigma surrounding it.

True

That's right! Calling out biases and finding support within a community can help break the stigma cycle.

False

Not quite. Calling out biases and finding support within a community can help break the stigma cycle.

Appendix C: Oral PrEP Arm Instruments

Activity Title: Baseline Information About You

Activity Description: Today we'll ask you to answer some questions about yourself. The survey is 17 questions and should take about 10 minutes to complete.

Baseline Demographic Survey

Question	Question #
What year were you born? [Write in]	1
Which of the following best describes your racial/ethnic background? (Select all that apply) <ul style="list-style-type: none"> <input type="checkbox"/> African American/Black <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Caucasian/White <input type="checkbox"/> Hispanic/Latinx <input type="checkbox"/> Native American/Alaska Native <input type="checkbox"/> A race or ethnicity not listed: [Write in] 	2
How do you describe your gender? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Transgender woman <input type="checkbox"/> Transgender man <input type="checkbox"/> Non-binary <input type="checkbox"/> A gender not listed: [Write in] 	3
How do you describe your sexual orientation? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Heterosexual/Straight <input type="checkbox"/> Gay or Lesbian <input type="checkbox"/> Bisexual <input type="checkbox"/> Queer or Sexually Fluid <input type="checkbox"/> Pansexual <input type="checkbox"/> A sexual orientation not listed: [Write in] 	4
What is the highest degree or school level you have completed? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Primary school <input type="checkbox"/> Some high school <input type="checkbox"/> High school diploma or GED <input type="checkbox"/> Some college <input type="checkbox"/> 2-year college degree <input type="checkbox"/> 4-year college degree <input type="checkbox"/> Graduate level degree <input type="checkbox"/> An school level not listed: [Write in] 	5
What health coverage are you currently enrolled with? (Select up to 2) <ul style="list-style-type: none"> <input type="checkbox"/> Medicaid <input type="checkbox"/> Medicare <input type="checkbox"/> Affordable Care Act <input type="checkbox"/> Uninsured <input type="checkbox"/> Private health insurance 	6

<input type="checkbox"/> A health coverage not listed: [Write in]	
Why are using pre-exposure prophylaxis (PrEP) to prevent HIV? [Select all that apply] <input type="checkbox"/> Reduce acquisition of HIV from sex <input type="checkbox"/> Reduce acquisition of HIV from IV drug use	7
The next 5 questions ask about your food, housing, and transportation routines from the past 12 months. If you have concerns and need support, please check in with your provider at your next visit or call 2-1-1 for immediate support.	
In the last 12 months, was there a time when you were not able to pay the mortgage or rent on time? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	8
In the last 12 months, was there a time when you did not have a steady place to sleep or slept in a shelter (including now)? <input type="checkbox"/> No <input type="checkbox"/> Yes	9
In the last 12 months, have you or the people you live with been unable to get utilities (heat, electricity) when it was really needed? <input type="checkbox"/> No <input type="checkbox"/> Yes	10
Within the past 12 months, the food you bought just didn't last and you didn't have money to get more. <input type="checkbox"/> Never true <input type="checkbox"/> Sometimes true <input type="checkbox"/> Often true	11
Within the past 12 months, has lack of transportation kept you from medical appointments, getting your medicines, non-medical meetings or appointments, work, or from getting things that you need? <input type="checkbox"/> No <input type="checkbox"/> Yes	12
Do you feel physically and emotionally safe where you currently live? <input type="checkbox"/> Yes <input type="checkbox"/> No	13
During the past 30 days, have you used any of the following? <ul style="list-style-type: none"> • An illegal drug (such as by snorting it or injecting it) • Pain killer to get high (like OxyContin, sometimes called Oxy or OC) or Percocet (sometimes called Percs) • Prescription drugs not prescribed to you <input type="checkbox"/> No <input type="checkbox"/> Yes	14
<p>People who experience discrimination may be at higher risk of negative health outcomes. Sharing your experiences with discrimination in everyday life and in healthcare settings may help researchers learn how to reduce negative health outcomes associated with discrimination.</p> <p>The next 3 statements describe how others may treat you.</p>	

In your day-to-day life, how often do any of these happen to you?	
You are treated with less respect than other people are. <ul style="list-style-type: none"> <input type="checkbox"/> Never <input type="checkbox"/> Less than once a year <input type="checkbox"/> A few times a year <input type="checkbox"/> A few times a month <input type="checkbox"/> At least once a week <input type="checkbox"/> Almost every day 	15
People act as if they're better than you. <ul style="list-style-type: none"> <input type="checkbox"/> Never <input type="checkbox"/> Less than once a year <input type="checkbox"/> A few times a year <input type="checkbox"/> A few times a month <input type="checkbox"/> At least once a week <input type="checkbox"/> Almost every day 	16
What do you think is the main reason for these experiences? (Select 1) <ul style="list-style-type: none"> <input type="checkbox"/> Your gender <input type="checkbox"/> Your sexual orientation <input type="checkbox"/> Your race <input type="checkbox"/> Your religion <input type="checkbox"/> Some aspect of your physical appearance <input type="checkbox"/> Your education or income level <input type="checkbox"/> Other: [Write in] 	17

End Message: Thank you for completing this survey!

Persistence Assessment

Activity Title: Are You Still Taking PrEP?

Activity Description: In this short survey, we'll ask you some questions about your PrEP journey and any challenges you may have encountered.

Activity:

1. Are you still taking PrEP medicine by mouth?

- Yes, I am taking PrEP (branching logic to question 4)
- No, I stopped taking PrEP (branching logic to questions 2)

2. Over the past week, how many days did you miss taking PrEP?

- 0
- 1
- 2
- 3
- 4
- 5
- 6

7

3. If you stopped taking PrEP, which of the following best describes the reason(s) why? [Select up to 2]

- I no longer feel I needed to take PrEP (branching logic to question 3 if selected)
- It was too difficult to take PrEP with my schedule
- I did not want people to know I was taking it or I felt I was being judged by others for taking PrEP
- I did not like the side effects
- I take too many medications
- There were too many appointments as part of my PrEP care
- I tested positive for HIV
- Other: [Fill in the blank]

4. Which of the following best describes why you no longer feel you need to take PrEP?

- I am no longer having sex
- I am in a monogamous relationship
- I am no longer using injectable drugs
- My partners and I are all regularly using condoms and getting tested for HIV
- Other: [Fill in the blank]

5. If you are still taking PrEP, what challenges have you experienced? [Select up to 2]

- Have not experienced any challenges
- Remembering to take PrEP every day
- Keeping up with clinical visits and laboratory testing
- Concerns about side effects
- Finding transportation to my appointments
- Stigma or discrimination from family, friends, or partner(s)
- Stigma or discrimination from healthcare professionals
- Other: [Fill in the blank]

6. Did a healthcare provider (for example, a doctor, nurse, or pharmacist) or navigator ever ask you what may make it difficult for you to take PrEP?

- Yes
- No
- Unsure

End Message: Thank you for completing this survey!

Patient Reported Outcomes – Set 1

Activity Title: Your Experiences with PrEP

Activity Description: This month we'll ask you to answer questions about your experience using PrEP and your thoughts about PrEP-related stigma. We'll also ask some questions about your experience using this mobile app to support you taking PrEP. The survey is 3 parts with a total of 24 questions. It should take you 10-15 minutes to complete.

Activity:

Part 1. Tell us about your experience using PrEP

The following questions are related to the PrEP medicine you use to protect you from HIV infection and your experience over the **past 4 weeks**. Please answer each question by selecting a number on each of the scales.

1. How satisfied are you with your **current medicine** for PrEP?
 - Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
2. How **bothered** are you by any **side effects** from the medicine you use for PrEP?
 - Very unbothered
 - Unbothered
 - Neither unbothered or bothered
 - Bothered
 - Very bothered
 - I have not experienced any side effects in the last 4 weeks
3. How satisfied are you with the **convenience** of PrEP recently?
 - Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
4. How satisfied are you with the **discreetness** of PrEP recently?
 - Very satisfied
 - Satisfied
 - Neither satisfied or dissatisfied
 - Dissatisfied
 - Very dissatisfied
5. How satisfied are you with your **understanding of using PrEP** to prevent HIV?
 - Very satisfied
 - Satisfied

- Neither satisfied or dissatisfied
- Dissatisfied
- Very dissatisfied
6. How satisfied are you with the extent to which PrEP **fits in with your lifestyle?**
- Very satisfied
- Satisfied
- Neither satisfied or dissatisfied
- Dissatisfied
- Very dissatisfied
7. Would you recommend this type of PrEP to someone else who wants to protect themselves from HIV?
- Yes, I would **definitely recommend** this type of PrEP
- Yes, I would **recommend** this type of PrEP
- Not sure if I would recommend or not recommend this type of PrEP
- No, I would **not recommend** this type of PrEP
- No, I would **definitely not recommend** this type of PrEP
8. How satisfied would you be to continue your present form of PrEP?
- Very satisfied
- Satisfied
- Neither satisfied or dissatisfied
- Dissatisfied
- Very dissatisfied

Part 2. What are your thoughts about PrEP-related stigma?

Stigma is a negative and unfair belief about someone because of a particular characteristic or attribute. Please answer the following statements to the best of your ability.

Indicate how much you agree with the following:

	Completely agree	Agree	Neither Agree or Disagree	Disagree	Completely disagree
I feel ashamed to take PrEP pills in front of others.	()	()	()	()	()
People experience negative judgment because they take PrEP.	()	()	()	()	()

Someone taking PrEP should keep their pills hidden.	()	()	()	()	()
---	-----	-----	-----	-----	-----

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
Someone taking PrEP would be seen by others as slutty.	()	()	()	()	()
People taking PrEP receive praise for being responsible.	()	()	()	()	()
My friends would be supportive of me taking PrEP.	()	()	()	()	()

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
Someone taking PrEP would be treated unfairly by their doctors.	()	()	()	()	()
People experience problems when they tell their sex partner(s) they are taking PrEP.	()	()	()	()	()
I feel proud to take PrEP.	()	()	()	()	()

	Completely agree	Agree	Neither agree or disagree	Disagree	Completely disagree
People on PrEP are taking care of their health.	()	()	()	()	()
My family would be supportive of me taking PrEP.	()	()	()	()	()

Part 3. What is your experience using the TheraPay mobile app?

Please assess your experience using the TheraPay mobile app to support you in your journey using PrEP.

	Completely agree	Agree	Neither agree nor disagree	Disagree	Completely disagree
1. The TheraPay mobile app meets my approval.	1	2	3	4	5
2. The TheraPay mobile app is appealing to me.	1	2	3	4	5
3. I like the TheraPay mobile app.	1	2	3	4	5
4. I welcome the TheraPay mobile app.	1	2	3	4	5

Patient Reported Outcomes – Set 2

Activity Title: Your Experiences With PrEP

Activity Description: This month we'll ask you to answer questions about your experience using PrEP (pre-exposure prophylaxis). We'll also ask some questions about your experience using this mobile app to support you taking PrEP. The survey is two parts with a total of 16 questions. It should take you 8-12 minutes to complete.

Part 1. Tell us about your experience using PrEP

Question	Question # Oral PrEP Arm [13]	Sub-concept
Over the past 4 weeks, how confident were you that PrEP prevented you from acquiring HIV ? <input type="checkbox"/> Very confident <input type="checkbox"/> Quite confident <input type="checkbox"/> Somewhat confident <input type="checkbox"/> A little confident <input type="checkbox"/> Not at all confident	1	Perceived efficacy
[Oral PrEP arm] Over the past 4 weeks, did you experience any side effects from the PrEP pill? <input type="checkbox"/> No (branching logic to question 5) <input type="checkbox"/> Yes (branching logic to show 3)	2	Acceptance of side effects
Over the past 4 weeks, how acceptable or unacceptable did you find the side effects from PrEP? <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	3 (branching logic)	Acceptance of side effects
Over the past 4 weeks, did the side effects of the PrEP medication interfere with your physical activity (such as lifting things, walking, jogging), your leisure or free time activities (such as gardening, reading, dancing, visiting friends), or your daily activities (such as shopping, working, house work, yard work)? <input type="checkbox"/> No, not at all	4 (branching logic)	Acceptance of side effects

<input type="checkbox"/> Yes, a little <input type="checkbox"/> Yes, somewhat <input type="checkbox"/> Yes, quite a bit <input type="checkbox"/> Yes, very much		
<p>[Oral PrEP arm] Over the past 4 weeks, did you ever feel like you needed to hide your PrEP pills so others would not see them?</p> <input type="checkbox"/> No, not at all <input type="checkbox"/> Yes, occasionally <input type="checkbox"/> Yes, often <input type="checkbox"/> Yes, quite often <input type="checkbox"/> Yes, all the time	5	N/A
<p>[Oral PrEP arm] Over the past 4 weeks, how acceptable or unacceptable did you find the time it took to take your PrEP pill every day?</p> <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	6	Convenience
<p>[Oral PrEP arm] Over the past 4 weeks, how acceptable or unacceptable did you find the number of times you had to take your PrEP pill?</p> <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	7	Convenience
<p>[Oral PrEP arm] Over the past 4 weeks, how easy or difficult was it to remember to take your PrEP pills?</p> <input type="checkbox"/> Very easy <input type="checkbox"/> Easy <input type="checkbox"/> Neither easy or difficult <input type="checkbox"/> Difficult <input type="checkbox"/> Very difficult	8	Convenience
<p>[Oral PrEP arm] Over the past 4 weeks, how easy or difficult was it to fit in taking the PrEP pill into your daily life?</p> <input type="checkbox"/> Very easy <input type="checkbox"/> Easy <input type="checkbox"/> Neither easy or difficult <input type="checkbox"/> Difficult <input type="checkbox"/> Very difficult	9	Convenience
<p>Over the past 4 weeks, how convenient or inconvenient did you find taking the PrEP?</p> <input type="checkbox"/> Very convenient	10	Convenience

<input type="checkbox"/> Convenient <input type="checkbox"/> Neither convenient or inconvenient <input type="checkbox"/> Inconvenient <input type="checkbox"/> Very inconvenient		
[Oral PrEP arm] In the future, would you choose to continue using the PrEP pill to protect yourself from HIV infection? <input type="checkbox"/> Yes, definitely <input type="checkbox"/> Yes, probably <input type="checkbox"/> I don't know <input type="checkbox"/> Probably not <input type="checkbox"/> Definitely not	11	Overall Acceptance
[Oral PrEP arm] In the future, would you choose to switch to using the PrEP injection to protect yourself from HIV infection? <input type="checkbox"/> Definitely not <input type="checkbox"/> Probably not <input type="checkbox"/> I don't know <input type="checkbox"/> Yes, probably <input type="checkbox"/> Yes, definitely	12	Overall Acceptance
Thinking about all aspects of using PrEP over the past 4 weeks, how acceptable or unacceptable did you find the medicine? <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	13	Overall Acceptance
Overall, over the past 4 weeks, how acceptable or unacceptable did you find taking all of your medicines, including PrEP and any other pills, tablets, or injections ? <input type="checkbox"/> Very acceptable <input type="checkbox"/> Acceptable <input type="checkbox"/> Neither acceptable or unacceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> Very unacceptable	14	Overall Acceptance

Part 2. What is your experience using this mobile app?

Please assess how **appropriate** the use of a mobile app has been to support you in your journey using PrEP.

	Completely agree	Agree	Neither agree nor disagree	Disagree	Completely disagree
1. Using a mobile app to support me using PrEP seems fitting.	1	2	3	4	5

2. Using a mobile app to support me using PrEP seems suitable.	1	2	3	4	5
3. Using a mobile app seems applicable.	1	2	3	4	5
4. Using a mobile app to support me using PrEP seems like a good match.	1	2	3	4	5

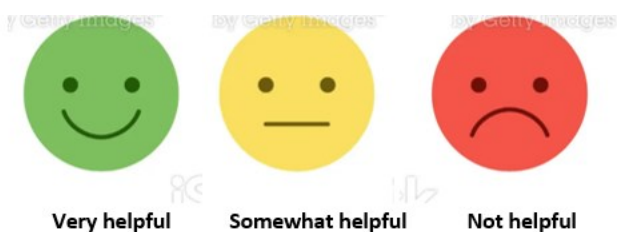
End Message: Thank you for completing this survey! We will ask you these same questions again later to see how your responses have changed.

Health Literacy Evaluation - Month 2

Activity Description: Was the pop quiz on PrEP medicine helpful? What did you learn?

Activity:

1. How helpful was the pop quiz reviewing important facts about PrEP?



2. True/False: A person who takes PrEP will also need to use condoms to prevent other STIs.

- True**
 - That's correct! PrEP only protects against HIV. Condoms will protect you against other sexually transmitted infections, such as syphilis, gonorrhea, or chlamydia. Condoms will also protect against unintended pregnancy.
- False**
 - Not quite. PrEP only protects against HIV. Condoms will protect you against other sexually transmitted infections, such as syphilis, gonorrhea, or chlamydia. Condoms will also protect against unintended pregnancy.

Health Literacy Evaluation – Month 4

Activity Description: Was the video on protecting yourself helpful? What did you learn?

Activity:

1. How helpful was the video on sexual health, safer IV drug use, and protecting yourself?



2. True/False: All body parts used for sex should be tested for HIV & sexually transmitted infections (STIs).

True

That's correct! In many cases, this means you should have three body parts tested – (1) the throat; (2) the front (vagina, front hole, penis, urethra); and (3) the back (anus and rectum).

False

Not quite. All body parts used for sex should be tested for STIs. In many cases, this means you should have three body parts tested – (1) the throat; (2) the front (vagina, front hole, penis, urethra); and (3) the butt hole and rectum.

3. True/False: All sexually transmitted infections (STIs) will cause symptoms.

a. True

Not quite. Many STIs do not cause any symptoms that you would notice. It is important to get regular testing.

b. False

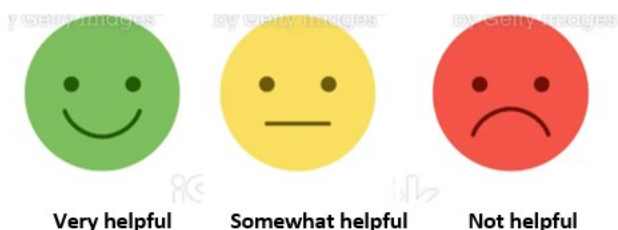
That's correct! Many STIs do not cause any symptoms that you would notice. It is important to get regular testing.

Health Literacy Evaluation – Month 6

Activity Description: Was the video on “Building a Support System for HIV Prevention” helpful? What did you learn?

Activity:

1. How helpful was the video on building your support system?



2. True/False: West Virginia Health Right has services available if you are facing stressors or challenges.

True

That's right! There are many services available including telehealth appointments, health education classes, support for alcohol or drug addiction, LGBTQIA+ health, help from social workers, family planning services, dental and vision care, primary health care, behavioral or mental health care, pharmacy, and testing and screening for different health concerns. You can contact WVHR at 304-414-5930 for more information.

False

Not quite. There are many services available including telehealth appointments, health education classes, support for alcohol or drug addiction, LGBTQIA+ health, help from social workers, family planning services, dental and vision care, primary health care, behavioral or mental health care, pharmacy, and testing and screening for different health concerns. You can contact WVHR at 304-414-5930 for more information.

3. True/False: A support person could be a partner, family member, friend, peer navigator, or social worker.

True

That's correct. Any one of these people could help support you. It's your choice and completely up to you who you want to bring on your support team.

False

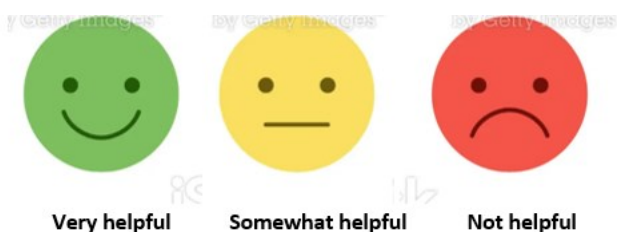
Not quite. Any one of these people could help support you. It's your choice and completely up to you who you want to bring on your support team.

Health Literacy Evaluation – Month 8

Activity Description: Was the article on “Being an Active Participant in Your Own Care” helpful? What did you learn?

Activity:

1. How helpful was the article on being an active participant in your own care?



2. Which of the following best describes shared decision-making?

- When your doctor makes a decision about your healthcare that they feel is in your best interest**

Not quite. Shared decision-making is a process where you and your healthcare providers work together to make decisions that reflect what's most important to you while making sure your medications are safe and effective.

- When you and your doctor work together to make a decision about your healthcare that considers your values, goals and concerns**

That's right! Shared decision-making is a process where you and your healthcare providers work together to make decisions that reflect what's most important to you while making sure your medications are safe and effective.

- When your doctor works with another member of the care team (such as a nurse or social worker) to make a decision about your healthcare**

Not quite. Shared decision-making is a process where you and your healthcare providers work together to make decisions that reflect what's most important to you while making sure your medications are safe and effective.

3. True/False: Asking questions during your appointments is an important part of shared decision-making.

- True**

That's right! By asking your healthcare provider questions, you can get all of the information you need to make decisions about your health.

- False**

Not quite. By asking your healthcare provider questions, you can get all of the information you need to make decisions about your health.

Health Literacy Evaluation – Month 8

Activity Description: Was the video on “Overcoming Stigma and Becoming a Health Advocate” helpful? What did you learn?

Activity:

1. How helpful was the video on overcoming stigma and becoming a health advocate?



2. True/False: Stigma is when someone views a person or themselves in a negative way because of their unique identity, circumstances, and/or experiences.

- True**

That's right! Stigma is a negative and unfair belief about someone because of a particular characteristic or attribute.

- False**
Not quite. Stigma is a negative and unfair belief about someone because of a particular characteristic or attribute.

3. True/False: Sharing your experience with PrEP can help fight stigma surrounding it.

- True**
That's right! Calling out biases and finding support within a community can help break the stigma cycle.
- False**
Not quite. Calling out biases and finding support within a community can help break the stigma cycle.

Appendix D: Clinician Instruments

PROVIDER SURVEY (Note: baseline survey)

Thank you for agreeing to be part of this quality improvement project to improve care for those individuals taking PrEP. Your responses will remain confidential and anonymous.

Part 1. Information About You and Your Patients

1. What year were you born? [Write in]
2. How do you describe your gender (response optional)? [Select 1]
 - Female
 - Male
 - Transgender woman
 - Transgender man
 - Non-binary
 - Prefer not to answer
 - A gender not listed: [Write in]
3. Which of the following best describes your racial/ethnic background (response optional)? (Select all that apply)
 - African American/Black
 - Asian/Pacific Islander
 - Caucasian/White

- Hispanic/Latinx
- Native American/Alaska Native
- A race or ethnicity not listed: [Write in]

4. What is your role within the interprofessional team? [Select 1]

- Physician
- Physician assistant
- Nurse practitioner
- Nurse
- Medical assistant
- Pharmacist
- Case manager
- Social worker
- Clinic administrative staff
- A role on the interprofessional team not listed: [Write in]

5. What is your role in the clinic for providing long-acting cabotegravir to your patients? (Select all that apply)

- Prescribing
- Medication procurement and/or dispensing
- Administering injections
- Patient scheduling
- Coordinating clinic flow (i.e., room availability, nurse scheduling, availability of injection during appointment, etc)
- Providing wraparound services (i.e., transportation, housing support, mental health resources, etc.)
- Patient counseling
- A role not listed: [write in]

Part 2. Acceptability, Appropriateness, and Feasibility of Implementing Long-Acting Cabotegravir Injections

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Our clinic process for providing long-acting cabotegravir injections to our clients meets my approval.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Our clinic process for providing long-acting cabotegravir injections to our clients is appealing to me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I like our clinic process for providing long-acting cabotegravir injections to our clients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I welcome our clinic process for providing long-acting cabotegravir injections to our clients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Our clinic process for providing long-acting cabotegravir injections to our clients seems fitting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Our clinic process for providing long-acting cabotegravir injections to our clients seems suitable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Our clinic process for providing long-acting cabotegravir injections to our clients seems applicable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Our clinic process for providing long-acting cabotegravir injections to our clients seems like a good match.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Long-term use of cabotegravir injections in our clinic seem implementable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Long-term use of cabotegravir injections in our clinic seem possible.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Long-term use of cabotegravir injections in our clinic seem doable.	○	○	○	○	○
4. Long-term use of cabotegravir injections in our clinic seem easy to continue.	○	○	○	○	○

Part 3. Barriers and Facilitators for Implementation of Long-Acting Cabotegravir for PrEP

- Please rate your confidence in **initiating** and **monitoring** long-acting cabotegravir for PrEP.
 - Very high
 - High
 - Moderate
 - Low
 - Very low
 - Not applicable
- Please rate your confidence in **administering** long-acting cabotegravir for PrEP.
 - Very high
 - High
 - Moderate
 - Low
 - Very low
 - Not applicable
- Please rate your confidence in **counseling** patients in HIV prevention, addressing barriers to using PrEP, and supporting persistence.
 - Very high
 - High
 - Moderate
 - Low
 - Very low
 - Not applicable

Please indicate how much you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
4. People experience negative judgment because they take PrEP.	()	()	()	()	()
5. Someone taking PrEP would be seen by others as slutty.	()	()	()	()	()

6. People taking PrEP receive praise for being responsible.	()	()	()	()	()
7. Someone taking PrEP would be treated unfairly by their doctors.	()	()	()	()	()

8. What barriers do you foresee in the implementation of long-acting cabotegravir for PrEP?

[Select up to 2]

- Patient's ability to keep bimonthly appointments
- Patient's transportation for bimonthly appointments
- Flagging/Clinic awareness of missed visits
- Staffing resourcing for clinic flow
- Rescheduling missed injections
- Patients acquiring HIV due to missed dose/visit
- Management of patients with other needs
- Patient injection/soreness

9. Which structural changes or resources may help facilitate long-acting cabotegravir implementation in your clinic? [Select up to 2]

- Increased coordination with other departments (i.e., pharmacy)
- Purchasing new refrigerators
- Finding room space or working around room availability
- Adjusting or extending staff working hours
- Use of different staff for injections
- Making transportation arrangements for patient participants
- Expanding hours for injection visits (i.e., visits in morning or during lunch breaks)
- Accommodating patients needing to reschedule injection visits (i.e. using walk-in visits, same-day appointments)
- Other: [write in]

10. How helpful do you think your clients will find the TheraPay mobile health app in supporting persistence with PrEP?

- Very helpful
- Somewhat helpful
- Neither helpful or unhelpful
- Somewhat unhelpful
- Very unhelpful

11. Do you have a preference for prescribing long-acting cabotegravir or daily oral PrEP?

- Prefer long-acting cabotegravir
- Prefer oral daily PrEP
- No preference

12. How likely is it that your clinic will continue to offer cabotegravir following the completion of this study?

- Very likely
- Somewhat likely
- Neutral
- Somewhat unlikely
- Very unlikely

Thank you for taking the time to complete this survey. Please provide your work email address. Your email will not be tied to your survey responses and will only be used for the purposes of this quality improvement initiative.

- Work email address: [Write in]

THANK YOU FOR COMPLETING THIS SURVEY.

PROVIDER SURVEY (Note: 6 months, 12 months and end of study)

Thank you for agreeing to be part of this quality improvement project to improve care for those individuals taking PrEP. Your responses will remain confidential and anonymous.

Part 1. Information About You and Your Patients

6. What year were you born? [Write in]

7. How do you describe your gender? [Select 1]

- Female
- Male
- Transgender woman
- Transgender man
- Non-binary
- Prefer not to answer
- A gender not listed: [Write in]

8. Which of the following best describes your racial/ethnic background? (Select all that apply)

- African American/Black
- Asian/Pacific Islander
- Caucasian/White

- Hispanic/Latinx
- Native American/Alaska Native
- A race or ethnicity not listed: [Write in]

9. What is your role within the interprofessional team? [Select 1]

- Physician
- Physician assistant
- Nurse practitioner
- Nurse
- Medical assistant
- Pharmacist
- Case manager
- Social worker
- Clinic administrative staff
- A role on the interprofessional team not listed: [Write in]

10. What is your role in the clinic for providing long-acting cabotegravir to your patients? (Select all that apply)

- Prescribing
- Medication procurement and/or dispensing
- Administering injections
- Patient scheduling
- Coordinating clinic flow (i.e., room availability, nurse scheduling, availability of injection during appointment, etc)
- Providing wraparound services (i.e., transportation, housing support, mental health resources, etc.)
- Patient counseling
- A role not listed: [write in]

Part 2. Acceptability, Appropriateness, and Feasibility of Implementing Long-Acting Cabotegravir Injections

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Our clinic process for providing long-acting cabotegravir injections to our clients meets my approval.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Our clinic process for providing long-acting cabotegravir injections to our clients is appealing to me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I like our clinic process for providing long-acting cabotegravir injections to our clients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I welcome our clinic process for providing long-acting cabotegravir injections to our clients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Our clinic process for providing long-acting cabotegravir injections to our clients seems fitting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Our clinic process for providing long-acting cabotegravir injections to our clients seems suitable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Our clinic process for providing long-acting cabotegravir injections to our clients seems applicable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Our clinic process for providing long-acting cabotegravir injections to our clients seems like a good match.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Long-term use of cabotegravir injections in our clinic seem implementable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Long-term use of cabotegravir injections in our clinic seem possible.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Long-term use of cabotegravir injections in our clinic seem doable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Long-term use of cabotegravir injections in our clinic seem easy to continue.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Part 3. Barriers and Facilitators for Implementation of Long-Acting Cabotegravir for PrEP

13. Please rate your confidence in **initiating** and **monitoring** long-acting cabotegravir for PrEP.
- Very high
 - High
 - Moderate
 - Low
 - Very low
 - Not applicable
14. Please rate your confidence in **administering** long-acting cabotegravir for PrEP.
- Very high
 - High
 - Moderate
 - Low
 - Very low
 - Not applicable
15. Please rate your confidence in **counseling** patients in HIV prevention, addressing barriers to using PrEP, and supporting persistence.
- Very high
 - High
 - Moderate
 - Low
 - Very low
 - Not applicable
16. Please rate the impact of providing long-acting cabotegravir injections for PrEP on your **workload** in clinic.
- Large increase in workload
 - Moderate increase in workload
 - No change in workload
 - Moderate decrease in workload
 - Large decrease in workload
17. What barriers have you observed with the implementation of long-acting cabotegravir for PrEP?
[Select up to 2]
- Patient's ability to keep bimonthly appointments
 - Patient's transportation for bimonthly appointments
 - Flagging/Clinic awareness of missed visits
 - Staffing resourcing for clinic flow
 - Rescheduling missed injections

- Patients acquiring HIV due to missed dose/visit
 - Management of patients with other needs
 - Patient injection/soreness
18. Which structural changes or resources have been most helpful in facilitating long-acting cabotegravir implementation in your clinic? [Select up to 2]
- Increased coordination with other departments (i.e., pharmacy)
 - Purchasing new refrigerators
 - Finding room space or working around room availability
 - Adjusting or extending staff working hours
 - Use of different staff for injections
 - Making transportation arrangements for patient participants
 - Expanding hours for injection visits (i.e., visits in morning or during lunch breaks)
 - Accommodating patients needing to reschedule injection visits (i.e. using walk-in visits, same-day appointments)
 - Other: [write in]
19. How could the process for use of long-acting cabotegravir injections for PrEP be improved? [Select up to 2]
- Increased clinic staff
 - Redistribution of clinic duties to allow dedicated healthcare providers more time to support long-acting cabotegravir processes
 - Regular evaluation of LA-CAB processes for efficacy and potential problems
 - Additional staff education/training
 - Improve documentation/EMR
 - Improve communication and care coordination within the clinical team
 - Improve communication with clients using PrEP (i.e. reminders of upcoming appointments, rescheduling of missed appointments)
 - Other: [fill in blank]
20. For participants who stopped taking long-acting injectable PrEP, which of the following best describes the most common reason(s) why? [Select up to 2]
- They no longer have an indication or need for PrEP
 - They found it too difficult to take PrEP as prescribed with their lifestyle
 - They felt stigmatized by others for taking PrEP
 - They experienced side effects from taking PrEP
 - They take too many medications
 - They felt there were too many appointments as part of PrEP care
 - They tested positive for HIV

21. How helpful do you think your clients find the TheraPay mobile health app in supporting persistence with PrEP?

- Very helpful
- Somewhat helpful
- Neither helpful or unhelpful
- Somewhat unhelpful
- Very unhelpful

22. Do you have a preference for prescribing long-acting cabotegravir or daily oral PrEP?

- Prefer long-acting cabotegravir
- Prefer oral daily PrEP
- No preference

23. How likely is it that your clinic will continue to offer cabotegravir following the completion of this study?

- Very likely
- Somewhat likely
- Neutral
- Somewhat unlikely
- Very unlikely

Thank you for taking the time to complete this survey. Please provide your work email address. Your email will not be tied to your survey responses and will only be used for the purposes of this quality improvement initiative.

- Work email address: [Write in]

THANK YOU FOR COMPLETING THIS SURVEY.

Appendix E: Incentive Mapping

Incentive Mapping for CAB-LA Arm

Time Frame	Activity	Incentive
Month 0	Baseline Demographic Survey	\$20
Month 1	Persistence assessment	\$5
	PRO Survey #1	\$10
Month 2	Health Literacy Survey	\$10
Month 3	PRO Survey #2	\$10
	Persistence assessment	\$10
Month 4	Health Literacy Survey	\$10
Month 5	Persistence assessment	\$15
	PRO Survey #1	\$15
Month 6	Health Literacy Survey	\$10
Month 7	Persistence assessment	\$15
Month 8	Health Literacy Survey	\$10
Month 9	Persistence assessment	\$15
	PRO Survey #2	\$20
Month 10	Health Literacy Survey	\$10
Month 11	Persistence assessment	\$25
	PRO Survey #1	\$25
Month 12	PRO Survey #2	\$30

Incentive Mapping for Oral PrEP Arm

Time Frame	Activity	Incentive
Month 0	Baseline Demographic Survey	\$20
Month 1	Persistence assessment	\$5
	PRO Survey #1	\$10
Month 2	Health Literacy Survey	\$5
	Persistence assessment	\$5
Month 3	PRO Survey #2	\$10
	Persistence assessment	\$10
Month 4	Health Literacy Survey	\$5
	Persistence assessment	\$10
Month 5	Persistence assessment	\$10
	PRO Survey #1	\$10
Month 6	Health Literacy Survey	\$5
	Persistence assessment	\$10
Month 7	Persistence assessment	\$10
Month 8	Health Literacy Survey	\$5
	Persistence assessment	\$10
Month 9	PRO Survey #2	\$15
	Persistence assessment	\$15
Month 10	Health Literacy Survey	\$5
	Persistence assessment	\$15
Month 11	Persistence assessment	\$15
	PRO Survey #1	\$20
Month 12	Persistence assessment	\$15
	PRO Survey #2	\$25

Appendix F: Overview of TheraPay App Screens for Aurora PrEP Study

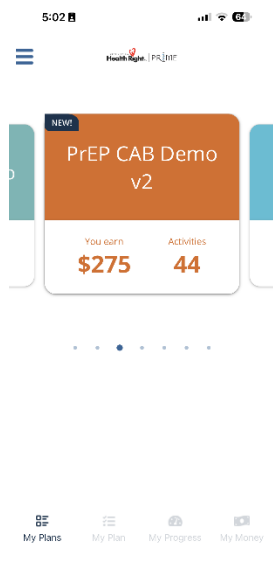
WVHR CAB LA PrEP DEMO 2023
Screenshots



Opening Screen (this is the first screen members see after going through the sign-up process)



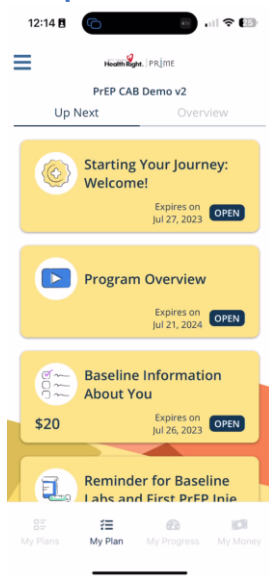
Multiple Plan Carousel screen shows the different Plans for which a Highmark Healthy Rewards member is enrolled, the number of activities in the Plan, and the total rewards available in the Plan.



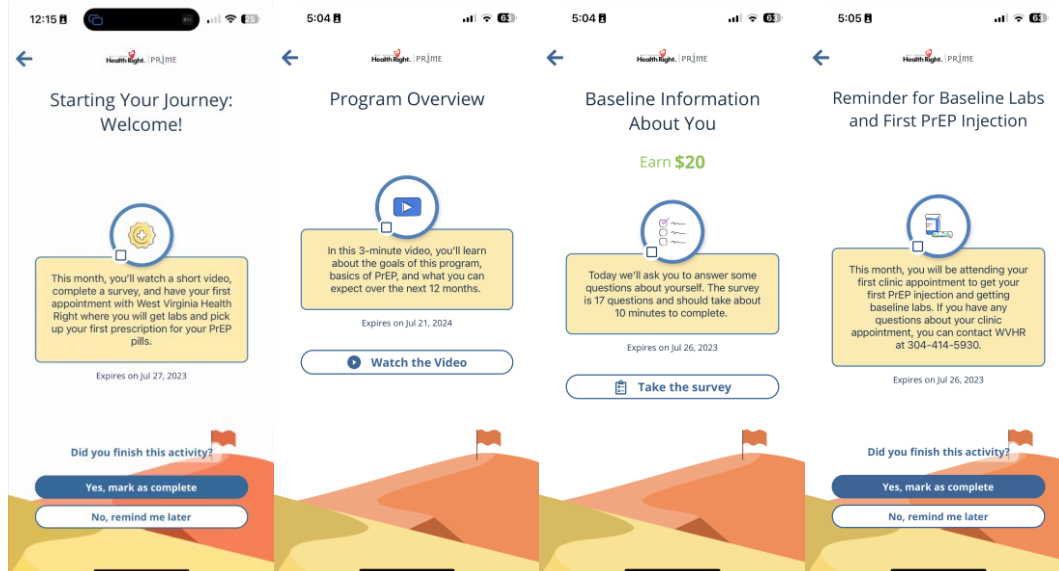
Overview screen shows all tasks each person is eligible within each plan, examples of the tasks in each plan are in the screenshots below. Tasks that have expired are marked by a red “x”, tasks that are open have an open check box, tasks that are still locked have a padlock image.

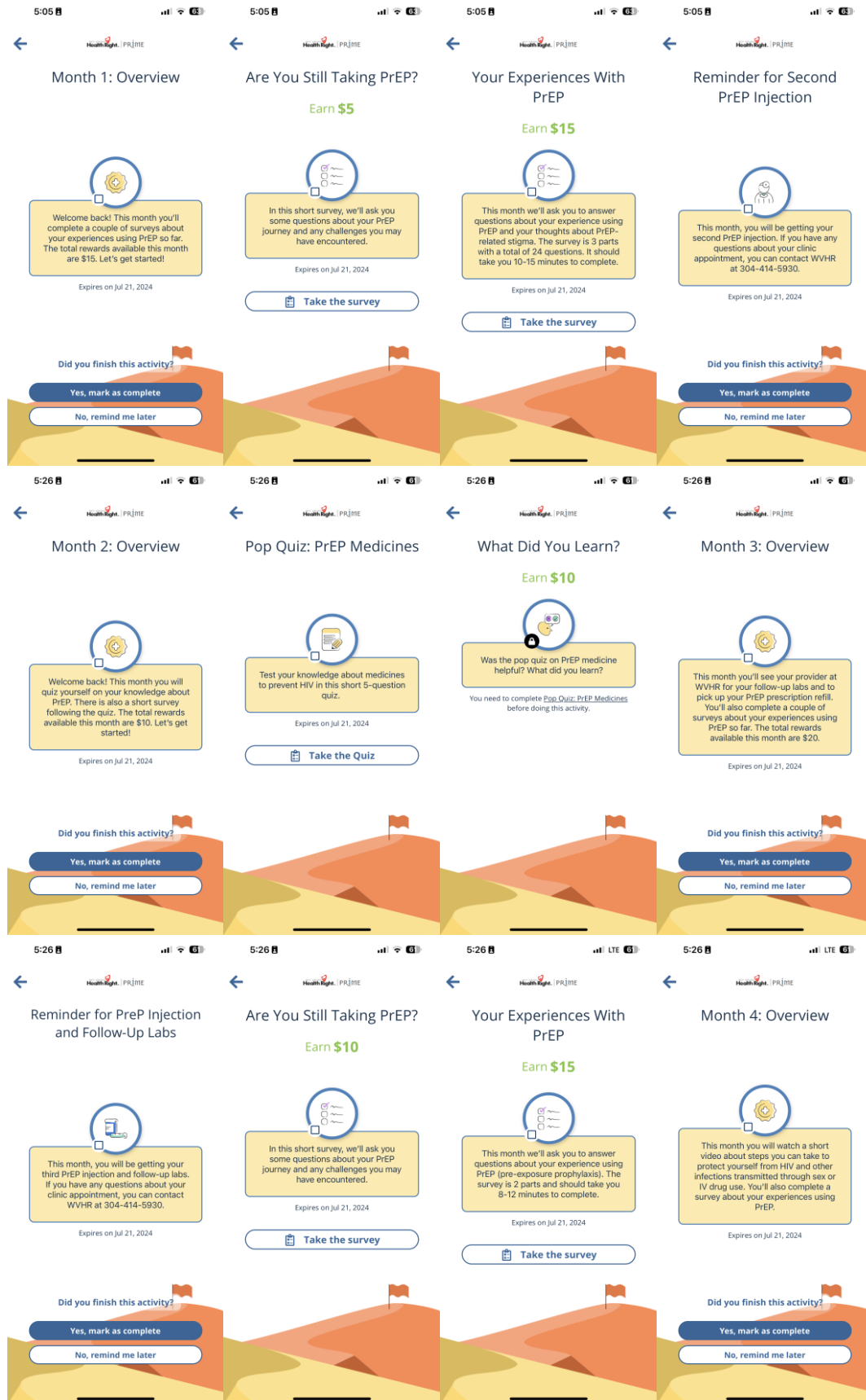


Up Next shows you only the open tasks, or in other words, all the activities that are available for you to complete now. Tasks will open on certain dates, or when previous tasks are completed that unlock the next task.



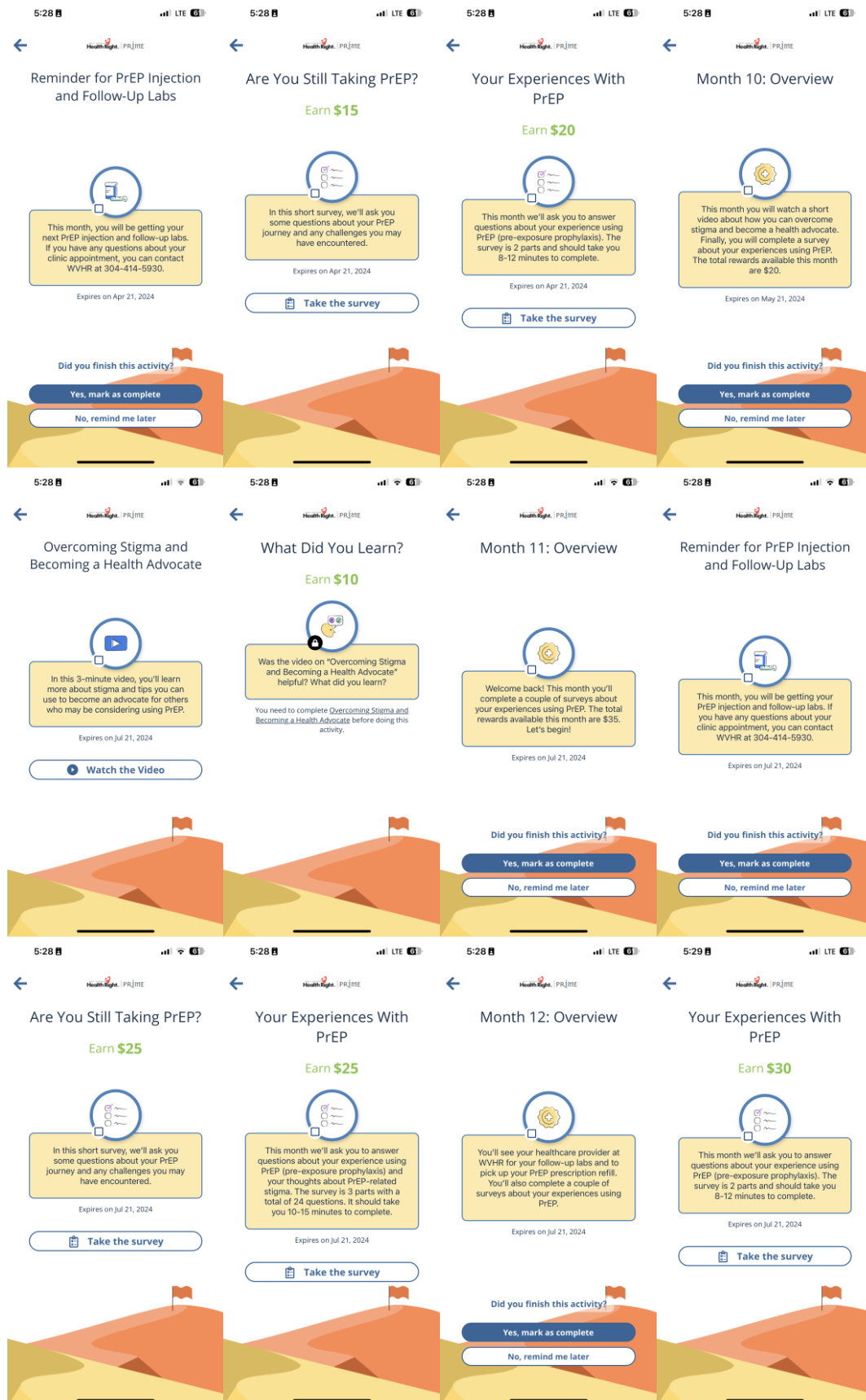
When members tap either the circles (in the Overview page) or the tiles (in the Up Next page), each one comes with more details. The screens below are for those pages.



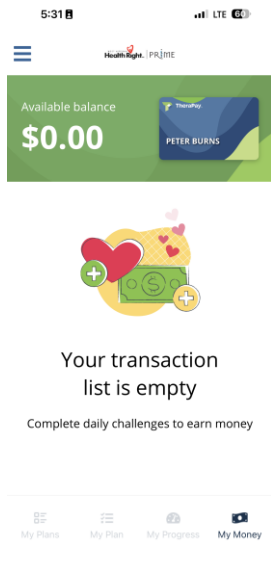




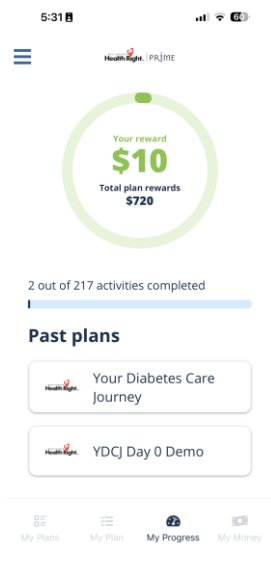




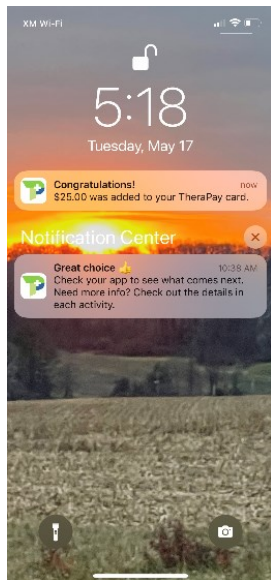
In the My Money section, the member can see what their balance is on their card, any transactions from their card, and any special offers available to them.



The My Progress Page shows how much progress a member has made against their activities and how much is still available.



Generic Push Notifications identify accomplishments, validations, and funds received.



Appendix G: Study Schema

Patients >18 y/o who are newly started on PrEP therapy at WVHR and have access to a smart phone with data (N=105)

- V. Participants will have been prescribed CAB-LA, daily FTC/TDF, or daily FTC/TAF in accordance with the WVHR standard of care by a licensed HCP prior to enrolling in the study
- VI. Not receiving HIV PrEP care outside of WVHR
- VII. No positive HIV diagnosis
- VIII. No contraindications to oral or injectable PrEP therapy

CAB-LA PrEP Arm
n = 70

- PrEP injections at months 0, 1, 3, 5, 7, 9 and 11
- Education modules at months 2, 4, 6, 8, and 10

Oral PrEP Arm
n = 35

- PrEP prescription fills at months 0, 3, 6, 9, and 12
- Education modules at months 2, 4, 6, 8, and 10

Primary outcome measure: mean patient-reported adherence and persistence at months 3 and end of study, validated by medication ratio between the CAB-LA and Oral PrEP cohorts

Secondary outcome measure 1: retention in care in patients receiving CAB-LA vs oral PrEP defined as the proportion of patients presenting for their follow-up appointments within 30 days of their scheduled visit at months 3, 9 and 12 for the Oral PrEP cohort and at months 3, 9, and 11 for the CAB-LA cohort

Secondary outcome measure 2: patient-reported outcomes including PrEP medication satisfaction, PrEP acceptance, and PrEP-related stigma, and barriers to adherence and reasons for PrEP discontinuation assessed through brief behavioral surveys

Secondary outcome measure 3: implementation outcomes including patient acceptability (AIM), appropriateness (IAM), and helpfulness of the education modules within the digital health program assessed using a Likert scale and health literacy evaluation

Secondary outcome measure 4: clinician acceptability, appropriateness, and feasibility of implementing long-acting cabotegravir injections (AIM, IAM, FIM), and barriers to and facilitators for implementation of CAB-LA

Appendix H: Study Timelines

CAB-LA PrEP Arm (N=70)													
Month 0	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Baseline labs and 1 st PrEP injection	Baseline evaluation and introduction to support group	2 nd PrEP Injection Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 3 rd PrEP injection PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 4 th PrEP injection Persistence Assessment PRO data collection – Set #1	Education modules and health literacy evaluation	Follow-up labs and 5 th PrEP injection Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 6 th PrEP injection PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation	Follow-up labs and 7 th PrEP injection Persistence Assessment PRO data collection – Set #1	PRO data collection – Set #2
Baseline demographic survey													

Oral PrEP Arm (N=35)													
Month 0	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Baseline labs and PrEP prescription filled	Baseline evaluation and introduction to support group	Persistence Assessment PRO data collection – Set #1	Education modules and health literacy evaluation Persistence Assessment	Follow-up labs and PrEP prescription refill PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation Persistence Assessment	Persistence Assessment PRO data collection – Set #1	Follow-up labs and PrEP prescription refill Education modules and health literacy evaluation Persistence Assessment	Persistence Assessment	Education modules and health literacy evaluation Persistence Assessment	Follow-up labs and PrEP prescription refill PRO data collection – Set #2 Persistence Assessment	Education modules and health literacy evaluation Persistence Assessment	Persistence Assessment PRO data collection – Set #1	Follow-up labs and PrEP prescription refill PRO data collection – Set #2 Persistence Assessment
Baseline demographic survey													

Reciprocity App – Education Modules <ul style="list-style-type: none"> Month 2: PrEP Medicines Month 4: Protecting Yourself from HIV, STIs, and other infections Month 6: Building a Support System for HIV Prevention Month 8: Being an Active Participant in Your Own Care Month 10: Overcoming Stigma and Becoming a Health Advocate 	Persistence assessment: patient self-report & barriers/challenges
PRO data collection (Set #1): <ul style="list-style-type: none"> PrEP Medication Satisfaction PrEP-Related Stigma AIM 	PRO data collection (Set #2): <ul style="list-style-type: none"> PrEP Acceptance IAM

Clinic Staff													
Month 0	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Baseline Provider Survey	AIM, IAM, FIM						AIM, IAM, FIM, Follow-Up Provider Survey						AIM, IAM, FIM, Follow-Up, Provider Survey

End of Study
 AIM, IAM, FIM, Follow-up Provider Survey

Appendix I: Forms for Safety Reporting

WV HealthRight will use GSK/ViiV reporting forms (for SAE, medical device incident and pregnancies). Completed forms will be sent to the GSK PV Operations group.

SAFETY DATA EXCHANGE

Adverse Event and Serious Adverse Event Definitions

For the purposes of this Agreement, an Adverse Event (AE) shall mean any untoward medical occurrence whether thought to have been caused by the ViiV IMP or the Study or not, and a Serious Adverse Event (SAE) shall mean any adverse event which is fatal, life threatening, disabling or incapacitating, requires in-patient treatment or prolongs existing hospitalization, is a congenital anomaly in the off-spring of the patient or which may require intervention to prevent the previously stated outcomes.

Medical Device Incident Definition

For the purposes of this Agreement a medical device incident is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. Device incidents include malfunctions, use errors, and/or deficiencies of the information supplied by the manufacturer. Device deficiencies/incidents may result in an SAE (including death or serious deterioration in health of a subject, or other non-participant person) or a non-serious AE, or lead to an SAE or AE if appropriate action had not been taken or, intervention had not occurred. The requirement to report medical device incidents applies to any incident occurring in association with a medical device provided in a ViiV commercial pack for the ViiV IMP(s) or any other known ViiV medicinal product.

Reporting Clinical Safety Information to GSK on behalf of ViiV

The Sponsor shall require the Participating Institution to report all Serious Adverse Events, Pregnancy Exposures and Medical Device Incidents disclosed by Study Subjects, or identified from review of Medical Records/Questionnaires during the course of the Study, for which the Participating Institution considers there to be a reasonable possibility of causal relationship with the ViiV IMP or any other known ViiV Product within 24 hours of first becoming aware of the event, regardless of Sponsor/designee expectedness assessments. Sponsor shall require of Participating Institutions that if the Participating Institution is unable to confirm whether ViiV is the manufacturer of the relevant product, Participating Institution shall nonetheless report the event to ViiV.

Routing of Clinical Safety Data to GSK

Notwithstanding Section 23 ['NOTICES'] of the Agreement, such reports and information as outlined above, including Investigator causality assessments against all concerned ViiV Products(s) and English translations of all information where reporting is from a non-English speaking country, shall be sent to the: GSK PV Operations Group at email: OAX37649@gsk.com OR if Sponsor is unable to email the report, Sponsor may send the report via facsimile

number+44-208 1814780. Should SPONSOR experience difficulty submitting a report, contact the ViiV individual listed in Section 23 "Notices".

Requesting Follow up information:

The Sponsor shall require the Participating Institution to provide GSK's safety department with details of whom GSK or ViiV shall address requests for follow up information from this Study, and further agrees to update such contact details as necessary. At the time of this Agreement, all such requests should be addressed to: David Hardy wdavidhardymd@gmail.com Sponsor shall require the Participating Institution shall submit to GSK (as specified above) such further detailed information relating there to as GSK shall request within 24 hours of it becoming available.