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Janelly Gonzalez	July 26, 2023

Development of a Home-Based Pre-Exposure Prophylaxis Care Delivery System for Long Acting Injectable Cabotegravir: A Formative Exploration of Patient Preferences

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By

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Bachelor of Arts
American University
2018

Thesis Committee Chairs: Paulina A. Rebolledo MD, MSc and Valeria Cantos, MD

An abstract of
A thesis submitted to the faculty of the
Rollins School of Public Health of Emory University
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Abstract

Development of a Home-Based Pre-Exposure Prophylaxis Care Delivery System for Long Acting Injectable Cabotegravir: A Formative Exploration of Patient Preferences

By Janelly Gonzalez

Background: CAB-LA – the only FDA-approved injectable PrEP – is effective and has the potential to address PrEP inequities impacting Black and Latino sexual minority men (SMM). Uptake of CAB-LA may require the development of innovative care delivery strategies, including home-based settings.

Objective: We aim to explore SMM perceptions on a future home-based CAB-LA PrEP care service delivery which will serve as guidance for the adaptation of an existing home-based oral PrEP system into an intervention that includes injectable PrEP.

Methods: We conducted 14 IDIs on SMM ages 20-29 who were current or prior participants of a clinical trial evaluating the efficacy of a home-based system for oral PrEP care (PrEP@Home). We explored their overall acceptability of a home-based injectable PrEP system, communication preferences, and specific pre-visit , in-visit , and post-visit logistics.

Results: The home-based CAB-LA delivery system was well accepted. We identified that convenience and comfortability were the main drivers of acceptability of the home-based system. Factors influencing acceptability included clinical teams' affiliation with a healthcare system, a two-person team with certified credentials, and being able to verify the staff's identity. Logistical preferences included receiving complete information prior to the visit, flexible scheduling hours,

and text message communication for user information. Concerns to privacy, safety, and potential costs were also identified.

Conclusions: Our findings demonstrate the acceptability of home-based injectable PrEP delivery system among SMM and highlight influencing factors of acceptability, logistical considerations, and concerns for implementation. These insights can inform future implementation methods for CAB-LA and contribute to the adoption of a home-based delivery system ensuring equitable access to injectable PrEP.

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Abbreviations

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
CAB-LA	Cabotegravir
CDC	Center for Disease Control and Prevention
CHW	Community health workers
COREQ	Consolidated Criteria for Reporting Qualitative Research
DSD	Differentiated PrEP service delivery
EMS	Emergency medical services
EMT	Emergency medical technician
ETA	Estimated time of arrival
F/TAF	Emtricitabine/tenofovir alafenamide
F/TDF	Emtricitabine/tenofovir disoproxil
FDA	U.S Food and Drug Administration
HIV	Human Immunodeficiency virus
IDI	In-depth interviews
IM	Intramuscularly
LAI-PrEP	Long-acting injectable pre-exposure prophylaxis
MSM	Men who have sex with men
PrEP	Pre-exposure prophylaxis
PnR	PrEP-to-need ratio
SMM	Sexual minority men
STI	Sexually transmitted infection
U.S	United States
WHO	World Health Organization

Key words: CAB-LA PrEP, Home-based system, injectable PrEP, SMM, patient preferences

Chapter 1: Introduction

Background Information:

At the end of 2021, there were approximately 38.4 million people living with human immunodeficiency virus (HIV) globally, 1.2 million of them in the United States (U.S) (1-3). In 2019, 70% of new HIV infections in the U.S occurred among sexual minority men (SMM) - gay, bisexual, and other men who have sex with men (MSM) (2). The southern region of the U.S accounted for half of the incident infections (4). Black/African American and Hispanic/Latino groups had the highest infection rate throughout the country at 40% and 29% respectively (1, 4).

Prevention remains crucial in reducing new infections and curbing the HIV epidemic (6). Antiretroviral preexposure prophylaxis (PrEP) significantly lowers the risk of HIV acquisition among individuals at high-risk (2, 5-7). While oral PrEP, with either combination tenofovir disoproxil fumarate and emtricitabine (F/TDF) or tenofovir alafenamide and emtricitabine (F/TAF), have demonstrated effectiveness in reducing HIV transmission, disparities in its uptake and utilization exist, particularly among minority SMM populations living in the southern US.

There are several barriers to PrEP uptake among SMM minority populations including limited access to healthcare services, low health literacy, stigma, discrimination, structural racism, lack of insurance coverage, and financial difficulties (8-12). Shortage of PrEP providers in certain geographical areas exacerbates access and utilization disparities. The recent U.S Food and drug Administration (FDA) approval of cabotegravir (CAB-LA), a long-acting injectable formulation for PrEP, represents a promising alternative to oral PrEP (13). CAB-LA, administered through intramuscular (IM) injections every two months, offers convenience and potentially improved adherence, especially among individuals who struggle with daily pill regimens. Landmark phase

3 clinical trials have shown CAB-LA to be superior to oral F/TDF in preventing HIV in cisgender men and transgender women (13, 14).

Problem Statement:

Per FDA regulations, CAB-LA is currently only authorized to be administered by healthcare providers in a clinical setting and it's not approved for self-administration (15). This requirement may represent a barrier to CAB-LA uptake for some SMM who would benefit from it, due to the stigma associated with attending a sexual health clinic, limited transportation, and difficulty scheduling clinic visits. To address this barrier, research on innovative strategies to provide CAB-LA in non-clinic settings is needed to address the needs and preferences of those who cannot or wish not to attend clinic visits for CAB-LA for PrEP. Delivering CAB-LA should consider the needs of SMM to minimize burden, promote equity, and increase HIV prevention uptake.

In response to the barriers associated with in-person clinical visits, Siegler et. developed and implemented a home-based system for oral PrEP care in a clinical trial setting (PrEP@Home, NCT03569813) (16). The PrEP@Home model had high acceptability among its users. Implementing home-based CAB-LA PrEP services will require adaptations to the PrEP@Home protocol to maximize the delivery potential of CAB-LA.

Research Objective:

The objective of this qualitative research study is to explore the opinions of SMM on the acceptability of a future home-based CAB-LA care service delivery, as formative research to guide the development of the intervention, using the PrEP@Home system as a template. Domains of in-depth interviews (IDI) will investigate the perceptions of SMM on the acceptability, communication preferences, and logistical considerations associated with the implementation of a home-based delivery system.

Significance Statement:

The findings of this study will serve as preliminary data to develop a home-based CAB- LA PrEP service delivery system that responds to the community's needs and preferences. Conclusions drawn from these findings may also guide the development of public health-based interventions to implement home-based CAB-LA PrEP services.

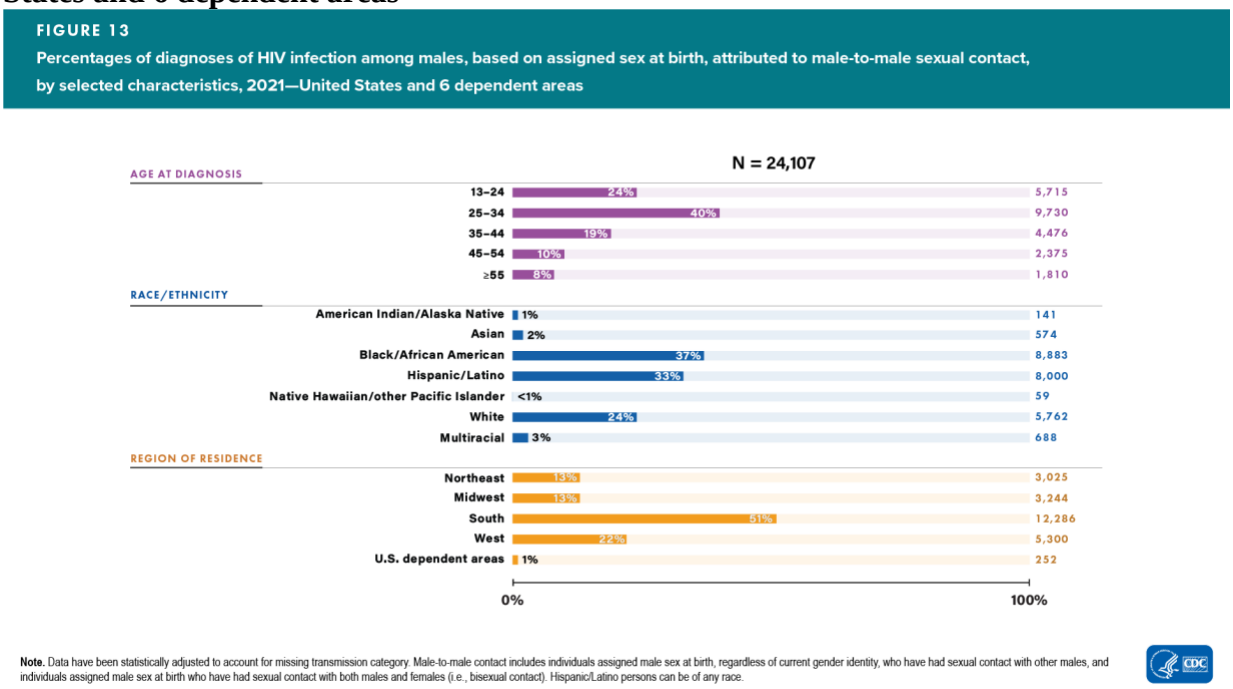
Chapter 2: Literature Review

HIV

HIV is a retrovirus that attacks the immune system and weakens the body's ability to fight off diseases (1). There is no cure, however, long-term antiretroviral therapy (ART) can re-establish or maintain immunocompetency by controlling viremia in the bloodstream. If left untreated it commonly leads to AIDS (Acquired Immune Deficiency Syndrome) and death. The virus is carried through body fluids including semen, vaginal fluids, anal mucus, blood, and breast milk. The infection is acquired through condomless vaginal or anal sexual intercourse, contact with used infected needles or syringes, contact of infected body fluids through an open wound, and breastfeeding.

Although new infections are declining, especially among white SMM, infection rates among Black and Latino SMM have remained stable and higher than that of any other racial group (2). In 2021, Black/African Americans and Latino SMM accounted for 37% and 33% of all new infections in the U.S, respectively. Geographically, the southern region of the country accounts for 52% of new infections, while only accounting for a third of the nation's population (2, 4). The table below outlines HIV infections among age, race/ethnicity, and region of residence among gay, bisexual, and other MSM.

Figure 1: "Percentages of diagnoses of HIV infection among males, based on assigned sex at birth, attributed to male-to-male sexual contact by selected characteristic, 2021- United States and 6 dependent areas" (17)



A recent analysis among SMM identified HIV clusters of rapid HIV transmission noting that Black and Latino SMM were disproportionately represented in the clusters (18). The identification of an HIV cluster indicates a lack of effective prevention services among these communities, highlighting the need for targeted interventions that address the unique barriers faced by these minority groups.

PrEP

PrEP is an effective and safe biomedical strategy to prevent HIV (19). Individuals who meet the following criteria may benefit from PrEP: 1) any sexually active adult who does not have HIV or has had anal or vaginal sex in the past 6 months, 2) has a partner who is HIV positive, 3) has had a sexually transmitted infection (STI) in the past 6 months, or 4) has had sex without

condoms (20). Injection drug users who have an HIV-positive injecting partner, or who share injection equipment have substantial risk as well.

In 2012, the FDA approved F/TDF as the first oral PrEP drug (20). The efficacy of F/TDF in preventing HIV has been demonstrated in several populations. In the iPrEX randomized, placebo-controlled clinical trial, 2,499 HIV-negative cisgender men and transgender women who had sex with cisgender men were enrolled and randomized to a F/TDF or placebo arms. Overall, F/TDF lowered HIV risk by 42%, compared to placebo (5). F/TDF efficacy was highly correlated with adherence, as it increased to 73% in those participants who had 90% adherence. A second landmark study took place in Kenya and Uganda among heterosexual serodiscordant partners with findings revealing that taking F/TDF reduced the risk of infection by 75% in the uninfected partner compared to placebo, those who weren't taking Truvada (6). Similar to the previous study, efficacy was dependent on adherence.

In 2019, F/TAF became the second oral drug approved for PrEP (20). This drug included a new formulation of tenofovir called tenofovir alafenamide in combination with emtricitabine (F/TAF), which allows its administration for individuals with chronic kidney disease with a creatinine clearance as low as 30 ml/min. Unlike F/TDF, F/TAF was only approved for cisgender men and transgender women who have sex with cisgender men. The approval did not include cisgender woman as they were not included in the study. The DISCOVER trial was a non-inferiority randomized phase 3 clinical trial that evaluated F/TAF's efficacy in preventing HIV compared to F/TDF among 5,387 participants (7). The results from this study showed that F/TAF was non-inferior to F/TDF. Consistent with previous research, there was a high adherence rate among participants correlating adherence and efficacy. Among those who acquired HIV, most had low concentrations of PrEP medication suggesting low adherence. (5-7)

For some people, taking medication daily may not be desirable or practical. High adherence is important to optimize PrEP effectiveness which highlights the need for new strategies for those with low adherence to a daily oral pill and for those who encounter barriers to achieving high adherence.

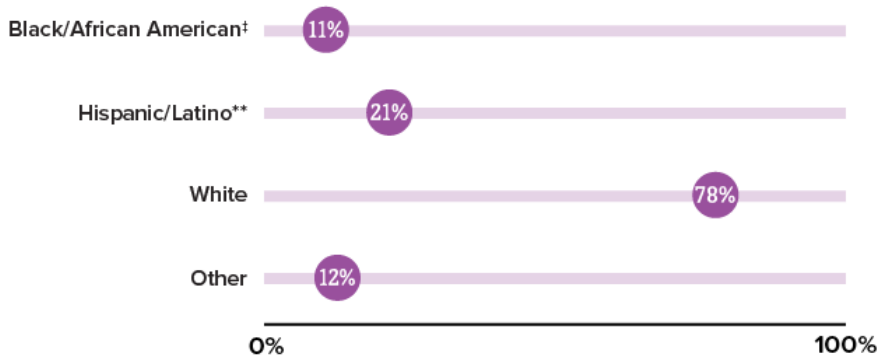
The protective impact of PrEP on HIV among minorities has been predicted to be greater than that of the White counterparts (21). Using a network model a study estimated the number of infections that could be prevented and the efficiency of PrEP under various coverage and adherence scenarios among Black and white adolescent SMM. The base model revealed a significant Black-White disparity in HIV prevalence, with a higher prevalence among Black individuals (12.4%) compared to White individuals (1.4%). However, the implementation of PrEP resulted in a substantial reduction in HIV incidence for both groups. The second analysis focused on coverage levels for eligible SMM. It showed that PrEP could prevent 3% to 20% of infections among Black SMM and 8% to 51% among White SMM, depending on coverage and adherence rates. Although the prevalence reduction was lower among Black SMM compared to White SMM, the number of infections averted was higher among Black SMM. The number needed to treat Black SMM was lower compared to White SMM. PrEP was found to reduce HIV incidence among both Black and White SMM, but it is particularly efficient for Black SMM due to their higher HIV incidence.

PrEP Disparities

In the US, 30% of 1.2 million individuals would benefit from PrEP. Of them, only 30% received a PrEP prescription in 2021 (2). There is inequitable PrEP coverage across the nation among racial and ethnic groups. In 2021, 11% of Black and only 21% of Latino PrEP-eligible individuals were prescribed PrEP. In contrast, 78% of white PrEP-eligible individuals were

prescribed PrEP the same year. The following shows the reported data from the CDC 2021 HIV Surveillance Report.

Figure 2. "PrEP Coverage in the U.S by Race and Ethnicity, 2021"[22]

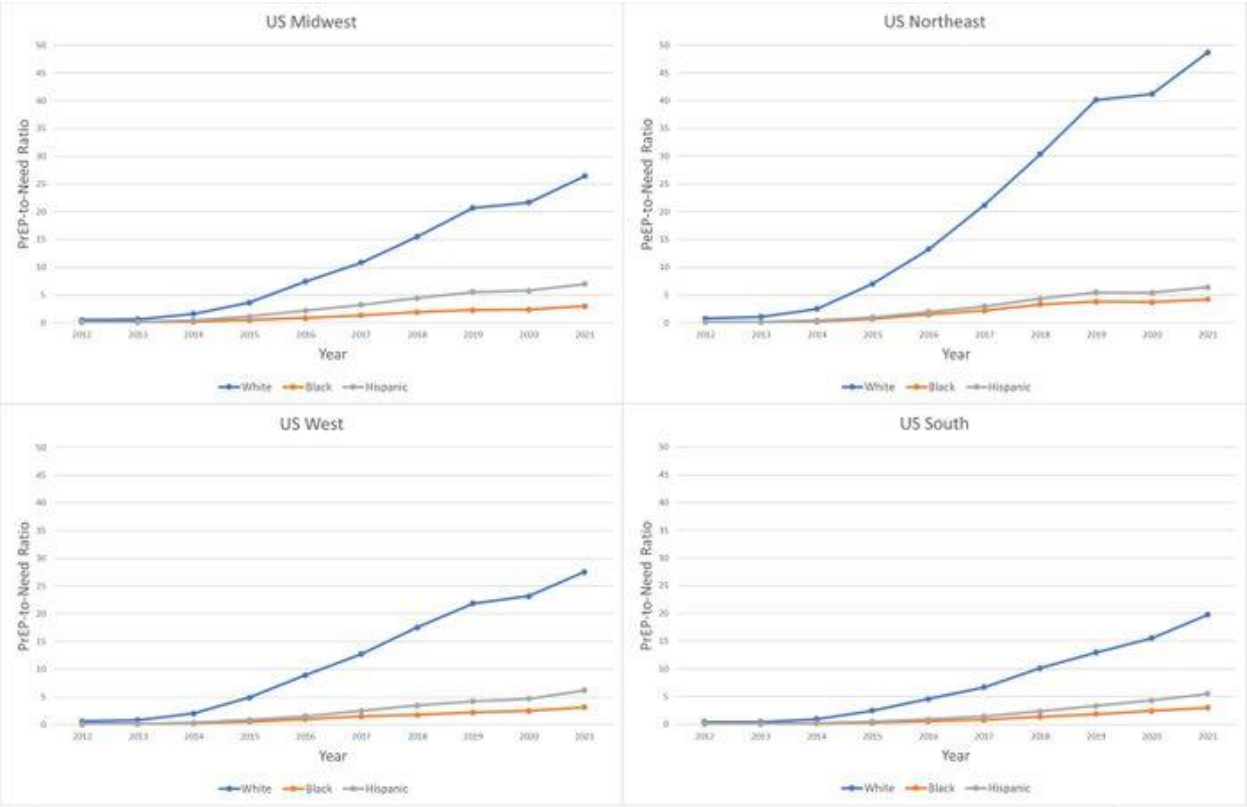


"*PrEP coverage is the estimated percentage of people with indications for PrEP classified as having been prescribed PrEP.
† Among people aged 16 and older.
‡ Race and ethnicity data are available for less than 40% of people prescribed PrEP.
** *Black* refers to people having origins in any of the Black racial groups of Africa. *African American* is a term often used for people of African descent with ancestry in North America.
†† Hispanic/Latino people can be of any race."[23]

Even though PrEP coverage has increased in the last decade, there are consistent discrepancies among PrEP use by geographical region and by race/ethnicity (24). A study analyzed commercial pharmacy data spanning from 2012 to 2021 to examine PrEP utilization among different racial groups and across U.S regions. The PrEP-to-Need Ratio (PnR), a metric that assessed equity in PrEP utilization, was employed to examine the ratio of PrEP users to diagnoses within each group and year. The findings, as shown in Figure 3, reveal an increase in PnR over the ten-year period for all racial groups and regions. However, the distribution of PrEP utilization was inequitable based on race/ethnicity. Across all regions, PnR was highest among white individuals and lowest among Black individuals. In the Northeast, where PrEP use was the highest in 2021,

White individuals exhibited a PnR value of 48.7, while Black individuals had a substantially lower PnR value of 4.2. Within the 10 years, PrEP utilization was consistently higher among White individuals nationwide. Figure 3 depicts the widening inequities in PrEP utilization over the past decade across all regions. Moreover, regional variations were identified, with the South having the lowest level of equitable PrEP utilization compared to other regions.

Figure 3: "Trends in PrEP inequity by race and census region, United States, 2012-2021" (25)



PNR is defined as the number of PrEP users in a group divided by the number of new diagnoses in that group in the same year. Data are not available for analyses of other races/ethnicities.

The PrEP continuum is a framework that outlines the sequential steps in the process of providing PrEP to at-risk individuals (26). It enables the identification of gaps and challenges within the delivery of PrEP services and facilitates the development of strategies to improve PrEP uptake, adherence, and retention. The continuum encompasses several stages including raising

awareness and cultivating the willingness to initiate PrEP, accessing healthcare providers, and undergoing screenings, receiving a prescription for PrEP, initiating PrEP usage, adhering to the medication regimen, retaining care, receiving additional HIV prevention services, and discontinuing or transitioning. While knowledge of PrEP among SMM has increased in recent years, gaps exist between awareness, willingness, and the utilization of PrEP (8, 22, 26, 27). In 2017, among gay and bisexual men without HIV, 85% reported being aware of PrEP but only 25% used PrEP (27). Within this group, 78% of Black/African Americans were aware of PrEP but only 19% were using PrEP and 81% of Hispanic/Latinos were aware of PrEP but only 21% used PrEP. Prevention and treatment are not reaching people who could benefit the most. To bridge the gap of such disparities, interventions need to address barriers faced by minority groups.

PrEP Barriers

Various barriers exist that hinder access to PrEP among minority SMM, encompassing individual, social, and structural factors. Individual barriers have been discussed in the literature including underestimation of HIV risk, lack of awareness about how to seek PrEP, and difficulties navigating the healthcare system (8, 10, 12, 28). Mistrust of the healthcare system contributes to the underestimation of HIV risk, HIV and anti gay stigma (8-12, 28).

Social and structural barriers impacting PrEP uptake are rooted in structural racism, discrimination, and poverty. The lack of transportation, lack of childcare, inability to take time off work, and housing instability impedes access to PrEP (9). It is reported that one in eight SMM in the South live at least 30-60 minutes away from PrEP providers and confront challenges with transportation (8). Other barriers to PrEP uptake include, inadequate health insurance coverage, limited access to PrEP information, low health literacy, language fluency, and low education

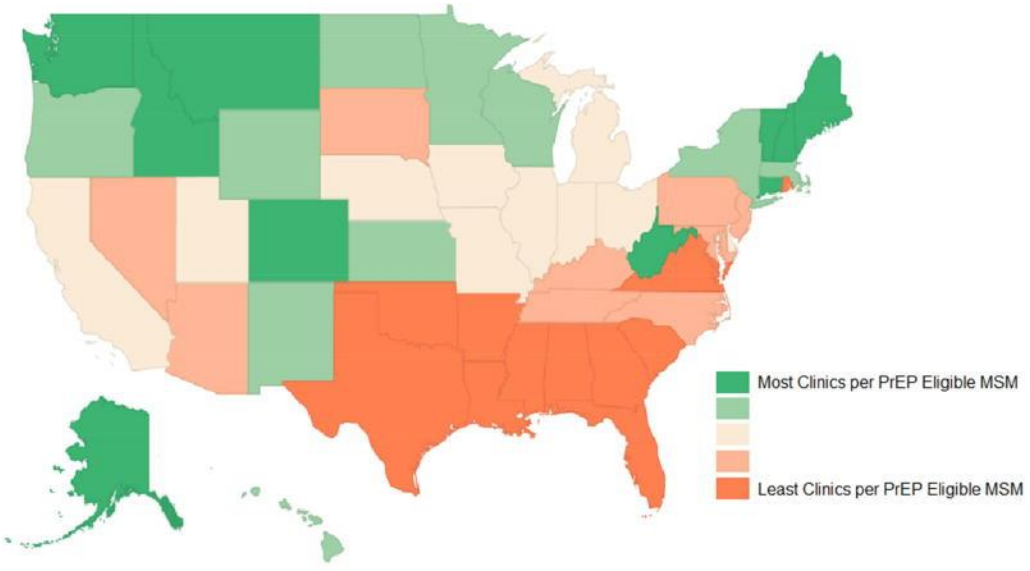
levels, all of them particularly prevalent in the southern region and among minority populations (8-12, 28).

Stigma, including negative experiences with healthcare providers, poses a significant barrier to PrEP initiation among Black MSM (8). In a study done in Atlanta, this was found to be particularly true among young Black MSM and among Latinos who believed that PrEP was only for individuals with high levels of risk (10, 29). HIV and anti-gay stigma have been reported by minorities to be a deterrent to PrEP and is more pronounced in the South creating mistrust in the medical system and influencing their willingness to take PrEP (8, 10, 28). Because the population of African Americans is greater in the South, stigma within the Black communities have a stronger influence on PrEP uptake.

Further, there are geographical disparities in PrEP accessibility particularly in the southern region of the U.S (8). Despite regional progress in PrEP uptake, in an analysis from 2012 to 2018 the lowest prevalence of PrEP uptake was found to be among southern states including Georgia, Kentucky, North Carolina, South Carolina, Virginia, and West Virginia (30). According to 2015 data, inadequate healthcare provider availability is a significant concern in the South, where less than half of the healthcare needs are met. The region encompasses four out of the six states with the lowest ratios of primary care providers to population (31). There is a lack of healthcare providers who are trained in PrEP and identifying who is eligible, including among primary care providers with low familiarity with prescribing PrEP (8, 31). A 2017 study done in six Southern states revealed that inconsistencies exist in how providers assess HIV risk and determine PrEP candidacy (8). Among healthcare providers, 52.3% had limited knowledge of PrEP and 18.1% had prescribed PrEP. Once linked to PrEP, the same barriers impact retention in PrEP care overtime as individuals on PrEP are advised by the CDC to have four clinician visits annually (31).

Census tracts in the South are disproportionately classified as PrEP deserts (travel times higher than a 30-minute drive to PrEP-providing clinics) compared to the Northeast, despite the South accounting for over half of all new HIV diagnoses in the country. Figure 4 shows the distribution of PrEP-providing clinics per new HIV diagnosis by state measuring the clinics available in areas with a higher need for HIV prevention (32). Many PrEP-eligible individuals in these deserts live in rural areas, experiencing even higher commute times (33). Urban areas also experience transit barriers, with a significant portion of the PrEP-eligible population residing in suburban PrEP deserts (33). The presence of PrEP deserts in both urban and rural areas highlights the need for interventions to expand oral and injectable PrEP access through non-clinic based methods, especially in the South. This region is overwhelmingly impacted by HIV and is where social and structural barriers heavily weigh on Black and Latino groups' ability to access and stay on PrEP (8, 31, 34, 35).

Figure 4: "Proportion of PrEP-providing clinics new HIV diagnoses by state, ranked by quantile 2018" [32]



b.

National Non Clinic-Based PrEP Delivery Services

Traditional clinic/hospital delivery settings including specialized clinics, reproductive health services, and community health clinics requiring in-person visits present numerous challenges for SMM (36, 37). To address the individual, social, and structural barriers to PrEP uptake, several innovative non-clinic-based PrEP care delivery strategies have been developed and implemented. These include methods such as pharmacy-based care models, community health workers (CHW) systems, telemedicine, mobile apps, and home-based PrEP care.

Community-based models have delivered oral PrEP through pharmacy clinics and by employing pharmacists (37). Pharmacists have been shown to deliver comprehensive PrEP-related services, including eligibility screening, counseling, testing, dispensing, and adherence support, under medical directives. Pharmacist-managed HIV PrEP Clinic model in Seattle, Washington has also shown that such models can achieve high initiation, low drop-out, and low lost-to-follow-up rates (38). Using such models can be beneficial for individuals who do not have access to traditional healthcare settings or live in areas with limited PrEP availability. Additionally, pharmacists can take on tasks of physicians outside of clinic settings to relieve strain on clinic space capacity and healthcare personnel capacity. Many pharmacy-based PrEP programs, however, face state-based policy challenges with restrictions on pharmacists' scope of practice that may not allow them to prescribe PrEP, order laboratory tests, or bill insurance plan (36, 39). In order to receive payment, regulations require insurance companies to recognize pharmacists as providers (38, 39).

CHW-based PrEP systems have been implemented in many low-resource settings, including in many countries abroad. CHW are members of a community, selected by community members or organizations to provide health related services to their own community. A large part of the success in utilizing CHW to increase PrEP uptake is that they are oftentimes trusted agents

and understand the cultural and contextual climate of the population (40). They have also been instrumental in involving geographically hard-to-reach populations with HIV related services. CHW have served in increasing PrEP knowledge at a community level, streamlining patient flow, assisting in health worker capacity, and providing effective counseling (40-44). CHW can also play an important role in navigating PrEP care, in peer support, and upkeeping follow-up and retention. While CHW may be key in mitigating stigma and enhancing public health communication, training is often not standardized, and they are not recognized as healthcare professionals.

Telemedicine approaches such as NurX and PlushCare are for-profit programs that offer telemedicine PrEP services in the private sector, limiting access to minority SMM individuals who could benefit from PrEP services the most (45). The Iowa TelePrEP Model, a regional partnered telehealth service, was a referral program connecting patients to sexual health services provided by University pharmacists at the Iowa Department of Public Health (36). In this model, almost all participants (96%) adhered to the quarterly laboratory monitoring testing, favoring the TelePrEP Model over in-person clinics. The model also achieved high rates of linkage to STI treatment and holds the potential to extend pharmacy-based PrEP services to small urban and rural areas.

Mobile apps represent an innovative tool to increase PrEP uptake. The Healthmindr app, developed by Sullivan et. al. as a comprehensive HIV prevention mobile app, was shown to impact its users' decision in starting PrEP (46). High acceptance of a mobile app for comprehensive HIV prevention was also evident among Latino SMM (28). Telemedicine and mobile apps can not only be valuable tools in virtual consultations, but they can also be useful for patient communication, for adherence monitoring, and counseling. These technological advancements offer useful tools to enhance accessibility for individuals facing geographical and transportation barriers. Telemedicine

and mobile apps-based care have several limitations. Some have evidenced poor retention with follow-up visits that may be attributed to not having a doctor physically present during the initial visit (47). Single strategies such as telemedicine alone will not suffice but may be used in combination with other methods.

Global Non Clinic-Based PrEP Delivery Services

Many strategies implemented globally have been successful in oral PrEP uptake. Pharmacy-based services have been accepted and successful, especially in regions like Africa where pharmacists are allowed to provide PrEP more widely (48). provided effective counseling and positively influenced levels of PrEP knowledge, uptake, adherence, and patient follow-up (40, 41, 43). Telehealth services have been adopted even in low resources settings and continuation of PrEP delivery was prioritized throughout the pandemic (49). Countries like Brazil, Vietnam, Thailand, and Kenya have implemented telehealth programs for PrEP consultation, home delivery, counseling, and provision of self-test kits and sexual health kits. Successful integration of home-based care with telehealth services has been demonstrated in various settings.

Home-Based Care:

Home-based care encompasses many different health services that are provided in a home setting (50). Home-based care has shown to be effective in delivering health services in various clinical scenarios globally and nationally. A randomized controlled trial in India measuring the effectiveness of a home-based childcare program using village health workers was successful in significantly reducing infant mortality rates, under-five mortality rates, and perinatal mortality rates in rural areas (81). This home-based childcare model was socio-culturally contextualized through the implementation of the village health workers and supported institutional backing.

In the U.S, home-based CHWs were used to provide education and management skills in the context of addressing childhood asthma and childhood nutrition (82, 104). The success of the home-based system is not exclusive to a single healthcare issue and has been proven to address patient social needs among the elderly as well (105). Home-based systems are adaptable to tailor the health needs of individuals and can be used to address many different health issues.

The climate in PrEP delivery has been changed by the COVID-19 pandemic when access barriers were heightened. Home-based strategies have been used for self-sampling for STI and HIV testing, and PrEP delivery, often in combination with counseling or consultation services via telemedicine. Home-based care strategies also have the potential to overcome barriers to access, barriers relating to stigma, transportation limitations, and geographical distance (37). The need for home-based PrEP care became more evident at the onset of the COVID-19 pandemic, as access barriers were augmented.

Home-based services have shown promising uptake with STI and HIV testing. During the pandemic, many home-based STI programs surfaced in the U.S (51). Online STI mail-in testing programs "I Want The Kit" and TAKEMEHOME" and HIV home testing program provided a dependable remote approach to access STI/HIV testing and manage results. The "TAKEMEHOME" program showed an increase in STI testing including among those who have never previously tested for HIV(52). Home-based methods have been found to reach more men and increased their access to HIV testing (53). In a US-based randomized clinical trial, MSM participants who received a home HIV self-testing kit achieved a 100% test rate compared to 72% who received a letter directing them to get tested at a local clinic.

Home-based HIV and STI testing are overall well accepted among SMM. (54). A study involving 11 SMM living with HIV and 1,070 HIV-negative SMM who completed STI self-

testing procedures for STI, showed that most participants found urine-based rectal swab STI self-sampling to be easy. A second needs assessment interviewed 18 MSM and 19 healthcare professionals who exhibited favorable attitudes toward self-sampling in a home-based setting (55). Leveraging established acceptance of home-based systems in HIV care could be crucial for the successful implementation of oral and injectable PrEP systems.

The acceptance of a home-based PrEP care in a nationwide study among participants who had not initiated PrEP was found to be high. About 75% of gay and bisexual men preferred to receive their ongoing PrEP care through home-based PrEP services, especially among younger men and those with recent HIV transmission risk (56). Young SMM of color in a separate study reported that remote care could mitigate stigma and promote PrEP use and retention (57). Findings support the importance of home-based care system potential in increasing PrEP uptake among high-risk younger SMM.

Siegler et.al. developed and implemented a home-based PrEP care strategy, PrEP@Home, to address the barriers associated with clinic-based PrEP care and increase PrEP uptake by offering an innovative care delivery system. (16, 58). The participants were 55% White, 22% Black, younger than 40 years old, and most with some college education. The PrEP@Home model was found to be highly acceptable among most of the patients and 48/55 would use PrEP@Home kits instead of clinic visits in the future. Additionally, more than one-third (22/55) of the patients reported they were likely to continue using PrEP if the PrEP@Home system was available over in-clinic visits. Of all 57 enrolled participants, only 4 patients required standard in-clinic care because of insufficient self-collected specimens or inability to perform a finger prick.

CAB-LA PrEP

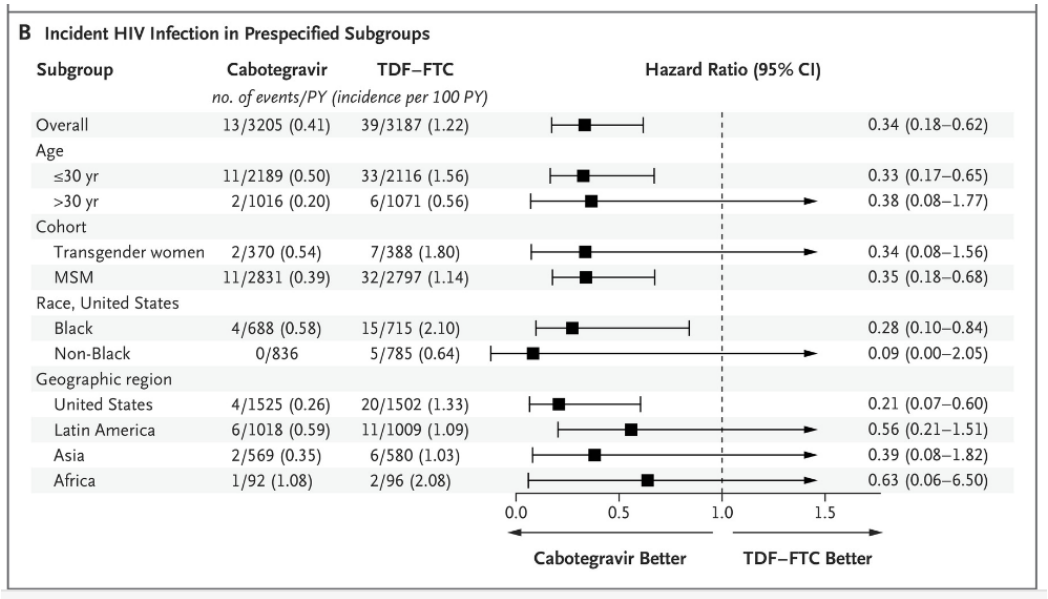
In 2021, the FDA approved the first long-acting injectable PrEP (LAI-PrEP) medication, Cabotegravir, for all adults and adolescents at risk for HIV including cisgender women, SMM, and transgender women (13). Unlike oral PrEP, CAB-LA is injected IM in the buttocks bi-monthly, after two monthly loading doses (20). Clinically eligible individuals for CAB-LA include anyone who is HIV negative within 1 week before the initial CAB-LA injection, without signs or symptoms of acute HIV, who is not taking any contraindicated anticonvulsants such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, or antimycobacterial rifampin and rifapentine medications (20, 59). There are no differences for clinical eligibility between oral and injectable PrEP except for patients who are allergic to the medication and those who have buttocks implants (60).

CAB-LA was found to be superior in preventing HIV infection when compared to F/TDF oral PrEP among cisgender MSM and transgender women who have sex with men in the HPTN 083 study, and among cisgender women in the HPTN 084 study (13). In the HPTN 083 study, the risk of HIV infection was 66% lower among those taking CAB-LA compared to those taking oral PrEP. Although most participants experienced mild to moderate injection site reactions among those taking CAB-LA, only 2.4% discontinued the injections due to injection site reactions. A systematic review of randomized controlled trials among cisgender men, cisgender women, and transgender women also reported similar results (61). In that review, the collective risk of HIV acquisition for CAB-LA users compared to oral PrEP indicated that CAB-LA had a 79% reduction in HIV risk. Adverse effects for both strategies remained similar.

The superiority of CAB-LA in preventing HIV compared to oral PrEP may be related to its ability to overcome the adherence-dependent efficacy of oral PrEP, especially among Black MSM and transgender women. According to a subgroup analysis from the HPTN 083 study, the

HIV incidence was 8 times lower among Black MSM and transgender women taking CAB-LA than those taking F/TDF. There were only 4 incident HIV cases among Black participants taking CAB-LA and 15 incident cases of Black participants on F/TDF (13). The difference in HIV incidence among non-Black participants taking CAB-LA was not significant compared to alternative F/TDF. Importantly, while Black participants had the lowest adherence to oral PrEP than any other racial groups in HPTN 083, there were no racial differences in adherence to CAB-LA injections (62).

Figure 5: "Incident HIV infection in prespecified subgroups" [(13)]



"Figure shows the hazard ratio between oral PrEP and CAB-LA for new incident HIV infections per subgroups. Race is self-reported. PY is person-years. A hazard ratio greater than one or less than one indicates the probability of prevention in a treatment group relative to the other over time."[(13)]

Emerging research indicates the favorable reception of CAB-LA, including among young SMM of color (57, 63, 64). In a cross-sectional survey of sexual and gender minority participants in the Southern US who have been on PrEP or were currently taking PrEP, willingness to use LAI

PrEP was high at 68% among all races with 75% in Latino, 58% non-Hispanic Black, and 69% White (64). Of these individuals, 81% preferred to use LAI-PrEP over a daily oral pill. Black and Hispanic participants reported a higher willingness to use LAI-PrEP than their White counterparts, at 54%, 59% and 52% respectively. This study indicated that future interventions to optimize education on LAI-PrEP is needed among the groups that would benefit the most from it, namely Black SMM.

CAB-LA Implementation Barriers

Despite CAB-LA's approval, it has been difficult to implement it in clinic settings including PrEP and sexual health clinics for several reasons.(15). First, CAB-LA requires more frequent clinic visits, every two months for injections and laboratory testing, compared to quarterly visits for oral PrEP. This poses a challenge to patients who confront accessibility barriers previously discussed such as lack of transportation, lack of childcare, and inability to time off work(12, 31, 65). Second, CAB-LA PrEP care requires HIV viral load testing every two months, per the CDC PrEP guidelines, which is not currently available in all clinics that offer PrEP in the US (20). Third, dedicated clinical staff and private clinic spaces are needed for injection administration, which may strain the established clinic's workflow and resources. Forth, as the health insurance coverage billing processes for CAB-LA are new, they are constantly changing over time and significantly vary across regions. Hence, significant administrative and pharmacy time is needed to navigate the system to procure the medication and minimize out-of-pocket costs for patients. (37, 66, 67).

Home-Based CAB-LA PrEP Care

Offering CAB-LA as part of a home-based PrEP care may help increase its uptake among the groups that may benefit from it the most . This will require modifications of the system's clinical flow, as it will require bimonthly home visits for IM administration of CAB-LA and venous phlebotomy for HIV RNA testing. (20). Understanding the opinions of current home-based oral PrEP care users is essential to guide the adaptation process, encouraging user-centered design, enhancing acceptability and uptake, identifying implementation challenges, and facilitating continuous improvement (11, 40, 66, 68-70). Gathering the opinions of SMM is crucial to optimize appropriateness and acceptability of CAB-LA delivery methods and will provide invaluable insights to guide the implementation process effectively.

Chapter 3: Manuscript

Development of a Home-Based Pre-Exposure Prophylaxis Care Delivery System for Long Acting Injectable Cabotegravir: A Formative Exploration of Patient Preferences

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ABSTRACT

Background
CAB-LA – the only FDA-approved injectable PrEP – is effective and has the potential to address PrEP inequities impacting Black and Latino SMM. Uptake of CAB-LA may require the development of innovative care delivery strategies, including home-based settings.

Objective
We aim to explore SMM perceptions on a future home-based CAB-LA PrEP care service delivery which will serve as guidance for the adaptation of an existing home-based oral PrEP system into an intervention that includes injectable PrEP.

Methods
We conducted 14 IDIs on SMM ages 20-29 who were current or prior participants of a clinical trial evaluating the efficacy of a home-based system for oral PrEP care (PrEP@Home). We explored their overall acceptability of a home-based injectable PrEP system, communication preferences, and specific pre-visit, in-visit, and post-visit logistics.

Results
The home-based CAB-LA delivery system was preferred by 11/14 participants. We identified that convenience and comfortability impacted the overall acceptance of the home-based system. Factors influencing acceptability included clinical teams' affiliation with a healthcare system, a two-person team with certified credentials, and being able to verify the staff's identity. Logistical preferences included preparation information for the visit, flexible scheduling hours, and text message communication for user information. Concerns to privacy, safety, and potential costs were also identified.

Conclusions
Our findings demonstrate the acceptability of home-based injectable PrEP delivery systems among SMM and highlight influencing factors of acceptability, logistical considerations, and concerns for implementation. These insights can inform future implementation methods for CAB-LA and

contribute to the adoption of a home-based delivery system ensuring equitable access to injectable PrEP.

Keywords
HIV prevention; home-based care; SMM; CAB-LA PrEP; Patient Preferences

INTRODUCTION

Background

PrEP is an effective and safe biomedical strategy to prevent HIV (71). Up until 2021, there were only two approved PrEP formulations (F/TDF and F/TAF), both oral (20). Efficacy of oral PrEP is closely related to adherence to daily intake (5-7). In 2021, CAB-LA was approved by the FDA as the first long-acting injectable PrEP medication approved for at-risk adults and adolescents (13). Unlike daily oral PrEP, CAB-LA is injected IM in the buttocks every two months, after two monthly loading doses (20). CAB-LA was found to be superior to F/TDF in the HPTN 083 and 084 study (13, 14). Its superiority may be related to its ability to bypass adherence-dependent efficacy, especially among Black SMM.

New HIV infections have seen a decline overall, particularly among white SMM. However, the infection rates among Black and Latino SMM have remained stable and continue to be higher than those of other racial groups (2). Significant racial and ethnic disparities in PrEP uptake and adherence exist, rooted on structural racism, poverty, and stigma (8-12). These include limited transportation, stigma, and competing priorities. Innovative strategies for non-clinic CAB-LA administration are urgently needed to better target SMM who are disproportionately impacted by HIV.

To address these disparities, home-based PrEP delivery care has been developed. Siegler et. al developed and launched the PrEP@Home project, a pilot test of a home-based system of oral

PrEP care delivery to overcome clinic-based related barriers to PrEP uptake and persistence (16, 58). A majority of the participants reported overall acceptability of the PrEP@Home model and 85% would use PrEP@Home kits instead of clinic visits. Additionally, more than one-third of the participants stated that if the PrEP@Home system was available, they would be more likely to continue PrEP use.

Including CAB-LA to a home-based PrEP care delivery system may help to increase PrEP accessibility to Black and Latino SMM, as it will address some of their social/structural barriers to accessing PrEP. Development and implementation of home-based CAB-LA PrEP services will require significant adaptations of clinical flow used for home-based oral PrEP. To do this, we need to explore the perspectives of SMM to guide the adaptation process.

Objectives

The objective of this project is to explore SMM's opinions on a future home-based CAB-LA PrEP care service delivery, including overall acceptability, communication preferences, pre-visit, in-visit, and post-visit logistics. To achieve these methods, we conducted 14 IDIs with past or current PrEP@Home SMM participants. Results from these IDI will serve as preliminary data to develop a home-based CAB LA PrEP service delivery that responds to the community's needs and preferences.

METHODS

Study Population and Recruitment

We conducted 14 semi-structured IDIs with SMM ages 20-29 between March and May 2022. Participants were current or prior adult research participants of the PrEP@Home study. Eligibility criteria included 1) male sex at birth, 2) had a minimum of 1 anal sex partner within the last year, and 3) able to understand and communicate in English. Trained research staff contacted eligible

participants in the PREP@HOME study to invite them to participate in the IDI and, for those who were interested, scheduled a date and time for their IDI. Interviews of a convenience sample were held until data saturation was reached. Verbal informed consent was obtained immediately prior to starting the IDI. The COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines were followed for study reporting (72).

Ethics Approval

This study was approved by the Emory University Institutional Review Board (IRB: IRB00096594).

Study Procedures

IDIs were conducted in English and led by one female interviewer V.C, who was trained in qualitative research. Interviews were used to explore complete context of individual opinions based on personal experience (72). Participants were interviewed using Zoom (Zoom Video Communication), a secure video conferencing service. We developed an IDI guide that addressed the following 4 domains 1) overall acceptability of a future home-based CAB-LA PrEP care delivery system, including thoughts on having an injection done at home versus in a clinic setting 2) preferences on pre-visit logistics such as scheduling appointments, methods of communication, and preparation instruction 3) home visit logistics regarding details of staff arrival and appearance, location and setting of medication administration, and characteristics of medical team and 4) post visit logistics targeting best methods for follow-up communication. Each IDI lasted approximately 30 minutes and was audio recorded. Once the IDI was completed, participants received a $75 stipend for their participation.

Data analysis

The digitally recorded IDI audio files were transcribed and deidentified prior to analysis. All interview transcriptions were uploaded to MAXQDA 2022 (VERBI Software, Berlin, Germany),

a qualitative software package. We used a modified version of grounded theory as our approach for coding and qualitative analysis. The major steps of the analysis included processing the data, developing codes, identifying themes, and refining the thematic relationship. Two members of the research team (J.G and W.H) reviewed two transcripts to construct preliminary codes using inductive and deductive coding methods. The research team met to discuss the preliminary codebook until inter-coding agreement was fulfilled. The rest of the transcripts were independently coded, and the results were brought together to discuss discrepancies and resolved with a third researcher (V.C). The codes were then analyzed into different themes. The research team interpreted the themes to inform the design of a home-based CAB-LA PrEP care delivery system. Descriptive statistics were used to analyze participants' baseline sociodemographic characteristics.

RESULTS

Participant's Characteristics

The mean participants' age was 24.3 years (20-29) and 92.9% (13/14) identified as cisgender men. Of all participants, 42.9% (6/14) were Black and 85.7% (12/14) identified as non-Hispanic. At baseline, 71.4% (10/14) had private/HMO insurance and 85.7% (12/14) were currently using PrEP. (Table I).

Main themes

Four main themes related to a home-based CAB-LA PrEP system were identified: 1. Overall acceptability, 2. Factors that would increase acceptability, 3. Logistical preferences, 4. Concerns

1. Overall acceptability of a home-based CAB-LA PrEP system

Of all participants, 11 would prefer the home-based CAB-LA PrEP system over a clinic- based care and 3 would rather use the clinic-based setting. Participants listed *convenience* and

comfortability as the two main factors impacting the acceptability of a home-based strategy for CAB-LA.

Convenience

Nearly all participants (13/14) voiced that a home-based CAB-LA PrEP system would be more convenient than a clinic-based CAB-LA PrEP system as it would be immediately accessible to them, eliminate patient transportation barriers, and allow more flexibility in scheduling appointments, and decrease the odds of missing a dose or needing to go to a pharmacy to get their medication refilled.

"The home-based system is always more convenient. It makes things more accessible, especially in terms of transportation and I think a home-based system would be great, especially since the injectable PrEP would be less frequent, so you don't need to worry too much about consistency or breaks in terms of getting a prescription refilled, or whatever the case may be."

IDI participant, Black, age 22

Comfortability

Of all participants, 11/14 felt comfortable with a home-based CAB-LA system. The participants who preferred a clinic-based setting (3/14) believed that health related procedures should be kept in a clinic setting, were uncomfortable allowing medical professionals to visit their homes, and have the medication administered in their home. They noted that administering an injection at home may be perceived as unprofessional, as this procedure is meant to be conducted in a clinic. One participant also mentioned that the home-based setting becomes more personal and may affect the patient-doctor relationship.

"I don't know. It just seems strange to – not strange, but I think it would just be better to have that take place in a setting where it would normally take place. I can't think of any other

injection or vaccine or anything that you would take like that someone would be administering at your house."

IDI participant, Black , age 24

2. Factors that would increase acceptability of home-based CAB-LA PrEP service

Participants described several characteristics of the clinical team that would increase their level of comfort with the home-based system. They also listed methods to verify the clinical team's identity, which would increase their acceptability of the home-based system.

Clinical team characteristics

Participants reported that clear signs showing that the home-based clinical team is affiliated to healthcare system would optimize their level of comfort as this affiliation would increase its perceived legitimacy. When prompted about preferences related to the clinical team's attire, they all considered that professional clothing, namely scrubs or healthcare-branded garments would be necessary.

"Yeah, just so it seems like more legit, as opposed to someone just coming in like a tee-shirt and jeans, and they're gonna pull out a needle to – you know what I mean?"

IDI participant, Black, aged 24

Other signs that would optimize comfort included the staff driving a new-looking vehicle and visible vehicle signage of a healthcare institution.

"They have that branding, right. It gives people a sense of comfort knowing that this person showing up to their house is well-established and credentialed and kind of vetted."

IDI participant, White, aged 26

The clinical team was proposed to be staffed by two medical personnel, including one EMS driver and one clinician. All participants found the two-person team to be acceptable. Most participants (11/14) felt comfortable with two team members entering their homes, three participants enforced it would ensure safety for both the patient and the medical team in case of an adverse reaction, while two participants preferred that only the clinician enters the house, for privacy concerns.

"*That is a very good idea, because if someone is there to provide the safety of the nurse and the other person – the person who is getting the injection and the blood draw - but also the fact that if something was to go wrong you have trained medical care there, and someone can do the care and the other person call for an ambulance, extra help if something was to go wrong."*

IDI participant, White, aged 28

Receiving home-based care by team members with certified healthcare credentials was also listed as a factor that would increase comfortability. Notably, three participants described how they would feel more at ease knowing that the person administering the CAB_LA injection is a skilled medical professional. In addition, participants who initially felt hesitant about having two people in the house for the visit became less hesitant knowing that the second team member was also a healthcare provider (an emergency medical technician).

"[…]whether it's a registered nurse or just like, you know, maybe a – how would you call it, like a health care professional. I guess it would depend on like the type of person that would be doing it, for me at least. […] I would want to know more about the person itself.

Interviewer: So would you feel more comfortable if it's a nurse?

Interviewee: I would, yes, because they probably have a little more knowledge."

IDI participant, Asian and White Mixed Race, age 23

Lastly, three participants said that having the same team members for every visit would increase the level of comfort.

Staff identity verification

All participants agreed that knowing and being able to verify the staff's meeting identity would increase the acceptability of the home-based system. Identity verification methods listed by participants included: 1. staff wearing an ID badge, 2. matching the ID badge with the staff member information provided by text message or mobile app, 3. ensuring communication leading up to the visit.

"I would imagine that the app would have some sort of face pic and a name on there and just some sort of confirmation […] if the person sends a message ahead of time saying, "Hey, I'm in your neighborhood," or whatever, […] like an automatic message sent by whatever tracking app. You know that the person is nearby, so you're expecting them, and if you can look at a picture and you can see through window or people, once the person knocks on the door and states their name, that should be sufficient."

IDI participant, Black, age 23

3. Logistical preferences of a home-based CAB-LA PrEP system

We identified the following subcodes: 1. Necessary information in preparation for the visit, 2. Flexible scheduling hours, and 3. Preferences on communication methods

Necessary information in preparation for the visit

All participants discussed the importance of clear communication preceding the visit to optimize their level of comfort with the system. Days before the visit, participants would like to receive general information about CAB-LA for PrEP, about how to prepare their home for the visit, including the area in the home where the injection would take place, potential care of pets, visit's date and time, duration and procedures of the visit, and potential medication side effects.

"Telling them how much space you need, what would be the most ideal situation, […] you need access to this, this should be here. If you have pets, put them in another room, […] if they're going to come into your home for whatever reason […] they tell you, "We'll be coming at this time on this date. Please put all pets away. Please do this." […] anything that is pertinent information, definitely have that listed ahead of time. […] if they need access to something other than your physical being. Like, does it need to be in a bathroom, because you need to have access to a sink. Or, does it need to be somewhere where you adequate enough space to stand or sit or –... whatever would be needed for them to adequately do their job."

IDI participant, Black, aged 24

On the day of the visit, 11 participants described how they would like to receive information confirming the appointment, the names of the staff members conducting the visit and establishing estimated time of arrival (ETA). Parallels were drawn by three participants with current food delivery or rideshare services communication strategies, where real-time information is provided to users.

"So when I get deliveries, so I'll get like a message from the app just over text; they'll send me an SMS saying "Your driver is on their way." And then after some time they will give me an update saying that my driver is approaching. And then usually after that time whoever is

delivering my food will come over to my door, or if they're having a hard time finding my place they'll call me on my personal phone and then I get to speak with them over the phone and guide them towards where I live."

IDI participants, Black, age 21

Flexible scheduling hours

Less than half participants (5/14) suggested having flexible appointment hours and various appointment window slots to accommodate participants' work or school schedule, including evening and weekend hours. A group of four participants also noted that having flexibility in scheduling appointments would allow for rescheduling or canceling on short notice.

"*So for me I think the most beneficial times, and this is the tricky part, I think is probably after 5:00, at least for my own personal schedule, and also having access to the weekends. Weekends because I think for the most part people have slowed the schedule, you have a larger window that they can actually get their PrEP administered."*

IDI participant, Black, aged 24

Several participants (6/14) outlined different potential scheduling challenges of the home-based system. These challenges include the staff being late to the patient's home due to traffic or from responding to a medication reaction, ensuring enough appointments and capacity for high demand, and patients forgetting to schedule or remembering they have an appointment after 2 months.

Communication methods

Most participants (12/14) reported that they would prefer to receive communication related to scheduling, appointment reminders, staff arrival updates, and ETA alerts through text messages,

as they already use them daily, are easily accessible to them, and makes communication more efficient. For urgent matters such as an unexpected medication side effect or a medical concern, or for personal conversations, most participants would prefer to have the option of calling the clinician directly.

"*So there's something very immediate about text messaging that I feel like would be really convenient reminders in text messaging, just having like a one-on-one kind of conversation with someone over text."*

IDI participant, Black, aged 24

Opinions on the use of a mobile app for communication were mixed. Although all participants had previously used the PrEP@Home research mobile app to schedule appointments and to receive reminders and updates, they were able to provide some feedback about its use. More than half of the participants (10/14) described factors that render the use of the mobile app difficult, including not receiving notifications through the app, having to manually log in every time one uses the app, and having to reset the password multiple times.

"*I would say the app would be better so long as notifications are automatically sent out. I think that's very important because I have many times not received notifications from the PrEP despite not changing settings. Like I've never disabled notifications. […] just the fact that you have to log in every time is a little frustrating, so it made me less inclined to use it."*

IDI participant, White, aged 20

Fewer participants (4/14) highlighted the benefits of using a mobile app as a "one-stop shop" where all home-based CAB LA PrEP–related communications could be done and suggested making edits to the app to optimize its functionality.

"*Mobile apps are great like anywhere where it can all be like a one-stop shop where you can schedule, reschedule, cancel, talk, message, anything where it can all be in one place would be the most helpful. … Like an app."*

IDI participant, Black, aged 22.

4. Concerns about a home-based CAB-LA PrEP system

Participants discussed concerns related to privacy, safety, and potential costs.

Patient privacy

Out of the total of 14 participants, six individuals voiced their concerns about other people (including roommates or neighbors) finding out they are on PrEP as a result of their engagement with a home-based CAB-LA PrEP services. Additionally, four other participants reported that although they personally did not worry about people knowing their PrEP use; they acknowledged that it could be a concern for others who would use the home-based system. To ensure patients' privacy, the signage in vehicles and staff members should remain general and not include any specific language about PrEP.

"I have friends who probably wouldn't be comfortable with that, especially if people are trying to take care of themselves and trying to get in PrEP. But they don't want anyone to know they're on PrEP because of the stigma associated with it or something like that..."

IDI participant, White, age 26

Less than half of the participants (5/14) had hesitations about using their bedrooms for injection administration, as it's the most intimate place of their homes, and would infringe the privacy of their bedroom.

"Yeah. I just think that – it's difficult to explain, but there's almost something very personal about a bed and a bedroom. It's similar to the idea that when you invite guests over having them sit on your couch is no big deal, right? That's what couches are for. But if you were to invite someone over and they didn't have anywhere to sit and your bed was kind of the only place, it would just feel a little bit too maybe intimate or too personal or too close to invite a guest onto your bed."

IDI participant, Black, age 21

Safety

Safety was addressed by the participants in several ways. Half of the participants (7/14) discussed staff and patient safety with the home-based model. Additionally, four participants mentioned that they would like to make sure that the staff members were safe during the home visit.

"Yeah, I would say probably the biggest thing, obviously, is first off making sure it's a safe environment for the person that's coming so for the clinician. Things like securing pets and making sure that there's safe access to the residence and stuff like that is obviously the first thing that I think of."

IDI participant, White, age 26

There were three participants who mentioned patient safety in terms of maintaining the same healthcare standards applied in healthcare environments, during the home visits. Their main concern was that the staff maintain sterile equipment and antisepsis of the injection site prior to injection.

"I would care more when the shot's given, make sure they clean the area."

IDI Participant, White, age 23

Potential costs

Concerns that the home-based system may be more expensive than the clinic-based system were expressed by two participants. They feared that the service would be financially inaccessible.

"Now I guess probably maybe the cost maybe or the system would be more costly, whether it was like a nurse coming to your house or going to a clinic, I would say that would be a big factor. But I guess each situation is different. I would think higher-income people might be able to afford that, but I think lower-income people might not […]"

IDI participant, Asian and White Mixed Race, age 23

Table I: Demographic characteristics of 14 interviews for Project Homebased Injectable PrEP

Demographics	Participants N=14, n(%)
Age in years	
Age range	20 - 29
Age mean (SD)	24.3(±2.9)
Sex at birth (male)	14 (100.0%)
Gender Identity	
Male	13 (92.9%)
Gender non-conforming/non-binary	1 (7.1%)
Race	
Black	6 (42.9%)
White	7 (50.0%)
Mixed Race	1 (7.1%)
Ethnicity	
Non-Hispanic	12 (85.7%)
Hispanic	2 (14.3%)
Baseline [a] Insurance Status	
Uninsured	4 (28.6%)
Private/HMO[b]	10 (71.4%)
Monthly Income	
Unknown	1 (7.1%)
$0 - $1,666	3 (21.4%)
$1,667 - $3,333	4 (28.6%)
$3,334 - $4,999	3 (21.4%)
$5,000 – or more	3 (21.4%)
Baseline [a] PrEP[c] Status	
Not on PrEP	2 (14.3%)
On PrEP	12 (85.7%)

[a]Baseline: at the time of study enrollment

[b]HMO: health maintenance organization

[c]PrEP: pre-exposure prophylaxis

Table II: Thematic analysis

Themes and subthemes	N
Theme 1: Overall acceptability of home-based injectable prep	14
Convenience	14
Comfortability	13
Theme 2: Factors that would increase acceptability of home-based CAB-LA PrEP service	14
Clinical team characteristics	9
Staff identity verification	11
Theme 3: Logistical preferences of a home-based CAB-LA PrEP system	14
Necessary information in preparation for the visit	14
Flexible scheduling hours	14
Communication methods	14
Theme 4: Concerns of a home-based CAB-LA PrEP system	12
Patient privacy	13
Safety	10
Potential costs	2

DISCUSSION

Principle findings

This formative qualitative study addressing SMM's perspectives of a home-based CAB-LA PrEP system identified four main themes: overall acceptability factors that would increase acceptability, logistical, preferences, and concerns. A home-based CAB-LA PrEP care was widely accepted, with most participants preferring it over a clinic-based setting, based on its convenience and how comfortable participants felt with it. Factors associated with increased acceptability of the home-based system included: healthcare affiliation of the clinical team and having a method to verify the staff's identity. Logistical preferences included the need for communicating preparatory instruction to the patient before the visit, allowing flexible scheduling hours, and using different communication methods for routine vs. urgent needs. A few participants voiced concerns associated with the home-based system were related to the infringement of their intimate space during visits, unintended disclosure of participants' PrEP use as a result of their engagement with the home-based system, ensuring participants' and staff's safety, and potential costs.

A few participants expressed concerns about the ability to maintain professional healthcare standards during home visits, especially when administering IM injections. This finding was unexpected and adds to the existing literature highlighting concerns regarding fear of injections and potential side effects associated with LAI-PrEP (73-75). These findings underscore the importance of addressing these hesitations before and during the home visit, to reassure participants that all healthcare standards used in clinic environments will be maintained during home visits.

Unlike prior literature suggesting that a more discrete approach may increase acceptability of PrEP interventions (68), most of our study participants expressed that a clear general healthcare signage of the home-visit vehicle and the staff's garments would increase the perceived legitimacy

of the provided services. In concordance with prior literature, a specific PrEP signage was discouraged. This finding highlights the delicate balance between maintaining privacy and establishing credibility in the context of PrEP stigma, providing valuable insights for the development and implementation of interventions that respect participants' privacy concerns while instilling confidence in the healthcare system.

During the exploration of logistical preferences for conveying essential information prior to home visits, participants made an interesting connection to popular mobile apps used for food delivery or ridesharing. They drew parallels between these apps' real-time communication features, such as ETA messaging and ongoing updates, and suggested incorporating similar methods in the context of home visits for healthcare services. Mobile apps have been shown to be accepted and valuable in PrEP uptake, especially among young SMM (28, 36, 46, 76). These findings highlight the need to optimize the functionality of healthcare-related apps to meet the real-time communication capabilities and intuitive features of frequently used commercial apps.

Limitations

There are several limitations of this study. First, the study participants represented a small convenience sample from the Prep@Home study. It is possible that participants who had a positive experience with PrEP@Home study were more inclined to participate in the IDI, creating a possibility of selection bias. Second, all IDI participants had either been on- or were on oral PrEP, so they were all familiar with the general concepts related to PrEP. Opinions on a CAB-LA PrEP care service, its acceptability, and concerns about it may be different among individuals who have never been on oral PrEP. Third, all participants were cisgender men, so our results may not be representative of transgender, nonbinary, and intersex individuals who engage in anal sex. Fourth, all participants lived in metro-Atlanta, most had access to healthcare, and were English speakers.

Moreover, some people who were comfortable with the home-based system were working from home. Thus, results from this study may not be generalizable to all areas of the U.S where PrEP access may differ, to people who can't work from home, or to non-English speakers. The inclusion of a diverse population, with half of our participants being non-white, helped to mitigate potential bias and provided a broader perspective on the acceptability and concerns surrounding a home-based CAB-LA PrEP system among racial and ethnic minority communities.

This study is the first formative evaluation of an innovative home-based system for CAB-LA PrEP. The study serves as the foundational guide for the development of an adaptation plan to integrate CAB-LA into a home-based PrEP care intervention. Many studies have explored home-based care barriers but seldom explore preferences of potential future users prior to the implementation of an intervention. Future steps will include developing the CAB-LA PrEP care intervention and conducting a pilot test with a limited number of participants to identify logistical issues and refine study procedures. Subsequently, a randomized controlled trial will be conducted to compare home-based vs. clinic-based CAB-LA PrEP care in terms of HIV prevention efficacy, medication adherence, persistence in PrEP care, safety, and cost-effectiveness. If found efficacious and safe, a home-based CAB-LA PrEP care model could be implemented in public health departments and in PrEP services integrating oral and injectable PrEP.

Chapter 4: Conclusion & Recommendations

CAB-LA is still not available globally but there is a desire for low-cost PrEP outside of the U.S. Many settings abroad have experience with non-PrEP regimens. Using those methods can be applied in home-based services. While our study focused on the U.S, the findings provide valuable insights into the preferences of SMM regarding at-home service delivery of CAB-LA PrEP, underscoring the significance of incorporating the perceptions of key populations. Although the considerations for implementation will vary worldwide, the insights from our study may guide future research and considerations for the adoption of differentiated PrEP service delivery systems globally.

The Global AIDS target for 2025 is to ensure that of the individuals at risk of HIV acquisition, 95% have access to options for HIV prevention (77). To achieve this goal, choices for effective HIV prevention options must be expanded. LAI-PrEP has shown high demand and acceptance not only in U.S. but potentially exceedingly more in other countries (78). The World Health Organization (WHO) has provided recommendations for CAB-LA service delivery, emphasizing its integration with other PrEP options and healthcare services tailored to individual needs and local contexts (77). Differentiated service delivery (DSD), informed by key populations, can mitigate barriers and optimize CAB-LA rollout by integrating home-based systems with other delivery in low-resource settings overcoming implementation challenges.

The acceptance, coordination, and sustainability of an integrated system combining these methods are vital for success. Integrated health services enhance convenience, privacy, and overcome barriers, but implementation science is necessary to ensure appropriateness and effectiveness. In conclusion, integrating home-based delivery systems with other healthcare elements and

considering marginalized communities' needs through DSD is crucial for the successful implementation of CAB-LA PrEP.

Further research is needed to assess the effectiveness of integrating CAB-LA with other PrEP services in diverse global settings, involving key populations in research efforts. Understanding the perceptions, regulatory restrictions, and training barriers of PrEP providers in different countries is crucial. Policy changes and standardized health training can maximize the potential of home-based systems administered by pharmacists and CHW, alleviating strain on healthcare capacity. Providing PrEP through various service delivery strategies can facilitate the effective implementation of CAB-LA outside traditional clinic settings, mitigating resource constraints.

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Appendices

Appendix I: Semi-structured Interview Guide

IDI guide

Hello, thank you for being here today. My name is Valeria Cantos, I am an Emory doctor and researcher, and I work with Dr. Aaron Siegler on the PrEP@Home study. As you may already know, the FDA recently approved a new injectable medication for PrEP called cabotegravir. It works for PrEP just like Truvada® or Descovy®. The difference is that it's given intramuscularly (in the buttocks) every 2 months instead of taking a daily pill. We are preparing a new project where we would integrate the administration of this medication into the PrEP@Home model. In other words, we would come to participant's homes to give them their shots every 2 months and we would also draw blood. We would like to hear your thoughts on how this process would look like. You will notice that I will start recording the conversation. This conversation will last for approximately 30 minutes. Do you have any questions before we start?

I. **Opening question (5 min)**

1. What are your thoughts on home-based injection of this new PrEP medication compared to doing it in a clinic?

Probes

- Which setting would make you feel more comfortable? Why?
- What concerns do you have about home-based injections?

II. **Pre-visit logistics (5 min)**

1. What preferences would you have around scheduling a home care visit in terms of hours?
2. How would you prefer to communicate with the team about scheduling your visits? (Through the app vs. Text. Vs. Phone call vs. Other?)
3. What instructions should we give people to help them prepare their home for our visit?

III. **Visit logistics (10 min)**

1. On the day of the visit, how would you like us to let you know we have arrived? (knock on the door, text message, through the app, other?)
2. What type of car would you prefer them to drive?
3. What type of signage would you want the car to have? (Emory, another healthcare system, no signage at all)
4. How would you want the person arriving at your home to identify themselves?
5. We are thinking of having two-person teams to ensure the safety of staff and participants. What are your thoughts on this?
6. What areas of your house would you prefer to receive injections? How would this work? Any concerns about this?

IV. **Post visit logistics (5 min)**

1. Currently, we have an app where people can follow-up with any questions for providers. What are your thoughts on using this as a main way to communicate with your provider after your visit?

V. **Closing (5 min)**

We are almost nearing the end of our conversation, is there something else you think we need to prepare for before we launch this? Any other comments or suggestions before we finish?