Evaluating the state of Wisconsin's HIV prevention program, PrEP Navigation: a multi-method study

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DEDICATION

I dedicate this work to the thousands of lives lost to the HIV/AIDS epidemic.

“ACT UP! FIGHT BACK! FIGHT AIDS!”

“Gay! Straight! Black! White! – Same Struggle! Same Fight!”

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ABSTRACT

Background: The HIV epidemic continues to be a national public health crisis, with more than 1.2 million individuals living with HIV and roughly 1 million at risk of contracting HIV in the United States. A vital component of ending the HIV epidemic is preventing new HIV infections, by increasing access to prevention services. However, one of the most effective prevention measures, pre-exposure prophylaxis (PrEP), is widely underutilized. PrEP Navigation has been an innovative evidence-based intervention that been widely accepted and adopted throughout the U.S., including in the state of Wisconsin, to increase access to and use of PrEP.

Objectives: This study aimed to (1) identify PrEP use and prescribing difference in the state of Wisconsin, (2) identify how PrEP Navigation is overcoming barriers to PrEP access and care in the state, and (3) identify how the program needs to improve to be effective at increasing PrEP uptake and adherence in the state.

Methods: PrEP use and prescribing differences were explored by conducting secondary data analyses on all-payers claim data provided by AIDSVu and WHIO. Linear regressions were performed to understand the effect of PrEP use in the state, and logistic regressions were performed to understand the use and prescribing relationships between Truvada and Descovy among various characteristics. Semi-structured interviews were conducted with patients on PrEP in the state, both in the navigation program and receiving care elsewhere. Using the PrEP Continuum of Care Model, interviews identified barriers and facilitators to the PrEP care process (awareness, uptake, and adherence). Semi-structured key informant interviews were conducted with the state Navigators to understand their unique experiences navigating clients in PrEP care. Utilizing the Practical, Robust Implementation and Sustainability Model interviews identified the contextual predictors of the navigation programs outcomes (PrEP use).

Results: PrEP use is increasing in the state, however racial/ethnic disparities persist. Truvada for PrEP use was found to me more likely among females and individuals residing in rural counties and prescribed by infectious disease providers. Descovy for PrEP use was found to me more likely in younger/middle-aged patients and prescribed by primary care providers. Various barriers and facilitators were identified by patients on PrEP. Importantly, having a navigator was valued in overcoming persistent barriers to PrEP use and adherence. PrEP Navigation has demonstrated to be sustainable and successful at linking and adhering individual vulnerable to HIV to PrEP care. However, the program needs to onboard more navigators and expand its services across the state to increase its effectiveness at increasing PrEP uptake and adherence in the state.

Implications: This study provides the state's Department of Health Services HIV Prevention Unit with a comprehensive program evaluation for the PrEP Navigation program, while also demonstrating PrEP use and prescribing trends that can be useful to consider when improving and expanding the program.

INTRODUCTION

Despite advancements in biomedical and scientific research that have led to the development of various successful HIV treatments, prevention strategies, and improved care for people living with HIV, the HIV epidemic continues to be a national public health issue**.** As of 2021, about 1.2 million people are living with HIV in the United States, and it is estimated that about 13% of them are unaware of their HIV status.[1] Although new infections are gradually decreasing, there are more than 36,000 new diagnoses annually, with the prevalence of HIV continuing to disproportionately affect gay and bisexual men and Black/African American and Hispanic/Latino individuals.[2] Preventing new HIV transmissions is vital to ending the epidemic. Unfortunately, there have been significant increases in the rate of new HIV infections among subpopulations, including people aged 13-34, people who inject drugs, and transgender women who have sex with men.[1,2]

One preventative measure that can be taken by individuals at risk of HIV includes the use of pre-exposure prophylaxis, commonly referred to as PrEP. PrEP is a biomedical treatment that HIV negative individuals take before coming into contact with HIV that prevents an infection from occurring (via blocking an enzyme called HIV reverse transcriptase, preventing HIV from coping and reproducing its genetic material and entering the body in the first place).[3,4] It is offered as a daily oral tablet (Truvada or Descovy) or as an intramuscular injection every two months (Apretude) that has been clinically proven to decrease HIV transmissions by 75-99%.[3,5] Individuals that could benefit most from taking PrEP include those populations that are at highest risk of contracting HIV; gay and bisexual men, Black/African American and Hispanic/Latino populations, people who inject drugs, and transgender women who have sex with men.[1,2]

Although PrEP use has drastically increased since its first availability, uptake remains low. It is estimated that about 1.2 million individuals have indications for PrEP use in the United

States, yet only 30% of them are being prescribed and taking it.[6] There are various barriers contributing to low PrEP uptake, such as the lack of awareness of PrEP and HIV risk, accessing a PrEP provider, affording a PrEP prescription and its required follow-up care, and adhering to the complexity of the drug therapy regimen.[7]

In response to these ongoing health disparities in HIV, the United States Department of Health and Human Services launched the *Ending of the HIV Epidemic Initiative: A Plan for America* (EHE) in 2019, which is an extensive plan that aims to reach a 90% reduction in the number of new HIV infections by 2030.[8,9] The strategic initiative prioritizes four main pillars: *diagnose* all individuals with HIV as early as possible, *treat* HIV infection rapidly and effectively to achieve sustained viral suppression, *prevent* at-risk individuals from acquiring HIV infection, and *respond* quickly to potential HIV outbreaks to get prevention and treatment to those in need.[9] Specifically, the EHE initiative leverages the scale up of PrEP as a critical component in preventing new HIV infections, and seeks to address barriers preventing successful PrEP uptake by raising awareness among eligible populations through targeted interventions, decreasing financial burden related to drug costs, and implementing PrEP clinics to provide care.[10]

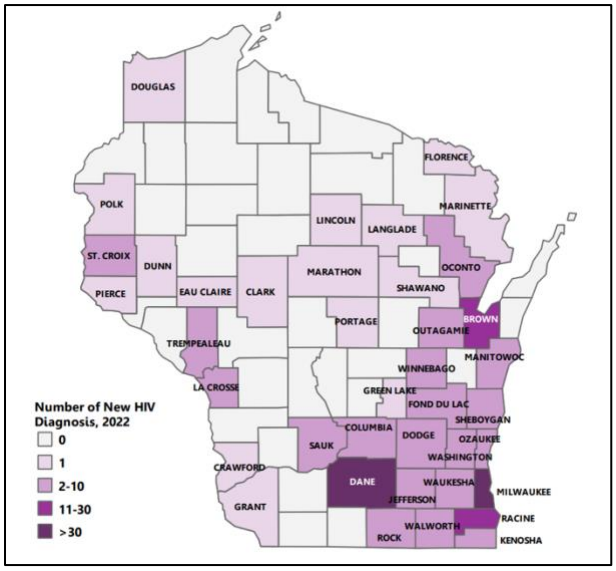

Figure 1. Geographic distribution of new HIV diagnosis in the state of Wisconsin in 2022

Although HIV largely impacts states in the south, HIV continues to be a concern in the state of Wisconsin (Figure 1). As of 2022, 7,310 individuals were living with HIV in Wisconsin and 289 people were newly diagnosed.[11] Trend data presented in Figure 2 shows the state is currently seeing the highest spike of new HIV cases in the past 10 years, and there have been substantial increases in HIV among subpopulations such as people who inject drugs, and young Hispanic men who have sex with men and transgender women of color.[12] People of color only make up 20% of the state's population, yet they account for 70% of new HIV diagnosis annually, demonstrating a large racial and ethnic disparity present in HIV incidences in the state.[11,12]

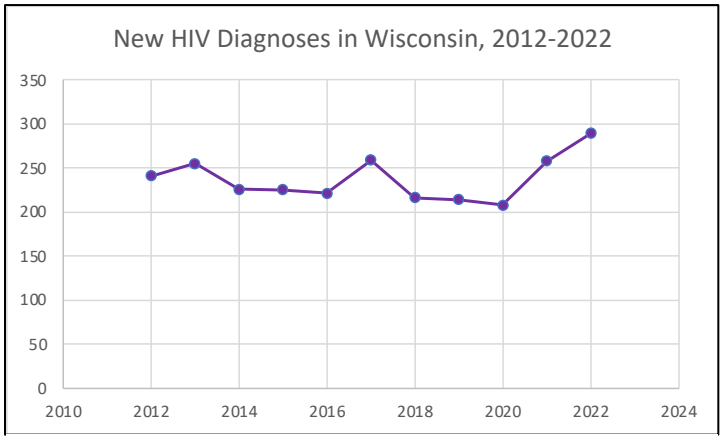

Figure 2. New HIV Diagnoses in WI from 2012-2022

While Wisconsin is not identified as a high-risk state for HIV, nor are they a partnered state in the EHE initiative, Wisconsin Department of Health Services (WDHS) has already begun to incorporate versions of the four EHE strategies to end HIV transmissions throughout the state. Specifically, WDHS launched an Integrated HIV Prevention and Care Plan: *Envisioning an End of the HIV Epidemic.*[13,14] This plan highlights key objective and strategies to achieve four main goals: (1) prevent new infections, (2) increase access to care and improve health outcomes for people living with HIV, (3) reduce HIV-related disparities and health inequities, and (4) achieve a more coordinated response to the HIV epidemic. Expanding access and utilization of PrEP has been identified as a key strategy to help achieve a reduction of new HIV infections. Within this plan, the scale up strategy identified for PrEP includes growing

the number of service providers offering PrEP, providing support to help people pay for PrEP, increasing PrEP adherence, and providing medical follow-up (Table 1).

Table 1. PrEP strategies and activities outlined in the Integrated HIV Prevention and Care Plans (2017-2021 and 2022-2026) to reduce new HIV infections.

Goal: Reduce New Infections	
2017-2021 Strategy: Pre-exposure Prophylaxis (PrEP)[13]	
Activity A: Expand availability of PrEP	• Maintain updated policy & procedure recommendations for WI providers who are dispensing or considering dispensing PrEP. • Maintain a regular working group of clinicians, providers, and community key informants to assist providers in developing and maintaining an effective PrEP program in their practice, and to look at issues of community access and attitudes about PrEP. • Assist providers in developing & supporting "wrap-around" services to increase the success of PrEP adherence (e.g., prevention case management). • Collaborate with family planning and STI providers to expand provision of PrEP.
Activity B: Increase Knowledge of and referral to PrEP in HIV/STI testing and HIV Partner Services	• Assist HIV testing programs in developing PrEP referral policies and procedures, as well as client-level tools such as PrEP screening checklists. Provide online & in-person training to HIV testing and care staff about PrEP and ways in which clients can be educated and encouraged to consider PrEP. • Ensure policies are inclusive of PEP (post-exposure prophylaxis) for clients where this is more appropriate than PrEP. • Create resources to inform primary care providers about PrEP, the availability of PrEP, and client referrals for PrEP.
2022-2026 Strategy: Expand and improve implementation of proven HIV prevention interventions including PrEP[14]	
Activity A: Expand PrEP awareness	• Expand awareness of PrEP among primary care clinicians, including proper billing and coding procedures to ensure that patients are not charged for clinical services, labs, or PrEP medications.
Activity B: Increase implementation PrEP	• Increase implementation of PrEP, including alternative PrEP options, such as the long-acting injectable and "on-demand" dosing, and other options currently being researched and developed.

Since the launch of the Integrated Plan in 2017, numerous PrEP-specific actions have been implemented (Table 2), including a statewide PrEP summit to educate physicians and providers in Wisconsin on PrEP, PrEP referrals through an HIV testing program in select Walgreen pharmacies, TelePrEP to expand access to PrEP for people living in rural areas, and PrEP provider expansion.[15,16]

Table 2. PrEP-specific actions taken in the state of Wisconsin since the launch of the Integrated Plan in 2017

Action/Intervention	**Description**	**Outcomes**
PrEP Navigation (2018-present)	Trained navigators assist clients in accessing, starting, and adhering to and retaining in PrEP care	7 agencies (clinical settings, AIDS services organizations, STI clinics, and community-based organizations), 10 Navigators, serving 10 counties. Roughly 1,500 clients served as of 2023.
TelePrEP (2021-present)	Vivent Health began offering PrEP services through telemedicine in northeast Wisconsin to increase access to PrEP for people living in rural areas that would typically need to travel long distances to a provider.	Not available.
PrEP Navigation and Adherence Workshop (2021)	The HIV Prevention Unit collaborated with Midwest AIDS Training and Education Center (MATEC) of Wisconsin and Washington University to offer a PrEP Navigation and Adherence Workshop.	The workshop focused on key updates to PrEP financing and shared tools to support clients facing barriers to PrEP adherence.
PrEP Provider Expansion (2021-present)	MATEC provided training and technical assistance to the Healthfirst Network so they could begin offering PrEP services. The Healthfirst Network is a family planning provider with clinics in nine counties of central and northern Wisconsin. This expansion increases PrEP accessibility in rural parts of the state and helps reach clients who may not have known PrEP was an option for them.	Healthfirst Network is offering PrEP services in the following 9 counties: Adam, Langlade, Marathon, Juneau, Lincoln, Portage, Sauk, Taylor, and Wood.
PrEP Referrals (2018-2019)	The HIV Program partnered with select Walgreen pharmacies, in high-risk neighborhoods of Milwaukee, to launch an HIV testing program. Pharmacists provided free, one-minute HIV tests and referred patients respectively to care or prevention.	Pharmacists counseled and referred 142 patients to PrEP care services. Unfortunately, due to the coronavirus pandemic, the program was paused and has not since been picked back up.

PrEP Summit (2018)	The Midwest AIDS Training and Education Center-Wisconsin (MATEC) and the Wisconsin HIV Program hosted a PrEP summit to educate physicians and providers in the state on PrEP and expanding access to PrEP services.	40 providers/physicians attended

The key intervention being deployed in the state involves the PrEP Navigation program. The long-term goal of PrEP Navigation is to increase the use of PrEP among individuals vulnerable to HIV to aid in decreasing HIV incidence. PrEP Navigation consists of trained "navigators" that assist individuals vulnerable to HIV in accessing PrEP care with as few barriers as possible.[17-20] PrEP navigators are involved in the PrEP Continuum of Care cascade, which describes engagement in key steps required to start and continue PrEP.[21] First, navigators identify individuals who are at risk of HIV infection, and screen them for PrEP eligibility. Individuals diagnosed as HIV-negative are referred and linked to a PrEP provider to start a PrEP regimen. Those diagnosed HIV-positive are referred and linked to an HIV-health care specialist. Navigators aid their clients by supporting retention in care and adherence to PrEP, with the goal of having clients maintain a HIV-negative health status. PrEP navigators uphold multiple roles and responsibilities, including educating clients, assisting in insurance, and accessing financial assistance, attending provider appointments, and linking clients to additional support services (Figure 3). Along with supporting clients on the proper and consistent measures of accessing, starting, and adhering to PrEP, navigators are key to identifying solutions to barriers that prevent individuals from engaging in their health care. Ultimately, navigators are there to support their clients in choosing the most fitting HIV preventative measure for them.

Figure 3. Navigator Workflow

There are a total of 10 navigators in the state, serving 10 counties. PrEP Navigation has been implemented in seven agencies within Dane County and Milwaukee County in the past four years, where HIV prevalence and incidence are highest in Wisconsin. Yet, PrEP is still being underutilized in these areas and throughout the state.[22] In 2017 (pre-implementation of PrEP Navigation) only 10% of individuals that had indications of PrEP (i.e., at risk of HIV) were utilizing this medication. A year later, post-implementation of the PrEP Navigation program, 15% of persons with indications of PrEP were using it state-wide. This increased to 20% in 2019 before it decreased to 16% in 2020, which is likely explained by the coronavirus pandemic. PrEP utilization again increased to 22% in 2021.[22] Although data trends indicate marginal but steady increases in PrEP use post-implementation, a large gap in PrEP uptake remains. As of 2022,

there were an estimated 14,000 individuals in the state considered at risk of contracting HIV, and only 26% of those individuals are being prescribed and taking PrEP.[22]

This prevention program in Wisconsin has been an active intervention for six years, however, the program has not undergone a formal evaluation to understand its impact in the counties and communities that it is serving. A large gap remains in reaching and assisting those at risk of HIV in the state; research shows at least 75% of those with PrEP indications are not engaged in preventative care. Therefore, the objective of this research is to evaluate the PrEP Navigation program by identifying these gaps in PrEP care in the state of Wisconsin, and whether the program is aiding in overcoming these gaps in care. Specifically, this study aimed to answer the following research question(s):

(1) What PrEP use and prescribing disparities are present in the state of Wisconsin, and how can the PrEP Navigation program address/overcome these disparities?

(2) What are the barriers and facilitators to PrEP care in Wisconsin, and how is the PrEP Navigation program overcoming the barriers to care?

(3) What aspects of the PrEP Navigation Program needs improved to be effective at increasing PrEP uptake and adherence in the state?

LITERATURE REVIEW

This chapter will provide an overview of the field's foundational research that had guided this study. First, studies that explore PrEP prescribing and uptake trends outlining the PrEP disparities present in different populations and demographics at risk of HIV. Second, studies that demonstrate and pilot PrEP Navigation interventions/programs to increase PrEP access, uptake, and adherence. Third, outlining the barriers and facilitators to PrEP Navigation, both at the client and navigator levels. Finally, the implications of this study.

PREP DISPARITIES

The ongoing HIV epidemic in the United States is subject to health disparities. Although HIV incidences are gradually decreasing in the U.S., transgender, and gender diverse individuals, Black, and Latinx communities (including heterosexual and men who have sex with men) continue to be disproportionately impacted by HIV. Additionally, other subpopulations, such as adolescents and people who inject drugs (PWID) have an increased HIV prevalence. Unfortunately, these same key demographics are continually underrepresented in PrEP prescriptions. The follow provides a comprehensive overview of the literature that explores and demonstrates this disparity in PrEP, both at the national and state level.

Disparities Outlined at the National Level

There have been four national studies looking at PrEP uptake broadly across the country between 2012, when PrEP first became available, to 2021. The first was conducted to look at the use of Truvada for PrEP within the first two years. Flash et. al. examined prescription claims for Truvada from just over half of the pharmacies in the U.S. and found that 58% of Truvada users were male, and only 12% were younger than 25.[23] This study demonstrates that PrEP use was relatively even across gender for the first two years of its availability, however there was a significant decrease of PrEP use among females from 2013 to 2014 (e.g., 45% to 23%).[23] From

then, the Centers for Disease Control and Prevention conducted a longitudinal analysis using IQVIA data, which captures about 90% of prescriptions and all payers' claims dispensed from all retail pharmacies in the U.S. to look at PrEP uptake by gender, age, and race/ethnicity between 2014 and 2016.[24] Key findings from this analysis included that PrEP had increased by 470% in the study period, however a large gap of PrEP use remained between the number of persons with indications for PrEP and those who were prescribed it.[24] Specifically, this study demonstrated a disparity among women and racial/ethnic minorities. For example, by 2016, 95% of all PrEP users were males and among the 42% of users that had race/ethnicity available, 69% were White.[24] A final key takeaway from this study was that although the South region of the United States had accounted for over half of the countries HIV diagnoses, only 27% of individuals in the South were using PrEP.[24] By the end of the first quarter of 2021 (April), Chen et. al. found that the South had increased PrEP use, to account for 41% of all PrEP users in the U.S.[25]

Another way PrEP uptake and prescribing disparities have been examined across the U.S. has been through identifying PrEP-to-need-ratios (PnR), such as the number of PrEP users per the number of new HIV diagnoses. The smaller the PnR, the more unmet need for PrEP there is. PnRs can be identified at various levels, such as region, state and/or county, and even across different demographics, including age, gender, and/or race. In 2017, Siegler et. al. used a national prescription database to determine the fourth quarters prevalence of PrEP use (using HIV diagnoses from 2016). By the end of 2017, the United States PnR was 1.8, indicating that for every new HIV diagnosis, there were about 2 PrEP users.[26] Other key findings include the South having the lowest PnR (1.0), states with the highest concentration of African American residents had lower PnRs (1.5 vs. 3.0), the PnR for females was more than 5-times lower than males, and the prevalence of PrEP use was lowest among individuals younger than 25 and older

than 55.[26] Interestingly, this study provided state-level PnRs, and at the end of 2017, Wisconsin had a total of 630 PrEP users, with a PnR of 2.8.[26] In addition to understanding PrEP uptake needs, Doherty et. al. used PnRs to understand race and other social determinants of health (SDOH) associations with PrEP use, using AIDSVu.[27] This study found that along with race, many county-level SDOH indicators were associate with PnR, such as household income, housing cost burden, and insurance.[28] Specifically, that, U.S. counties with higher percentage of African American residents and uninsured residents had lower PnRs, and that counties with higher median household incomes had higher PnRs.[28] Both studies examining PnRs demonstrate racial disparities in PrEP uptake, and as Doherty et. al. further explains, county-level factors may be leading to disparate PrEP prescribing and uptake.

Other studies that have explored PrEP prescribing and uptake trends at the national level have done so by looking at trends among specific populations, such as people who inject drugs, transgender men and women, and veterans. Streed et. al. analyzed prescription claims data from 2010-2019 to estimate PrEP uptake among commercially insured persons with opioid or stimulant use disorder by injection drug use status (IDU). Among the roughly 548,000 commercially insured persons with an opioid and/or stimulant disorder, only about 110,600 had evidence of IDU, and less than 1% of IDU were using PrEP.[29] Although PrEP use is significantly low among people who inject drugs, the study did find that it had significantly increased among individuals with opioid and/or stimulant use disorders and IDU during the study period.[29] This study, specifically, demonstrates a disparity among PrEP uptake based on HIV-risk characteristic (e.g., people who inject drugs). Another specific population at high risk of HIV includes transgender men and women who engage in riskier behaviors (i.e., having unprotected sex with men and/or using drugs). Zarwell et. al. assessed PrEP uptake and discontinuation among a U.S.

national cohort of transgender men and women and found that only 17% had reported ever having a prescription for PrEP. Transgender men had a significantly greater percentage of PrEP use compared to transgender women.[30] Although PrEP discontinuation was high across the study population (49%), transgender women were more likely to discontinue PrEP use than transgender men.[30] A final study that investigated PrEP uptake at the national level, interestingly examined PrEP use and gaps in the veterans' health administration, from 2012-2016.[31] This study further demonstrates a racial/ethnic disparity in PrEP use. In 2016, 48% of all HIV-infected persons in care at the VA were Black, yet only accounting for 20% of the VA PrEP users.[31]

Nationally, PrEP is significantly increasing in use, which is a great step towards ending the HIV epidemic by preventing new HIV infections. However, as demonstrated by these studies, not every population at risk of HIV is being prescribed PrEP, despite being engaged in healthcare. For example, Chinbunchorn et. al. found that across the United States in 2021, health centers prescribing PrEP had higher portions of sexual, gender, racial, and ethnic minority patient populations compared to centers that are not prescribing PrEP.[32]

Disparities Outlined at the State Level

In addition to looking at PrEP trends across the United States as a whole, other studies have also examined PrEP prescribing and uptake at the state-level. In the current literature, there were 4 studies that conducted multi-state analyses and 12 studies that focused on a primary state of interest. From 2014-2017, there were three studies that looked at PrEP awareness and uptake among men who have sex with men (MSM) in roughly 20 U.S. cities and urban areas with the highest HIV prevalence/incidence, using the National HIV Behavioral Surveillance System.[33-35] Although PrEP awareness had increased 500% among MSM in the study period, only

approximately 1 in 3 men at risk of HIV reported using PrEP.[33,34] These studies also looked at age and race/ethnicity associations with PrEP use. Like national reports, although PrEP use had substantially increased among Black and Hispanic MSM, White MSM were significantly more likely to be using PrEP (even after controlling for income, health insurance, and region).[33-35] One of these studies specifically looked at PrEP awareness, discussing PrEP with their provider, and PrEP use. This study found that, again, White MSM were significantly more likely than Black and Hispanic MSM to report PrEP awareness (10% more likely), discussing PrEP with a healthcare provider (20% more likely), and using PrEP (20% more likely than Hispanics, and 40% more likely than Blacks).[35] The OPERA (Observational Pharmaco-Epidemiology Research & Analysis) cohort study, examined electronic health record data across 18 U.S. states to identify whether PrEP was reaching persons at greatest risk of HIV, and what population seroconversion was happening among.[36] Seroconversion, in this study, was defined by when an individual was HIV-negative and prescribed PrEP but then diagnosed HIV-positive throughout their time on PrEP. This study found that a greater proportion of younger individuals (aged 13-24), women, Black individuals, and IDUs were diagnosed with HIV than they were initiated PrEP – indicating under-prescribing of PrEP among these subpopulations.[36] Additionally, the highest incidences of seroconversion were among young Black men (twice as likely to convert than older Black men).[36] These multi-state studies further demonstrate the PrEP prescribing and use gap among racial/ethnic individuals that are at highest risk of contracting HIV. Furthermore, Kanny et. al. and the OPERA cohort studies underscore the need for further support in these vulnerable populations to initiate PrEP and then monitor adherence to PrEP.

One final multi-state study looked at prescribing trends between general internal medicine and family medicine physicians within a specific healthcare system (SSM Health).

From 2013-2021, there were just over 14,000 PrEP patients in the SSM healthcare system, and that there were 40% increased odds of PrEP prescribing among eligible patients per year.[37] This study also found that females and Black patients were less likely to be prescribed PrEP than their counterparts. The major finding from this study was that 83% of patients were first "diagnosed" as PrEP eligible among family medicine physicians, however being prescribed PrEP was significantly more likely among patients treated in general internal medicine verse family medicine. Additionally, only 1% of individuals received PrEP in the first year after being identified as PrEP-eligible.[37] This study not only further supports PrEP prescribing disparities among gender and race/ethnicity, but also demonstrates the under-prescribing of PrEP, especially among primary care.

Finally, there have been studies that have examined PrEP prescribing and uptake trends among primary states of interest, and/or specific cities or neighborhoods of highest HIV risk. These studies have also used a mixture of HIV case surveillance data, electronic health records, prescription data, and/or all-payers claims data to identify various PrEP gaps and disparities present in their states. Much like key findings presented by the other studies already outlined, common findings across these state-level studies include PrEP prescribing and use has significantly increased since 2012, however, patients being prescribed PrEP are significantly associated with being non-Hispanic white, cisgender men, and/or middle-aged/older.[38-49] Additionally, other subpopulations at high risk of HIV, such as PWID and transgender individuals, are less likely to be prescribed PrEP.[38,39,41,42,44,47] Although, women, Hispanics, Blacks, and injection drug users have been found to be more likely to discontinue PrEP use (when prescribed), they have also been more likely to reinitiate PrEP than their counterparts.[41,42] Most importantly, individuals linked to PrEP but not prescribed it are more likely to be

diagnosed with HIV after linkage, indicating missed opportunities for preventing new HIV infections.[43,47,48] This is especially true when the patient is seeking or asking for PrEP. For example, Patel et. al. found that in St. Louis, Missouri, nearly half of their study sample had asked for PrEP from their primary care provider but were not prescribed it, and although majority of patients were referred to another provider to receive PrEP, 20% were not.[43] While PrEP prescribing has predominantly been done by infectious disease clinicians and primary care providers, there have been recent expansion of provider and prescribing status among pharmacists. Havens et. al. piloted a pharmacy-led PrEP prescribing program in Nebraska, and similar prescribing trends are present regrading patient demographics being prescribed PrEP (i.e., predominately White men who have sex with men).[40] This study, although one of few to demonstrate other PrEP prescribers, demonstrates that PrEP prescribing across the board is disparate among populations that are disproportionately impacted by the HIV epidemic.

PrEP has been an available option for HIV prevention going on over a decade and has since had expansions to clinical guidelines and policies to increase equitable access to those at greatest risk of contracting HIV. However, as demonstrated by the ongoing literature in the field, PrEP prescribing and uptake disparities exist, and are impacting our racial/ethnic and gender diverse individuals disproportionately. In addition to these studies, the field has had an abundance of studies to explore why these differences in PrEP prescribing and uptake exist. Pleuhs et. al. provides a systematic review of barriers to PrEP prescribing, as outlined by the provider perspective, which includes a lack of PrEP knowledge, discordance in who should prescribed PrEP (i.e., HIV specialists vs. primary care), concerns about PrEP costs, concerns about behavioral and health consequences being on PrEP (i.e., riskier behaviors), interpersonal stigma, and concerns about patient adherence.[50] Despite these barriers, addressing this disparity

in PrEP prescribing and uptake is vital to ending the HIV epidemic. One intervention strategy that is being deployed in the United States to address PrEP disparities is by implementing PrEP Navigation programs to increase PrEP uptake and persistence among underserved populations.

PREP NAVIGATION

Navigation is a community-based services delivery intervention designed to promote access to timely care by eliminating barriers to care. It was first introduced as a promising and evidence-based practice in the field of cancer, where navigators assisted low-income women that were diagnosed with breast cancer to care services.[51] It has since been adopted by other chronic diseases, including HIV; first, to navigate HIV-positive individuals to HIV care and now, to navigate individuals at risk of HIV to preventative measures, such as PrEP.[52,53] In the literature of navigation, there are three common modalities: (1) patient navigators, (2) peer navigators, and (3) system navigators. These modalities of navigation are predominately offered in-person; however, they are beginning to utilize virtual platforms to extend navigation reach to clients in need of support and assistance in overcoming barriers to their healthcare needs.

Although navigation is widely utilized intervention strategy to increase access to healthcare, it is more recent in the field of PrEP. Additionally, in PrEP navigation patient navigators appear to be taking on the role of system navigators. Therefore, the following provides a comprehensive review of the PrEP navigation literature, including patient and peer navigators.

Patient Navigation in PrEP Care

Patient navigation is the most used modality, and includes a trained individual (i.e., community health worker, case manager, social worker, nurse, etc.) that links clients to health care services, address social determinants of health, and overcome the structural barriers and

complexities of coordinating care to meet individuals' needs.[53] These navigators are taking on the role of system navigators, which are specialized to assisting clients with health insurance and communicating with the multi-sectors of the healthcare system.[53] Patient navigators are implemented and disseminated across many settings such as health departments, community-based organizations, community health centers, sexual health clinics, and/or hospitals. Patient navigators can provide many services such as educating clients on PrEP, screening them for PrEP eligibility (risk-level for HIV, HIV & STI tests, etc.), referring and linking them to a PrEP provider, scheduling PrEP appointments (and accompanying them to the appointment, when needed), ensuring they received a PrEP prescription, referring and linking them to additional social services, and then providing on-going support to ensure clients are adhering to PrEP.

See Table 3 for an overview of the published studies that have implemented patient navigation programs. Note that most of the navigators hold the same/similar responsibilities across studies, however differing depending on the primary outcome of the program. Of the 18 programs/studies, ten had a primary outcome of PrEP uptake, four had a primary outcome of PrEP adherence, and four reported only on the barriers and facilitators of the program (which will be provided in the barriers & facilitators section, below, and outlined in Table 6).

PrEP Uptake

PrEP Navigation was first introduced in 2015, in response to the Center for Disease Control and Prevention's (CDC) 3-5 year multi-site demonstration project, Project PrIDE.[53,54] This project aimed to reduce new HIV infections, increase access to care, and reduce HIV-related disparities and health inequities by supporting health departments in implementing public health strategies to expand and enhance PrEP uptake. Project PrIDE was specifically implemented to reach and engage Black and Latinx men who have sex with men (MSM) and/or

transgender individuals in PrEP care. Of the twelve health departments across the U.S. that the CDC funded for Project PrIDE, five implemented PrEP Navigation programs (California[55], Chicago[56], Colorado[57], New York City[58], and Tennessee[59]). These navigation programs had an emphasis on PrEP uptake as the reported outcome of the program.

Another CDC demonstration project, THRIVE (Targeted High-Effective Interventions to Reverse the HIV Epidemic), was also launched in 2015, to support state and local health departments develop community collaborations to provide comprehensive HIV prevention and care services for MSM of color.[60] THRIVE was implemented in seven U.S. public health jurisdictions (Alabama, Baltimore, Louisiana, New York City, Philadelphia, Virginia, and Washington D.C.) from 2015-2020 and utilized PrEP navigation (a mixture of patient and peer) to increase the number of MSM of color to PrEP, again with the primary outcome being PrEP uptake/initiation.[61]

Following the CDC funded demonstration projects, additional patient navigation programs started being piloted throughout the United States. In 2016, Doblecki-Lewis et. al. conducted a randomized study on a passive verse active PrEP patient navigation on a diverse population in Miami, FL, to understand the impact on PrEP uptake.[62] In 2017, the Tennessee-PrIDE project expanded to include four other cities that demonstrated high HIV prevalence and incidence among the priority group.[63] Additionally, from the start of 2017 to the end of 2018, a sexual health clinic in New York City assessed the effect of having an intensive on-site navigation for linkage to PrEP.[64] Then, in 2019, two more patient navigation programs were piloted in New York City, one in a health department and the other in an emergency department, aimed to increase PrEP uptake.[65,66]

The major finding that was demonstrated across all studies, was that linkage to PrEP (i.e., clients attending their first PrEP provider appointment) was largely impacted by loss of follow-up between the time in which a navigator first engaged with a client to the time in which clients had their schedule appointment. Only five of the studies had a 50% or higher linkage rate, and the largest linkage rate was 63% which may have been influenced by having the opportunity of same-day PrEP initiation.[55,58,61,62,66] The THRIVE demonstration project found that individuals who received navigation services were 17-times more likely to be linked to a PrEP provider than those who opted out of navigation services.[61] A congruent finding from majority of these studies was that more than 50% of clients that attended their appointments, were prescribed PrEP.[55,57,58,64-66] Frank et. al. found that clients who received navigation services in co-located clinics (PrEP provider was in same location) were more likely to receive a prescription, which further supports the same-day PrEP initiation.[57,66] The Miami study did not find that active patient navigation had a significant effect on PrEP linkage compared to passive navigation, however percentages were higher in the active group.[62]

These study findings suggest that patient navigators should provide more support to clients following their initial engagement, and when available scheduling appointments closer to initiation of PrEP interest. Navigation programs should consider implementing navigators in the co-located clinics or associated with a specific PrEP provider, that may have availability to offer same-day PrEP appointments. A final takeaway from these studies is that PrEP navigation is feasible and accepted, therefore it should be considered as the standard of PrEP care.

PrEP Adherence

Once an individual is prescribed PrEP, the most important component of the PrEP care process is being adherent to PrEP. Therefore, one of the most important roles of a navigator is

ensuring their client is adherent to PrEP and retains in care. Four patient navigation studies have tracked/reported on PrEP adherence, all of which were piloted in 2018 or later.

In 2018, a community-based health center in Massachusetts piloted a navigation program to link and adhere homeless individuals at risk of HIV to PrEP.[67] Also, in 2018, a community-based health center in Mississippi piloted a program to link and adhere Black MSM to PrEP.[68] In 2019, a sexual health clinic that was co-located with a PrEP clinic in Louisiana, piloted a navigation program, specifically looking at the effect of navigator-client linkage (i.e., direct hand-off of client to navigator day of vs. navigator reaching out to client vs. client reaching out to navigator) had on linking to and then adhering to PrEP.[69] Then, in 2021/2022, New York and Philadelphia piloted a navigation program to engage, link, and adhere cisgender women at risk of HIV to PrEP.[70]

Two of the four studies reported linkage and adherence rates. The linkage rates for these two studies were fairly similar (39% and 42%), which is consistent with some of the studies that only reported on linkage rates.[63,64,69,71] Three of the four studies reported PrEP adherence at the 3-month mark, two of which had control groups. Reported adherence at the 3-month mark across these three studies were vastly different: 70% in Mississippi, 25% in Louisiana, and 11% in NYC/Philadelphia.[68,69,71] When compared to the control group, in Mississippi adherence at the 3-month mark was 62% more likely, whereas, in NYC/Philadelphia there was no significant difference.[68] As for adherence rates at the 6-month mark, the two studies found similar rates (44% vs. 37%).[67,68] The pilot in Mississippi found that clients were 38% more likely to be adherent to PrEP at the 6-month mark than the control group.[68] Another key finding from the Louisiana piloted program was that clients that were directly linked to the navigator on the day of their visit to the clinic were more likely to attend their initial PrEP appointment.[69]

Across all studies, the navigator facilitated/supported client adherence by on-going and consistent follow-up. For example, in the Massachusetts study was that there was high adherence among individuals that were homeless, which may be facilitated by street-based navigation: daily medication administration and follow-up appointments/check-ins.[67] In Mississippi, navigators were checking-in every other week with clients and ensuring clients attended follow-up appointments by providing reminders 1-week before, followed by the day before.[68] Then, in the NYC/Philadelphia study, clients received weekly text messages to support adherence.[71] However, loss to follow-up was still present in these studies, and can be explained by persistent barriers individuals may face while being on PrEP. Findings from these studies provide further support for training navigators to be in direct contact with their clients, and fully engaged throughout their entire PrEP care process.

Finally, there were three other PrEP patient-navigation programs that have been implemented in the U.S. (New York[72], Pennsylvania[73], and Florida[74]). These programs did not report quantitative metrics of the program, however they all reported barriers and facilitators to their programs that are explained below and outlined in Table 6.

Table 3. Overview of the Patient-PrEP Navigation Intervention/Programs in the U.S.

Author	**Location**	**Setting(s)**	**Priority Population**	**Services / Nav Workflow**	**Outcomes**
Andrade et. al.[72]	New York City, New York	Community-based organization & Community Health Center partnership	Latino MSM	CBO Navigator: determines interest in PrEP, PrEP education, connects client to health center navigator CHC Navigator assesses insurance status/need, schedules Telehealth or in-person appt with MD, follows up with patient	Quant outcomes not available Barriers & facilitators to program outlined in Table 4
Bazzi et. al.[67]	Boston, Massachusetts	Community-based organization	Homeless	Street-based outreach, PrEP education, rapid testing, assist in accessing prescription, supports referrals to other services, intensive follow-up	2018-2019 (2 year): Linked 239 individuals to PrEP services, 44% PrEP persistence at the 6-month mark (based on Rx refills)
Bonett et. al.[73]	Philadelphia, Pennsylvania	Health department & Sexual Health Clinic	Not specified	Community outreach, PrEP education, HIV & STI testing, rapid linkage to PrEP, on-site PrEP treatment	Quant outcomes not available, Barriers & facilitators to program outlined in Table 4
Brantley et. al.[63]	Tennessee (Memphis, Nashville, Knoxville, Chattanooga, and Johnson City)	Health department & Community-based organization	Black MSM and transgender persons (Memphis) not specified in other locations	Identifying clients, PrEP education, refer and link to a PrEP provider, scheduling appointments, provide transportation, ensure PrEP prescription is obtained, follow-up on PrEP adherence, ongoing case management	Jan - Dec 2017: 1385 PrEP eligible clients (94%) 700 accepted PrEP (51%) 463 linked to PrEP (33%) 378 prescribed PrEP (27%)
Butts et. al.[74]	Miami, Florida	Health Department	Not specified - located in resource poor and underserved neighborhoods	Mobile PrEP Clinic HIV & STI testing, PrEP education, lab monitoring, medication prescribing, on-going navigation/case-management	Quant outcomes not available Barriers & facilitators to program outlined in Table 4

Cheek et. al.[65]	New York City, New York	Health Department	Black and Latina Cisgender Women	PrEP education, insurance & financial assistance, refers and lines to PrEP provider, confirms attended appointment, attends appointments with clients, if necessary, confirms PrEP prescription, provides referral & linkage to other services (behavioral health, medical care, housing & food assistance)	Jan - Dec 2019 2,631 clients enrolled in program 70% MSM, 21% cisgender women 79% were Latina or Black 145 (26%) initiated PrEP Latina women who had unstable housing, but that were aware of PrEP were more likely to initiate PrEP Clients who received benefits navigation were more likely to initiate PrEP (64%) Latina women had significantly higher rates of initiating PrEP than white women
Doblecki-Lewis et. al.[62]	Miami, Florida	Not specified	Not specified	Enhance standard of care group vs. Patient navigation group Navigators provided PrEP education, discussed available resources in community for PrEP, supported & motivated clients in engaging in PrEP care	61 participants (31 in control, 30 in treatment) 53% of treatment clients saw a PrEP provider in the 12 weeks (vs. 32% of control) 40% of treatment clients started PrEP in the 12 weeks (vs. 29% of control) Percentages of PrEP were higher in treatment Did not find a significant difference between the groups in linkage to a PrEP provider or starting PrEP within a 12-week span Barriers & facilitators to

					program outlined in Table 4
Frank et. al.[57]*	Denver/Aurora, Colorado	Health department & Community-based organization	Black MSM and transgender persons	Supporting clients making informed decisions about PrEP, screened for PrEP eligibility, assisted clients to access available resources, referred clients to a PrEP prescriber, ensured they attended their appointments and received their prescription	Jan 2016 - Dec 2018 10,9111 screened 7,836 received navigation (72%) 6,193 eligible for PrEP (57%) 1,522 attended PrEP appt (25%) 1,483 received Rx (97%) Clients who received navigation services in co-located clinics were more likely to receive a Rx Clients who received payment assistance were more likely to receive a Rx
Goedel et. al.[68]	Jackson, Mississippi	Community health center	Black MSM	PrEP education, financial assistance, transportation assistance, developed personalized approaches to supporting goals and overcoming perceived barriers to PrEP, weekly check-ins for first month on PrEP, check-ins every two weeks subsequently up to the 6-month mark to facilitate connections to resources and support adherence	70% (21/30) attended 3mo follow-up, 62% more likely than control 37% attended 6mo follow-up, 38% more likely than control 80% purchased more than 1 Rx, 2x more likely than control 70% had greater than 80% days covered by Rx's, 3x more likely than control 67% used payment assistance programs, 2x more likely than control

Greene et. al.[56]*	Chicago, Illinois	Community-based organization, Community health centers, academic medical center/hospitals	Black and Latino MSM and transgender individuals	Outreach, referral and linkage coordination for clinical appointment, and follow-up support Services: screen and link to SDOH, HIV/STI & PrEP education, benefits navigation, patient advocacy, schedule appointments, provide medication adherence support	2017/2018 client survey results: 233 PrEP project participants, 95% reported very satisfied or satisfied with navigation services & rated the services as excellent or good Navigator barriers and facilitators outlined in Table 4
Kimball et. al.[61]**	Alabama, Baltimore, Louisiana, New York, Philadelphia, Virginia, and Washington DC	Health departments & Community-based organization	Black and Latino MSM	Mixed patient and peer navigators 3 sites required navigation, 4 offered navigation as optional Screened clients for service needs, provide education about services, referred clients to PrEP provider, assisted clients in scheduling and attending appointments, followed up with clients as needed	13,034 program-eligible individuals at THRIVE centers 11,878 (91%) were screened for PrEP 9,538 (80%) of those screened were eligible for PrEP 5,130 (54%) of those eligible were lined to a PrEP provider 3552 (37%) were known to be prescribed PrEP 4,895 (51%) used a PrEP navigator 55% linkage to PrEP among clients who used navigation services across the 7 sites Navigation users were 17 times more likely to link to PrEP than those who opted out of navigation services

Lillis et. al.[69]	Louisiana	Sexual Health Clinic & co-located PrEP clinic	Not specified	Triaged to navigator from SHC via 1 of 3 methods: warm hand off, HER message, and referred client to navigator via business card PrEP education, schedules PrEP appointments, answers question the client has about process	2,481 SHC patients available for PrEP 220 (9%) referred to the PrEP clinic 186 (85%) were seen by the navigator 114 (52%) scheduled an initial appt for PrEP 94 (43%) attended initial appt 55 (25%) attended follow-up appts Warm-hand off: 36 (16%) à 81% attend initial EHR message: 162 (74%) à 36% attend initial Card-only: 22 (10%) à 27% attend initial Navigator barriers & facilitators outlined in Table 4
Mahal et. al.[66]	NYC, NY	Emergency Department	Not specified	Sexual health education (including PEP & PrEP), HIV & STI point-of-care testing, schedules an appt with in-house HIV treat & prevent clinic, accompany clients if needed, scheduled follow-up appts, provided appt reminder calls	Jan - Nov 2019: 1,174 clients seen at SHC 111 (9%) clients were PrEP eligible 22 (20%) was interested in initiating PrEP 13 (59%) was seen same-day 11 (85%) received a PrEP prescription 8 (36%) did not show for their appt & 7 did not respond to calls to reschedule Client barriers outlined in Table 4

Parrish et. al.[55]*	California	Health Department & Community-based organization	MSM, transgender women, and people with alternative gender identities	Navigators screened for PrEP eligibility, referred, and linked clients to PrEP provider and then reviewed whether clients obtained, filled, and initiated PrEP	2015-2018 1090 clients screened for PrEP 1067 (98%) were eligible for PrEP 920 (86%) were referred to a provider 474 (52%) attended their first appointment 421(89%) obtained/received a PrEP prescription 410 (97%) filled their prescription 407 (99%) initiated/took the first pill of their prescription Barriers and Facilitators outlined in Table 4
Pathela et. al.[64]	NYC, NY	Sexual Health Clinic	MSM	PrEP education & counseling, HIV tests & results, benefits navigation, referred clients to an external PrEP provider, scheduled appointments, follow-up efforts to ensure clients linked to provider and received PrEP prescription, provided other referrals and services as needed (i.e., risk-reduction counseling, referrals to reproductive health services, behavioral & psychosocial services)	From 2017-2018: 2,494 individuals visited the SHC clinic (345 were already on PrEP, 43 were not offered navigation) 2106 were offered navigation services 1301 (62%) accepted navigation 1114 (86%) were navigated through the PrEP care process 628 (56%) accepted referrals (53% wanted more time to consider PrEP for them) 288 (46%) attended their PrEP appointment 235 (82%) were prescribed PrEP 465/628 (74%) had

					initiated PrEP navigation on the same day of their SHC visit
Pichon et. al.[59]*	Memphis, TN	Health Department& Community-based organizations	Black MSM and transgender women	Mixed patient & peer navigators at 5 locations (4CBOs & 1 HD) PrEP education, screened for PrEP eligibility - HIV & STI testing, refer and link to PrEP provider, schedule appointments, provide transportation to appointments, ongoing case management and follow-ups to ensure adherence	June 2016 - June 202: 2,777 clients identified as PrEP candidates In 2017: 724 clients were eligible for PrEP 304 (42%) accepted a referral to a provider 67 (22%) went to their PrEP appointment 15 (17%) was prescribed PrEP Navigator barriers and facilitators outlined in Table 4
Saleh[58]*	NYC, NY	Community-based organizations & Sexual Health Clinic	Black and Latino MSM and transgender individuals	Community setting: peer navigator (7) Community outreach, screened for PrEP eligibility, PrEP education, referred & linked to PrEP provider, follow-up for PrEP initiation Clinic setting (8): patient navigator (20 & 10 social workers) Triaged from clinic staff, PrEP education, benefits navigation, referred & Linked to PrEP provider, Follow-up for initiating PrEP	Sexual Health Clinic: Black & Latino MSM 284 screened 218 eligible (77%), 107 referred (48%), 54 linked (50%), 49 prescribed (91%) Community: Black & Latino MSM 368 screened, 355 eligible (96%), 68 referred (19%), 51 linked (75%), 27 prescribed (53%)

Teitelman et. al.[71]	NYC & Philadelphia	Not specified	Cisgender women	Counseling-navigator providers a 60-90 minutes 12-module education seminar: HIV/STI education, PrEP education, acknowledging facilitators & barriers to PrEP, PrEP-stigma in women, insurance & payment assistant programs Linkage to community-based PrEP care following initial session Test-messaging program to promote adherence Control group just received a PrEP packet that the navigator briefly ran through (5-10 min)	83 participants: 61 intervention, 22 control 79% Black, 26% Hispanic 3-month follow-up: 75 participants (54 intervention, 21 control) 45% had made appt to see a PrEP provider 39% attended an appt 13% were prescribed PrEP 11% started PrEP 11% intervention clients started PrEP 9% control clients started PrEP Non-significant difference between groups in engaging in PrEP care process Client barriers outlined in Table 4
*CDC Project PrIDE funded programs **CDC THRIVE funded program(s)					

Peer Navigation in PrEP Care

Peer navigators are trained role models, such as individuals in the community that share similar characteristics and identities to provide social support and guidance to help clients overcome barriers that may prevent engagement in care.[53] Peer navigators uphold similar roles and responsibilities as patient navigators, such as educating clients on PrEP, screening them for PrEP eligibility, referring them to a PrEP provider, scheduling appointments (accompanying, when needed) for PrEP and other social services, and following up with clients to provide on-going support for adherence to care. Aside from shared identities and characteristics, the main difference between peer navigators and patient navigators are the level of support/assistance they provide for benefits navigation (i.e., insurance and financial assistance).

See Table 4 for an overview of the published studies that have implemented peer navigation programs. Of the 5 programs/studies, one had a primary outcome of PrEP uptake, two had a primary outcome of PrEP adherence, and one reported only on the barriers and facilitators of the program (which will be provided in the barriers & facilitators section, below, and outlined in Table 6). The fifth study reported on referrals to various care services, one being PrEP.[75]

PrEP Uptake

A community-based health center located in two New York neighborhoods (Harlem and Bronx) piloted a peer navigation intervention to increase PrEP uptake among cisgender and transgender women with a history of exchange sex and/or substance use. A total of 52 individuals received the navigation intervention, however only 3 attended their initial appointment with a PrEP provider and none of them received a PrEP prescription.[76] Similar to patient navigation studies that focused on PrEP uptake, a significant impact on PrEP uptake is the drop-off of care from interest in PrEP to actually attending a PrEP appointment. Again,

suggesting that that navigators should provide more support to clients following their initial engagement, and when available scheduling appointments closer to initiation of PrEP interest.

PrEP Adherence

A separate community-based health center located in the Harlem neighborhood of New York utilized peer navigators to reach Black MSM and TGW in PrEP Care, and looked at the effective navigation has on PrEP adherence, verse standard of care for PrEP in their clinic. This pilot study did not find a significant effect on PrEP adherence between peer navigation verse started of care.[77] However, the other study that utilized peer navigation to look at the impact on adherence among the same priority population in California found that on-going support from navigators (i.e., text messages) was significantly associated with PrEP adherence.[78] Although this study did not utilize a control group, it does demonstrate that on-going navigation with clients can have a significant impact on PrEP adherence.

Table 4. Overview of the Peer-PrEP Navigation Intervention/Programs in the U.S.

Author	**Location**	**Setting(s)**	**Priority Population**	**Services / Nav Workflow**	**Outcomes**
Blackstock et. al.[76]	Harlem & Bronx, NY	Community-based organization/community health center	Cisgender and transgender women with a history of exchange sex and/or substance use	PrEP education, PrEP counseling to address attitudes about & behavioral intentions toward initiating, engaging, and taking PrEP, guidance on scheduling appointment, accompanying them to the appointment, assistance with transportation, assistance with subsequent appointment schedule (other social services), and appointment reminders	Two peer navigators (one cisgender & one transgender woman) 72 individuals were screened, 66 were eligible, and 64 completed the baseline survey 52 individuals received the intervention (46 cisgender and 6 transgender) 38 (73%) reported interest in PrEP 27 (71%) accepted aa PrEP appt offer 13 (48%) scheduled an appt 3 (23%) attended initial appt 0 received a PrEP prescription
Colson et. al.[77]	Harlem, NY	Community-based organization with a federally qualified primary healthcare provider	Black MSM and transgender women (TGW)	Education on HIV risk reduction, PrEP, PEP, local health services, referrals, etc.; helping participants obtain needed non-medical services (such as housing or employment); accompanying participants to appointments; and offering informal counseling about adherence, including their personal experience with PrEP, adherence tips and discussion of barriers to adherence; offered PrEP focused in-person & online support groups, and automated text message reminders	Enhanced PrEP adherence support (peer navigator) vs. Standard of PrEP care enPrEP: 101 individuals initiated PrEP, 67 (66%) attended 3-mo & 6-mo check-ins, 63 (62%) attended 9-mo check-in, and 69 (68%) attended 12-mo check-in sPrEP: 103 individuals initiated PrEP, 64 (62%) attended 3-mo check-in, 61 (59%) attended 6-mo check-in, 62 (60%) attended 9-mo check-in, and 63 (61%) attended 12-mo check-in Overall, self-reported adherence declined at each check-in and at the 12-mo check-in adherence was only 30% No significant intervention effect was observed

Hammack et. al.[75]	Louisiana	Community-based organization/community health center	LGBTQ+ community, people who inject drugs, Black cisgender, and heterosexuals	Community outreach, referrals to care, assistance with scheduling appointments to care/treatment (HIV, PrEP, SUD, etc.), HIV testing, referrals to other social services & resources as needed (employment, insurance, food assistance, housing, mental health, substance use, and other social determinants of health)., substantial follow-up assistance (as needed) and accompanying clients to appointments	5 community health workers (navigators) conducted outreach from Oct 2019 - Dec 2020: They had a total of 977 encounters and provided assistance and referrals to the following services - STI testing (356), health education (550), SSP (32), Primary care (32), HIV care (10), PrEP (14), Job readiness (11), mental health (6), insurance enrollment (14), transportation (9), HepC treatment (6), Syphilis treatment (4), PEP (1), other (64)
Reback et. al.[78]	Los Angeles County, California	Not specified	MSM and TGW	5-session peer navigation program (ASK-PrEP) PrEP education, assessed for PrEP readiness, assessed structural & individual barriers to PrEP, developed individual PrEP adherence goals with clients, referred and linked clients to support services (as needed): substance use treatment, mental health, housing, food, hormone therapy, care & counseling for intimate partner violence; provided on-going text message support for adherence (opt-in/out option)	Total of 187 clients (129 MSM and 58 TGW) Linkage to PrEP: 92% for MSM & 90% for TGW Adherence (90-day follow-up): 70% for MSM and 81% for TGW Text message support on adherence: 160 Total (112 MSM and 48 TGW) 86% were on PrEP at the 90-day adherence mark & were receiving support texts 61% were on PrEP at the 90-daay adherence mark & not received support texts 14% were not on PrEP at the 90-day mark but receiving support texts

Zamudio-Haas et. al.[79]	San Francisco, California	Community health center	Spanish-speaking transgender Latina women	TRIUMPH program - efforts to increase community-level PrEP awareness, increase empowerment around HIV prevention, and decrease PrEP stigma PrEP education, scheduled initial and follow-up appts, accompanied clients between clinical departments (registration, labs, pharmacy), outside-clinic navigation as needed (legal appts, supporting name change application, transportation to services outside the clinic), organized the monthly groups about health & wellness, organized larger culturally-informed social events focused around PrEP and larger outreach at local Latinx nightclubs and bars	3 trans-Latinx peer navigators Oct 2017 - March 2020 enrolled 185 transgender/gender diverse clients Quant data not available See Table 4 for client identified navigation facilitators/benefits

Table 5. Overview of the Protocols for PrEP Navigation Intervention/Programs in the U.S.

Author	**Location**	**Setting(s)**	**Priority Population**	**Patient or Peer Navigation**	**Services / Nav Workflow**
Bazzi et. al.[80]	Massachusetts	Syringe Service Programs	People who inject drugs	Peer	"PrEP for Health": 2 session intervention Sessions will cover PrEP uptake and PrEP adherence & persistence and then navigators will provide ongoing motivational interviewing and support for overcoming and coping with ongoing or new PrEP challenges for 3-months
Creasy et. al.[81]	Pennsylvania	TeleHealth	Criminally involved young adults (18-29)	Peer	e-Health enhance peer navigation program to refer and link criminally involved young adults to substance use treatment and PrEP services. Program involves 4 sessions: (1) program orientation, relationship building, and needs assessment, (2) substance use education & treatment cascade, (3) HIV and PrEP education and care cascade, (4) Scheduling appointments to substance use treatment & PrEP and goal setting Navigators will then maintain regular follow-up contacts with clients for the first 3-months in care

Edwards et. al.[82]	Los Angeles County, California	TeleHealth / Not specified	MSM and transgender women incarcerated or just re-entering society from incarceration	Peer	Mobile Enhanced Prevention Support (MEPS): PrEP and substance use treatment services Navigate individuals to PrEP uptake including finding a PrEP provider, being screened for PrEP, stat PrEP, and adhere to PrEP and remain on PrEP for at least 3 months. Navigators will follow-up with clients every week for the first 2 months, then do monthly check-ins and be available as needed from months 3-9. At the end of the intervention peers and clients will plan for successful transition to managing PrEP care on their own Similar navigation will be provided for substance use services and treatment
Goodman-Meza et. al.[83]	Five major US cities	Mobile Medical Unit vs. Community-based organizations	People who inject drugs	Peer	26-week randomized control trial to provide "one-stop" integrated health services supported by peer navigation to improve PrEP and medications for opioid disorder (MOUD). Both settings will be provided peer navigation. Services: screen for services, enroll clients in MOUD and PrEP services, peer navigation for 26 weeks to support ongoing care & adherence to treatments either through mobile unit or from community-based organization.

Martel-Laferriere et. al.[84]	Miami, Florida and Montreal, Canada	Opioid agonist therapy clinics (OAT) and Sterile Syringe Programs	People who inject drugs	Patient	Miami-Montreal HepC and PrEP trial: On-site care vs. Patient navigation to off-site clinics Screen for PrEP eligibility, those assigned to intervention arm (navigation) will be introduced to navigator to facilitate in linkage to primary care for PrEP, schedule appointment, arrange transportation, assist client in clinic registration or health insurance enrollment. Navigators will be required to have 5-personally tailored meetings (30-45 min) with clients to support ongoing health needs, such as linkage and referrals to substance use treatments and hard reduction services. Control clients will be integrated into PrEP and HCV care with adherence counseling in the OAT and SSPs venues by nurses, physicians, and counselors trained in PrEP and HCV treatment. These clients will receive 5 follow-up sessions over 6 months with care team to support ongoing treatment and adherence to PrEP
McMahan et. al.[85]	Seattle, Washington	Community health center & Pharmacy (with PrEP clinic)	Cisgender MSM and transgender people Methamphetamine users	Peer	Hit Me Up! Peer navigation vs. text messaging program to promote PrEP adherence. Participants are already initiated or initiating in PrEP, from one of the two sites. Peer Navigation: in-person meetings, appointment reminders, accompany appointments if needed, PrEP refill assistance, and follow-up check-ins about adherence Text messaging: 3 texts/day starting about the first day of the intervention, and discuss PrEP adherence and social/health services, HIV/STI prevention education, Meth-specific hard reduction tips, and/or drug injection hard reduction tips Initial protocol was evaluated by intended audience, see manuscript for feedback on intervention

Ramsey et. al.[70]	Northeastern U. S	Correctional facility & a Community-based PrEP care clinic	Women experiencing incarceration	Patient	Motivation Interviewing-Navigation (MI-NAV) Intervention: promoting PrEP uptake during incarceration and linking women to community-based PrEP care upon release Navigator will conduct needs assessment and use MI to explore PrEP interest, navigator will then schedule an appointment to initiate PrEP with a correctional-provider. Then 2-weeks before being released, the navigator will assess continuation of PrEP, discuss strategies to overcome barriers to PrEP in the community, and schedule and accompany the client to the community-based PrEP care clinic. Navigator will also aid with substance use services as needed. Ongoing navigation will continue for 6 months following release.
Ridgway et. al.[86]	North Carolina, Florida, and Illinois	Community health clinics	Black cisgender women	Patient	PrEP Optimization among Women to Enhance Retention and Uptake (POWER-UP): (1) routine PrEP education, (2) standardized provider training for identifying women who are PrEP candidates, discuss HIV risk and teach women about PrEP, and prescribe PrEP, and engage in PrEP care (3) EMR tools for identifying, prescribing, and tracking PrEP outcomes, (4) PrEP navigation to assist with PrEP initiation and persistence, (5) clinical champions for supporting the successful creation and implementation of the PrEP care process
Springer et. al.[87]	4 U.S. Communities	Mobile Health Unit vs. Community Based Organizations	Justice-involves persons	Patient	Patient Navigation vs. Mobile Health Unit Service Delivery to connect individuals to community-based HIV and substance use prevention and treatment services Patient Navigators: link participants to community-based providers Mobile Health Unit: clients will be provided integrated HIV and SUB prevention and treatment services

Stocks et. al.[88]	Los Angeles, California	Digital app	Racially and ethnically diverse sexual gender minority youth	Patient	PrEPresent digital navigation: 4 sessions (1) build rapport, introduce intervention, overview of navigator role, PrEP education, and needs assessment; (2) developing tailored linkage to PrEP plans, adherence strategies, supporting ongoing patient activation; (3) reviewing progress, follow-up and adjustments to tailored linkage to PrEP plan, adherence strategies, and supporting ongoing patient activation; (4) reviewing progress, intervention off-boarding, reinforcement of adherence strategies, and maintenance of patient activation; Weekly check-ins to ensure needs are being met, provide reminders, medication refills, and adherence support
Weber et. al.[89]	California	Online	Not Specified	Patient	PleasePrEPMe Online-chat Navigation program Bilingual (Spanish and English) navigators will help locate PrEP services, provide links to prevention resources, and support uninsured, insured, and undocumented clients with benefits navigation (insurance and financial assistance)

Although current literature is sparse on patient and peer navigation programs being implemented throughout the United States, PrEP navigation is a growing public health strategy in addressing PrEP uptake and adherence barriers. For example, there are currently 10 protocol papers on PrEP navigation programs intended to be implemented and disseminated throughout the U.S. (Table 5). Importantly, many of these are intended for priority groups that have yet to be studied in navigation programs but have an increased risk of HIV. For example, PrEP navigation programs/intervention to reach people who inject drugs, people who are incarcerated or newly re-entered society from incarceration, cisgender women with elevated risk of HIV, and youth with elevated risk of HIV. See Table 5 for an overview of these protocol navigation programs.

BARRIERS & FACILITATORS TO NAVIGATION

There have been various PrEP Navigation programs evaluated in terms of understanding barriers and facilitators that are faced by navigators and clients. There are distinctive challenges and advantages identified by navigators when providing services to their clients in linking them to PrEP and then ensuring they adhere and retain in PrEP care. Additionally, there are distinctive challenges and advantages identified by clients when seeking PrEP care. The following table provides a comprehensive summary of the barriers and facilitators identified in the current literature (Table 6).

The PrEP care process is outlined as a continuum, *the PrEP Continuum of Care*, and depicts all the necessary steps involved in linking and retaining in PrEP care: identifying an individual at risk of HIV as a PrEP candidate, screening them for PrEP interest and eligibility, referring them to a PrEP provider, linking them to the provider to receive a PrEP prescription, starting them on a PrEP regimen, and ensuring they adhere to and retain in PrEP care to maintain HIV-negative.[21] Therefore, there are numerous steps a navigator/client must take before getting

linked to, started on, and retaining in PrEP care; all of which have the potential for facing barriers and facilitators.

Barriers & Facilitators to the PrEP care process

The first step in the process of engaging clients in PrEP care includes identifying them as an individual that is at risk of contracting HIV (reaching them). One major barrier has been highlighted by navigators, related to reaching, or identifying, clients to begin their PrEP care process. Many PrEP navigation programs are being disseminated through organizations or clinics that are predominately providing HIV services, which can be very stigmatizing to individuals that do not have HIV.[59] There is a large concern that the individuals that navigators are supposed to be identifying, are not being reached because they are not visiting or associating their selves with the clinic/organization that the navigators are working for/through, due to the stigmatization of HIV.

Studies have identified many facilitators to addressing the stigmatizing clinic barrier, such as introducing a mixture of participating organizations/clinics to reach all potential clients and collaborating with community-based organizations that are already serving the intended audiences through other services.[56,59,90,91] Additionally, navigators identified the benefit of having widespread dissemination of PrEP information and their program services available to share through community organizations that are serving individuals at high risk (i.e., homeless shelters, drug detox shelters, methadone clinics, LGBTQ+ centers, etc.) in reaching individuals not yet enrolled.[67] Importantly, introducing potential clients to PrEP and the navigation services available through community advertising has helped clients self-identify to navigators as individuals that are not only at risk of contracting HIV but are also interested in receiving more information on PrEP and being navigated through the PrEP care process. Similarly, navigators

have stated that clients having prior awareness of PrEP and the services being provided in the community has been helpful in identifying and reaching them, also underscoring the value of community advertising.[56] Lastly, navigators from one study shared that an important facilitator in reaching clients includes working on-site, or in-person, at their respective organizations/clinics.[56] This is uniquely stated, because before the coronavirus pandemic, this would be without question in regards to how navigators would be serving their clients. However, as the world around us continues to adjust to and navigate through the ongoing change introduced by the spread of the coronavirus, such as organizations restructuring their workplace dynamics and expectations, navigators may still be working remote. Therefore, it is important to understand the pandemic influence of working on-site has on reaching and engaging individuals at risk of HIV in preventative care.

The studies show that client barriers and facilitators have also been assessed in terms of connecting with navigators to begin their PrEP care process. Like the highlighted navigator identified barrier above with identifying clients, clients have shared that the perceived stigma surrounding HIV has been a challenge for them to seek out preventative interventions/programs.[90] Other barriers include a lack of disclosure of risky behaviors (i.e., sexual and/or drug use history) during health appointments, and a lack of knowledge or awareness of PrEP.[92] Particularly a barrier of concern is individuals having a perceived low risk of HIV, especially if they are not currently involved in risky behaviors (i.e., sexually active or using drugs).[66,92,93]

Many client-identified facilitators to beginning their PrEP care process echo those that navigators find as advantages to identifying clients at risk. For example, clients have shared that having PrEP-specific clinics and organizations that are not linked to HIV services is beneficial in

overcoming self-perceived and social stigma surrounding HIV and receiving PrEP services as a preventative measure.[56] Additionally, clients also see that intensive outreach and navigation in the community, through community driven and targeted PrEP education and recruitment, as a facilitator to seeking navigation services.[67] Other facilitators that clients shared in these studies include training or recruiting navigators (as well as organization/clinic staff) that are friendly, informative, welcoming, and respectful, as well as being connected with a navigator of similar background, identity, and lived experiences.[56,59,90,91,94] Ultimately though, client self-advocacy and self-efficacy are the true advantages to seeking PrEP and navigation services.[92]

The next step in the continuum involves screening interested individuals for PrEP eligibility, which includes providing an HIV test and educating them on HIV risks and preventative measures available such as PrEP, and assessing their PrEP awareness and interest, and then counseling on any concerns the individuals may have.

The only shared navigator-level barrier involved in screening individuals for PrEP is private space constraints.[53,56] Many navigation programs are being disseminated through community-based organizations, for which may not have the organizational infrastructure to offer an entirely secure and secluded room for the navigators to discuss one-on-one with their clients. Although this concern has not been documented as a client-level barrier to the screening process, it has been shared that a facilitator to moving forward in this step in the PrEP care process involves the navigators providing a safe and secure space.[67]

Navigators have found that being culturally competent and providing client-centered services, including discussing PrEP in a non-stigmatizing manner, have been advantages to reaching clients in terms of educating and counseling them as well as being comfortable in taking an HIV test.[56,59] In fact, clients have shared that having an informed navigator during the

education and counseling session has been helpful in informing their decision to move forward with PrEP as the preventative measure for them.[56,91]

Additionally, navigators have emphasized that being patient with their clients is key to their engagement in PrEP care.[59] The first time a client meets with a navigator, they may be hesitant to take an HIV test, or even move forward with discussing their preventative options. Specifically, navigators should be mindful and patient because their clients may have previous negative interactions with healthcare systems, providers, or other health professionals.[59,62,91] It is important to remember that their clients are a part of a vulnerable population, and due to previous interactions in the healthcare systems they may anticipate similar negative interactions with the navigators and the navigation services they are providing.

Following screening, navigators will refer those that test HIV-negative to a PrEP provider, for which there is always the option for the client to accept or decline the referral. One of the largest challenges that navigators face in this phase of the process is assessing client readiness to move forward with a PrEP provider.[59] There may be times that an individual meets with a navigator with the intention of only taking an HIV test or taking a test and receiving information about prevention options, but without the intention of going beyond that. Additionally, clients may be overwhelmed by the information provided by the navigators and not ready to accept a referral, as they may want to take the time to process the information before deciding to move forward. Therefore, navigator patience and understanding are important in facilitating clients through the referral process. Another challenge with referrals includes the limited number of providers available that is willing to prescribe PrEP.[53,59] Therefore, it has been helpful for navigators, and the success of navigation programs, to partner with specific providers in the area or even work under a collaborative practice agreement with them.[56]

There have not been many documented referral-related barriers at the client level, however one includes that some clients may have a specific provider they want to be referred to – whether it be their primary care provider or a provider that they have heard highly of.[91] Although navigators may not always be able to connect clients to their preferred provider, clients have emphasized that the direct assistance and engagement by their navigators has been beneficial in accepting referrals and moving along the PrEP continuum.[56] Similarly, navigators find this as an advantage to clients accepting referrals, especially when navigators schedule their initial appointment for them.[53,59]

The Linking step of the process involves clients physically attending their scheduled appointment to receive a PrEP prescription, which may include additional lab testing that navigators may not be able to perform. Various barriers and facilitators have been identified in the literature by both navigators and clients to help begin to understand this drop-off in PrEP care. First, navigators have shared the concern that clients may be dealing with a social desirability bias; that is, accepting a referral without further intention to link with the provider, which is a difficult variable for navigators to measure when trying to understand discontinuation in navigation services and PrEP care.[64]

However, in some cases, a client's failure to link may just be due to scheduling barriers. For example, clients have shared that challenges with linking include the limited availability of desired appointment times, conflicts with work to meet scheduled appointments, or even the issue with prolonged wait times for an appointment (i.e., not getting into see a provider until a month out), while also facing prolonged wait times at appointments to see the provider.[59,62,91,93] Therefore, it has been an advantage for both clients and navigators to have the option of same-day PrEP appointments, which may be feasible if the navigation program is working under a

collaborative practice agreement or partnered with specific providers.[66,90,92] Additionally, clients may also be dealing with a transportation barrier.[62,64,90,91] Fortunately, most navigators can provide transportation services for clients to attend their appointments.[90] In fact, some navigators will even offer to take their client to and from their appointments, while also accompanying them during the appointment.[53,59,90,91]

Nonetheless, there is still the challenge of medical mistrust, anticipated negative interactions with providers, stigmatizing providers and clinics, and/or clients being uncomfortable talking to providers.[59,62,90,91] Navigators have also shared that clients experiencing medical mistrust has been a challenge for them to ensure their clients are attending their appointment with a PrEP provider. Specifically, some navigators have stated that advocating for their clients with medical mistrust has been a barrier for them.[53] Fortunately, navigators have found that establishing good rapport with the providers, by developing and maintain interpersonal relationships with them and the healthcare systems they are working within, has been beneficial to ensuring their clients are linked to a provider for a PrEP prescription.[59,67,68]

Once an individual is "linked" to PrEP care, then the individual must fill the provided prescription for PrEP and start the PrEP regimen agreed upon by the client and provider. There are many barriers faced by clients that keep them from starting PrEP. First, many clients are concerned about the short- and long-term side effects of the medication.[91-93] Additionally, many clients seeking PrEP may also be diagnosed with other chronic diseases. Therefore, there has been concern about the drug interactions between PrEP and their other chronic disease medications.[91]

Another major concern for clients starting PrEP involves financial barriers. Clients have shared concerns for medication costs and the complexity behind navigating insurance, or even

reluctancy to use insurance due to concern of parent/spouse notification, as reasons for not starting PrEP.[62,64,92-94] Additionally, navigators have shared concerns on their ability to assist clients with payment and coverage, especially if dealing with insurance company restrictions.[53,56,90] However, it has been documented by both clients and navigators that their direct assistance and engagement with insurance and payment assistant programs have been beneficial in overcoming many financial barriers.[53,56,90]

Other client-identified barriers to starting PrEP includes social barriers and fear of being adherent. Often, clients may not start PrEP due to fear that their family and/or friends will see that they are taking a medication, specifically a medication that is associated with HIV.[59] Until recently, PrEP was only offered as a once-daily pill, which is most effective when taken every day. Clients have shared that concerns surrounding adherence have kept them from starting PrEP in the first place.[67,92,93]

The ultimate facilitator, both shared by navigators and clients, to starting PrEP involves having same-day access to PrEP.[66,67,90,92] Specifically, offering a one-stop shop to PrEP care, where clients can meet with a navigator to be screened and referred, then meet with a provider for additional labs and a prescription, and follow-up with the pharmacy to fill the prescription – all in the same building.

The final action step along the PrEP continuum includes adhering to and retaining in care. This involves taking PrEP as prescribed (i.e., daily or every 2 months) and attending follow-up appointments for ongoing lab tests required for a prescription refill. Many challenges that clients face with adhering and retaining in PrEP care, are similar to those addressed above when linking to a provider and starting PrEP: scheduling, transportation, and financial barriers.[59,62,64,90-94] Additionally, clients have shared that the extensive medication regimen can

be quite exhausting, as PrEP requires more than just remembering to take a pill every day with the addition of quarterly labs.[67,92,93] Although being adherent and retaining in PrEP care can be challenging, clients have been able to identify tools to aid in adhering and retaining. Specifically, clients have shared that having medication reminder apps on their phones and medication logs have been successful to being adherent to PrEP.[92] Additionally, they have emphasized that having appointment reminders, independently, from their navigators, and from their providers have been helpful in retaining in care.[92] Again, highlighting the advantage of direct navigator assistance and engagement beyond the initiation of PrEP.

However, navigators have shared that client engagement can be very time consuming.[59,68] Often, navigators are juggling more than a dozen clients, that they are supporting with medical appointments and regimen adherence. Not to mention, navigators must build authentic relationships with each client for direct assistance and engagement to be successful. Without an established relationship between the navigator and client, the navigator's consistent involvement/follow-up could come off as bothersome to some clients. Nonetheless, navigators have recognized that establishing good rapport with their clients by developing and maintaining interpersonal relationships have been advantages to clients adhering and retaining in care.[53,59,67,68]

Additional concerns from navigators in ensuring their clients are adhering and retaining in care involves challenges to follow-up. Often, client discontinuation in PrEP care may be the result to a loss of follow-up, especially among clients that have limited or no modality of contact (i.e., cell phone, access to Wi-Fi or a computer, etc.).[56,91] However, navigators and clients emphasize the influence consistent check-ins (i.e., monthly) has on adherence and retention.[53,59] Navigators are aware of how their support and assistance with appointments (i.e., scheduling and

transportation) and adherence (i.e., consistent check-ins) is key to their clients retaining in PrEP care, and ultimately maintaining HIV-negative.

Table 6. Barriers and Facilitators to PrEP Navigation

Level	Barriers	Facilitators
Client	Perceived low risk Perceived stigma Low PrEP knowledge Lock of disclosure during sexual history/activity Anticipated negative interactions with provider Limited available PrEP providers Wanting to be connected to their PCP Transportation Limited availability of appointments Work-schedule conflicts with appointments Medical mistrust with providers Uncomfortable talking with provider Client privacy and confidentiality Financial concerns (costs & insurance) Concerns of side-effects Concerns of drug-interactions Extensive medication regimen Social barriers Stigmatizing social networks Fear of PrEP effect on fertility Focused on other co-occurring health conditions Accessing services outside of the provided community org that the program is being initiated in Housing insecurities Food insecurities Systemic issues/logistic barriers	Navigators of similar backgrounds, identities & lived experiences Community driven/targeted PrEP education Intensive outreach & navigation in the community Friendly, informative, welcoming & respectful navigators/program staff PrEP-specific/focused agencies/settings outside of HIV care clinics Self-advocacy Self-efficacy Informed PrEP education Navigators & providers providing a safe space Transportation to services Navigators accompanying to appointments Same-day PrEP appointments Same-day PrEP prescription One-stop shop Appointment reminders Medication reminders Benefits navigation (insurance & payment assistance) Direct navigator assistance & engagement throughout the entire PrEP care process

Navigator	Stigmatizing clinic (HIV-clinics) Private space constraints Assessing client readiness Limited number of PrEP-providers Social desirability bias to accept referral without intent to link Stigmatizing providers Advocating for clients with medical mistrust Assisting with payment & coverage barriers Insurance company restrictions Requirement of extensive relationship building with clients Time-consuming client engagement Supporting clients with medical appointments & medication adherence Following up with clients with limited or no modality of contact Client loss to follow-up Prioritizing self-care practices & emotional boundaries with clients Navigator turnover Restricted access to protected health information Clinic and staffing capacity Navigating social determinants of health influence clients involvement with PrEP	Having a mixture of participating orgs/clinics to reach all potential clients Program collaboration/rooted in an establish CBO serving the intended audiences through other services Widespread dissemination of PrEP information Working on-site/in-person with clients Client awareness of services Having shared experiences & identities, mirroring community diversity in program staff Discussing PrEP in a non-stigmatizing way Offering a safe space Practicing patience with clients Providing culturally competent & client-centered care Scheduling appointments for clients Accompanying clients to appointments Providing transportation services Establish good rapports with providers & clients Developing & maintaining interpersonal relationships with providers/healthcare system Navigating insurances & payment assistance programs with clients Same-day PrEP appointments & prescriptions Consistent & periodic client check-ins Supporting clients with medical appointments & adherence Maintain an organized client tracking system Case management skills Receiving feedback from clients Agency input on navigation process Technical assistance Assessing & utilizing preferred communication methods of their clients Motivational interviewing skills Staff buy-in Training/assistance/knowledge of resources on social determinants of health issues/insecurities Screening for social determinants of health Connecting clients to resources & services outside of PrEP

NAVIGATION IMPACT ON PREP-RELATED HEALTH DISPARITIES

Few studies reported on the impact PrEP navigation programs have had on known PrEP-related health disparities. However, those that did were focused specifically on the differences between race/ethnic groups and their engagement in navigation and ongoing involvement in PrEP care. These studies shared similar findings, such that Latinx individuals (MSM, transgender and/or cisgender women) were more likely to engage in navigation and be linked to a PrEP provider compared to Black clients.[57,61,63-65] Additionally, they found that Black clients were less likely than White clients to engage in navigation and be linked to a PrEP provider[57,61,63,64] Specifically, the Project PrIDE demonstration project across the 12 health departments (5 of which implemented navigation programs), found that Hispanics and Non-Hispanic others were more likely to be linked to a PrEP provider and prescribed PrEP than Non-Hispanic Whites, but that non-Hispanic Black persons were less likely to be linked and prescribed PrEP than Non-Hispanic Whites.[95] The THRIVE demonstration project reported that, across the 7 health departments that implemented navigation programs, there was no significant difference between race/ethnicity to PrEP screening and linkage.[96,97] However, they did find that non-White MSM (Black, Hispanic, Other/unknown) were less likely to be prescribed PrEP than White MSM.[96,97]

These differences between racial/ethnic groups to engagement with navigation, and starting PrEP, have been found to be associated with numerous barriers discussed (i.e., HIV/PrEP-stigma, perceived low risk, medical mistrust, other social determinants of health, etc.).[57,61,63-65] Although these studies report differences in PrEP care among racial/ethnic groups, they have demonstrated that these groups are reachable and capable of being engaged in PrEP care. However, future navigation efforts need to address these ongoing barriers to PrEP that

people of color are facing. Specifically, they need to consider the facilitators outlined from these studies to support ongoing efforts to increase PrEP uptake among these underserved populations as they continue to be disproportionately impacted by HIV.

PURPOSE OF PRESENT STUDY

Available literature has demonstrated PrEP prescribing and uptake trends across minority populations that are disproportionately being impacted by the HIV epidemic. Additionally, current literature has provided evidence of PrEP navigation programs increasing access to PrEP while addressing persistent barriers along the PrEP care process and highlighting navigation barriers and facilitators (both at the client and navigator level). However, a gap remains in understanding: (1) PrEP prescribing and uptake specifically in the state of Wisconsin, and (2) barriers to PrEP navigation in a real-world setting. Therefore, this study will be the first to:

1. Identify what PrEP disparities are present in the state of Wisconsin, and how PrEP Navigation has the potential to address them.
2. Provide a real-world evaluation of PrEP Navigation, and identify what barriers are consistent in the real-world setting and since these demonstration and pilot studies as PrEP has evolved.
3. Utilize a real-world “control”, such as looking at barriers and facilitators to the PrEP care process at individuals taking PrEP who received navigation verse those who do not.

CONCEPTUAL FRAMEWORKS

This section will discuss the conceptual frameworks utilized in this study, how they have been applied in the field of HIV prevention, and how they are applied in this study. This study was guided by two frameworks, the PrEP Continuum of Care Model and the Practical Robust Implementation and Sustainability Model.

PREP CONTINUUM OF CARE MODEL

The PrEP Continuum of Care Model (Figure 4) is a model that conceptualizes factors that depict the necessary steps in achieving protection from HIV with PrEP.[21,98,99] It was first introduced in 2014, by McNairy and El-Sadr, as a fundamental framework that emphasizes and illustrates each step in the spectrum of HIV preventative care that is necessary to decrease HIV acquisition and transmission.[98] The model was developed from the same theoretical approach as the HIV Continuum of Care (or HIV Care Cascade) and intended for similar measurements of care.

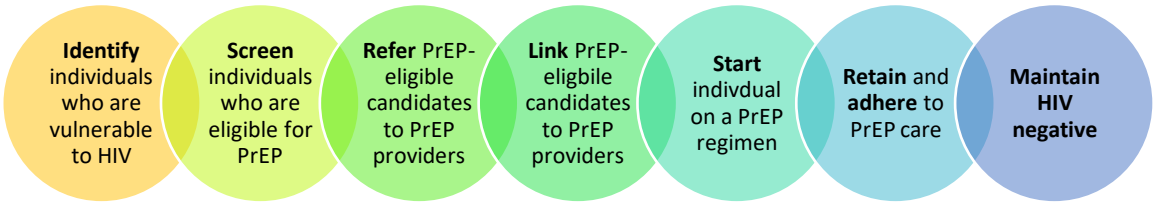

Figure 4. PrEP Continuum of Care (adapted by Nunn et. al. 2015)

McNairy and El-Sadr's model (HIV prevention continuum) includes four components: HIV testing, linking HIV-negative individuals to preventative services, retaining HIV-negative individuals in services, and supporting adherence to preventative services. Kelley and colleagues revised this model, coining the PrEP Continuum of Care Model, in 2015, to address specific barriers to PrEP effectiveness at the individual and population levels.[99] Kelley et. al.'s model

identifies four steps to achieving effective PrEP uptake: awareness/willingness to take PrEP, access to PrEP care, receiving a PrEP prescription, and adhering to PrEP.

Then, in 2017, the PrEP Continuum of Care Model was refined and revised by Nunn and colleagues to assess progress in PrEP implementation, including specific steps in uptake, adherence, and retention.[21] The necessary steps in PrEP care from initiation to maintaining HIV-negative include identifying and screening individuals at risk of HIV, referring and linking them to a PrEP provider, prescribing and starting them on a PrEP regimen, and retaining and adhering to PrEP care, to ultimately maintain HIV-negative. This version of the model has been a fundamental guide in the PrEP Navigation Program, facilitating clients along the PrEP care process.[17]

The model has since been modified by the Centers for Disease Control and Prevention (CDC) and advertised as a fundamental framework in the PrEP delivery system that includes the necessary steps for population health and HIV prevention with PrEP (Figure 5). The modified model composes of three main constructs: awareness, uptake, and adherence & retention. Awareness involves multiple levels/stakeholders, such that not only are populations of risk of HIV are aware of PrEP but that providers, public health officials, and the public at large are also aware of PrEP as an HIV preventative option. This construct then includes planning and implementing public health programs and services, educating populations and providers, and engaging individuals at risk in PrEP care. Uptake can be summarized by the process in which an individual goes through to start the medication. This includes linking to a PrEP provider, screening for PrEP eligibility (i.e., necessary labs and exams), being prescribed PrEP in a regimen that meets the needs of the individual and then, filling that prescription to physically start PrEP. Adherence & Retention involves how adherent the individual is in taking their

prescribed PrEP regimen and retaining in care, such as attending their follow-up labs (every 3-6 months) that are necessary for a prescription refills.

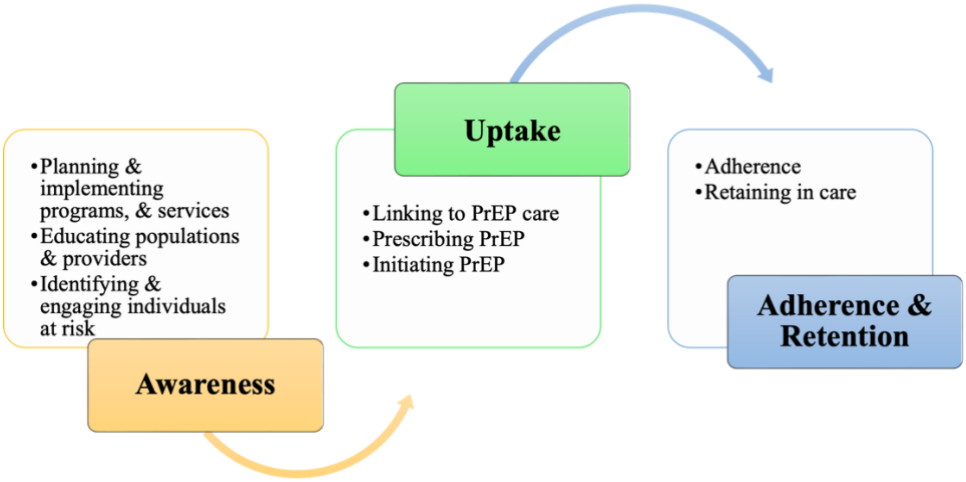

Figure 5. The Continuum of PrEP Care (adapted from the CDC modified version)

Additionally, the CDC has presented how this model can be applied to PrEP care being delivered in a clinical setting, as well as in a collaborative care setting. The PrEP Clinical Care Model (Figure 6), includes identifying and engaging patients in need of PrEP, conducting the necessary exams and lab tests to prescribe PrEP, and ongoing monitoring with follow-up visits and prescription refills. The Collaborative Model for PrEP Care involves national, state, and local levels of public health collaborating with and supporting clinics and nonclinical community-based organizations to ensure that PrEP is available, accessible, and affordable.

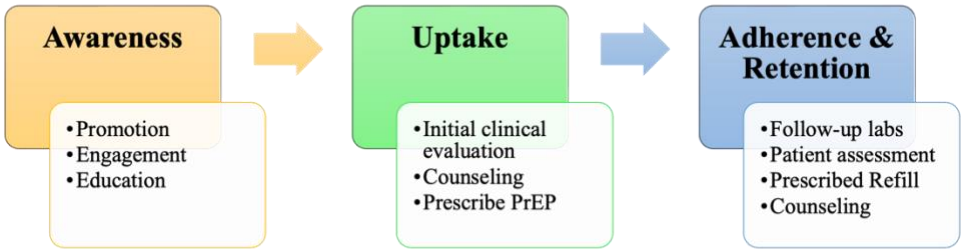

Figure 6. The PrEP Clinical Care Model (adapted by the CDC)

PrEP Continuum of Care Applications in the field

The PrEP Continuum of Care Model was developed to facilitate and conceptualize interventions and system-based approaches to enhance PrEP use.[99] It has been widely used to guide HIV preventative research that has primarily focused on PrEP scale-up and intervention effectiveness, including examining barriers and facilitators involved in moving along the PrEP care process.[100-103] The model has also been used to guide systematic reviews of PrEP interventions among various subpopulations to identify what areas of the continuum interventions are focused on.[100,103-106] Importantly, the PrEP continuum of care model has been utilized to inform future intervention efforts among the populations of highest risk of HIV that are not being engaged in PrEP care.

The PrEP Continuum of Care Model Applied in this Study

For this study, the CDC modified version of the model (Figure 5), in conjunction with the clinical model (Figure 6), was used to conceptualize and understand the unique experiences individuals are facing throughout their PrEP care process. Specifically, the model was used to facilitate the development of the interview guide to capture individuals' process accessing,

initiating, and adhering to PrEP for HIV prevention. This model was imperative in addressing one of the study's research questions: how effective PrEP Navigation is at overcoming barriers to PrEP access and care. The following demonstrates how each construct of the model was addressed in the study.

Awareness was assessed at the patient level, such as how PrEP was promoted to them, how they were educated on PrEP, and how they were engaged in PrEP care/HIV prevention. *Uptake* was assessed by the process in which the individual took to start PrEP, specifically looking at the accessibility of PrEP care (i.e., barriers and facilitators). This included asking individuals about their experience to finding and linking to a PrEP provider, being screened for a PrEP prescription, and starting their PrEP regimen. *Adherence & Retention* was evaluated by understanding the barriers and facilitators involved in adhering to and retaining in PrEP care. This included inquiring about whether individuals were taking their medication as prescribed, if they had taken breaks from being on PrEP, and the process in which they take to schedule follow-up labs and receive prescription refills. See Appendix B for more information about the interview guide outlined by the PrEP continuum of care.

PRACTICAL, ROBUST IMPLEMENTATION AND SUSTAINABILITY MODEL

The Practical, Robust Implementation and Sustainability Model (PRISM) is an implementation science framework that can be used for planning, implementing, sustaining, and/or evaluating interventions. It was first introduced in 2008, by Russel Glasgow and Adrianne Feldstein, and is derived from the following key elements of the evidence-based models in implementation and diffusion research: Diffusion of Innovations, Chronic Care Model, Model for Improvement, and RE-AIM.[107] PRISM considers the multilevel and dynamic interactions between the intervention, recipients, infrastructure, and external environment, while connecting

the RE-AIM framework (Figure 7).[107,108] PRISM can be useful in identifying, describing, and connecting the multi-level contextual predictors of the intervention outcomes (reach, effectiveness, adoption, implementation, and maintenance).

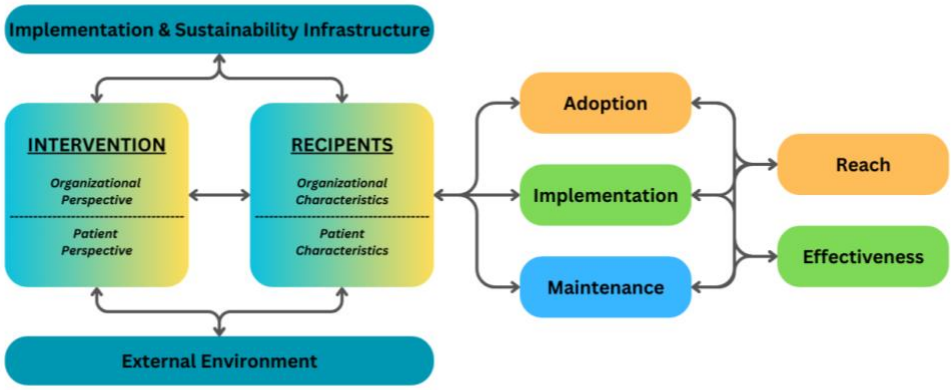

Figure 7. The Practical Robust Implementation and Sustainability Model (adapted by Glasgow & Feldstein)

The Practical Robust Implementation and Sustainability Model consists of two main parts: the contextual domains of PRISM and the RE-AIM outcomes.[107-110] PRISM considers the perceptions and characteristics of the intervention/program at the organizational level (at three levels: leaders, managers, and staff) and patient level. Recipient characteristics are important to capture, as organizational characteristics affect the ability to successfully change behaviors and patient characteristics affect the interventions reach and effectiveness. Implementation and sustainability infrastructure is the dynamic support structure to facilitate the intervention adoption, implementation, and sustainability. The infrastructure domain includes both implementation and sustainability to emphasize the importance of support throughout the entirety of an intervention, from initial adoption and implementation to long-term maintenance.

External environment is one of the key predictors of success for an intervention and are important to consider for implementation and sustainability. This domain includes policies and regulations, clinical practicing guidelines, and historical considerations.

Reach is a measure at the individual-level of participation in a program, concerned with participant characteristics, and refers to the percentage of people who receive the program service. This is measured by comparing the program participants and the complete sample of a defined population. Effectiveness is an individual and organization-level construct, that refers to the impact (both positive and negative) of the program on important outcomes. There is an emphasis on the need to consider behavioral, quality of life, and participant satisfaction outcomes in addition to intervention outcomes. Adoption is a measure at the organization-level and refers to the portion of settings that adopted the program. Implementation is an individual and organization-level construct, that refers to the extent in which a program is delivered as intended. Maintenance is a measure at the individual and organization level and refers to the extent in which a program is sustained over time. See Table 7 for the key elements to consider within the domains of PRISM.

PRISM Applications in the field

The Practical Robust Implementation and Sustainability Model is a relatively new implementation science framework; however, it is beginning to gain attraction by translational research scientists for use in planning, adapting, and evaluating clinical and community-based prevention and health behavior programs. In the field of HIV, PRISM has been utilized for planning, implementing, and evaluating HIV treatment and prevention programs. The model has been used to facilitate scoping reviews, qualitative interviews, and mixed-methods approaches to understanding various intervention outcomes and impacts.[111-114] Specifically in the field of PrEP

for HIV prevention, the framework has been utilized to assess the benefits and challenges of people who inject drugs using PrEP, and their perspectives on implementing PrEP in an ongoing syringe service program in Kentucky.[113] However, this study only utilized the *recipient* and *intervention/program* contexts of the domain at the client-level.

Although PRISM has not been widely reported in the field of HIV, the RE-AIM Framework, which is a core component of PRISM, has been. The RE-AIM framework was also developed by Glasgow in 1999, and is used as an outcomes framework to planning, adapting, and evaluating public health interventions.[108,110,115] The framework outlines five key factors in translating research into action: reach, effectiveness, adoption, implementation, and maintenance. The framework has been widely applied to public health and health behavior programs, including in the field of HIV treatment and prevention. Like PRISM, RE-AIM has been used to facilitate scoping reviews for interventions and implementation strategies, and qualitative and mixed-method research approaches to evaluating outcomes. In fact, RE-AIM has been one of the top implementation science frameworks utilized in conceptualizing and measuring outcomes for interventions addressing the *Ending of the HIV Epidemic* prevention pillar strategieis.[116] Specifically, addressing PrEP for HIV prevention the framework has been widely used to evaluate various interventions/programs to increase PrEP awareness, uptake, and retention.[117-121] One study in particular used RE-AIM to perform a mixed-methods evaluation on a community health worker intervention on PrEP knowledge and use in Uganda and provides further support of its use in evaluating similar PrEP implementation strategies; much like the PrEP Navigation program being evaluated in this study.[118]

PRISM Applied in this Study

The proposed study used PRISM as an evaluation tool to conceptualize the outcomes of the PrEP Navigation Program. Specifically, the model was used to facilitate the development of the interview guide with navigators to capture the organizational perspective of the program and RE-AIM outcomes. See Appendix C for more information about the interview guide outlined by PRISM. Additionally, the model was used to conceptualize the findings from the interviews with clients in the program. PRISM was imperative in addressing one of the study's research questions: what aspects of the program needs improved to be effective at increasing PrEP uptake and adherence in the state. The following demonstrates how each construct of the model was addressed in the study.

Intervention perspectives were at the organizational-staff level and patient level and involved the navigator and clients perceived benefits and challenges of the program. *Recipient characteristics* were captured at the organizational-staff level and patient level and included navigator and client demographics. *Implementation and Sustainability Infrastructure* involved reviewing quarterly reports provided by the navigators to the state, reviewing navigator training and onboarding materials, and an assessment of technical support. *External Environment* considered program reimbursement, community resources, PrEP policies, and PrEP clinical guidelines. *Reach* was assessed at the organizational-staff level and patient level and involved client awareness of the program and navigators' promotion and recruitment strategies of the program. *Effectiveness* was assessed at the organizational-staff level and patient level and involved a comparative analysis between clients and patients and their barriers and facilitators to PrEP care in addition to navigator barriers and facilitators to providing services. *Adoption* assessed navigators' reasons for becoming a navigator and continuing to be one. *Maintenance*

sassed how navigators have adapted their approach to navigation to achieve success in their organizations. Additionally, maintenance considered the perceived long-term impact of navigation services on client's adherence and retention in PrEP care.

Table 7. Elements to consider for each domain of PRISM (adapted by Feldstein et al)

PRISM Domain	Elements
Intervention – Organizational Perspective	Readiness Strength of the evidence base Addresses barriers of frontline staff Coordination across departments Burden (cost and complexity) Usability and adaptability Trialability and reversibility Ability to observe results
Intervention – Patient Perspective	Patient centeredness Provides patient choices Addresses patient barriers Seamlessness of transition between program elements Services and access Burden (cost and complexity) Feedback of results
Recipients – Organizational Characteristics	Organizational health and culture Management support and communication Shared goals and cooperation Clinical leadership Systems and training Data and decision support Staffing and incentives Expectation of sustainability Demographics
Recipients – Patient Characteristics	Demographics Disease burden Competing demands Knowledge and beliefs
Implementation and Sustainability Infrastructure	Performance data Dedicated team Adopter training and support Relationship and communication with adopters Adaptable protocols and procedures Facilitation of sharing or best practices Plan for sustainability
External Environment	Payor satisfaction Competition Regulatory environment Reimbursement Community resources

PAPER 1: PRE-EXPOSURE PROPHYLAXIS USE AND PRESCRIBING TRENDS IN WISCONSIN: AN EXPLORATORY STUDY

ABSTRACT

Background: Increasing access to and use of pre-exposure prophylaxis (PrEP) is one of the key strategies outlined under the prevent pillar in the U.S. Ending of the HIV Epidemic Initiative. In alignment, the state of Wisconsin is focused on reducing the number of new HIV infections, by increasing the use of prevention measures, such as PrEP. However, PrEP trends at the state level are currently not being tracked, or reports are inconsistent. It is important to explore PrEP trends in the state, especially in understanding where further attention and efforts are needed to increase PrEP use and prescribing in the state.

Objective*:* The objective of this study was to explore PrEP use by identifying prescribing trends and disparities in the state of Wisconsin.

Methods*:* Using PrEP coverage data provided by AIDSVu, linear regressions were performed to understand the effect of PrEP use and PrEP-to-need ratios (PnR) in the state. Using all-payers claims data provided by Wisconsin Health Information Organization, logistic regressions were performed to understand the use and prescribing relationships between Truvada and Descovy among age, sex, county regions, and provider specialty.

Results: Linear regressions found that PrEP and PnRs are significantly increasing in the state of Wisconsin. Logistic regressions found that: (1) males were more likely to be prescribed/using Descovy than females, (2) younger patients were more likely to be prescribed/using Descovy than older patients, (3) Truvada was more likely to be used/prescribed in rural counties than urban, and (4) infectious disease providers were more likely to be prescribing Truvada than

Descovy, whereas primary care providers (internal and family medicine) were more likely to be prescribing Descovy.

Conclusion*:* The results from this study can be useful when developing, implementing, and disseminating PrEP intervention/programs for HIV prevention. Specifically, findings can be beneficial in addressing present disparities in PrEP use, by guiding efforts to target underserved populations. Future studies should consider additional analyses to understand all factors contributing to PrEP use and prescribing in the state.

BACKGROUND

As of 2021, about 1.2 million people were living with HIV in the United States, and it is estimated that about 13% of them are unaware of their HIV status.[2] Although new infections are gradually decreasing, there are more than 36,000 new diagnoses annually, which continues to disproportionately affect gay and bisexual men, and Black/African American and Hispanic/Latinx individuals.[1,2] Unfortunately, there have been significant increases in the rate of new HIV infections among subpopulations, including people aged 13-34, people who inject drugs, and transgender women of color who have sex with men.[1]

Preventing new HIV infections is vital to ending the epidemic. One preventative measure that can be taken by individuals at risk of HIV includes the use of pre-exposure prophylaxis (PrEP). PrEP is a biomedical treatment that is offered as a daily oral tablet (Truvada[122] or Descovy[123]) or as an intramuscular injection every two months (Apretude[124]) that has been clinically proven to decrease HIV transmission by 75-99%.[3,5] Individuals that could benefit most from taking PrEP include those populations that are at highest risk of contracting HIV. Although PrEP use has drastically increased since it was first available in 2012, it continues to be widely underutilized.

In 2022, it was estimated that 1.2 million people in the U.S. could benefit from PrEP, yet only 36% of them were prescribed it.[6,125] We are seeing similar trends in health disparities in PrEP-care as there are in HIV treatment and care. In 2021, Black/African American and Hispanic/Latinx men and women made up more than 60% of the U.S. new HIV diagnoses in the U.S.[2]Yet, in 2022, they made up only 31% of the people prescribed PrEP for HIV prevention.[27] To achieve the *Ending of the HIV Epidemic*[126] (EHE) overall goal of reducing the number of new

HIV infections by increasing use of prevention measures, there is a need for equitable PrEP access, uptake, and adherence.

In alignment with the EHE, the state of Wisconsin has launched an *Integrated HIV Prevention and Treatment Plan*[14] to address the four pillars involved in ending the HIV epidemic: diagnose, prevent, treat, and respond. Similarly, Wisconsin aims to reduce the number of new HIV infections by increasing the use of prevention measures, such as PrEP. As of 2022, roughly 7,000 people were living with HIV in Wisconsin, and 300 individuals were newly diagnosed.[11] Currently, the state is seeing the highest spike of new HIV cases in the past 10 years, and there have been substantial increases in HIV among people who inject drugs, young Black/African American and Hispanic men who have sex with men, and transgender women of color.[12] People of color only make up 20% of the state's population, yet they account for 70% of new HIV diagnoses annually, demonstrating a large racial and ethnic disparity present in HIV incidences in the state.[11,12]

Fortunately, HIV treatment and care trends are being reported and tracked in Wisconsin, both at the state and federal level. However, PrEP trends at the state level are not being tracked, or their reports are inconsistent. This is important to explore, especially in understanding where further attention and efforts are needed to increase PrEP use in the state. Therefore, the purpose of this study was to explore PrEP use in the state of Wisconsin to identify prescribing trends and disparities. This exploratory study will facilitate in further evaluation of PrEP implementation and future efforts to address PrEP disparities present that hinder ending the HIV epidemic in Wisconsin.

METHODS

Data Sources

This study utilized two data sources to explore PrEP use and prescribing trends in the state of Wisconsin: AIDSVu and WHIO.

AIDSVu

AIDSVu is a publicly available resource for visualizing HIV surveillance data and other population-based information relevant to HIV prevention and care in the United States.[27] In terms of HIV prevention components, the data source provides information on the rate and number of PrEP users, at the national, state, and county levels. Additionally, the source provides PrEP-to-Need ratios, defined by the number of PrEP users divided by the number of new diagnoses each year, at the national, state, and county levels. The PrEP use data available from AIDSVu is provided by IQVIA Inc which is derived from commercially available pharmaceutical claims data and reflects patients who are taking FTC/TDF monotherapy (i.e., Truvada, Descovy, Apretude, and Generic Truvada for HIV-prevention only) and who did not have a diagnosis of Hepatitis B or HIV infection. The available data reflects sex, age, and race/ethnicity characteristics of PrEP users. The AIDSVu data used in this study was PrEP data across Wisconsin from 2012-2022.

WHIO

Wisconsin Health Information Organization (WHIO) is an all-payers claims database (APCD) that provides Wisconsin with the largest sources of healthcare data and information, dating back to January 1, 2017.[127] WHIO's information system is comprised of all care settings (e.g., hospital, clinics, long-term, etc.), services (e.g., labs, radiology, pharmacy, etc.), and professions (e.g., physicians, therapists, chiropractors, etc.) that are subsidized by insurance

companies. WHIO contains 320 million claims from 18 statewide insurers, for care provided to 75% of Wisconsin's population, exceeding $147-billion billed charges. Data provided by WHIO is used to identify gaps in care and provide real-world data about the costs per episode of care. WHIO contains information on diagnostic codes, medical claims, and pharmaceutical claims for every patient who used their health insurance to pay for health care or medications. This includes patient, provider, and pharmacy level data. Patient-level data includes date of birth, sex, and zip-code and county of residency. Provider-level data includes the National Provider Identification code, provider names, the system in which they are prescribing within, and their specialty. Pharmacy-level data includes the pharmacy name and system, prescription date, payment process date, insurance coverage class, and prescription supply (days). The WHIO data used was PrEP prescription claims in Wisconsin from January 2017 to June 2023. See Table 19 in Appendix A for a list of the variables present in the provided WHIO dataset.

Variables

The variables provided and utilized from the AIDSVu dataset included time (in year), PrEP-count (overall, per gender, per age group, and per race/ethnicity), and PnRs (overall, per gender, per age group, and per race/ethnicity). The main variables of interest from the WHIO dataset included patient gender, age, and county of residence, and the PrEP-drug prescribed (Descovy or Truvada). The patient's age was calculated by their given date of birth, and then grouped into six groups: less than 25, 25-34, 35-44, 45-54, 55-64, and 65+. The patient's county of residence was grouped into regions (South, Southeastern, Northeastern, Western, and Northern) as well as grouped into rural/urban identifiers. Additionally, provider-level variables were of interest, such as the provider specialty. Due to numerous specialties prescribing PrEP to Wisconsin patients, the research team identified the top 5-provider specialties present in the data

and then grouped all the other specialties into one and classified it as ‘other’. Dummy variables were then created for each main variable of interest to perform appropriate analyses. See the consort diagram in Appendix A (Figure 11) for the process in which claims were excluded from the study.

Analyses

Descriptive statistics were utilized to identify the characteristics of the patients prescribed PrEP for each dataset. PrEP-counts and PnRs were already calculated and provided by AIDSVu. Linear regressions were then performed on the PrEP-counts and PnRs to evaluate the significance of PrEP trends in the state (AIDSVu data only). Logistic regressions were then performed to evaluate the associations between patient characteristics (e.g., gender, age, county region, and rural/urban county) and taking Truvada or Descovy for PrEP. Additionally, logistic regressions were performed to evaluate the association between provider specialty and prescribing Truvada or Descovy for PrEP. Logistic regressions were only performed on WHIO data. Finally, a sensitivity analysis was performed to see the difference in logistic regression results when comparing Truvada and Descovy in the same time frame, as Descovy was not approved for PrEP use until 2019, whereas Truvada was approved in 2012. The sensitivity logistic regression was performed on all patient characteristics and provider specialty.

RESULTS

AIDSVu

Findings from the linear regressions (Table 8) found that PrEP use in Wisconsin and PrEP-to-Need Ratios from 2012-2022 have significantly increased from 74 to 3,342 (p<0.001) and 0.34 to 13.21 (p<0.001), respectively (see Figure 8 for PrEP Trends, see Appendix A, Table 20 for the PrEP and PnR Trends). Additionally, linear regression found significant increases in PrEP use over time by gender, age, and race/ethnicity (Table 8). Although, all subgroups of characteristics were found to significantly increase PrEP use overtime, minority groups are increasing at smaller rates than others. For example, roughly 295 new White individuals are using PrEP every year, compared to 32 new Black individuals and 22 new Hispanic individuals (Table 8). Similar findings are presented when looking at PnRs, PnR is/are significantly increasing overtime but at lower rates among minority populations. For example, Blacks and Hispanics have a more unmet PrEP need than Whites (PnR: 2.67, 4.20, 32.02, respectively; Table 20 in Appendix A).

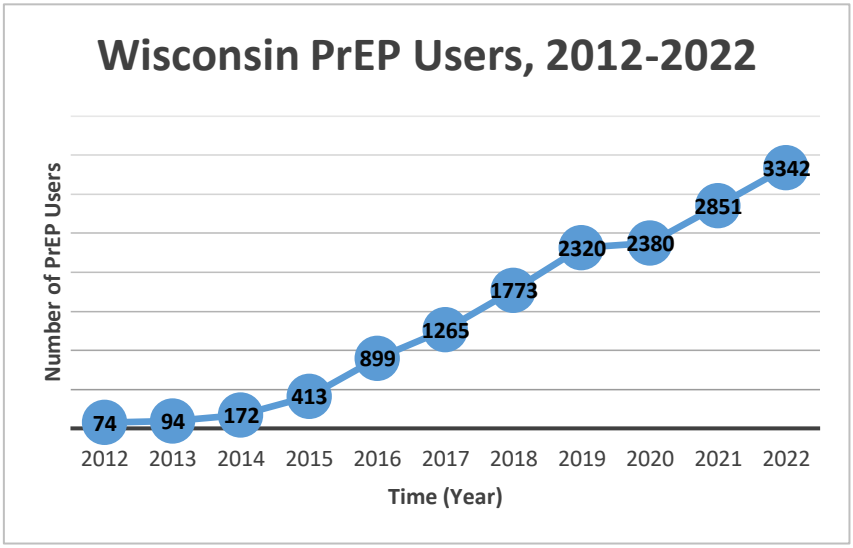

Figure 8. PrEP Use in Wisconsin, 2012-2022 (provided by AIDSVu data)

Table 8. Linear Regression Results of PrEP use and PrEP-to-need Ratios in Wisconsin

	PrEP		PnR	
Variable	**Unstandardized Coefficient**	**P-value**	**Unstandardized Coefficient**	**P-value**
Overall	351.6	<0.001*	1.47	<0.001*
Sex				
Males	334.3	<0.001*	1.71	<0.001*

Females	17.4	<0.001*	0.404	<0.001*
Race/Ethnicity				
Whites	294.7	<0.001*	3.56	<0.001*
Blacks	32.2	<0.001*	0.356	<0.001*
Hispanics	22.1	<0.001*	0.397	0.015*
Age				
Less than 24	62.1	<0.001*	1.27	<0.001*
25-34	142.5	<0.001*	1.48	<0.001*
35-44	73.9	<0.001*	1.63	<0.001*
45-54	39.1	<0.001*	1.45	<0.001*
55+	34.5	<0.001*	1.72	<0.001*
				*significant at p<0.05

WHIO

The WHIO data contained a total of 58,994 PrEP prescription claims during the study period (Jan 2017- June 2023). The research team identified a total of 49,189 claims for PrEP, that were prescribed by a Wisconsin provider (Table 9). See the consort diagram in Appendix A (Figure 11) for the process in which claims were excluded from the study.

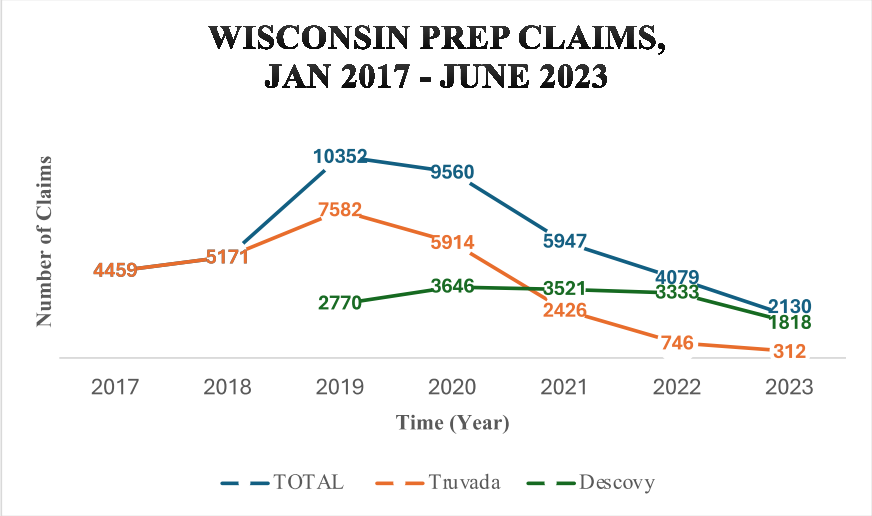

Figure 9. PrEP Claims 2017-2023 (provided by WHIO)

The overall PrEP trends examined showed that PrEP claims decreased following 2020. Specifically, Truvada-PrEP claims show a decrease starting in 2020, followed by major decrease in claims in 2021 (Figure 9). Descovy-PrEP claims, however, remain consistent from 2019-2022 with minor decreases starting in 2021. Table 9 shows the frequency distributions of the PrEP claims. Of the 49,189 total PrEP claims about 54% of claims were for Truvada-PrEP.

Table 9. Descriptive Statistics of PrEP Claims in the WHIO data

	TOTAL	**TRUVADA**	**DESCOVY**
Variable	**Frequency n (%)**		
TOTAL	**49189**	26610 (54.1)	22579 (45.9)
Gender			
Male	38667 (78.6)	22440 (84.3)	16227 (71.9)
Female	9130 (18.6)	3117 (11.7)	6013 (26.6)
Missing	*1392 (2.8)*	*1053 (4.0)*	*339 (1.5)*
Age			
Less than 25	1629 (3.3)	975 (3.7)	654 (2.9)
25-34	11572 (23.5)	8159 (30.7)	3413 (15.1)
35-44	10488 (21.3)	6756 (25.4)	3732 (16.5)
45-54	9672 (19.7)	4320 (16.2)	5352 (23.7)
55-64	11137 (22.6)	3996 (15.0)	7141 (31.6)
65+	3302 (6.7)	1354 (5.1)	1948 (8.6)
Missing	*1389 (2.8)*	*1050 (3.9)*	*339 (1.5)*
County Region			
Southern	16518 (33.6)	11211 (42.1)	5307 (23.5)
Southeastern	19983 (40.6)	8079 (30.4)	11904 (52.7)
Northeastern	4427 (9.0)	1777 (6.7)	2650 (11.7)
Western	1732 (3.5)	1218 (4.6)	514 (2.3)
Northern	1564 (3.2)	923 (3.5)	641 (2.8)
Missing	*4965(10.1)*	*3402 (12.8)*	*1563 (6.9)*
County Rural vs. Urban			
Rural	4356 (8.9)	2199 (8.3)	2157 (9.6)
Urban	40102 (81.5)	21243 (79.8)	18859 (83.5)
Missing	*4731 (9.6)*	*3168 (11.9)*	*1,563 (6.9)*
Provider			
Infectious Disease	18317 (37.2)	7256 (27.2)	11061 (49.0)
Nurse Practitioner	11914 (24.2)	6219 (23.4)	5695 (47.8)
Family Medicine	7035 (14.3)	5588 (21.0)	1447 (20.6)
Internal Medicine	4917 (10.0)	2969 (11.2)	1948 (39.6)
Physician Assistant	4596 (9.3)	3055 (11.5)	1541 (33.5)
Other	2398 (4.9)	1512 (5.7)	886 (36.9)
Missing	*12 (0.02)*	*11 (0.04)*	*1 (0.004)*

Exploring PrEP claims by gender, males made up 79% of all claims (Table 9). Findings from the logistic regressions found that compared to females, Truvada was 0.4-times less likely

to be prescribed to females (p<0.001, C.I. 0.36-0.39; Table 10), whereas Descovy was 2.3-times more likely to be prescribed to females (p<0.001, C.I. 2.21-2.46; Table 10). The sensitivity analysis did not change the outcome for Truvada (Table 11).

PrEP claims by age groups found that nearly half were among middle-aged adults (25-44-years old; Table 9). The logistic regressions found that younger patients were more likely to be using Descovy-PrEP over Truvada than older patients (Table 10). Specifically, individuals 25-34 were 2.1-times more likely to be using Descovy than the other age groups (p<0.001, C.I. 2.05-2.26; Table 10), and individuals 55-64 were 2.6-times more likely to be using Truvada than other age groups (p<0.001, C.I. 2.44-2.67; Table 10). The sensitivity analysis did not change the outcome for Truvada (Table 11).

Table 10. Logistic Regression Results

	TRUVADA			**DESCOVY**		
Variable	**P-value**	**Odds Ratio**	**95% C.I. for OR**	**P-value**	**Odds Ratio**	**95% C.I. for OR**
Gender	<0.001*	0.375	0.357 - 0.393	<0.001*	2.333	2.212 - 2.459
Age						
Less than 25	<0.001*	0.764	0.691 - 0.845	0.295	1.059	0.951 - 1.179
25-34	<0.001*	0.387	0.370 - 0.404	<0.001*	2.152	2.048 - 2.261
35-44	<0.001*	0.561	0.537 - 0.587	<0.001*	1.708	1.623 - 1.797
45-54	<0.001*	1.558	1.490 - 1.630	<0.001*	0.658	0.626 - 0.692
55-64	<0.001*	2.552	2.442 - 2.667	<0.001*	0.434	0.413 - 0.456
65+	<0.001*	1.716	1.597 - 1.844	<0.001*	0.681	0.628 - 0.739
County Region						
Southern	<0.001*	0.369	0.354 - 0.384	<0.001*	2.158	2.064 - 2.256
Southeastern	<0.001*	2.484	2.391 - 2.581	<0.001*	0.511	0.490 - 0.534
Northeastern	<0.001*	1.759	1.651 - 1.874	<0.001*	0.574	0.535 - 0.615
Western	<0.001*	0.457	0.412- 0.508	<0.001*	1.718	1.536 – 1.921
Northern	<0.001*	0.768	0.693 - 0.850	0.804	1.015	0.910 - 1.130
County Rural vs. Urban	<0.001*	1.105	1.038 - 1.176	<0.001*	0.809	0.756 - 0.866
Provider						
Infectious Disease	<0.001*	2.562	2.467 - 2.660	<0.001*	0.456	0.437 - 0.475
Nurse Practitioner	<0.001*	1.106	1.061 - 1.153	0.603	0.988	0.942 - 1.035

Family Medicine	<0.001*	0.258	0.242 - 0.274	<0.001*	3.011	2.820 – 3.214
Internal Medicine	<0.001*	0.752	0.708 - 0.798	<0.001*	1.137	1.065 - 1.214
Physician Assistant	<0.001*	0.565	0.530 - 0.602	<0.001*	1.464	1.366 - 1.569
Other	<0.001*	0.678	0.623 - 0.738	<0.001*	1.131	1.034 - 1.237
						**significant at p<0.05*

Looking at PrEP claims in the state by counties, the Southern and Southeastern regions of the state made up roughly 75% of the PrEP claims from 2017-2023 (See Table 9). PrEP claims were fewest among the Northern and Western regions of the state, and sparse among Descovy-PrEP claims specifically. Findings from the logistic regression shows that Descovy for PrEP was 2.2-times more likely to be used in the Southern region than others (p<0.001, C.I. 2.06-2.26-; Table 10) and that Truvada for PrEP was 2.5-times more likely to be used in the Southeastern region than others (p<0.001, C.I. 2.39-2.58; Table 10). As for the other regions, Truvada was 1.8-times more likely to be used in the Northeastern region (p<0.001, C.I. 1.65-1.87; Table 10), whereas Descovy was 1.7-times more likely in the Western region (p<0.001, C.I. 1.54-1.92; Table 10). The Northern region was found to be not significant in terms of Descovy-PrEP, and that Truvada-PrEP claims in this region were 0.8-times less likely than other regions (p<0.001, C.I. 0.69-0.85; Table 10). As for exploring rural verse urban counties, Descovy was 0.8-times less likely (p<0.001, C.I. 0.76-0.87; Table 10), whereas Truvada was 1.1-times more likely to be used in rural areas than urban counties (p<0.001, C.I. 1.04-1.18; Table 10). Findings from the Truvada sensitivity analysis found that there was no significant difference between the Northern region compared to others (p=0.153, Table 11).

Exploring PrEP prescribing trends overtime, about 37% of PrEP claims were prescribed by infectious disease providers and about 25% by primary care providers (family and internal medicine; Table 9). PrEP claims prescribed by infectious disease providers decreased, whereas

claims prescribed by primary care providers increased. Among providers in the state, from 2017-2023, infectious disease providers were 2.5-times more likely to prescribe Truvada for PrEP compared to other providers (p<0.001, C.I. 2.47-2.66; Table 10). As for Descovy for PrEP, family medicine providers were 3-times more likely to prescribe Descovy than other providers (p<0.00, C.I. 2.82-3.21; Table 10). The sensitivity analysis found that nurse practitioners had no significant difference compared to other providers (p=0.233; Table 11).

Table 11. Truvada Sensitivity Logistic Regression Analysis Results

Variable	**P-value**	**Odds Ratio**	**95% C.I. for OR**
Gender	<0.001*	0.433	0.408 - 0.459
Age			
Less than 25	<0.001*	0.697	0.624 - 0.778
25-34	<0.001*	0.417	0.395 - 0.439
35-44	<0.001*	0.602	0.570 - 0.639
45-54	<0.001*	1.543	1.460 - 1.632
55-64	<0.001*	2.762	2.609 - 2.924
65+	<0.001*	1.706	1.552 - 1.876
County Region			
Southern	<0.001*	0.441	0.420 - 0.463
Southeastern	<0.001*	2.028	1.934 - 2.126
Northeastern	<0.001*	1.754	1.622 - 1.897
Western	<0.001*	0.654	0.579 - 0.738
Northern	**0.153**	**1.092**	**0.968 - 1.233**
County Rural vs. Urban	<0.001*	1.276	1.182 - 1.376
Provider			
Infectious Disease	<0.001*	2.780	2.649 - 2.916
Nurse Practitioner	**0.233**	**1.032**	**0.980 - 1.087**
Family Medicine	<0.001*	0.295	0.276 - 0.316
Internal Medicine	<0.001*	0.760	0.709 - 0.815
Physician Assistant	<0.001*	0.721	0.669 - 0.778
Other	<0.001*	0.678	0.623 - 0.738
significant at p<0.05*; **changes from initial analysis			

DISCUSSION

This study had six major findings, the first that overall PrEP use and PrEP-to-need ratios (PnR) are significantly increasing in the state of Wisconsin which is vital in ending the HIV epidemic. Although Wisconsin's PnR is fairly low (13.21, as of 2022; Appendix A, Table 20), it is however above the national average (12.06).[6] Importantly, these findings indicate that the state is on target to achieving prevention goals outlined in Wisconsin's *Integrated Plan,*[13,14] which is in alignment with the U.S. *Ending the HIV Epidemic Initiative.*[9] However, to achieve these goals, the state needs to address the racial/ethnic disparities present in PrEP use. Despite PrEP use significantly increasing among all race/ethnic groups, Blacks and Hispanics have substantially lower PnRs than Whites (2.67, 4.10, and 32.02, respectively; Appendix A, Table 20), indicating a more unmet need for PrEP. Racial//ethnic disparities are also demonstrated at the national level. Although not completely up to date, Flash et. al. found that in 2016 70% of the U.S. PrEP claims were among White individuals.[23] Additionally, Siegler et. al. found, in 2017, that states with a higher concentration of Black and Hispanic residents had an unmet need for PrEP compared to states with lower concentration of Black and Hispanic residents.[26] Future analyses should consider interactions between gender and race, race and age, and/or gender and age to better understand the relationships between these independent variables on PrEP uptake.

The second important finding, demonstrated by the WHIO all-payers claims data, was that overall PrEP claims in the state of Wisconsin saw an initial decrease in 2020. This decrease may be explained by the coronavirus pandemic. Hong provides a comprehensive review of the impact of the COVID-19 pandemic on PrEP care for HIV prevention and found a decline in PrEP use and initiating PrEP during the pandemic.[128] Additionally, study findings demonstrate a substantial decrease in Truvada claims between 2020-2021, and then tapering off by 2023. The

U.S. national cohort study, Together 5,000, found that a large portion of patients were switching from Truvada to Descovy, for safer long-term effects from the drug.[129] This may support, and partially explain the current study findings in that Descovy PrEP claims remained consistent during this time of the substantial downfall of Truvada claims.

The third key finding in the study was that when examining PrEP use in gender, males were more likely to be prescribed Descovy than females. This is important, because Descovy was not clinically tested or approved for use in individuals assigned female at birth.[130] Therefore, this study finding demonstrated that Wisconsin providers are following clinical guidelines for prescribing PrEP to individuals at risk HIV. The fourth was that younger clients were being prescribed Descovy over Truvada, whereas older clients were being prescribed Truvada over Descovy. Clinical studies found that Descovy has fewer bone- and kidney-related problems than Truvada.[131] Although it is valued that younger patient are being prescribed the safer PrEP option, in terms of long-term side effects (e.g., bone and kidney health), it may be of concern that older adults in the state of Wisconsin are being prescribed Truvada over Descovy. There is a need for further analysis to understand this study finding, as other factors may impact this prescribing/use pattern found (i.e., including interactions in the logistic regressions between age and provider).

The fifth important takeaway from this study was that when looking at rural verse urban counties in Wisconsin, Descovy was less likely and Truvada more likely to be prescribed in rural areas than urban. This finding could be explained by rural areas having more primary care providers than infectious disease providers.[132] Although primary care providers have a growing awareness of PrEP, they may be less likely to be up to date on HIV prevention innovations, such as newer PrEP medication options (e.g., Descovy).[50] However, when looking at prescribing differences between providers in the state, this assumption does not align. The sixth and final key

finding from this study was that infectious disease providers were more likely to prescribe Truvada than Descovy, whereas primary care provider (and all other prescribers in the data) were more likely to prescribe Descovy than Truvada. Further analysis is needed to understand this study finding, such as including various interactions in the logistic regressions (i.e., region and prescriber effect on PrEP uptake).

Implications

Findings from this study can be beneficial to the state of Wisconsin when developing, implementing, and disseminating HIV prevention/PrEP interventions and programs. Additionally, utilizing all-payers claims data can be a valuable approach to understanding PrEP uptake and implementation across the U.S.[45] Analyzing PrEP use and prescribing trends is useful in understanding who is currently taking PrEP, where PrEP users are located, and who is prescribing PrEP in the state. This information is valuable in demonstrating the subpopulations that are being reached by current PrEP programs and provides evidence for where attention is needed by the efforts to increase PrEP use. Additionally, knowing who is prescribing PrEP in the state is valuable to ensure appropriate education is being provided to these providers to support staying up to date on PrEP innovations and guidelines. Exploring PrEP use and prescribing trends is essentially in understanding the impact PrEP is having on the state, in terms of reaching goals of ending the HIV epidemic in Wisconsin.

Study Limitations

There are numerous limitations that need to be outlined in this study. First, the WHIO data provided to the research team only claims of individuals prescribed PrEP in the state, therefore analysis options were limited as there were no data on individuals not prescribed PrEP. Second, the diagnostic codes were not included in the WHIO data, therefore there is no

guarantee that all the included PrEP claims in the study were specifically for HIV prevention, rather than an HIV-infection. Third, patient race/ethnicity data was not provided in the WHIO data, therefore PrEP use and prescribing differences among race/ethnicity groups was not available for analysis. Additionally, the gender code provided by WHIO was dichotomized by male and female, which provides an unclear definition of how transgender individuals in the state taking PrEP are being classified in terms of gender in the WHIO database. Fourth, although Apretude, the long-acting injectable option for PrEP that became available in 2022, was not found in the WHIO prescription claims, the NDC was requested by the research team. Finally, although WHIO captures a large portion of the state's population, there is still roughly 25% of state's population not captured in the database and of the data provided there was a substantial amount of information per claim missing (i.e., gender, age, etc.).

Study Advantages

Despite the limitations outlined, this study has its advantages. First, it is the first study to explore PrEP use and prescribing in the state of Wisconsin. Additionally, it is one of the first, if not first, study to examine the differences between PrEP use and prescribing by medication type (i.e., Truvada verse Descovy).

CONCLUSION

This study utilized all-payers claims data to explore PrEP use and prescribing trends in the state of Wisconsin. PrEP use is significantly increasing, however racial and ethnic disparities persist. Findings from this study can be useful in guiding the development, implementation, and dissemination of PrEP programs/interventions in the state that can target underserved populations to increase their PrEP use. Additionally, future studies should consider additionally

analyses, such as multivariable binomial logistic regressions to understand all factors contributing to PrEP use and prescribing in the state.

PAPER 2: EVALUATING THE STATE OF WISCONSIN'S HIV PREVENTION PROGRAM, PREP NAVIGATION, EFFECTIVENESS TO OVERCOMING BARRIER TO PREP CARE

ABSTRACT

Background: The HIV epidemic continues to be a public health concern, with more than 1.2 million individuals living with HIV and roughly 1 million at risk of contracting HIV in the United States. A key component to ending the HIV epidemic is preventing new HIV transmissions using proven interventions and increasing access to prevention services, such as pre-exposure prophylaxis (PrEP). However, PrEP is widely underutilized in the U.S. One intervention strategy being deployed to increase PrEP uptake is PrEP navigation, which addresses the key components of the PrEP care including awareness, access, and adherence to PrEP treatment.

Objective: The aim of this study was to identify the barriers and facilitators to the PrEP care and how PrEP Navigation may be assisting in overcoming barriers to PrEP access and care in the state of Wisconsin.

Methods: Semi-structured virtual interviews were conducted with individuals taking PrEP in the state of Wisconsin, including individuals that received PrEP care through navigation services and individuals that received PrEP care elsewhere in the state to understand their barriers and facilitators to care. The interviews were analyzed using inductive and deductive thematic analysis along the components of PrEP Continuum of Care Model (awareness, uptake, and adherence). The themes were then further analyzed using a comparative analysis to identified

similarities and differences between the two group of individuals receiving PrEP care in the state.

Results: Themes were identified as benefits and challenges to PrEP awareness, uptake, and adherence. Participants were aware of PrEP either from mass-advertisement or their social circles. Two challenges to awareness were surrounding PrEP coverage and costs and PrEP eligibility. Benefits to uptake included having an informed provider, an LGBTQ+ friendly provider, proficiency of care, destigmatized perceptions of PrEP, referrals & recommendations to care, and self-advocacy. Ongoing challenges to uptake identified were having uninformed primary care providers, insurance coverage, side effects, stigmatization/pathologization, and clinic logistics. Adherence benefits identified were having financial resources, ease of care, 90-day prescription supply, prescription mail order, adherence aids, and navigator support/advocacy. Ongoing challenges to adherence included insurance/costs, side effects, frequency of labs, prescription supply quantity, and casual forgetfulness.

Conclusion: The results from this study demonstrate that PrEP Navigation is assisting patients in overcoming barriers to their PrEP care process and offers additional benefits to care. Future research is warranted to assess more patient experiences from the program that have not been captured and gather navigator perspectives to better understand the navigation programs effectiveness at a larger and multi-level scale.

BACKGROUND

In 2024, the HIV epidemic remains a public health concern, with more than 1-million individuals living with human immunodeficiency virus (HIV) in the United States.[1,2] A key component to ending the HIV epidemic is preventing new HIV transmissions using proven interventions and increasing access to prevention services. Pre-exposure prophylaxis (PrEP) is a bio-medical prevention measure that, when taken as prescribed, reduces the risk of an HIV infection by 75-99%.[3,5] Currently, PrEP is offered as a daily oral tablet (Truvada[122] or Descovy[123]) or as an intramuscular injection every 2 months (Apretude[124]). Although there has been significant uptake in PrEP since it was first available in 2012, it continues to be underutilized. It is estimated that only 30% of the 1.2 million individuals that have indications for PrEP use (such that they are at risk of HIV), are being prescribed and taking it.[6]

To increase PrEP use among individuals at risk of HIV, these individuals must be aware of their risk of contracting HIV and of PrEP as a preventative safety measure, be able to access and afford a prescription and routine PrEP care and adhere to their PrEP regimen. Unfortunately, various barriers contribute to PrEP uptake and consistent use across the United States. Despite PrEP being available for over a decade, there continues to be awareness barriers, whether it be knowledge of PrEP as a preventative measure or being aware of their perceived risk of HIV.[7] However, individuals that are aware, often run into barriers initiating PrEP, such as their provider not being knowledgeable and comfortable starting them on it or even locating a provider that will.[7,133,134] Once overcoming awareness and accessibility, affordability becomes one of the largest reported barriers to PrEP care, due to the cost of the medication and required labs in addition to concerns about insurance coverage.[7,135] Even when PrEP is affordable, there are persistent barriers that sustain PrEP use, such as long-term side effects (i.e., reduced kidney

and liver functions), ongoing financial constraints, and maintaining the extensive medication regimen (i.e., required quarterly labs).[7,136]

PrEP Navigation is a promising evidence-based intervention strategy that addresses key components of the PrEP care continuum related to increasing awareness, access, and adherence to PrEP treatment.[21] Navigation was first introduced in 2011in the field of cancer, but was then adopted in the field of HIV to navigate HIV-positive individuals to receive HIV preventative health care.[51,52] It has since expanded to a preventative intervention strategy.[53] Navigation interventions explore and disseminate a variety of innovative care approaches, such as utilizing peers as navigators towards receiving healthcare, having online-chats or applications, and/or having a trained navigator that essentially takes the role as a PrEP case manager, care coordinator, and/or community-health worker.[53]

Since 2018, PrEP Navigation has been one of the key prevention interventions being deployed in the state of Wisconsin. The PrEP Navigation program in Wisconsin includes trained "navigators" that assist individuals at risk of HIV by increasing access and adherence to PrEP care and minimizing as many barriers to care as possible for everyone.[17-20] Navigators are educating individuals and communities about PrEP, linking interested individuals to PrEP providers, assisting them with insurance and accessing financial assistance to initiate PrEP, and supporting them in retaining in care and adhering to PrEP. Most importantly, navigators are key in identifying solutions to overcome barriers that may prevent individuals from engaging in their HIV preventative health care.

The navigation program has been implemented into seven agencies across the state of Wisconsin, reaching at least 10 counties with the highest HIV prevalence in the state. It continues to be an active and funded prevention program, with aims of growing and expanding to

reach more individuals at risk of HIV. However, the program has yet to undergo a formal evaluation to understand the program's effectiveness in overcoming barriers to PrEP care for the patients it's currently serving. Therefore, the goal of this research was to evaluate the program by identifying how PrEP Navigation is alleviating barriers to PrEP, and where improvements are necessary to increase PrEP access and care in the state.

METHODS

This study was conducted in collaboration with the Wisconsin Department of Health Services' HIV Prevention Unit. The study was determined to be exempt and approved by the University of Wisconsin Health Sciences Institutional Review Board.

Participants

This study included individuals that received PrEP services through agencies that are involved in the PrEP Navigation program, and individuals that received PrEP care elsewhere in the state. Participants were recruited through a recruitment flyer that included information about the study, what was expected for participation, who was eligible, and a QR-code to sign up through a pre-screening survey. Recruitment flyers were distributed to health departments (via email) and known HIV PrEP provider clinics throughout the state (in person), including the agencies involved in the PrEP Navigation program. Each agency or health department was instructed to display recruitment flyers in their waiting areas and exam rooms. Additional means of recruitment included snowball sampling and assistance by the state PrEP Navigators. Individuals were eligible to participate in the study if they were 18-years of age or older, able to speak and understand English, actively taking PrEP or taken PrEP in the past 12 month and receiving their PrEP care in the state of Wisconsin. Those that filled out the pre-screening survey

and deemed eligible to participate were contacted by the research team via email to schedule an interview. See Appendix B for recruitment materials.

Data Collection

The semi-structured, one-on-one interviews lasted approximately 30-45-minutes, and were conducted virtually using Zoom.[137] Because this study was IRB-exempt, verbal consent was sufficient. Before beginning the interview, the interviewer asked a screening question about where the participant received their PrEP care, as there were two interview guides: one for participants receiving PrEP care through a PrEP Navigation clinic and one for participants receiving PrEP elsewhere. At the start of the interview, the interviewer provided a brief overview of the interview purpose and gave the participant time to ask any questions.

The interview guides were developed using the PrEP Continuum of Care model.[21] All participants were asked questions regarding their awareness of PrEP, their uptake process, and their adherence to PrEP, as well as questions about improvements to the PrEP care process in the state and the impact PrEP has had on them. The participants that individually received care through a Navigation clinic were asked additional questions about their experience with their Navigator and the care they are receiving. The participants that were not receiving care through a Navigation clinic were given information regarding the program and asked questions about how this level of care may differ from what they are receiving elsewhere. Demographics including age, race/ethnicity, gender, etc. were collected from the participants via a Qualtrics Survey (via link) following the end of the interview. See Appendix B for the interview guides.

Participants were compensated with $50 Amazon gift cars for their participation. Interviews were conducted until data saturation was reached, marked by the lack of additional information regarding their PrEP care process and experiences.

Data Analysis

The interviews were audio recorded by Zoom and transcribed by the Premium Business Services; a transcription services business that specializes in interviews and focus groups. The interview data was thematically analyzed in NVivo14.[138] Thematic analysis is a method used to analyze and identify themes of salient meaning present in data. Themes were identified following the criteria assigned by Braun and Clarke.[139] The analysis was performed using both a deductive approach, with a preconceived codebook based on the major components of the interview topics: PrEP awareness, uptake, adherence & retention, and navigation services. The research team was also encouraged to inductively analyze the data for emergent themes. Following the thematic analysis, the research team conducted a between-group comparative analysis, to explore differences and similarities in themes among the interviews with individuals receiving PrEP care through the Navigation program and those receiving PrEP care elsewhere.

RESULTS

Demographics

In total, 29 of the 31 eligible individuals agreed to participate and completed an interview with the research team (93.5%). The demographic characteristics of the 29 participants are shown in Table 12. Of all participants, 16 were receiving PrEP care services from one of the PrEP Navigation programs in the state (*program participants*) and 13 were receiving PrEP care services elsewhere in the state (*non-program participants*). Compared to those receiving care from the navigation program, those in the control group were generally younger, more gender and racially diverse, had lower household income, and were newer to PrEP use. Most participants were white, cis-male, self-identified as gay, bisexual, or other men who have sex

with men, and had health insurance. No significant differences were found between the two group of participants based on their demographics (analysis: Fischer's Exact test).

Table 12. Participant Demographics

Characteristic	**Item**	**Frequency n (%)**		
		Total (n=29)	Program (n=16)	Non-program (n=13)
Age				
	18-24	4 (13.79)	1 (6.25)	3 (23.08)
	25-35	14 (48.28)	10 (62.5)	4 (30.77)
	36-45	10 (34.48)	4 (25)	6 (46.15)
	46-55	1 (3.45)	1 (6.25)	0 (0)
Gender				
	Cis Male	25 (86.21)	15 (93.75)	10 (76.92)
	Cis Female	1 (3.45)	1 (6.25)	0 (0)
	Non-binary	1 (3.45)	0 (0)	1 (7.69)
	Trans Male	2 (6.89)	0 (0)	2 (15.38)
Race/Ethnicity				
	Non-Hispanic White	25 (86.21)	15 (93.75)	10 (76.92)
	Hispanic White	1 (3.45)	1 (6.25)	0 (0)
	Asian	3 (10.34)	0 (0)	3 (23.08)
Household Income				
	<50,000	6 (20.69)	3 (18.75)	3 (23.08)
	50-70,000	10 (34.48)	4 (25)	6 (46.15)
	70-100,000	7 (24.14)	3 (18.75)	4 (30.77)
	100,000+	6 (20.69)	6 (37.5)	0 (0)
County				
	Dane	20 (68.97)	11 (68.75)	9 (69.23)
	Cook	1 (3.45)	1 (6.25)	0 (0)
	Rock	1 (3.45)	0 (0)	1 (7.69)
	Milwaukee	3 (10.34)	2 (12.5)	1 (7.69)
	Waukesha	1 (3.45)	1 (6.25)	0 (0)
	Racine	1 (3.45)	1 (6.25)	0 (0)
	Kenosha	2 (6.89)	0 (0)	2 (15.38)
Health Insurance				
	Insured	28 (96.55)	16 (100)	12 (92.31)

	Uninsured	1 (3.45)	0 (0)	1 (7.69)
Medication Assistance				
	Yes	11 (37.93)	5 (31.25)	6 (46.15)
	No	18 (62.07)	11 (68.75)	7 (53.85)
HIV Risk Characteristic				
	Gay, Bisexual, Other MSM	26 (89.66)	14 (87.5)	12 (92.31)
	HIV+ partner	2 (6.89)	1 (6.25)	1 (7.69)
	Other	1 (3.45)	1 (6.25)	0 (0)
Average time on PrEP (years)		3.25	2.5	4

Themes

Themes were identified and comparatively analyzed across the program and non-program groups for each component of the PrEP continuum of care: awareness, uptake, and adherence (Table 13 for Barriers and Table 14 for Facilitators to the PrEP Care Process). For the Awareness domain of the PrEP Continuum of Care, four total themes were identified: two challenges, including awareness surrounding PrEP coverage and costs and PrEP eligibility, and two benefits to PrEP awareness, including PrEP being discussed in social circles and PrEP being advertised across different mediums. For the Uptake domain, there were 11 total themes identified: five challenges, including uninformed primary care providers, insurance coverage, side effects, stigmatization/pathologization, and clinic logistics, and six benefits, including having an informed provider, an LGBTQ+ friendly provider, proficiency of care, destigmatized perceptions of PrEP, referrals & recommendations to care, and self-advocacy. For Adherence, there were 11 total themes identified: five challenges, including insurance/costs, side effects, frequency of labs, prescription supply quantity, and casual forgetfulness, and six facilitators, including financial resources, ease of care, 90-day prescription supply, prescription mail order, adherence aids, and navigator support/advocacy.

Table 13. Participant Identified Barriers to the PrEP Care Process

PrEP Continuum of Care Domain	Theme	Group(s) From Which This Theme Arose	Illustrative Quote(s)	
AWARENESS	**PrEP coverage assistance**	Program & Non-program	"With healthcare being so expensive nowadays, that's kind of been like a stopper for me from, you know, because I've known about PrEP probably for about a couple years, three or four years, but I've never really taken the steps towards it, because I thought, you know, I don't know if my insurance covers this, or, you know, expense wise. So, I've just tried to, you know, be safe in other ways. But knowing now that like there are these options, I think definitely making that more known to the public would be really helpful for a lot of people. " – Program Participant 29	"I wanted to get a prescription, but I didn't know where to start. And I also was not connected to like UW Health or any like insurance, or community-based health clinics there was a lack of awareness about how to use the health system and what costs money and don't." -Non-program Participant 10
	PrEP Eligibility/ Risk Factors	Program & Non-program	"I really didn't seek out any more information, mainly because I like didn't feel like I fit the criteria for PrEP like from what my understanding was. And so, I didn't really look into it more until like, I mean, I started working there, and then obviously I learned for work. But I didn't start until like I had like higher risk factors, I guess." – Program Participant 21	"there wasn't a ton of literature geared towards transmasculine folks, and so it was kind of a crapshoot of like, at that point, there weren't like best practices or recommendations." – Non-program Participant 22

UPTAKE	**Uninformed Primary Care Provider**	Program & Non-program	". . . like I've been a nurse for years, and so like, and I worked at Planned Parenthood before I worked at Holton Street. And I honestly don't feel like I really heard about PrEP much before I was like in the world a little bit more like, I mean, I know like I went to Holton Street as a patient and heard about it, and that was kind of like the first. And I think I might have heard it from somebody else, but like it was not something that was like, I guess with any employers or like other nurses that like I'd ever really heard about outside of sexual healthcare. And even when I worked at Planned Parenthood, it wasn't something. And it may be different now, but like it wasn't something that like was in training and stuff like that, like that I remember." -Program Participant 21	"I called to make an appointment. The receptionist was kind of clueless, but she was like, I'll pass on the note down to the doctor. And then, of course, the nurse calls . . . well, she basically told me, no, we're not going to do it. We don't know what it is. And I, that's when I like challenged her. And I said, well, you don't write prescriptions, so you need to talk to the provider. And it was like a battle for about two weeks. And then finally, I was able to secure an appointment with a provider, and we talked about it. And he wasn't really aware of it either. He did really some ad hoc research while I was in the room with him and then wrote me a script."-Non-program Participant 5

	Insurance Coverage	Program & Non-program	"I like got a call from the pharmacy after that my insurance like wouldn't be covering it at all. But they basically told me that I could just like sign up for like a program to like to help me cover the cost. And the first time I filled out the application for it, I had like filled out the wrong thing. And then I learned that like the application was like more work than what I had done before, so I had just like decided that I was just going to like to wait until a later date to do it. So, after all that, I just like, I had ended up kicking it the first time I tried to go get it." - Program Participant 9	Now I would know, and I do tell people, there are ways that I can help you get on PrEP if you don't have insurance. But I didn't know that at the time. And I think that in general, that is one of those things that, yes, you hear at the end of a commercial that if you, if, you know, cost is a barrier, Gilead can help. You hear those things, but I don't think people know what to do to do that. And so, for me, it would have stopped me. Had, you know, the excessive lab costs and then having to pay true price for, you know, the medication, it would have prevented me from continuing. I can guarantee that that would have stopped me. -Non-program Participant 19
	Side Effects	Non-program	"When I was talking to my friends initially, one of my friends had bad side effects. And it was something, what was it, something about their kidneys maybe. Some result wasn't good, and they had to be switched to some other kind of PrEP, Descovy maybe. So Truvada and Descovy are the two different ones. And he had side effects on the Truvada, so they switched him. But so that was kind of a like, oh, well, I guess I can get side effects on it. I don't really want kidney damage." -Non-program Participant 4	"Well, I did start right away, but I do agree that like the whole kidney test thing and the nurse saying that like, oh, and you should come back in three months so we can check your kidney function, that made me more conscious of like the possible side effects. So that worries me, I guess." -Non-program Participant 27
	Stigmatization/Pathologization	Program & Non-program	"There are some doctors where you could see it on their face, where their demeanor sort of changes, because they realize you're gay and you're on an HIV prescription drug, like a prevention drug." -Program Participant 18	"And then I heard from people around here that like primary care providers are still, there's a stigma that they are uneducated about it, or they refuse to prescribe it" -Non-program Participant 10
	Clinic Logistics	Program	"I wish it was more accessibly like physically and not in the middle of a hospital . . . more like an outpatient clinic would be my only feedback" – Program Participant 6	"I mean, it took me a little bit of time to just get an appointment, because I work during the day usually, Monday through Friday, to be able to go in and kind of find a time that works for me with the clinics hours." -Program Participant 8

ADHERENCE	**Side Effects**	Program & Non-program	" I would only say the side effects. When I was first put on PrEP, I was taking Truvada, and it had, because I was getting it done through Vivent and getting the testing done every three months, they noticed that my kidney levels, blood levels were starting to get a little off kilter. And because of that, I had to be taken off the Truvada. And then when I went to get it restarted at Holton Street Clinic, they put me on Descovy. " -Program Participant 16	"I went from Truvada to Descovy because Truvada was giving me liver issues. So, when Descovy came out, she switched me to Descovy. And then like it was really weird. I did really well on it, and then all of a sudden, that was giving me issues with my liver. So, then I'd came off of Descovy for, I would say, almost a year. Then once the injectable came out, I started that and have been on it since, and we are just watching my liver enzymes." -Non-program Participant 23
	Insurance Billing / Costs	Program & Non-program	"it's frustrating, every three months, to have to deal with this. I get a bill, and then I'm like, okay, like need to get help again. I'm planning on switching insurances because I'm on the marketplace insurance right now. So, yeah, I'm just, the insurance aspect is my biggest frustration." -Program Participant 14	"I have private insurance, and it's a constant battle every three months I go in to get my blood work because the physician is not coding it correctly, it's not going through billing correctly, insurance rejects it because it wasn't coded correctly, blah, blah, blah. ... they basically like refused all the blood work costs. So, I basically, I'd pay for that out of pocket." -Non-program Participant 5
	Casual Forgetfulness	Program & Non-program	"I would say the biggest barrier would be is if, because it's just part of a normal routine for me, so anything that disrupts what would otherwise be my normal, daily routine. So, you know, like traveling or being on vacation or out of town or something like that, where that normal cadence might, you know, that normal sort of morning cadence is interrupted, and then it's sometimes difficult to, it's easy to forget about it, or at least forget about it until later in the day. And I really, I rarely miss a day, but I can see how it would be very easy to do so in that situation, for me." -Program Participant 13	"I do take it daily. Every once in a while, I do miss a dose, but I typically follow it up the next day. Then, over the summer, depending on like my activity, if I'm going somewhere, I've been visiting family, or if I'm on like vacation, I will stop it. But then I will take it for a full seven days before I'm doing any sort of like sexual activity." -Non-program Participant 28

	Frequency of lab visits	Non-program	"I have to go in and see an infection disease specialist every three months, which is a lot. It's a lot of doctor visits and a lot of copays. ... I kind of mentioned to my doctor because we, you know, I, all my tests would come back negative for everything, and my doctor would kind of ask me, you know, how are things going with it? And I would say fine, and it would be in and out in five minutes and be like, okay. It's a lot of work for not a lot of payback." -Non-program Participant 4	"Like I think it just felt almost like a chore, in a way. Like just I already have to go see a doctor like every three months for mental health stuff, so it just felt like yet another like kind of inconvenient like thing that I had to go do in person every three months. And so, I think that's kind of what stopped me that first time. ... I just wish it wasn't every three months. It's just, it's too much. It's too often." -Non-program Participant 20
	Supply Quantity	Program	"you can't get more than a month's prescription at a time, so you're always refilling your prescriptions. And I think, I don't know if that's a federal thing or a health insurer thing. But you, I mean, you don't have to go to the doctor for three months to get your prescription renewed, but you can't get your prescription filled for three months. You can only get a 30-day prescription. So, you're constantly getting refills." -Program Participant 11	"They would give me a three-month prescription but then send out a month supply. So, they weren't giving me it all up front. They would just send it all a month at a time. Like I would have to request it, which that was kind of a pain. " -Program Participant 15

Table 14. Participant Identified Facilitators to the PrEP Care Process

PrEP Continuum of Care Domain	Theme	Group(s) From Which This Theme Arose	Illustrative Quote(s)	
AWARENESS	**Social Circles**	Program & Non-program	"Yeah, actually, it was just through friends. I didn't even know that HIV prevention was a thing. I'm a child of the '80s, and so in my brain, I didn't know that that was possible. And so, not to get into it too much, but I came out a little bit later in life, just a couple years ago, and so for me, that was a brand-new piece of information. So, through some of my friends, they let me know about it." -Program Participant 18	"Yeah, definitely. I would definitely say it was through friends, like who were gay, who were taking it before I was." -Non-program Participant 1
	Media Advertisements (social media, magazines, TV commercials & shows, & dating/hookup apps)	Program & Non-program	"I think social media and like television shows were probably my first knowledge of it." -Program Participant 9	"Honestly, actually I'm pretty sure maybe Grindr played a part in it. I feel like they sent me an ad and then the fact that like you can like identify that you're on PrEP like on the app, I would say that probably raised my awareness. " ... "I also heard about MISTR [online PrEP services] through Ads. I think I saw an ad on Instagram. And then I was like, oh, this looks interesting. That kind of sounds almost too good to be true. But I'd been wanting to get back on PrEP for a while. I think it took me seeing that ad maybe like five more times to like drill into my brain, but then like each time I'd see it, I'd be like, oh, I should go do that because like there's no excuse not to really. Like it seems so easy. So, then I did." -Non-program Participant 20
UPTAKE	**Informed Provider**	Program & Non-program	"I definitely feel like talking with somebody that's kind of in that field that's, you know, very comfortable talking with people that are on PrEP, that have taken PrEP, or are going to. It just kind of makes you feel like you're more in a safe spot or space to like talk about these things." -Program Participant 29	"Having a willing doctor, because he was willing to educate himself to become that informed provider. He wasn't there to begin with. So that was a big thing, a major positive that helped me to get there, was a willing provider. That, to me, was the biggest." -Non-program Participant 19

	LGBTQIA+ Friendly Provider	Program & Non-program	"I wanted to find a provider that had experience doing that, a doctor that specialized in PrEP. ... I feel like if you went to your regular primary care provider that doesn't specialize in PrEP, there wouldn't be a lot of understanding around the gay community. Even if they are gay friendly, they wouldn't understand. So having a sex-positive, and specialized doctor was really great because you feel very comfortable."-Program Participant 11	"I feel very lucky that my previous provider had a lot of knowledge with queer clients... They've had many other gay patients, so they were like, yep, totally, I, they were like, I've prescribed this a lot recently, so I'll get you onboard..." -Non-program Participant 1
	Proficiency of Care	Program & Non-program	"I was able to get in with them right away. They did my blood work right then, provided any instant results, and I can always get my medication refilled at the pharmacy downstairs in the clinic." -Program Participant 16	"And I would say that was kind of stressful for me, but the main thing was that he was in the same office. It was very easy. He just filled out a paper sheet and handed to the phlebotomist, and then they were able to do the blood draw in the same clinic." -Non-program Participant 28
	Destigmatized perceptions of PrEP	Program & Non-program	"Just it seems like at least like most gay people already pretty much know about PrEP. And there might be some who maybe should have it but like just haven't taken the time to get it, but I feel like a lot of gay men are, at least are, have already kind of like gone through the motions of figuring it out." -Program Participant 12	"But I didn't feel anything after starting it, so that part was okay. I don't, I didn't feel any stigma with PrEP because everyone, not everyone but like over 50% of people on Grindr use PrEP, so." -Non-program Participant 24
	Referrals & Recommendations to Care	Program	"I asked my PCP, and at the time, I think that it was still somewhat new across a lot of PCPs, and I think a lot of the family med physicians were like, hey, I'll continue you on it, but we don't have the infrastructure to start it. So, So my PCP referred me to the HIV clinic at UW, scheduled the appointment, and I've proceeded to do my PrEP services through there."-Program Participant 3	"My partner, he was like, you know, why don't you just like reach out and try and get some help with Vivent because he obviously has had great care, and they're super knowledgeable because they are more specialized for that service." -Program Participant 14

	Self-Advocacy	Non-program	"So, I did a decent amount of my own research and then had like an in-depth conversation with a sexual health provider about options." -Non-program Participant 22	"Usually, I do research on any medication I take, so I'll start there, and then I'll go to my general practitioner and ask questions" -Non-program Participant 25
ADHERENCE	**Adherence Aids (reminders, paired with routine, pill organizer)**	Program & Non-program	"It's, yeah, it's part of my morning routine. When I rinse my mouth after brushing my teeth, the left-over water in the cup is what I take my pills with. ... I also use a pill thing; you know the Sunday through Saturday organizer. ... I put a reminder on my phone, and it comes up on the 15th of every third month, and I go to the clinic and just walk in and do the lab." -Program Participant 2	"So, I set reminders on my phone every morning at 7:00, so that I can remember to take PrEP. Also, I just put my medications on my desk, so I see that every day. Also, I'm pretty sexually active, so that also serves as a reminder." -Non-program Participant 24
	Financial Resources	Program & Non-program	"Well, we run it through the insurance first, but thankfully, there's the, if it wasn't for the discount coupon or co-pay card that the manufacturer has, I would not be able to even bother doing the PrEP because it would be too expensive. " -16T || "They offer great support, and then even when it came to the price for screening, they have a program that, if you can't afford either a certain portion of your screenings or you can't afford it at all, they have a program that like, kind of like that will take care of it for you, like a sponsorship program." -Program Participant 17	"The problem with that [Descovy], it was not covered by my insurance. My copay ended up being like $960 a month. But then my pharmacist assisted me with contacting Descovy and getting a special card that basically brought the cost down to just under $25 a month. But I have to do that annually in order to get that help." -Non-program Participant 26
	Receiving a 90-day supply	Non-program	"Yeah, I, so I get 90-day supply at a time of the medication, so I kind of know when my supply is running out. I'm also due for labs, and I just keep track of it for myself that way. And they always have the lab orders in on time and things, so I usually know when the three-month point is coming up." -Program Participant 8	"They give me three bottles. So, I get a three-month. I'm very appreciative I only have to go once every three months. I think it would be a lot harder to go monthly. I feel like, it makes sense to get a 3-month supply at a time. You have to do your labs every three months, so it is a great way to keep track of when your labs are due. It's kind of like, oh I'm almost out of PrEP, I need to do my labs, versus if I have to go monthly, I might forget what month I'm on and when my labs might be do." -Non-program Participant 1

	Navigator Support	Program	"And, you know, it was through the help of the PrEP navigator that, you know, I got the codes resubmitted. Without her, then I just would've stopped taking it. I would have said like, there's no way I'm going to do these screening labs anymore." -Program Participant 3	"I would really, this is where I have to advocate, because I'm sure you probably know from [the navigator] because she has been an absolute saving grace in this entire process, ever since I moved back here and the entire time I've been on PrEP. Like I've never had, I mean, I've had like my providers that I've worked with. But I've never had somebody like her kind of being like a social worker. It's really helped me with my individual cases and like problems." -Program Participant 7
	Rx Mail Order	Non-program	"The specialty clinic or specialty pharmacy is only mail order, and one other thing I should mention too is that they're actually really good with working with you about doing like the robocalls and, for auto-refills." -Non-program Participant 5	"It's really convenient for me to just like run to the hospital really quickly and grab anything, since I work there. Recently, I've just got it delivered to my house by the UW Health mail pharmacy. It's even easier." -Non-program Participant 27
	Ease of Care	Non-program	"They're pretty easy. I mean, my practitioner puts in an order. He'll send me an email and say, hey, you know, I've got a lab order for you. Please make sure it's done by this time. And then I can just go in within that time period, same process. And, yeah, it seems to be pretty seamless process." -Non-program Participant 25	"It's an easy process. I guess they order the labs, so they're always like on file before the meeting, and then I show up at the drop-in lab clinic, and say I have labs to take care of." -Non-program Participant 4

Awareness

All participants identified similar challenges to PrEP awareness (Table 13). One such barrier to PrEP awareness relates to PrEP coverage. For example, minimal information is provided to the public that PrEP is available to anyone eligible at no cost. Another common awareness-related barrier that was identified in interviews was whether PrEP was something they were eligible for. This barrier was commonly identified by gender minorities (i.e., transmasculine and cis-woman having sex with men who have sex with men), as they expressed that there is limited information surrounding "best practices" for trans-men or "criteria" for cis-women.

Although there are known barriers to PrEP information, there is awareness by the public that there is a bio-medical HIV prevention method available. All participants identified awareness of the preventative medical benefit related to PrEP (Table 14). Avenues of their PrEP awareness came from their social circles and/or media advertisements. It was most common that participants heard about PrEP from their friends. As for media advertisements, majority of participants expressed that they're seeing PrEP advertised on social media, tv shows and informercials, magazines, and even dating apps.

Uptake

All participants identified that having an uninformed primary care provider was one of their biggest barriers to PrEP. Fortunately, participants identified various facilitators to overcoming this barrier including being referred or recommended to care and being able to self-advocate. Many program participants expressed that although their primary care provider was not knowledgeable on PrEP, they were able to refer them to a provider that was (which in turn linked them to a navigator). Additionally, program participants shared that their social circles

were recommending places for them to go to receive care. Other ways non-program participants have approached getting help from uninformed providers is through self-advocacy. Importantly, participants from both groups shared that having a provider that was knowledgeable and aware of PrEP was a huge benefit to being able to start it right away.

Another important barrier to PrEP uptake identified involve the stigmatization and pathologization of PrEP. Although many participants shared similar experiences of stigma, others were able to share that having or finding an LGBTQ+ friendly provider was something beneficial to overcoming this pathologization. Additionally, most participants expressed that PrEP and HIV is being destigmatized in queer spaces which is important to increasing the use of PrEP among this vulnerable population. Unfortunately, another deterring factor to PrEP uptake for individuals is insurance. In fact, one participant shared that it was their insurance company denying coverage of their prescription that stopped them from starting PrEP. Another potential barrier to starting PrEP that non-program participants shared was the fear of side effects. A final challenge to starting PrEP that was shared by program participants included a variety of clinic-related logistics, such as the location of the clinic, the physical accessibility of the clinic once arriving, and scheduling appointments. However, all participants expressed that the proficiency of care once getting an appointment scheduled was a benefit, such as getting all the necessary care done in the initial visit.

Adherence

One of the most common barriers to PrEP adherence identified by all participants is the constant battle with insurance. One issue identified by participants is that insurance is only covering so many lab visits per year. The second issue that serves as a barrier to adherence involves PrEP care being coded incorrectly for insurance billing, and participants either being

denied their PrEP prescription or getting bills for their lab work. Fortunately, several participants from both groups have access to financial resources to aid in bills they're receiving from their insurance companies. One means of financial assistance includes the manufacturer's advancing access medication assistance program and/or co-pay program. Additionally, those receiving PrEP care from the navigation services have access to other financial resources through the program funds to cover lab costs. Importantly, the participants receiving care from the navigation services expressed that having a navigator to support and advocate for them throughout their PrEP care process has been beneficial in adhering and retaining in their PrEP care. In many cases, without the navigators' advocacy with insurance claims, participants would have stopped taking PrEP.

Another challenge related to PrEP adherence, shared among many participants, is the long-term side effect PrEP has on users' kidneys and liver. For example, one participant had to switch from Truvada to Descovy, and then from Descovy to the injectable due to the drugs impact on their liver (Table 13), causing various lapses in PrEP care.

A challenge to adherence that was only identified by participants receiving care outside of the navigation services was the frequency of lab visits. These participants expressed frustration with having to get follow-up labs done every three-months to retain in PrEP care. However, they did express that a facilitator to the frequency of lab visits was the ease of care, such as their providers having standing lab orders, receiving reminders about labs and follow-up visits, and visits being prescheduled.

A challenge to adherence that was only identified by participants receiving care from the navigation services was related to the supply quantity in which they're receiving their PrEP prescription for pick-up at the pharmacy. PrEP is prescribed for 3-months at a time, however, most program participants expressed that they're only receiving a 30-day supply at a time. This

has been identified as a barrier to adherence in the sense that having a 90-day supply upfront helps an individual know when it is time to schedule the required quarterly follow-up labs in which to get a prescription refill. In fact, one of the biggest facilitators to adherence identified by the non-program participants was their ability to receive a 90-day supply. Another adherence facilitator identified by only non-program participants was receiving their prescriptions in the mail.

A final challenge to adherence that was identified by all participants includes causal forgetfulness or just being out of their daily routine and remembering to take it. Fortunately, they all have identified various adherence aids that they use to minimize the number of missed doses they have. The adherence aids that participants identified as useful to them include daily reminders and alarms on their phone, pairing taking the medication with a routine (i.e., brushing their teeth, taking a multivitamin, etc.), and utilizing a weekly pill organizer. Additionally, some mentioned that their sexual activity levels act as reminders.

Awareness of the PrEP Navigation Program

Non-program participants were provided information on the PrEP Navigation program being deployed in the state and asked various questions about their knowledge and perceptions of the program. Out of the 13 control participants, only 4 were aware of the program. Of those 4, one participant has worked with one of the navigators in helping dispute insurance bills but remains receiving his care through his primary care provider. Additionally of note, among the program participants, 4 out of 16 were unaware that they had a navigator available to them through the agency in which they receive their care from.

Eight out of the 13 non-program participants expressed that it would be beneficial to them to have access to a PrEP navigator. In particular, participants expressed that it would be

nice to have someone that is specialized in PrEP and the process of its continued care, especially at the beginning; “I think at the beginning, it definitely would, you know, give me a little insights and, if I had any questions, or further questions that I'd maybe feel, you know, more comfortable with a queer person or, a queer ally or, you know, somebody that I know for sure is informed on this. And then, you know, if hardships were to happen, it would be a good thing to have access to and know of.” (Participant 25). Additionally, participants explained that having someone, such as a navigator, as an advocate for accessible and affordable PrEP would be useful. For example, Participant 19 states: “They would provide more than my primary care would because they're there to advocate, right? Primary care may have concerns and questions, and in this case, mine is willing to be educated. But a PrEP navigator that can be there to be an advocate is always a benefit, to have that person that may be able to speak up for you and advocate, because some people have a hard time with that in medical settings, to actually ask for what they want.”

Improvements to PrEP Access and Adherence

Final items of discussion in interviews with both group of participants included their thoughts and ideas about how the state of Wisconsin could improve access and adherence to PrEP (Table 15). In terms of improving access to PrEP, most participants agreed that there needs to be more navigators in the state, that PrEP care services need to expand across the state, and that resources need to be more accessible. Additionally, many participants expressed that there is a need for increasing awareness of PrEP among primary care providers, especially about the 2-1-1/on-demand regimen. In terms of improving adherence to PrEP, aside from addressing the consistent barriers that have already been discussed participants really took accountability for their responsibility in adhering and retaining in PrEP care.

Table 15. All Participant Perceptions on Improvements to PrEP Access in the State

Themes	**Illustrative Quotes**	
	Program Participant Quotes	**Non-program Participant Quotes**
More Navigators	"Not off the top of my head other than just maybe expanding the navigator program. I don't know how prevalent it is." -Program Participant 6	"I think that's where more PrEP Navigators would be very beneficial. I think the first appointment should really be with a PrEP navigator to talk about it and then go into the whole situation because I feel like it would be a lot more, the patient would be a lot more educated." -Non-program Participant 5
Expand Services	"I think access in rural areas, especially at like rural clinics and stuff. Yes, there's this smaller community, but it's also probably more of an at-risk community than someone coming from Madison or Milwaukee, just because a lot of times they're positive, and they're still having unprotected sex, and they're having unprotected sex with people who don't know their status. So, like I think more access, more awareness in rural communities would be, and like it makes it a little more difficult, because how do you do that discreetly? You know, with a lot of people who like can't or don't want to come out, I think would be good." -Program Participant 15	"I do think that that can be a hindrance, especially outside of metro areas like Milwaukee and Madison, because even going down into Kenosha, the fourth-largest city in the state, the resources aren't there. The information isn't there. There's a lot of people that kind of struggle through the PrEP world in those areas, Kenosha, Racine. And I can only imagine what it's like in La Crosse and Eau Claire and Superior and all these, you know, Hayward and all the other places throughout the state that don't have the rich resources that the metros have." -Non-program Participant 19
Accessible Resources	"But I think just more knowledge right in the beginning, just more access to it would have been helpful so I didn't feel like I was kind of going in so kind of like oblivious and blind." -Program Participant 7	"Potentially, having like a website that like lists by area providers that provide PrEP services just because I don't know if there's any sort of list or directory that exists." -Non-program Participant 28
Increase Primary Care Provider Awareness	"I do kind of think that, and I don't know how like much like traditional healthcare providers are like allowed to tell you that you can use medications in a way that's like not technically approved, but it seems like if there are people who just like can't handle the everyday style, like the 2-1-1 thing, seems like it would make more sense for people. But I definitely don't think my doctor, who didn't even know what the medication was, would've been able to tell me about that." -Program Participant 12	"Providers should have like an awareness. Like most if not all of our primary care providers are able to provide PrEP care and should be." -Non-program Participant 10

DISCUSSION

PrEP Navigation is a promising intervention, not only to increase PrEP use but also for increasing adherence and retention in PrEP care. PrEP Navigators are essential members to the PrEP care team, as they are often the only members to have direct engagement with patients throughout the entire PrEP care process.[56] Most importantly, they are essential to patients' continuation of PrEP care, as they are the initial contact point and health care liaison for patients that face barriers to care. This study, along with others that have evaluated navigation programs, have demonstrated ways in which navigators are effective at facilitating barriers to PrEP care.

Although awareness surrounding PrEP as an HIV preventative medication has significantly increased since its first availability, through the facilitation of mass media advertisements and outreach in queer-identified spaces, there is still concern surrounding PrEP awareness. Specifically, there is a need to increase awareness of PrEP eligibility among individuals that have a risk of HIV outside of men who have sex with men. This is not only demonstrated in this study, but in previous studies looking at PrEP awareness.[7] Navigators can bring awareness of PrEP to all individuals, not just those in the queer community, that can benefit from this preventative medication. Although not demonstrated by the findings in this study, other studies have found that navigators being involved in intensive outreach and targeted PrEP education within the communities of highest risk of HIV has influenced awareness of PrEP and the navigation services available.[67] Therefore, increasing navigators' involvement in the communities throughout Wisconsin to provide informative PrEP education can increase the number of individuals aware of PrEP as an HIV preventative option for them, as well as the navigators available to assist them in their care.

Once becoming aware of PrEP, individuals need to find a provider to start them on it. As demonstrated in the literature and further supported by this study, one barrier to PrEP uptake involves having or finding a PrEP-informed provider.[59,62] This includes being LGBTQ+ friendly, without bias and stigma, and being comfortable prescribing PrEP to anyone interested and eligible. Fortunately, being assisted by a navigator for PrEP care in Wisconsin, all navigators are associated with clinics and/or providers that are specialized in sexual health and/or HIV prevention and treatment.

The most commonly reported barrier to PrEP, identified in this study and others, is financial concerns.[62,64,74,93] There is a need to bring awareness to the affordability of PrEP, including medication payment assistance programs available (i.e., Gilead copayment and/or patient assistance programs) and required health insurance coverage. In 2023, the PrEP Access & Coverage Act was passed ensuring that PrEP medications and any associated costs be covered by all private and public health insurance plans/programs.[140] Although patients may not be entirely knowledgeable on this, navigators are. Therefore, those receiving PrEP care with facilitation of a navigator have them to advocate on their behalf in disputing ongoing insurance bills from their PrEP care. Bringing awareness to individuals that PrEP care is covered by insurance and has minimal, if not any, costs associated with care can increase the number of individuals that seek, start, and adhere to this preventative medication.

Although there were barriers to PrEP care that navigators aren't necessarily capable of overcoming or eliminating, such as patients having side effects, the prescription quantity supply, clinic logistics, or the frequency of lab visits, they have demonstrated ways to support their patients in ensuring these barriers or others are not detrimental to their adherence and retention to care. Patients experiencing side effects from one form of PrEP can try the other daily medication

or the injection, for which a navigator can help advocate for or just inform them of their options.

Navigators may have no control over whether a patient receives a 30- or 90-day supply from their pharmacy or the frequency of the required lab visits, but they are engaged with their patients to remind them to pick up their monthly prescriptions or attend their quarterly labs for retention in care. Finally, although navigators aren't responsible for clinic logistics, they are available to patients in locating the clinic and most importantly finding an appointment time that works best for the patient.

All patients receiving PrEP in Wisconsin appear to be experiencing similar barriers throughout their care process. However, those receiving care with the assistance of a navigator have demonstrated to have solutions to barriers at their disposal, whereas patients without navigators have increased burden which can result in discontinuation of care. Findings from this study have further supported that navigators are effective at overcoming barriers to PrEP care, especially those involved in initiating, adhering, and retaining in PrEP care. The PrEP Navigation program in Wisconsin has the potential to increase PrEP uptake and adherence in the state. However, Wisconsin Department of Health Services HIV Prevention team needs to consider expanding the program to increase its effectiveness in PrEP care. This expansion should include training more navigators that are available across the state and have the accessibility to be more involved in the communities doing outreach and education to reach underserved populations that can benefit from PrEP.

Study Advantages

This study has three important advantages. First, it is the first study to examine the effect of PrEP Navigation in the state of Wisconsin. Second, it is the first evaluation study to utilize the PrEP Continuum of Care Model to understand patients' unique experiences in PrEP care.

Finally, it is the first study to utilize a comparative analysis between individuals receiving PrEP care services from a navigator and those receiving PrEP elsewhere, when evaluating the barriers and facilitators to PrEP Navigation.

Study Limitations

First, the research team acknowledges that study findings may not transfer to all PrEP care processes or navigation programs as they might not be applicable. However, the study design, including a "control" group to understand the effectiveness of the program, which this study is the first to do so, should be considered when evaluating other navigation programs. Second, the research team acknowledges the studies sample size as a limitation. Although almost 30 participants are a good sample size for qualitative data, and data saturation was reached, this sample is small in relation to the total number of individuals on PrEP in the state and the total number of individuals utilizing the states navigation program. Finally, participants from the navigation program were only represented from half of the navigation agencies involved in the program. However, the data across the treatment participants shared similar experiences with their navigators.

CONCLUSION

This study utilized the PrEP Continuum of Care model to evaluate the effectiveness of the state of Wisconsin's PrEP Navigation Program on alleviating barriers to PrEP care. The program being disseminated in the state of Wisconsin has demonstrated to be effective at overcoming barriers to initiating, adhering, and retaining in PrEP care. Future efforts should consider improving navigators' role in awareness of PrEP and expanding the program to have a larger reach on all individuals and subpopulations that could benefit from PrEP.

PAPER 3: UTILIZING THE PRACTICAL ROBUST IMPLEMENTATION AND SUSTAINABILITY MODEL TO EVALUATE THE STATE OF WISCONSIN'S HIV PREVENTION PROGRAM, PREP NAVIGATION

ABSTRACT

Background: New HIV infections continue to occur annually throughout the U.S. Although largely impacting states in the south, HIV continues to be of concern in the state of Wisconsin. Wisconsin's plan to prevent new HIV infections involves increasing access to and use of pre-exposure prophylaxis (PrEP), by improving and expanding the implementation of proven HIV prevention interventions, such as PrEP Navigation. PrEP Navigation is an evidence-based HIV prevention intervention that increases access and adherence to PrEP, while addressing and overcoming barriers to PrEP care (i.e., awareness, uptake, and adherence).

Objective: The purpose of this study was to conduct a program evaluation utilizing the Practical, Robust, Implantation and Sustainability Model (PRISM) to understand the multi-level interactions between the state of Wisconsin's PrEP Navigation program components and their influence on program outcomes (i.e., PrEP use).

Methods*:* Semi-structured key informant interviews were conducted with Wisconsin PrEP Navigators to understand their unique experiences navigating clients in PrEP care. Additionally, semi-structured interviews were conducted with clients receiving PrEP from one of the navigation programs to understand their unique experiences receiving care, facilitated by one of the program navigators. Interviews were analyzed using inductive and deductive thematic analysis.

Results: Themes were identified across the domains of PRISM, while considering and encompassing the components of the continuum of PrEP care (i.e., awareness, uptake, and

adherence) for both the clients and navigators' data, while also identifying benefits and challenges to PrEP Navigation in Wisconsin.

Conclusion: Utilizing PRISM, the results from this study found that there are many challenges and benefits to the PrEP Navigation program from the client and navigator perspective. Future efforts should consider navigator and client program-related needs, while expanding the program both in the state and within the agencies currently deploying the intervention to achieve the states' goal of preventing new infections. Findings from this study may not be transferable to other navigation programs, however, the application of the evaluation may be applicable in evaluating other PrEP Navigation programs.

BACKGROUND

New human immunodeficiency virus (HIV) infections continue to occur annually throughout the United States (US).[1,2] Although largely impacting states in the south, HIV continues to be of concern in the state of Wisconsin. As of 2022, roughly 7,300 individuals were living with HIV and on average more than 200 individuals are newly diagnosed annually.[11] In alignment with the US Department of Health and Human Services' *Ending of the HIV Epidemic Initiative*, Wisconsin Department of Health Services (WDHS) launched an *Integrated HIV Prevention and Care Plan* to address the four pillars involved in ending the epidemic; diagnosis, prevent, treat, and respond.[9,13,14] One strategy to WDHS' plan to prevent new HIV infections involves increasing access to and use of pre-exposure prophylaxis (PrEP), by improving and expanding the implementation of proven HIV prevention interventions.[14]

PrEP is a bio-medical prevention measure that reduces an individual's risk of contracting HIV by 99%, when taken as prescribed.[3,5] Currently, PrEP is offered as a once-daily medication (Truvada[122] or Descovy[123]) or as an intramuscular injection every two months (Apretude[124]). Those that could benefit most from PrEP include individuals at highest risk of contracting HIV, such as gay, bisexual, and other men who have sex with men, people who inject drugs, transgender women who have sex with men, and men and women of color (due to a higher prevalence and incidence among their racial and ethnic demographics).[1,2] PrEP care can be looked at as a continuum, starting with an individual identifying at risk of HIV, screening for HIV and sexual transmitted infection status', being referred and linked to a PrEP provider to start a PrEP regimen, and then adhering to and retaining in care to maintain HIV-negative.[21]

PrEP Navigation is one evidence-based HIV prevention intervention that has been adopted, implemented, and disseminated throughout the US to increase PrEP uptake, including

in Wisconsin.[18,53,61] PrEP Navigation involves training "navigators", to assist individuals who are vulnerable to HIV, access PrEP and further support them in continuation of care.[17] Navigators uphold many roles and responsibilities, including educating individuals on PrEP, assisting with insurance, and accessing financial assistance, and linking individuals to additional support services to address other ongoing social determinants of health that impact their retention in PrEP care. Along with supporting individuals on the proper and consistent measures of accessing, starting, and adhering to PrEP, navigators are key to identifying solutions to barriers that prevent individuals from engaging in and continuing their HIV preventative health care.

PrEP Navigation has been demonstrated as a promising intervention, especially when it comes to a navigator's roles in overcoming barriers to PrEP care (i.e., awareness, uptake, and adherence).[53,55-59,61-69,71-74] Navigators are increasing awareness of PrEP through community outreach and targeted PrEP education. Importantly navigation has alleviated barriers to PrEP by having direct navigator assistance and engagement throughout the entire PrEP care process, including linking them to care and routinely following up with appointment, medication, and lab reminders to ensure adherence and retention.

PrEP Navigation was first implemented in Wisconsin in 2018 and continues to be one of the key intervention strategies in the state to increase access to and uptake of PrEP. It is currently being funded and offered in seven different agencies across the state reaching at least 10 counties with the highest HIV incidence. Yet, PrEP remains underutilized in these areas and across the state. As of 2022, there were an estimated 14,000 individuals in the state considered at risk of contracting HIV, however only 26% of those individuals are being prescribed and taking PrEP.[22]

The long-term goal of PrEP Navigation is to increase the use of PrEP among individuals at highest risk of contracting HIV, to aid in decreasing new HIV infections.[17] Before WDHS can

improve and expand the program, there is a need for the program to be evaluated. Therefore, the purpose of this study was to conduct a program evaluation utilizing the Practical, Robust, Implementation and Sustainability Model (PRISM) to understand the multi-level interactions between program components and their influence on program outcomes (i.e., PrEP use).

METHODS

This study was conducted in collaboration with the Wisconsin Department of Health Services' HIV Prevention Unit. The study was determined exempt and approved by the University of Wisconsin Health Sciences Institutional Review Board. This study included a review of the navigation program's training materials, quarterly review documents, PrEP clinical guidelines and policies, and interviews with program clients and navigators.

Theory

The Practical, Robust Implementation and Sustainability Model (PRISM) is an implementation science framework that can be utilized for planning, implementing, sustaining, and/or evaluating interventions.[107] This model includes the multi-level interactions between an intervention, the perspective, and characteristics of the recipients (i.e., patients, staff, managers, leaders, etc.), implementation and sustainability infrastructure, external environment, and the contextual domains of the RE-AIM outcomes (reach, effectiveness, adoption, implementation, and maintenance).[107,108] This theory was considered when creating the interview guides and applied when analyzing and conceptualizing the interview data findings.

Participants & Setting

This study included PrEP Navigators and clients that are involved in the state of Wisconsin's' prevention program, PrEP Navigation. At the start of the study, there were seven agencies participating in the program; five non-profit health clinics that specialize in sexual

health, LGBTQ+ health, and/or HIV prevention and treatment, one clinic within a private hospital, and one clinic within a public hospital.

Client participants were recruited through a recruitment flyer that included information about the study, what was expected for participation, who was eligible, and a QR-code to sign up through a pre-screening survey. The recruitment flyers were displayed in the waiting areas and exam rooms of the clinics that offered PrEP Navigation services. Additional means of recruitment included Navigators from the clinics emailing their clients information about the study along with the recruitment flyer and link to the sign-up / pre-screening survey. Individuals were eligible to participate in the study if they were 18-years of age or older, able to speak and understand English, actively taking PrEP or taken PrEP in the past 12 months and receiving their PrEP care at one of the participating agencies/clinics that offered PrEP Navigation services in the state of Wisconsin. Those that were deemed eligible to participate were contacted by the research team, via email, to schedule an interview.

Navigator participants were recruited through an email that included information about the study and what was expected for participation. Navigators were eligible to participate in the study if they were actively serving as a PrEP Navigator. Those that were eligible to participate were contacted by the research team, via email, to schedule an interview. See Appendix B and C for all recruitment materials.

Data Collection

Interviews with clients were conducted virtually through Zoom[137], and were semi-structured, one-on-one, and took approximately 30-45-minutes. At the start of the interview, the interviewer gave the participant time to ask any questions. Because this study was IRB-exempt, verbal consent was sufficient. The interview guide was developed using the PrEP Continuum of

Care Model[21] and components of the PRISM[107] framework.[107] Client participants were asked questions regarding their awareness of PrEP, their uptake process, and their adherence to PrEP, as well as questions about improvements to the PrEP care process in the state. Additionally, participants were asked questions about their experience with their Navigator and the care they are receiving. Demographics including age, race/ethnicity, gender, etc. were collected from the participants via a Qualtrics Survey (via link) following the end of the interview. Client participants were compensated with $50 Amazon gift cards for their participation. Interviews were conducted until data saturation was reached, marked by the lack of additional information regarding their PrEP care process and experiences. See Appendix B for the client interview guide.

Key informant interviews with Navigators were conducted virtually through Zoom, and were semi-structured, one-on-one, and took approximately 60-75-minutes. At the start of the interview, the interviewer gave the participant time to ask any questions. Because this study was IRB-exempt, verbal consent was sufficient. The interview guide was developed using PRISM and encompassing the PrEP Continuum of Care Model. Navigators were first asked to walk the interviewer through their navigation process from their first interaction with a client to any follow-up interactions. Then, asked questions about how they are reaching individuals for navigation services, how their navigation skills have adapted since first in the role, barriers and facilitators to starting and retaining clients on PrEP, the support they're receiving from the state, perceived changes needed to the program, and the benefits and challenges of being a navigator. Demographics including age, race/ethnicity, gender, etc. were collected from the navigators via a Qualtrics Survey (via link) following the end of the interview. See Appendix C for the navigator interview guide.

Data Analysis

All interviews were audio recorded by Zoom. The client interviews were transcribed by the Premium Business Services – a transcription services business that specializes in interviews and focus groups. The navigator interviews were transcribed by the transcription function in Zoom and cleaned by the research team. The data was analyzed similarly for both the client and navigator interviews in NVivo14. Using thematic analysis, the research team identified salient themes present in the data following the criteria assigned by Braun and Clarke.[139] The analysis was performed using both an inductive and deductive approach, with a preconceived codebook based on the major components of the interview topics.

RESULTS

Demographics

In total, 16 of the 17 interested and eligible clients agreed to participate and completed an interview with the research team (94%). The demographic characteristics of the 16 participants is shown in Table 16. Most participants were young to middle-aged adults, cis-males and self-identified as gay, bisexual, or other men who have sex with men. All client participants were white and had health insurance. Two of the three state navigators were interested and agreed to participate in the key informant interviews (66%). Both navigators were non-Hispanic white, cis-female with higher education working in Dane and Milwaukee county. The average time as a navigator between the two was five years. See Table 23 in Appendix C for all Navigator demographics.

Table 16. Client Demographics

Characteristic	Item	Frequency (n=16) n (%)
Age		
	18-24	1 (6.25)

	25-35	10 (62.5)
	36-45	4 (25)
	46-55	1 (6.25)
Gender		
	Cis Male	15 (93.75)
	Cis Female	1 (6.25)
Race/Ethnicity		
	Non-Hispanic White	15 (93.75)
	Hispanic White	1 (6.25)
Household Income		
	<50,000	3 (18.75)
	50-70,000	4 (25)
	70-100,000	3 (18.75)
	100,000+	6 (37.5)
County		
	Dane	11 (68.75)
	Cook	1 (6.25)
	Milwaukee	2 (12.5)
	Waukesha	1 (6.25)
	Racine	1 (6.25)
Health Insurance		
	Insured	16 (100)
Medication Assistance		
	Yes	5 (31.25)
	No	11 (68.75)
HIV Risk Characteristic		
	Gay, Bisexual, Other MSM	14 (87.5)
	HIV+ partner	1 (6.25)
	Other	1 (6.25)
Average time on PrEP (years)		2.5

Themes

Themes were identified across the domains of PRISM, while considering and encompassing the components of the continuum of PrEP care (i.e., awareness, uptake, and adherence) for both the clients and navigators' data (Table 17). Additionally, there have been

identified benefits and challenges to the intervention, PrEP Navigation. The following outlines the findings from the interviews with clients and navigators for each domain of PRISM.

Table 17. PrEP Navigation evaluated at the client and navigator levels outlined by the PRISM Domains

PRISM Domain	**Level of Assessment**	**Theme**	**Illustrative Quote(s)**
Intervention	Client & Navigator	Benefits Financial assistance	"The PrEP Navigator helped me access the discount coupon or co-pay card that the manufacturer has, if it wasn't for that I would not be able to even bother being on PrEP because it would be too expensive." -Client 12
		Patient advocacy	"It's all just been quite an easy process, a lot easier than I would have expected it to be. And just the support from the clinic and the navigator has just been amazing, and I'm glad that the navigation within the state is there." -Client 13 "I think that there's a lot of my role that becomes directing them to other resources. I think that helps them stay in care because it's like a human connection. I think that's especially true for patients who present with higher acuity, who have more complex psychosocial needs having a real person that they can text me, and they can call me, and they know it's going to be me. That's really helpful, not only to them persisting with PrEP as long as they want to, but in staying connected with primary care, or in getting, you know, showing up to that housing, counseling appointment, you know, whatever the case may be, I think that for some people the fact that this is a personal relationship is really beneficial to them." -Navigator 1
		Safe, specialized, & supportive clinic	"I feel very comfortable walking into that place. I remember being in college, going to get tested, you're a little awkward, and you're not sure what's going on. But I feel very comfortable and relaxed walking in there and getting to know the staff, you know. I think they all know my name and stuff now too, which is nice. So, like it feels good." -Client 11
		Increased knowledge of PrEP	"Well, I think that just, you can educate more people, right? And like I said before, I get clients who PrEP is not necessarily a something that they need for themselves. But I've had a lot of people walk out saying, hey? I'm glad that you told me about that. I'm glad that I know that that exists. I do have somebody who I know who that would probably be a good idea." -Navigator 2

		Challenges Limited navigators	"There should be more navigators, especially in every clinic that is specialized in PrEP/HIV treatment, prevention, and care." -Client 2 "My week is full, like I am busy, yet I am not doing everything in my job description. ... It's difficult to do it all, and like I have, you know, perhaps erred on the side of be more clinical. I think that having another, I think that there could at least be 2 of me like that, we could at least, we could have another full-time navigator, and we would both be busy, and it would allow us to meet the clinical needs of patients that would allow us to work within our system to create the better processes and relationships that keep PrEP accessible." -Navigator 1
		Time spent on insurance & billing	"So, insurance changes are tough to navigate, because sometimes criteria changes. So different medications are accessible. That's tough. The billing issues are tough. When I step back, and I like, think about how much of my job billing issues take up and like how much of a present thing it is that I talk about with clients. It takes up too much space like it. The amount of time and effort not just of like my time and effort. But like our Admin staff, and like other staff as part of this program. it just feels like it is taking up more than its share." - Navigator 1
		Outdated case management techniques	"We're still on paper charting. You know, the most high tech that I've got is my stinking spreadsheet, right? Which has its pros and cons. I mean, it's at least a way to keep me fairly organized, but we are in the process of switching over to an EHR type charting." - Navigator 2
		Communication	"Any person that's a navigator needs to be good with communications, so better communicating. This person is supposed to help me figure out, okay, what do I need to do, so that I can continue on PrEP at either low cost or no cost. The struggle with that is that person hasn't followed up with me very well." -Client 14
Recipients	Client & Navigator	*See Table 1 on Client Characteristics. See Appendix C on Navigator Characteristics*	
Reach	Client & Navigator	Referrals	"My doctor was like; I don't know much about it. Go talk to them. You know, he knew, but he was like, go talk to these people. ... It made, that made things easier [being referred out]." -Client 1 "Other healthcare facilities know about us and have suggested clients come to us either because they can't suit their needs one way or the other. If for whatever reason, they can't take care of that client they will advise them to come to us, and we usually can accommodate." - Navigator 2

		Recommendations	"But then I talked to one of my friends who goes to [redacted clinic name], and he said I should just go there, and so I did." -Client 8 "Friends are telling friends. I trust these people. They're nice to me. There's no judgment. They do what needs to be done, and they're quick. You know that also is our reputation preceding us. That is. that's word of mouth getting out saying, these people know what they're doing." -Navigator 2
		Outreach	"We have outreaches at some of the bars at night; Woody's, Cruise Club, Icon, there's probably a couple of others in there that I probably am not remembering, cause I'm not the one who actually staffs them. But, you know, evening time, nighttime, we've got staff who go out to the bars and do on site testing" - Navigator 2
		Consult to PrEP Navigation	"Yeah, I went to the Public Health office, had a visit there, and then was kind of just trying to get some just preliminary tests done, and then wanted some more information on PrEP and like how to start it. And they were able to offer kind of a PrEP navigator who, [redacted navigator name], she was kind of the one to help me get everything scheduled with my primary care." -Client 16 "Sometimes there's also we have created a specific referral for PrEP, called the consult to PrEP navigation. So, I have been spending one afternoon a week at public health for about the past, and they have QR codes posted around their clinic that patients can fill out the form. They give like name, email. It's like basic contact information. And then it comes to me, and I can then reach out to the patient." -Navigator 1
		Advertisements	"Then we also have, a few years ago we did a pretty big well, I don't know if it's big, but we did an advertising campaign. It felt big. Where we did a lot of ads like on social media. We had ads and dating apps. I think we had ads on Madison City buses." - Navigator 1
Effectiveness	Client* & Navigator	Influx of clients	"So, our numbers continue to grow and that tells us that we're doing something right. Like the number of patients who like, they grow in both ways like the number of new patients, grows and the number of total patients grows which tells us that we have patients who are persisting in care as long as they want to, and we continue to get more." - Navigator 1

		Facilitators PrEP on-hand	"At our clinic, we now have some medication on hand. We have some bottles in stock, so a lot of times, if they want, I can just go ahead and give them a bottle from our stock. Once our rapid HIV test comes back negative. I can hand that over to them at the end of their first visit." -Navigator 2
		Community testing	"But, you know, evening time, nighttime, we've got staff who go out to the bars and do on site testing and so if they swing through the bar, and it's like kind of their 3-month mark, like, you know, over a year. But 3 months mark they can just they can just say, Hey, PS, you know, make sure you tell Nicky this is my HIV test, for you know, whatever." -Navigator 2
		Affordable labs	"I also tell various clients, say if they get PrEP elsewhere, normally, and they're fine with that like, maybe through their primary care, through Vivent, through inclusion clinic, anything like that. They can always just come to me just for labs if labs are a problem elsewhere because insurance is sometimes problematic. If they are having troubles they can come to me." -Navigator 2
		Assistance to resources	"If someone, for whatever reason. doesn't want to use their insurance now there's good Rx and single care, the coupon programs that are that make it pretty reasonable they have to do a little bit more shopping to make sure that, like you know, this place versus that place has the best coupon for them. And then HHS program is great, it's a really easy program to utilize as well for people who don't have insurance." - Navigator 2
		Organized care management	"But the goal is that I am checking in with every patient every 3 months to make sure that they have what they need. That they have a way to do labs if they want to continue doing that. If they're taking a break, and they don't need that refill, then we can document that. And we and we know and understand that. And they know how to reach us. So, it is every 3 months." -Navigator 1
		Challenges Insurance & billing	"The amount of effort that it that we have put into solving this problem [insurance & billing] is quite big and the impact it has on the patients who have this problem is also quite big. You know, people who are getting bills every 3 months are upset and they're annoyed. And some of those people have been like, you know what I'm taking like, I'm taking this elsewhere. You know, I'm going to an online provider, or this isn't worth it for me." - Navigator1

		Loss to follow up	"They may end up sort of falling off my list because they end up kind of get. They kind of ghost me for no apparent reason, like they just, I just can't get a hold of them anymore. They stop, you know. I text them. I call them. I email them. They're just not returning my messages all of a sudden, I start getting like requests from the pharmacy like, oh, there's you know, they haven't picked up, or they need a new prescription or something, and if I can't get a hold of them to get them to come back in, you know. Then what can you do?" -Navigator 2
Adoption	Navigator	Positively impacting patient care	"I like the intersection of sexual health with other social determinants of health. Being able to address stigma that comes up in sexual health like that's all stuff that I feel like interests and what drove me to want to do this. Being able to work to address issues of sexual health with patients to promote access in you know, as part of the system. Just being able to increase access for patients, and impact different aspects of their social determinants of health and overcome different health, and HIV related health disparities." -Navigator 1
Implementation	Navigator	*See Figure 10 for Navigator Workflow and how the navigators are disseminating the program as intended*	
Maintenance	Client & Navigator	Navigators following up	"They call to remind me about labs, you know, hey, we've got your PrEP labs that need to get done." -Client 12
		Navigators disputing insurance	"There were times when because the billing issues were so complicated that I was like, I'm just going to go off of it because it's not worth it. But having the navigator kind of help advocate for me has also been, in that way, really helpful." -Client 5
		Continuing care with navigator/clinic	"I've really liked it. I, you know, wanted to go there instead of my like primary care provider because I wanted a place that was like more familiar with, you know, PrEP specifically and just sexual health in general. And they've definitely like been great at, they filled that role kind of exactly how I was hoping they would." -Client 9
		Outreach/community partnerships	"Our expansion of our work down at [redacted community clinic name], we have started doing more specific stuff down there, including more PrEP outreach right there at [the clinic] t on Tuesdays and Wednesdays and some Thursdays." -Navigator 2
		Increased accessibility	"We have kind of a more of an evening time, a free clinic on certain Thursdays. We do have a Saturday clinic here. At the clinic. Like every other Saturday, we have, like morning Saturday hours." -Navigator 2

		Advancing clinical practices	"But also, the whole program, like we very quickly added a lot of telehealth space we very quickly adopted at home testing our clinic. One of our providers has been really instrumental. In expanding access to self-collection of swab testing. We've had that for a long time in our clinic, like patients, could come into clinic and self-collect. And at home testing. Oh, you can't make it in, let's send you a kit, or Oh, I don't have to drive across town. I can go to the lab down the street from my job like it's we. We have more options now than we did then. And I think that's been the biggest change." -Navigator 1
Implementation & Sustainability Infrastructure	Navigator	Trainings	"I okay, formally, I have no idea in terms of...definitely, I would say on average monthly that we, I and others in our program are participating in some type of training, like an online webinar on TelePrEP, uptake, or you know same day PrEP initiation. But a lot of that is like we just self-select to do that. I don't think that there's a lot that's required. I don't think there's a lot that's required beyond, like initial orientation." -Navigator 1
		Technical assistance/support	"when we first started trying to do at home testing, we had quite a few conversations with the technical assistance group at WashU and we always kind of came away like didn't tell us anything we didn't know, you know, like, I don't know." -Navigator 1
		Agency/clinic support	"I think our program is really responsive. I certainly have felt elements of burnout, or like, you know, it's hard to be kind of just like constantly barraged with people's problems. And you know, like, especially in prevention, I do think that there's the opportunity for things to be like a lot more upper like, if we're focused on the opportunity. We're not focused on the problem. but nonetheless it can be a lot, but I do think that part of what has I don't know if I if I would have persisted in the role as long as I have had it not been for our program. Like other programs and admin staff who are very responsive." -Navigator 1
		Quarterly reports	"So, we put out quarterly reports which I don't think have changed their format in quite a while, but every time there's a question like, what else would be helpful? And every time we say like statewide guidance and advocacy around health insurance and billing. I don't know if, like our partners at DHS feel that they have a similar restriction around that, but like oh, I can't contact them, so it doesn't have to be that. But I do think that some like guidance would be helpful, you know, and I think that the stuff that they've pointed us towards in the past, tell us what we already know." -Navigator 1

		Site visits	"I think, we may have only had one ever I could be wrong. I know that we had one. I think, in the fall. It was not observing in clinic. It was like looking. We were like in a conference room, looking at numbers, looking at timelines for future grant proposals. You know, [redacted DHS partner name] was explaining the changes in the grants that are coming from the CDC, and how that may or may not be impacting us. So, I mean, it was a very collaborative conversation, and it certainly was a time where we could get like our questions answered. But it was like big programmatic questions like, Are we going to be able to continue using this funding for this purpose. You know, is this Grant going to be renewed? It's less about them seeing the day-to-day work to my knowledge, that has not happened." -Navigator 1
		Short staffed	"We've got so many clients that, like we're trying. We're trying not to do much better right now, because we can't handle the load any further. I mean. But that being said, you know there's always people kind of coming and going, for whatever reason so if anybody ever does show up, we do take. We have not. I don't think we've turned anybody away. If they come in asking for PrEP. We put them on our program, but it is really becoming kind of hassle." -Navigator 2
External Environment	Navigator	Community resources	"We also have a satellite clinic down at [redacted community clinic] people can also go in there and get whatever they need from us. If it's just the quickie HIV and syphilis quick swabs, or even if it's really, if it's even if it's the whole 9 yards." -Navigator 2 "I think, like our presence at public health is the most effective way for reaching people who are most at risk for HIV." -Navigator 1
		Reimbursement	"We have an agreement with Evita that every time they get a prescription filled from us through them. Then we get a little bit of money back. And that money, anything that we get from Evita goes right back into, we have a grant here specifically for PrEP. People who can't afford the labs. they can come here." -Navigator 2
		Grant funds	"Another factor that kind of makes that happen is that we are able to use some of our grant funding to provide care for people who don't have insurance, and that has been a huge factor that has allowed us to also meet people who are at higher risk for HIV infection. So, the numbers aren't huge. We have less than 20 people who are uninsured, who are coming into our clinic for PrEP care, but those people are overwhelmingly Spanish speaking, and not eligible for insurance in other ways." -Navigator 1

		Government funding	"When I first started, the HHS program didn't exist. And that's a really, that's one that I use primarily now. It's a really great and easy program to utilize as well for people who don't have insurance." - Navigator 2
		PrEP policies & laws	"The ACA, the law that said that people should be able to get preventative care without a copay right. That had nothing to do with me. I didn't do that, but it certainly made my life easier" -Navigator 2
**Effectiveness at the client has been reported in Paper 2.*			

Intervention

Three salient themes were identified as benefits to the navigation program from the client's perspective, and two challenges. From the navigators, five salient themes were identified, two as benefits and three as challenges. Clients found it beneficial to their PrEP care process that navigators were not only knowledgeable of PrEP, but that they were associated in clinics with specialized providers that offered a safe and supportive space to provide PrEP care. Having a knowledgeable navigator lead to other benefits when accessing, starting, and adhering to PrEP, such as financial assistance and having someone to advocate on their behave and further support them in their healthcare. Clients found it beneficial that navigators were able to share financial resources, including manufacturer medication assistance and/or co-pay programs and additional funds provided by the state program to cover lab costs that may not be covered by insurers. Importantly, clients appreciated the ongoing advocacy from the navigators, especially when it comes to the surprise bills that continue to happen throughout their time on PrEP. In fact, being a patient advocate is something that the navigators shared as a benefit to the program and their role as a navigator. A final benefit identified by navigators were that the program has increased awareness of PrEP to the public, because if someone comes into the clinic to get tested for STIs they're being educated on PrEP and if it is not something they necessarily need it is something they can share with their peers that may benefit from it.

When asked what challenges Clients have had or where the program could improve, most could only suggest having more navigators available in the state. Similarly, the navigators identified that being short staffed, and the only navigators for their given agency/clinic as a challenge to the program. Additionally, both navigators expressed that they have outdated techniques of case management for the program, such as using an excel sheet to organize and

track the progress of their client's care. Although most clients have had great experiences with their navigator, some did mention that they had not been in contact with their navigator at all, or that their navigator hasn't been the best at communicating with them in a timely manner. A great suggestion from a client to improve this challenge in communication included having the navigator be the first point of contact when an individual inquiry about starting PrEP; "I think having the navigator communicate at the first appointment the ins and outs of PrEP, especially the financial stuff. It could have been a little bit better." (Participant 11). The final challenge to the program identified by the navigators involves navigating insurance changes and the ongoing billing issues that are occurring; one navigator shares that "it just feels like it is taking up more than its share." (Navigator 1).

Reach

Interestingly, most clients were only aware of the navigation program because they were referred to a participating clinic from their primary care provider when inquiring about PrEP, or recommended to a participating clinic from friends that received their PrEP care from there. This was further supported by interviews with navigators. A few clients that came across the program outside of referrals and recommendations, were visiting a county public health office for an STI screening and was given information about the navigator associated with that public health office. This navigator shared that a QR-code is posted around the public health office that individuals can scan to sign up for a PrEP Navigation consultation. Other ways clients could have been reached for the navigation program have been through community outreach at bars, high schools, and community centers. Additionally, one navigator shared that at the launch of the program, there was mass advertisements on social media, dating apps, and city buses. Finally, one navigator shared two ways in which she thinks would improve the reach of the program: (1)

increasing navigator presence in community spaces where individuals are already going for care or additional services and (2) having more diverse navigators that represent the communities most at risk of HIV.

> "Community spaces, or community clinics where people are already going for care and services and have a presence there to makes it an easier connection. So doing that [what is done in public health office] in other locations, where people are accessing services, health care or otherwise, I think would be a good idea. ... I don't look like most of the patients who are most at risk for HIV, and so, having a PrEP navigator who speaks Spanish, having a PrEP navigator who's not white? I think that that would be t great step forward in promoting access. Because I think that even as welcoming and helpful as I try to be, and accessible as I try to be like, I look like a lot of people that have made health care unacceptable to a lot of patients. And that in itself can be a barrier. So, I think, having more representation in the role from the communities. Most at risk would be a step forward." - Navigator 1

Effectiveness

The effectiveness of the program at the client level was reported in Paper 2, where the research team analyzed the effectiveness of the navigators' overcoming barriers to the PrEP care process by comparing client experiences with individuals receiving PrEP care elsewhere in the state. As for assessment of effectiveness at the navigator level, both shared that the biggest indicator for success for their program is the continuous influx of clients they have, both starting and returning. In terms of barriers the navigators face to starting patients on PrEP, both stated that the biggest challenge is navigating the complexity of insurance. Fortunately, both have been able to overcome this barrier to uptake for their patients through assisting clients in accessing/enrolling in payment and/or co-pay assistance programs and offering affordable and flexible labs. Another facilitator to PrEP uptake for clients in one clinic involves the clinic having a starter bottle of PrEP on-hand to give clients at the end of their initial appointment. As with uptake, a barrier navigators face to retaining their clients in care also involves the ongoing challenges with insurance and improper billing. Aside from insurance challenges, navigators shared that the only other challenge to ensuring clients retain in their PrEP care is loss to follow-

up, including clients ignoring or not returning calls/texts/emails and/or clients moving or changing phone numbers and are no longer reachable. Fortunately, both navigators are organized and tracking their patients care, which aids them in consistently following up with their patients every three to six months. Another facilitator to potential loss of follow-up, one navigator mentioned that their clinic does community outreach events where they do HIV and STI testing in the community, where their clients can go for their routine follow-up care if they are unable to make it to the clinic.

Adoption

Adoption was only assessed at the navigator level, and when asked the navigators what made them choose to become a navigator and why they continue to stay in their role they shared a common theme of having a positive impact on patient care. For them it is about being a part of a program that is increasing access to care and overcoming health disparities.

Implementation

When being trained as a navigator, the navigators were introduced to the navigator workflow (Figure 8). The navigators were asked to walk the interviewer through their navigation process, from the first interaction with a client, what that interaction involves, and then any follow-up interactions, to gauge the fidelity of the navigation program. Both navigators are disseminating the program as it was intended to be delivered, except for a few items. First, one navigator is not assessing insurance status or enrolling uninsured clients in insurance programs. Additionally, this same navigator is not assessing or linking clients to other support services that may be needed. Although the navigators may not be following the exact follow-up and adherence support plan outlined in the workflow, both navigators indicated that they are having consistent follow-up with their clients and assessing for adherence support during these follow-

ups. Importantly, one navigator shared: “Navigation is perpetual as long as they are part of the program.” (Navigator 1). See Table 24 in Appendix C for quotes from the navigators to support their dissemination of the navigation program within their agency.

Figure 10. The PrEP Navigation Workflow in WI as Outlined by the PrEP Continuum of Care
**one navigator indicated doing this step; **both navigators indicated doing this step*

Maintenance

The average time being on PrEP was 2.5 years, and majority of clients started their PrEP care through the navigation program. Clients expressed that they have since continued their PrEP care with their navigator and at the respective clinics instead of transitioning their care to their primary care providers. Some of the navigators have offered clients with additional support that they may not get with their primary care providers, such as following-up with them about their PrEP care and reminding them about labs and appointments. Most importantly, the clients

emphasized that the navigators ongoing assistance with disputing insurance has been crucial in their adherence and retention to PrEP.

As for maintenance at the navigator level, the navigators shared ways in which their services have adapted over the years to continue to increase PrEP access, uptake, and adherence/retention for individuals. First, the navigators have developed community partnerships and are offering their services in other locations outside of their clinics, such as the public health office and other community centers that are already serving the targeted audiences for the program. Second, the navigators have also increased accessibility by offering telehealth services and more flexible hours of services such as having evening and weekend consultations. Then, a final, their clinical practices have adapted, such as being able to offer clients their first month supply of PrEP at the end of their initial appointment and/or offering at-home testing and self-collecting in the clinics.

Implementation and Sustainability Infrastructure

The following items were assessed at the navigator level to understand the navigation programs implementation and sustainability infrastructure: trainings, technical assistance/support, quarterly reports, and navigator turnover. The navigators shared that aside from the onboarding/orientation training received, they have not been required to do on-going training in their role. However, both navigators stated that they are participating in monthly national webinars and state workgroups to learn more about HIV prevention and care. Additionally, a nationally available online PrEP Navigation certificate program has recently become available through HealthHIV that the state's HIV prevention team is requiring all navigators to participate in. When asked about technical assistance and support from the state, one navigator shared that they were unsure of any additional support outside of the state PrEP

workgroups and the other navigator shared that most technical assistance and support has been referred to the state's external partners in the program (Washington University). However, both navigators shared that their individual agencies on-going support and guidance in their role as a navigator has been beneficial in overcoming challenges that they are faced with, as well as have played a significant role in their retention as a navigator. As part of annual program reviews, navigators are asked to submit quarterly reports and the state is expected to do a site visit. One navigator shared frustration with the quarterly reports and their lack of value and impact on the states support and assistance with challenges. Additionally, this navigator shared that they have only been involved in one site visit in the span of time they have been a navigator.

External Environment

There are many external environment characteristics that impact the program, such as community resources, reimbursement, grant funds, government funding, and PrEP policies and laws. Both navigators shared that having community resources, such as satellite clinics and partnering with telehealth services. One navigator mentioned that their clinic partners with an online pharmacy, and for every prescription from their clinic filled through this pharmacy, they are reimbursed some money back. This money goes into a fund that is specifically for their PrEP clients that might need help covering their labs and care from the clinic. Additionally, the state provides grant funds to the program agencies, where a portion of the funds are set aside to offer to clients that need financial assistance in covering their care. There are also federal government programs and funding opportunities (Ready, Set, PrEP) to assist with the financial burden that occurs with PrEP care, especially for those that are on PrEP and uninsured. Most importantly, there is a law/policy under the Affordable Care Act, that PrEP is a preventative service and should be covered without charging a co-pay or co-insurance.

Changes/Needs for Improvements and Expansion of the Program

When the navigators were asked what would be needed for the program to expand in their agency and in the state, they shared three themes (Table 18). First, the program needs more funding to (1) support more agencies to adopt the program, (2) subsidize equipment needed in the clinics to support the expansion of the program and flow of clients, and (3) to hire more navigators not only in the agencies already involved in the program but throughout the state. Then, importantly it was suggested that the navigators have a shared space with other navigators in the state to share a community of practice, such as monthly meetings with just navigators to share these consistent challenges they are faced with and have a collaborative practice in addressing these barriers to the program and patient care. A final need shared was more support and facilitation from the state's HIV prevention team in addressing challenges, which could be met with the monthly community of practice meetings suggested.

Table 18. Navigators' Suggestions to Improving and Expanding the Program

Theme / Suggestion	**Supportive Quotes**
Increase funding	"More funding to fund more agencies to provide PrEP, specifically community-based organizations not large traditional healthcare systems, I mean they should continue doing this, but I think that the greatest place to grow PrEP is outside of those places, it's in community clinics. So, increasing funding allows you to hire more people who can then be doing more outreach, and who can be a greater support." -Navigator 1
	"I mean, potentially kind of grant slash subsidizing for like equipment that we need. An EHR will help with flow. We're still on paper charting. And we're not, like the most high tech that I've got is my stinking spreadsheet, right? Which has its pros and cons. I mean, it's at least it's a way to keep me fairly organized but we need to switch over to an EHR type charting. " -Navigator 2
	"I would love to not be the only one, I think, that we could do a lot more and we could be far more effective if there were more of us." -Navigator 1
Community collaborations	"It would be nice to have that community of practice. It would be nice to have connections to be able to, you know, share stories and ideas and challenges with others. But there's not really a space." -Navigator 1

Increased state support/facilitation	“But like, those are questions that we've brought to the state like, here's a problem we're having. Do you have any support? Do you know how other people are handling it, and they haven't helps like the ways we've made. Those connections have been on our own, not through facilitation with the state, so I think that that would be helpful." -Navigator 1

DISCUSSION

Using qualitative methods guided by PRISM, this study outlines the salient themes at the client and navigator level of how PrEP Navigation is being disseminated and sustained in Wisconsin to increase PrEP uptake. A vital component of ending the HIV epidemic in the U.S. involves reducing new infections through the scale-up of evidence-based HIV prevention measures, including PrEP.[10] By the end 2026, the state of Wisconsin aims to increase PrEP uptake to cover at least 50% of all people who could benefit from the medication, as outlined in the *Integrated HIV Prevention and Care Plan.*[14] To do so, the state has prioritized expanding and improving the implementation of HIV prevention interventions, presumably including the PrEP Navigation program. Therefore, the findings from this study are aimed to inform the state of Wisconsin, along with others deploying this intervention, efforts for increasing PrEP use and retention in care through PrEP Navigation.

PrEP Navigation is an evidence-based intervention that is sustainable while increasing awareness, access, and adherence to PrEP among individuals at risk of HIV. Navigators are an integral member of an individual’s PrEP care process when one is available and accessible to them.[56] The navigation program in Wisconsin has demonstrated to bring awareness of PrEP to individuals that can benefit from it, through community outreach and partnering with other community centers and public health offices. Other studies that have evaluated PrEP navigation programs have shared those important benefits to reaching the intended audience includes having a mixture of participating organizations and clinics, collaborating with or being rooted in

community-based organizations, having a widespread of PrEP outreach, and having navigators that share experiences and identities of the targeted population.[56,59,67,91,94] There is an opportunity for the Wisconsin program to consider these benefits when improving the reach of the program. For example, community outreach should extend beyond the queer bars and include other populations at risk such as Latinx and Black communities. As shared by one of the navigators in this study, the program could benefit by hiring navigators that mirror the diversity of the communities at risk of HIV in the state, including people of color and individuals who can speak Spanish.

Although the program is small scale, it has demonstrated to be effective at increasing PrEP uptake and supporting individuals in continuing their PrEP care, within the organizations its being offered in. It's implemented in the counties of high HIV prevalence in the state, and within organizations that offer a safe space for PrEP care. Importantly, the program in Wisconsin have navigators that are linked specifically to PrEP providers, eliminating the barrier of finding a provider that is PrEP informed and willing to prescribe it.[7] Other key aspects of the navigation program, that is further supported by the literature, includes having same-day access to PrEP, scheduling appointments of clients, navigating and advocating on persistent insurance and billing issues, and connecting clients to resources and services for other social determinants of health that impact their retention in PrEP care.[53,56,57,59,61,63-67,92] One of the most important benefits of a navigator is their consistent and direct involvement with clients care after PrEP initiation.[56] Specifically, maintaining an organized client tracking system and having case management skills.[53,59,62,64]

The program was initially adopted and implemented in six agencies in Wisconsin, including seven navigators to reach and retain individuals in PrEP care across ten counties.

However, at the time of the study, the program had only been maintained in half of the organizations that it was adopted and implemented in over the past six years. Two organizations currently do not have a navigator hired on staff, and one organization no longer offers their localized PrEP clinic and removed their involvement in the program. Unfortunately, navigator turnover, and staff/clinic capacity, has been a significant issue with maintaining this program, both in this study and others.[53] Therefore, considering the implementation and sustainability infrastructure and external environment is imperative in evaluating, adapting, and expanding PrEP Navigation.

Fortunately, in this study the external environment, such as policies, community resources, reimbursements, and government funding have all been identified as positively impacting the program. However, the contexts of infrastructure need further attention to have the desirable impact (i.e., adapting and expanding). Other navigation programs emphasize the importance of program support and technical assistance, both from their organization and those who are supporting the program (i.e., the state department of health).[73,74] Although navigators in this study felt supported by their organization, they expressed limited interaction and support/assistance from the state. Additionally, ongoing evaluation and adapting of a program is important to sustainability.[107] The program in Wisconsin has quarterly reports intended for ongoing evaluation, however as demonstrated by the navigators perspective, these reports may not be as beneficial as they are intended to be in evaluating the success and challenges of the program, and facilitating necessary changes and/or ongoing assistance and support.

The use of PRISM to conduct this program evaluation was strategic of the research team. PRISM was developed as an implementation science framework that can be used for planning, implementing, sustaining, and/or evaluating evidence-based programs.[107] Although the planning

and implementation of the PrEP Navigation program in the state was not guided by PRISM, moving forward the program can utilize the model to further support sustainability, evaluations, and more importantly adaptations. The developer of PRISM has since created an interactive webtool, iPRISM (iterative, Practical, Robust Implementation and Sustainability Model), that is publicly available and free to use, as an individual or team, at any stage of the programs lifecycle (i.e., planning, implementation, sustainment).[141] The purpose of the webtool is to assess and align a program, assess progress on important outcomes, inform adaptations, and plan for sustainability.[141] The states HIV prevention team should consider using iPRISM in correspondence with key navigation stakeholders (i.e., organization managers, navigators, and clients) if they plan to adapt and expand the implementation of the program. This webtool can facilitate necessary planning to address the areas of success, challenges, and needs for adapting, improving, and expanding the program to further increase PrEP uptake and retention in the state of Wisconsin.

Study Advantages

This study has three important advantages, the first being that it is the first time the Wisconsin PrEP navigation program has undergone a formal evaluation since it's been implemented and disseminated in the real-world setting. Second, this is the first evaluation of a PrEP navigation program to utilize the Practical Robust Implementation and Sustainability Model, and among one of the few to apply the model to evaluating navigation services more broadly. Finally, this study captures both the perspective of the clients and navigators, which is allows for a more robust program evaluation.

Study Limitations

However, this study also has limitations. First, the research team acknowledges that the results of this study may not transfer as they may not be applicable to other PrEP Navigation programs. However, study findings can inform considerations for implementation and/or adaptations for other navigation programs (PrEP or other). Second, this study acknowledges the small sample size as a limitation. The client participants are only representative from three of the six participating agencies and are not representative of all individuals that could benefit from taking PrEP. However, they all shared similar experiences with the program and their navigators. Although the study only conducted interviews with two navigators, there were only three navigators in the program population size to conduct interviews with at the time of the study. The third navigator's perspective would have been beneficial as they are a community health worker and more involved in the community aspects of the role of a navigator than the clinical, as shared by the other two navigators. However, these were key informant interviews and addressed all essential contextual factors that are associated with implementation and program outcomes.

CONCLUSION

This study utilized the Practical Robust Implementation Sustainability Model to conduct a multi-level evaluation of the state of Wisconsin's HIV prevention program, PrEP Navigation. Although the current implementation and dissemination of this program is small-scale in the state, it has demonstrated to be sustainable, and more importantly successful at accessing, starting, and adhering individuals vulnerable to HIV to PrEP, while addressing barriers to care. Future efforts should consider navigator and client program-related needs, while expanding the

program both in the state and within the agencies currently deploying the intervention to achieve the states' goal of preventing new infections.

CONCLUSION

This study aimed to answer three questions. First, what PrEP use and prescribing disparities are present in the state of Wisconsin, and how can the PrEP Navigation program address/overcome these disparities. This study found that despite PrEP use significantly increasing in Wisconsin, there are racial/ethnic disparities present. The PrEP Navigation program can address this disparity by expanding into communities and neighborhoods with highest Black and Hispanic residents to increase their reach in PrEP care.

Second, what are the barriers and facilitators to PrEP care in Wisconsin, and how is the PrEP Navigation Program overcoming barriers to care. Findings from this study demonstrate various benefits to awareness, uptake, and adherence to PrEP, including mass-advertisement and social circles discussing PrEP, having informed and/or LGBTQ+ friendly providers, and having access to financial resources. The biggest barrier to PrEP care is the perceived cost and the persistent insurance bills, due to inconsistent billing for care. Fortunately, patients that have connected with a PrEP Navigator, have additional support and guidance in disputing these ongoing bills/costs for free HIV preventative care, which has been quoted as a key aspect to retaining in PrEP care.

Finally, what aspects of the PrEP Navigation program needs improved to be effective at increasing PrEP uptake and adherence in the state. This study found that the PrEP Navigation program in the state needs to increase the number of navigators providing services, while also expanding the program to other areas that are seeing high HIV incidences. Importantly the program needs to be better advertised to the target communities, as there is a gap in awareness around the program and Navigators available to assist individuals in accessing and adhering to PrEP. Lastly, the state needs to continue, and potentially increase, support and facilitation to the

Navigators to minimize navigator turnover which will have a downstream effect to improve the program's effectiveness in increasing PrEP uptake and adherence in the state.

This work supports the ongoing efforts to ending the HIV epidemic in the state. However, future efforts are needed to achieve the state's goal of preventing new HIV infections. To quote Dr. Robyn Neblett Fanfair, the Director of the CDC's Division of HIV Prevention, "the only way we can truly end the HIV epidemic is by eliminating the barriers that prevent people from accessing HIV care and prevention."

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APPENDIX

Appendix A – Paper #1

WHIO Data Variables

Table 19. List of Variables Provided in the WHIO Dataset

Variable	Definition
Whio_ClaimHeader	A claim identifier created by WHIO to ensure all claims, from all submitters, have unique IDs (in place of the submitted claim IDs).
Whio_ClaimLine	Listed as 001 for every pharmacy claim.
Whio_MemberId	ID generated by WHIO as persons are matched across all data submissions. This ID is unique to each person and persists across all data releases.
ProductSectorMod	Line of business for the insurance coverage. Values are: COM = Commercial MED = Medicare or Medicare Supplemental MCD = Medicaid
DateOfBirthMod*	Person's year of birth. WHIO establishes all birth dates as July 1 of the actual year of birth as part of the de-identification process. The field is displayed in MMDDYYYY format.
GenderCode*	Person's gender. Values are: M = Male F = Female U = Unknown
MemberStateCode	Abbreviation of state where person resides.
MemberZipCodeMod	The 5-digit ZIP code for the most recent record of a person's residence.
MemberCountyMod*	County name for the most recent record of a person's residence.
PrescriptionDate	The date the prescription was filled.
PaymentProcessDate	The date the claim was paid or processed by the insurer.
CoverageClassCode	Type of coverage under which this claim was paid. Values are: MED = Full medical coverage SUP = Supplemental coverage only OTH = Other supplemental or partial coverage that is not Medicare Supplemental
DeniedFlag	Indicates whether or not payment for a claim was denied by the insurer. Values are: Y = Claim was denied for payment N = Claim was not denied for payment

SecondaryPayerFlag	Indicates whether or not the insurer was a secondary payer on the claim. This field can be used to explain why other values, such as the requested (billed) amount, are different from expected. Values are: Y = Insurer is secondary payer on claim N = Insurer is primary payer on claim
PharmacyNpi	National Provider Identifier (NPI) for the pharmacy where the prescription was filled.
PharmacyName	Name of pharmacy in which the claim is through
PharmacySystemName	Name of pharmacy system in which the claim is through
PharmacySpecialtyCode	Unique pharmacy specialty code associated with the pharmacy
PharmacySpecialty	Pharmacy specialty
PharmacyState	State in which the pharmacy is located in
PrescribingProviderNpi	National Provider Identifier (NPI) for the prescribing provider as submitted on the claim.
PrescribingProviderTaxId	The prescribing provider tax identification number (TIN) for the claim.
PrescribingProviderName	Name of provider who prescribed the drug
PrescribingProviderSystemId	Unique system identifier associated with prescribing provider
PrescribingProviderSystemDesc	Description of the health system to which the provider is primarily assigned, as recorded in WHIO's provider registry.
PrescribingSpecialty*	The specialty in which the prescribing provider is practicing in
PrescribingProviderState	The state in which the provider is practicing in
NationalDrugCode	The unique numeric code assigned to a drug product by the Federal Drug Administration (FDA) and the manufacturer or distributor. The NDC identifies the manufacturer/distributor, drug, dosage form, strength and package size. All prescription drug products regulated by the FDA must use an NDC.
DrugName*	Full name of the drug associated with the individual NDC.
DrugGroup	Description of the group to which individual drugs are grouped.
DrugClass	Description of the group to which individual drugs are grouped.
DrugSubclass	Additional detailed description of the class to which a drug belongs. Often the values in this field will match those in the DrugClass field.
DrugBaseName	Brief description of the drug.
DrugNameExt	Additional detail on the drug name. Often the values in this field will match those in the DrugBaseName field.
DrugNameDoseForm	Provides additional detail for a drug.
DrugNameStrength	Provides additional detail for a drug.
MetricQuantity	The drug volume prescribed, expressed in number of tablets, grams, or milliliters for liquids, creams, ointments and injectables.
DaysSupply	The number of days of medication prescribed.
RequestedAmount	The gross billed charges submitted by a service provider to an insurer for payment.
	**Variables utilized in the study*

Results Supplement Tables/Figures

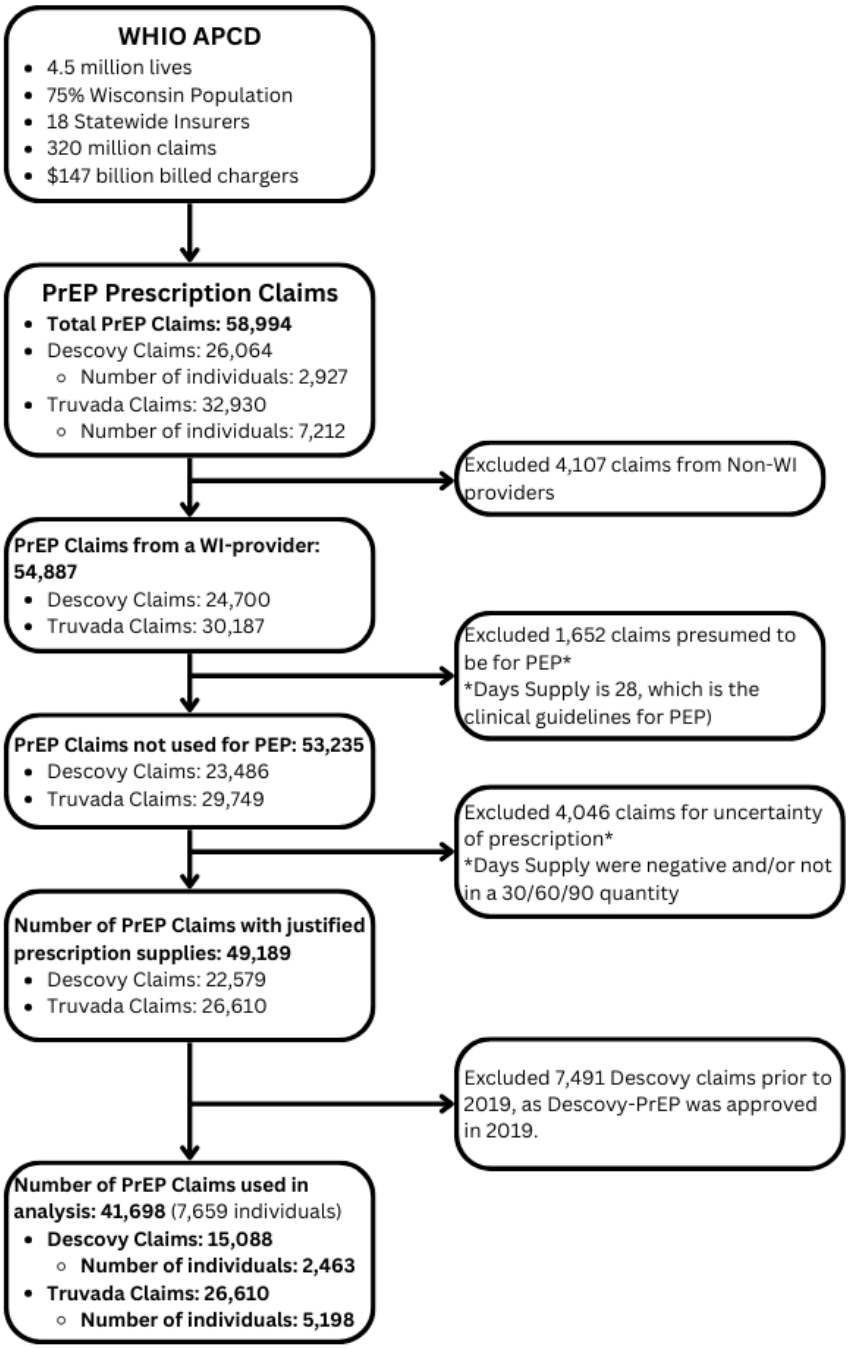

Figure 11. Consort Diagram for PrEP Claims included in study

Table 20. PrEP Use and Pred-to-Need Ratio Trends in Wisconsin, 2012-2022 (provided by AIDSVu)

	PrEP Count (PnR)										
Year	**Overall**	**Male**	**Female**	**Age LE 24**	**Age 25-34**	**Age 35-44**	**Age 45-54**	**Age 55+**	**Black**	**White**	**Hispanic**
2012	74 (0.34)	39 (0.22)	34 (0.79)	15 (0.28)	8 (0.14)	25 (0.6)	15 (0.34)	10 (0.53)	-	61 (0.72)	1 (-1)
2013	94 (0.39)	51 (0.25)	42 (1.11)	18 (0.34)	32 (0.44)	15 (0.35)	21 (0.50)	8 (0.25)	9 (0.10)	60 (0.63)	6 (0.16)
2014	172 (0.79)	139 (0.74)	34 (1.10)	19 (0.30)	69 (1.10)	47 (1.24)	25 (0.61)	12 (0.92)	1 (-1)	143 (2.17)	12 (0.27)
2015	413 (1.82)	382 (1.92)	31 (1.11)	65 (1.14)	132 (1.69)	98 (2.45)	99 (2.68)	19 (1.27)	26 (0.29)	332 (4.00)	42 (1.24)
2016	899 (3.98)	825 (4.25)	74 (2.31)	145 (2.10)	317 (4.80)	203 (6.15)	169 (5.83)	69 (2.38)	50 (0.48)	716 (9.94)	106 (3.79)
2017	1265 (4.90)	1183 (5.43)	81 (2.03)	197 (2.98)	457 (5.02)	283 (7.26)	216 (5.27)	110 (5.24)	91 (0.86)	1001 (10.32)	128 (3.66)
2018	1773 (8.61)	1655 (9.19)	119 (4.58)	325 (7.07)	678 (9.04)	351 (10.64)	268 (8.93)	153 (6.95)	139 (1.62)	1451 (20.73)	153 (4.37)
2019	2320 (11.00)	2182 (12.99)	136 (3.16)	398 (8.29)	924 (13.01)	472 (10.49)	306 (11.33)	224 (11.20)	194 (1.96)	1931 (29.71)	147 (4.20)
2020	2380 (11.17)	2251 (13.24)	130 (3.02)	371 (8.83)	968 (11.39)	497 (10.57)	302 (15.89)	245 (12.25)	223 (2.79)	1969 (23.72)	135 (3.38)
2021	2851 (11.27)	2677 (12.69)	175 (4.17)	512 (9.85)	1164 (11.19)	583 (12.96)	319 (9.97)	273 (13.65)	245 (2.66)	2404 (27.63)	162 (2.75)
2022	3342 (13.21)	3140 (14.88)	202 (4.81)	604 (11.62)	1309 (12.59)	748 (16.62)	368 (11.50)	318 (15.90)	246 (2.67)	2786 (32.02)	242 (4.10)

Appendix B – Paper #2

Recruitment Materials

Recruitment Flyer

Figure 11. Patient Recruitment Flyer

Recruitment email sent to Health Departments
Subject: Student Researcher Needs Help Recruiting PrEP Takers

[Greetings, Health Department or Health Officer's Name],

Allow me to introduce myself; my name is Maeleigh Tidd, and I am a PhD candidate in Health Services Research at the University of Wisconsin-Madison's School of Pharmacy. I am currently collaborating with the Wisconsin Department of Health Services' HIV Prevention Unit to evaluate the states HIV prevention measures to increasing pre-exposure prophylaxis (PrEP) access and adherence.

I am looking for individuals that are taking PrEP for HIV prevention to participate in a research study that seeks to understand the advantages and challenges to the PrEP care process in the state of Wisconsin.

I am reaching out to you and the [Health Department], to ask if you could post the study's recruitment flyer (attached) throughout the department where the targeted audience for this study may visit (i.e., sexual health clinic/area). Additionally, if you have known clinics in your county that may be serving this audience and offering HIV prevention/PrEP education and services, please feel free to forward the recruitment flyer to them.

It is important to not only the study, but to the states HIV Prevention Unit, to have a robust sample to truly understand how the state can move forward in improving their efforts to increase PrEP access to those of most need for HIV preventative measures.

If you have any questions, please contact me at mtidd@wisc.edu.

Thank you!

Recruitment email sent by Navigators to encourage client participation
Subject: Recruiting individuals taking PrEP for a research study to understand advantages and challenges to the PrEP care process

Interested in providing your unique lived experiences' in accessing, starting, and maintaining on PrEP for HIV prevention?

Mae Tidd, a UW-Madison graduate student, is seeking individuals that are taking PrEP for HIV prevention to participate in a study that seeks to understand the advantages and challenges to the PrEP care process in the state of Wisconsin. Your experiences will help provide a better understanding of how and where the state can improve their efforts to increase PrEP access to those of most need for HIV preventative measures.

Involvement includes a 30-45-minute one-on-one, virtual, interview with Mae. Those that participate will be compensated with a $50 gift card.

If you are interested in participating, follow the below link to sign up. If you have any questions, please contact Mae, directly, at mtidd@wisc.edu.

Link to sign up: https://uwmadison.co1.qualtrics.com/jfe/form/SV_cO5Z84a2RoRypL0

Scheduling Interview Email
Subject: Scheduling interview for PrEP research study

[Greetings],

My name is Mae, and I am following-up with you about scheduling an interview for the PrEP study. Thank you for your interest in participating in my study and for providing your weekly availability.

If the availability times you provided is still accurate/fitting, would you be available for a 30–45-minute virtual interview (on Zoom) with me on [date & time]?

I look forward to meeting with you and getting to know your experiences navigating the PrEP care process!

Please follow-up with me to confirm, find a new time/day, and/or decline your interest in participating in the study. Thanks!

I do apologize for any delay in follow-up/scheduling!

Consent Form for Patient Participants

Title of Study: Identifying barriers and facilitators to accessing, starting, and maintaining on PrEP for HIV Prevention in the state of Wisconsin
Principal Investigator (person in charge): Maeleigh Tidd, MS
How to contact the study team: email: mtidd@wisc.edu or call: 812-216-6212

This sheet provides key information you need to know about this study. Taking part in a study is voluntary. You can stop taking part in this study at any time, no questions asked. Feel free to ask the researchers any questions about this study. **The following consent form includes more information about taking part in this study.**

What is the purpose of the study?
To understand the unique advantages and challenges that individuals are facing when accessing, starting, and staying on PrEP (pre-exposure prophylaxis) for HIV prevention.

Why are you being asked to participate in this study?
You have been asked to participate because you have self-identified as an individual currently taking or has taken PrEP in the past 12 months.

What will you do if you choose to participate in this study?

If you choose to participate in this study, you will be asked to take part in an audio-recorded interview (virtually on an online platform, i.e. Zoom). The interview is expected to take approximately 30-45 minutes and will be recorded and transcribed. The researcher will ask you various questions about your experiences throughout the PrEP care process. You can choose not to answer any of the question you are asked and can stop the interview at any time. Being in this study is voluntary.

Are there any benefits in participating in this study?
I cannot guarantee any direct benefits to you from joining this study. However, you will contribute to providing a better understanding of how the state of Wisconsin's HIV preventative measures can improve to increase access to PrEP. Additionally, your involvement in this study will help shape the direction of future research and interventions in the state's response to HIV preventative care.

Are there any risks in participating in this study?
There is always a risk of a confidentiality breach, or of revealing personal, sensitive, or identifiable information. However, I will protect participants by deleting highly sensitive personal information from analysis.

How will privacy/confidentiality be protected?
Participants' privacy and confidentiality will be protected in various ways. The interview will be conducted in a confidential and safe space, identifiable information will be omitted from the transcripts, and interview materials will be destroyed after they have been analyzed. All data collected will be secured in a safe and secure location that only the study team has access to.

Will there be compensation for participation in the study?
You will receive $50 upon completion of your interview

Who to contact with questions?
If you have questions about the research after you leave today, you should contact Maeleigh Tidd at mtidd@wisc.edu or 812-216-6212.

Agreement to participate in this study and permission to use
I have read this consent and authorization form describing the research study procedures, risks, and benefits. I have had a chance to ask questions about the research study, and I have received answers to my questions. By continuing, I agree to participate in this research study, and permit the researcher to use the information I have provided today in their study.

Interview Guides

PrEP Patients in the Navigation Program

Intro

[Greeting – Good morning/afternoon/evening, etc.]
My name is Mae Tidd, I use she/they pronouns, and I am a PhD student at the University of Wisconsin-Madison. For this study, I am working with the state's Department of Health Services to understand individuals' experiences with starting and being on PrEP for HIV prevention. The

aim of this 30–45-minute interview is to get to know your experience accessing PrEP, while understanding any challenges you may have or continue to face being on PrEP.

Before getting into the interview questions, I want to make sure you had the chance to review the consent form that I emailed you. Did you have any questions about the information provided in that document?

Just to remind you, I will be recording our discussion today, however I will keep your comments confidential and private. You may skip any question you do not feel comfortable answering and you may also choose to stop participating in the interview at any time. What questions do you have before we begin?

Screening (for which set of questions to ask the participant)
We have a state-wide program, PrEP Navigation, that offers hands-on PrEP services and assistance to those interested. Do you by chance receive your PrEP care services from any of the following agencies/clinics:

Vivent Health, UW Health HIV clinic, Horton St. Clinic, Diverse & Resilient, Health Connections, 16th St. Community Health Center, MCW Froedert Sargent Health Center, or BestD Clinic in Milwaukee

---

This interview is going to be outlined along the PrEP continuum of care (i.e., awareness, uptake, and adherence/retention), where I am trying to understand your unique experiences, and get a better idea of where attention is needed in the process to maintain PrEP uptake and adherence in the state.

<u>Awareness</u>

1. Thinking back to before you started PrEP, how did you hear about PrEP?
    a. Probe: infomercials, advertisement throughout the city, friends, etc.
2. Where did you receive most of your information about PrEP from?
    a. Probe: did you do your own research, prevention programs throughout the state, provider/clinics
3. Have you been engaged in any PrEP programs or interventions?

<u>Uptake</u>

4. Thinking back to when you decided to start on PrEP, what was your process to linking to a PrEP provider like?
    a. Probe: were you able to go through your PCP, did you go to a sexual health clinic, did you have to do an intake through a clinic and be referred out, etc.
    b. *If screened outside of a provider*, what was the experience with being referred to a provider and then actually linking with that provider to get a prescription?
5. How was your screening process, such as getting the necessary labs done to "qualify" for PrEP?
    a. Probe: done in the same clinic, anything taxing about this step of the process
6. Once being prescribed PrEP, were there any barriers to starting your medication?
    a. Probe: cost barriers, pharmacy related barriers, etc.
7. Were there any initial barriers that kept you from starting the PrEP care process?

a. Probe: getting information, finding a provider, scheduling, transportation to appointment, etc.

8. What was helpful to you when initiating/starting PrEP?
    a. Probe: informed provider, medication assistance programs, etc.

Adherence & Retention

9. As you know, being adherent to PrEP is essential to maintaining HIV negative. How adherent are you to your PrEP therapy?
    a. Probe: do you take it daily, have you taken breaks from being on PrEP, etc.
10. Another key to adherence is retaining in care, which includes attending follow-up labs for prescription refills. What is your process like for follow-ups?
    a. Probe: any barriers to follow-up labs
11. What barriers have occurred throughout your time on PrEP, that have impacted your adherence to PrEP?
    a. Probe: cost, pharmacy barriers, scheduling for follow-up labs, transportation, SDOH
12. What has been most helpful to you to main adherent and retain in PrEP care?

PrEP Navigation

I'm not sure if you are aware but the state currently has an HIV Prevention Program called PrEP Navigation where they have trained health workers that assist those who are at risk of HIV access PrEP. Along with facilitating clients in the PrEP care process, these navigators uphold multiple roles and responsibilities including educating clients, assisting in insurance issues, accessing financial assistance, attending provider appointments, and linking clients to addition support services when necessary. Most importantly, the navigators are staying in contact with their clients, sending them reminders for labs and prescription refills to help clients retain in care. The organization you receive your care through, [insert name], is involved in this program. The following questions to get a better idea of your experience with this clinic and their navigator.

13. How has been your overall experience at [location from above] and receiving care through one of their navigators?
14. Do you feel supported by your navigator and their clinic?
    a. How can you navigator and clinic be more supportive for not only you but others seeking PrEP services?
15. What parts of the program have helped you stay involved in your PrEP care (from beginning to starting and adhering to PrEP)?
    a. Probe: additional services (financial assistance, insurance assistance, transportation, attending appointments, etc.)
16. What changes of the program could help you stay more involved in your PrEP care?
17. Have you received PrEP services from anyone/any other clinic?
    a. How did you care compare to the care received by a navigator at (one of the locations above)?

Improvements

18. What ways do you think the state could improve measures when it comes to PrEP access?
19. How can the PrEP care process improve to help you maintain adherent to PrEP?
20. In what way has PrEP had a positive and/or negative impact on your life?

Wrap-up
Is there anything else you would like to add/share about your experience with your navigator, agency, and/or process along the PrEP continuum of care?

To wrap up the interview I just need to collect your demographic information. I am going to provide the link to the demographic survey in the chat for you to fill out. I will give you a few minutes to complete that form, if you have any questions just let me know.
Closing
Thank you very much for being part of this interview and sharing with me your experience with starting and staying on PrEP. Following this interview, you will receive an e-gift card in your email as a thank you for your time and participation in my study. Thank you again and enjoy the rest of your day!

PrEP Patient not in the Navigation Program
Intro
[Greeting – Good morning/afternoon/evening, etc.]
My name is Mae Tidd, I use she/they pronouns, and I am a PhD student at the University of Wisconsin-Madison. For this study, I am working with the state's Department of Health Services to understand individuals' experiences with starting and being on PrEP for HIV prevention. The aim of this 30–45-minute interview is to get to know your experience accessing PrEP, while understanding any challenges you may have or continue to face being on PrEP.

Before getting into the interview questions, I want to make sure you had the chance to review the consent form that I emailed you. Did you have any questions about the information provided in that document?

Just to remind you, I will be recording our discussion today, however I will keep your comments confidential and private. You may skip any question you do not feel comfortable answering and you may also choose to stop participating in the interview at any time. What questions do you have before we begin?

Screening (for which set of questions to ask the participant)
We have a state-wide program, PrEP Navigation, that offers hands-on PrEP services and assistance to those interested. Do you by chance receive your PrEP care services from any of the following agencies/clinics:

> Vivent Health, UW Health HIV clinic, Horton St. Clinic, Diverse & Resilient, Health Connections, 16th St. Community Health Center, MCW Froedert Sargent Health Center, or BestD Clinic in Milwaukee

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This interview is going to be outlined along the PrEP continuum of care (i.e., awareness, uptake, and adherence/retention), where I am trying to understand your unique experiences, and get a better idea of where attention is needed in the process to maintain PrEP uptake and adherence in the state.
<u>Awareness</u>

1. Thinking back to before you started PrEP, how did you hear about PrEP?
    a. Probe: infomercials, advertisement throughout the city, friends, etc.

2. Where did you receive most of your information about PrEP from?
    a. Probe: did you do your own research, prevention programs throughout the state, provider/clinics
3. Have you been engaged in any PrEP programs or interventions?

Uptake

4. Thinking back to when you decided to start on PrEP, what was your process to linking to a PrEP provider like?
    a. Probe: were you able to go through your PCP, did you go to a sexual health clinic, did you have to do an intake through a clinic and be referred out, etc.
    b. If screened outside of a provider, what was the experience with being referred to a provider and then actually linking with that provider to get a prescription?
5. How was your screening process, such as getting the necessary labs done to "qualify" for PrEP?
    a. Probe: done in the same clinic, anything taxing about this step of the process
6. Once being prescribed PrEP, were there any barriers to starting your medication?
    a. Probe: cost barriers, pharmacy related barriers, etc.
7. Were there any initial barriers that kept you from starting the PrEP care process?
    a. Probe: getting information, finding a provider, scheduling, transportation to appointment, etc.
8. What was helpful to you when initiating/starting PrEP?
    a. Probe: informed provider, medication assistance programs, etc.

Adherence & Retention

9. As you know, being adherent to PrEP is essential to maintaining HIV negative. How adherent are you to your PrEP therapy?
    a. Probe: do you take it daily, have you taken breaks from being on PrEP, etc.
10. Another key to adherence is retaining in care, which includes attending follow-up labs for prescription refills. What is your process like for follow-ups?
    a. Probe: any barriers to follow-up labs
11. What barriers have occurred throughout your time on PrEP, that have impacted your adherence to PrEP?
    a. Probe: cost, pharmacy barriers, scheduling for follow-up labs, transportation, SDOH
12. What has been most helpful to you to main adherent and retain in PrEP care?

PrEP Navigation

I'm not sure if you are aware but the state currently has an HIV Prevention Program called PrEP Navigation where they have trained health workers that assist those who are at risk of HIV access PrEP. Along with facilitating clients in the PrEP care process, these navigators uphold multiple roles and responsibilities including educating clients, assisting in insurance issues, accessing financial assistance, attending provider appointments, and linking clients to addition support services when necessary. Most importantly, the navigators are staying in contact with their clients, sending them reminders for labs and prescription refills to help clients retain in care.

13. Have you heard about this program, or these navigators?
14. Do these services from a navigator seem to be more than what your current provider/clinic provides you?
    a. Does your provider follow-up with you, send reminders etc.
15. Do you think receiving care through a navigator would benefit your experience with PrEP (now or at the beginning)?
16. What ways do you think the state could improve measures when it comes to PrEP access?
17. How can the PrEP care process improve to help you maintain adherent to PrEP?
18. Finally, In what way has PrEP had a positive and/or negative impact on your life?

Wrap-up

Is there anything else you would like to add/share about your experience with PrEP and the care you receive maintaining on PrEP?

To wrap up the interview I just need to collect your demographic information. I am going to provide the link to the demographic survey in the chat for you to fill out. I will give you a few minutes to complete that form, if you have any questions just let me know.

Closing

Thank you very much for being part of this interview and sharing with me your experience with starting and staying on PrEP. Following this interview, you will receive an e-gift card in your email as a thank you for your time and participation in my study. Thank you again and enjoy the rest of your day!

Demographic Survey

1. In what age range do you fall under?
    a. 18-24
    b. 25-34
    c. 35-44
    d. 45-54
    e. 55-64
    f. 65+
2. What gender do you identify as?
    a. Cis-male
    b. Cis-female
    c. Non-binary
    d. Trans-male
    e. Trans-female
    f. Prefer not to say
3. What is your race?
    a. White
    b. Black or African American
    c. American Indian or Alaska Native
    d. Asian

    e. Native Hawaiian or Pacific Islander
    f. Other
4. Are you of Hispanic, Latino, or Spanish origin?
    a. Yes
    b. No
5. What is your household income?
    a. Less than $50,000 annually
    b. $50-70,000 annually
    c. $70-90,000 annually
    d. $100,000+ annually
    e. Prefer not to say
6. What is your residential zip code?
7. What county do you live in?
8. Do you have health insurance?
    a. Yes
    b. No
    c. Prefer not to say
9. Do you receive any medication payment assistance for PrEP?
    a. Yes
    b. No
    c. Prefer not to say
10. What HIV risk characteristic do you fall under, if any at all?
    a. Someone who has sex with a partner that is HIV+
    b. Gay, bisexual, or other man who has sex with men
    c. Transgender woman who has sex with men
    d. Injection drug user
    e. Other
    f. Prefer not to say
11. How long have you been on PrEP?
12. Where do you receive your PREP care services at?

Results Supplement Tables

Participant Identified Barriers to the PrEP Care Process

Table 21. Supplement table on patient identified barriers to the PrEP care process

PrEP Continuum of Care Domain	Theme	Group(s) From Which This Theme Arose	Illustrative Quote(s)	
AWARENESS	**PrEP coverage assistance**	Control & Treatment	"So, yeah, I found it more just like frustrating, I guess. Like it wasn't easy, or it wasn't like difficult to find the information. I feel like I just didn't ever really know that like for example PrEP was, like it should be covered, until I found I think it was some, almost like government website." -7T	"I think the barrier there is just that I didn't have the information about it. Like right now, in my brain, I think of that as probably something that's either expensive or that like I would have to pay something for, since I don't have insurance right now." -20C
	If PrEP was suitable for them (risk factors)	Control & Treatment	"I trusted the doctor, like the Canadian doctor when he said, well, yeah, like I don't, like basically like I don't think you have enough sexual partners to warrant like the cost of PrEP versus the benefits, right?" -27C	"They had said that there was a possibility, but by the time that happened, I really wasn't sexually active for a time, so I really didn't feel I needed the PrEP." -16T
UPTAKE	**Uninformed Primary Care Provider**	Control & Treatment	"And then I heard from people around here that like primary care providers are still, there's a stigma that they are uneducated about it or they refuse to prescribe it" -P10C	"I think I went to my primary care doctor, and it was pretty apparent they were not the most knowledgeable about PrEP, and I noticed that right away." -P06T
	Insurance Coverage	Control & Treatment	Before it was generic, yes, we were worried about it a little bit but got access to the copay cards, and so it was fine. I felt very fortunate to have that coverage because I know I heard stories of other people who weren't able to get coverage, and so that was really scary…When it became generic, there was concern over if insurance companies would cover, like what they would cover because the formularies were still being worked -P10C	"Yeah, insurance is actually one of the, my biggest gripes. And, you know, obviously I know healthcare really well because I live it every day. But my insurance, did not, they cost shared the preventative labs with me. ... And then there was like a period of maintenance where they weren't covering anything, and I was getting these like outrageous bills. ... Whether your first labs aren't covered or your second labs aren't covered, it's still, you're not going to

				become a regular user if this is what you have to go through." -P3T
	Side Effects	Control	"The only thing that I was slightly hesitant about was just a few of the side effects. I've seen a couple friends, you know, take it, and they reacted differently. " -P25C	"So I consulted a few of my friends, and one of them said they had really bad side effects from Truvada. I think, I don't exactly remember what they said, but it's probably diarrhea and some liver function abnormalities." -P24C
	Stigma	Control & Treatment	There was the like pharmacy, the specialty pharmacy's like, their like med adherence screening protocols were like reeked of stigma and had this kind of paternalizing feel to them, that there were some like knock-down, drag-out conversations with the managing pharmacist in the like initial months of taking PrEP. That, you know, and how much of it was like my own internalized stigma around AIDS having like grown up when I did, is an interesting question. -P22C	My primary care doctor was Ascension or whatever, kind of the more, you know, religious hospital, if you will. So, yeah, my primary care doctor, when I brought it up to her, she was like, oh, like I'm not super knowledgeable on this. I'm going to refer you up to an infectious disease specialist doctor up in Wausau. So she set me up with an appointment with somebody up there, again, keeping in mind that it's a saint-whatever hospital that it is. Met with him. I was anticipating going into it where he would be like, oh, yeah, makes sense. Like you're with a partner that is positive. Like here's what you need to know and prescribe it to me, which he actually very much advised against it, was, you know, it was a very weird visit for me. I was not comfortable in the sense of, like I didn't even feel comfortable telling him that, oh, like we are in like a slightly open relationship too. -P14T

	Clinic	Treatment	"I don't remember it being stupidly long, so, you know, a couple weeks. I would say that's sufficient. Like it wasn't like you got to wait six months. But if it was four or five weeks, I would think that would be normal. Sad to say, but four to five weeks is normal."-P02T	"That was the main barrier [PCP refusing to provide]. But then, when I moved to Stevens Point, so like rural Wisconsin, that was a little bit harder. Like I would have liked to find somebody in person to do it with versus having to drive like, you know, two hours to Madison or an hour to Wausau." -P15T
ADHERENCE	**Side Effects**	Control & Treatment	"yeah, I was like going through like a health thing at the time that I wasn't sure if it was related to me taking PrEP. So, I went off of it just to like to see if that was it, because I had like, I've had like bad experiences with like unrelated medications in the past. So obviously trying to think of anything different that I had been doing, and I came across just like my, what was going on with me, and like how PrEP could have been causing it." -9T	"So, like the impact on my kidneys, right, was a thing. And I think it remained a thing for a year or two of like there's something weird with my kidneys and so a little bit of like collective holding our breath." -22C
	Insurance Billing / Costs	Control & Treatment	"I know once in a while, with my insurance, lab is an issue because they only cover so much a year. So, a lot of times, I get my labs done at the, my doctor, but there are times I have to go to another clinic because my insurance won't cover it. I mean, I just got a bill literally for $1,000 for an HIV test. Like what!?" -23C	"Definitely the cost. That was definitely the biggest barrier that I have, and frustration that I've dealt with all of this is the bills that I've gotten after my visits for the labs. And to my point of all the research and stuff that I've done, after the fact because I learned, I mean, I paid some of the bills in the beginning. But I learned over time, through my own research, that, yes, I should not be paying for this necessarily, and it should be covered." -7T

	Casual Forgetfulness	Control & Treatment	"I think I noticed it like with family trips or like weekends being away. Like I was on a family trip for a week to Disney with my family, and I was like, oh, my gosh, I didn't bring my bottle. You know, like I was like the whole week I totally forgot." -1C	" So, I'm not the best at taking it, though, okay, I'd say I probably realistically take it like probably five out of seven days. I usually forget a couple days, and I haven't really been too worried about it just because like my risk factors are a lot lower now. Like I don't currently have sexual contact with anybody transgender or any men who sleep with men. And so, I am not too worried about it, like actually coming in contact with HIV, but I still want to stay on it." -21T
	Frequency of lab visits	Control	"I mean, the, especially in the first year, the, you know, every-three-months labs and trying to do that through the doctor's office is a little bit harder. In the early days, that was kind of a bumpy road, I guess, is to get all the labs done as they were supposed to be done and trying to do that." -19C	"The manufacturers have a very strict with testing for the injectable, it has to be three to five days prior. It can't be any more than that. Otherwise, you start all over. Because I made the mistake about, of going a week before, because I thought it's only a week, and they don't like that. It has a potential to be a barrier." -23C
	Supply Quantity	Treatment	"Well, getting three months at once would be helpful because then you're not wondering if you need to schedule a follow-up appointment yet or not. Because if, you know, if all of a sudden, you run out, and I had an instance where I ordered a refill online, like I normally would, and it processed like normal, but the refill never came. And it was because I was due for my testing to get the prescription renewed, but there wasn't any sort of alert that let me know, hey, by the way, we're not sending you any more pills because you need to go into the clinic." -13T	"The actual pharmacy would only give me a monthly bottle, and right now, the only, I mean, I wouldn't call it a problem. It's just more back and forth. It's that now I'm on what is called a six-month prescription, a 90-day, two 90-day prescriptions, and my provider told me that I should be able to get like 90 pills just at once. But my pharmacy, for some reason, isn't doing that." -17T

Participant Identified Facilitators to the PrEP Care Process

Table 22. Supplement table on patient identified facilitators to the PrEP care process

PrEP Continuum of Care Domain	Theme	Group(s) From Which This Theme Arose	Illustrative Quote(s)	
AWARENESS	**Social Circles**	Control & Treatment	"I think I'd heard murmurs from friends that they had taken, they were on some sort of preventative medication." -4C	"Friends, mostly through friends. I was at college when I first heard about it, and a friend had told me, was on it and told me about it and stuff. " -15T
	Media Advertisements (social media, magazines, TV commercials & shows, & dating/hookup apps)	Control & Treatment	"I'd say probably you hear TV commercials for drugs, but you really probably don't pay much attention to that because there's so much of that. But I just, more in magazines. There's a national magazine called, oh, goodness, The Advocate, and then there's a local magazine called Our Lives, both of which have PrEP ads in them. -11T	"So, for me, I mainly learned most of it through TV infomercials in terms of my first exposure to it." -28C
UPTAKE	**Informed Provider**	Control & Treatment	"I think providers who actually had time to have like an extended conversation about it… And so, to have a provider who is willing to like to look holistically at things I think was super important, and a provider who had the time built into their clinical like practice model to have the conversation. And because of my kidney stuff, like my provider, like networking with other providers who could like talk about her ability to have consultation, I think informed my process to secure that like multiple providers, and in particular, that she had like consulted with providers at Vivent who like this is what they do, and that those providers were like, yeah, if you've got the nuclear medicine study like you're fine." -P22C	"The staff there [Vivent] was, has been really helpful. They're always, you know, informative and helpful and able to answer questions. They've been great. They've probably been the best resource of anything." -P13T

	LGBTQIA+ Friendly Provider	Control & Treatment	"Then I went to my new, I got a new primary care because mine left. And thank god he's an LGBT doctor. He runs an LGBT clinic. He's wonderful. So, he actually was talking to me about Apretude and said . . . blah, blah, blah. So, he actually did all of the work for me . . . And like I said, my doctor is starting an LGBT clinic here, so he, he's very up on everything that's going on. So, he literally will suggest the exact place you should go. So that's kind of nice." -P23C	"I have to remember, yeah, because it's been a couple years now. I think I went through my, I think I just switched to a different clinic before. So, for additional context, I was living on the East Coast. I was living in Washington, D.C., and I went to, when I first moved out there like an LGBTQ friendly clinic. So, it was very centered on that kind of stuff. And I wasn't taking PrEP at that time, but I switched clinics just because I think, like with my job insurance had changed and that of things. So, I just had to go to different primary care doctor. And they weren't as much of like a, you know, LGBTQ centered clinic." -P07T
	Proficiency of Care	Control & Treatment	"There is a clinic attached to all the provider offices that I've been at, so I have been able just to get the labs there at the same time of my appointment, which has been super helpful."-P01C	"I filled out like a very general form online. It was very confidential, which was comforting to me, because this was a brand-new experience for me. And then got a call from somebody from Vivent in Milwaukee, who asked me just a slew of questions to get me started and also was giving me kind of some basic information, things I didn't know about as well. And then got an appointment set up in Kenosha, and truthfully, from the first appointment to getting the PrEP and starting the PrEP, I want to say was like within days I was able to do that. I was impressed how quickly I was able to start on it."-P18T
	Destigmatized perceptions of PrEP	Control & Treatment	"Every, like people were talking about it like just sharing information through like, you know, what is it, at like casual social networks or whatever, which was cool."-P10C	I was at the pride block party on King Street in front of WOOF'S, and Vivent was there, and they were doing testing and like promoting stuff. And I see that like every like queer event that I go to in the area, so that's good. Continue to do that kind of stuff. -P08T

	Referrals & Recommendations to Care	Treatment	"I feel like I stopped on the way out and made the appointment with like a receptionist or whatever. But I honestly don't remember But that's usually how it works. Like they do the referral, and you, you know, on the way out, they make the appointment for the other people." -P02T "It made, that made things easier [being referred out]. Yeah. Well, no, even my primary at the time, I didn't expect him to know everything and refer. And I, because it was so new, I think, what, it, PrEP came out in maybe '14 or '15? Well, it was still new, right, that people really didn't hear about it until '14, '15. Even for the primary just to say, hey, I don't know, but these people do, hey, that, I'll take that. Or trying to do it and then screwing something up and it not be correct." -P02T	"But then I talked to one of my friends who goes to Vivent, and he said I should just go there, and so I went to Vivent." -P12T
	Self-Advocacy	Control	"So I went to my new provider, and I'm like, hey, can we start PrEP again. And she was like, oh, I've never prescribed that before. And I was like, oh, I would really like to get PrEP, so like can we have a conversation about that? I felt like I had to advocate for myself a little bit." P1C	"Well, I just, yeah, I did my own research. And then I wasn't ready to start it at that time, but then later, when I wanted to start it, I contacted my doctor and asked." -P26C
ADHERENCE	**Adherence Aids (reminders, paired with routine, pill organizer)**	Control & Treatment	"Like I, you know, I use a pill organizer. I refill it every week. I also take it with my Vitamin D. It's engrained in a routine." -10C	"I would say depending how sexually active I am, I think that has a direct correlation to how well I adhere to it. If I'm particularly active, then I'm going to be very, I'm going to much more concerned, and I'm really making sure I'm taking it. Whereas if I'm less, then I may forget about it more. But with my pillbox, I still take it regardless, but I have noticed that in the past. -6T

	Financial Resources	Control & Treatment* (treatment has additional financial resources through program funds)	"For me, it was initially cost. I walked into Walgreens not knowing my out-of-pocket cost at the time, you know, what the copay was going to be, which at the time was a few hundred dollars per month. That's when the pharmacist told me to go and get the Advancing Access, sort of the Gilead prescription card to cover that. Once I did that, it pretty much eliminated all my barriers." -19C	"Yeah, and then, you know, she, UW, she was able to connect, UW has financial resources for people who couldn't pay their labs. You know, she offered it to me, and I was like, no, no save that money for people who can't pay their labs, you know, because I have the resources to pay them." -3T
	Receiving a 90-day supply	Control & Treatment* (only 1 treatment individual)	"For my first one, I got a 30-day supply. But after that, they were all 90-day supply. And I definitely prefer it that way." -24C	"They used to send three bottles at once, which was also very convenient. It would, you know, less trips for me to go to a pharmacy if I needed to, and I had a more steady supply." -4C
	Navigator Support	Treatment	"I mean, there was, there were times when because the billing issues were so complicated that I was like, I'm just going to go off of it because it's not worth it. But having the navigator kind of help advocate for me has also been, in that way, really helpful." -8T	"Yeah, all of them are great & I feel very supportive by them all! Honestly, like they're always just willing. They're like, if you have issues, whether it's with insurance or whatever, like just reach out, and, you know, we'll help you out. And every time that I have, they are there, and they help me out. They figure out the issues that I have. Yeah, they're just, on top of that. We're very lucky to have them for sure!" -14T
	Rx Mail Order	Control	"I do mail order pharmacy. And before that, I did, I forget what their company is called, but I did another mail order service because I thought it was easier. And then that company was no longer working with my insurance program, so I had to switch. But then UW had a mail order, and so it was fairly easy." -10C	"Oh, actually, I did get mail order once, but I actually prefer picking it up, but that's because I work there. Otherwise, I would prefer the medications mailed to me directly." -24C
	Ease of Care	Control	"Yeah, so I believe she's doing like standing orders for six months or three months, whatever it would be. And then probably when the pharmacy requests a refill, she's probably putting in additional orders." -5C	"Yeah, it's definitely helpful to have my doctor email me reminders for labs. It's, I guess I kind of took that for granted, in hearing you say that. So, I was like, oh, I guess a lot of people don't do that." -25C

Appendix C – Paper #3

Recruitment Materials

Navigators and the lead researcher had had prior introductions through collaboration with the state partner, Department of Health Services HIV Prevention Team.

Email sent to navigators to invite to participate in interview

Subject: Inquiring about PrEP Navigation Interview

[Greeting]

I hope you are going well, and that your 2024 is off to a great start!

I am reaching out in hopes to schedule a time that we could meet for a formal interview for the PrEP Navigation research study. I was able to chat with a handful of your clients and got a great patient perspective on PrEP care! I think it would be very valuable to understanding the program and continuum of care if I was able to get your perspective as a Navigator. Would you be interested in chatting with me for about 75-90-minutes.

If you're interested, let me know if there is a day/time that works for you, and we can schedule it. If you would like me to follow up closer to the beginning of March to schedule, we can do that as well!

I look forward to hearing from you, and the potential of chatting with you more about your experiences as a Navigator.

Consent Form for Navigator Participants

Title of Study: Evaluating Wisconsin's HIV Prevention Program, PrEP Navigation
Principal Investigator (person in charge): Maeleigh Tidd
How to contact the study team: mtidd@wisc.edu or (812)216-6212

This sheet provides key information you need to know about this study. Taking part in a study is voluntary. You can stop taking part in this study at any time, no questions asked. Feel free to ask the researchers any question about this study. **The following consent form includes more information about taking part in this study.**

What is the purpose of the study?
To understand the unique advantage and challenges PrEP Navigators are facing when reaching, starting, and retaining clients on PrEP (pre-exposure prophylaxis) for HIV prevention.

Why are you being asked to participate in this study?
You have been asked to participate because you have been identified as a PrEP Navigator involved in the state of Wisconsin Department of Health Services HIV Prevention Unit's HIV prevention program, PrEP Navigation.

What will you do if you chose to participate in this study?

If you choose to participate in this study, you will be asked to take part in an audio-recorded interview (virtually, on Zoom). The interview is expected to take approximately 45-60-minutes and will be recorded and transcribed. The researcher will ask you various questions about your experiences navigating individuals on their PrEP care process. You can choose not to answer any of the questions you are asked and can stop the interview at any time. Being in this study is voluntary.

Are there any benefits in participating in this study?
The research team cannot guarantee any direct benefits to you from joining this study. However, you will contribute to providing a better understanding of: (1) how the state of Wisconsin's HIV preventative measures can improve to increase access to PrEP and (2) how the state can improve the PrEP Navigation program to better support you as a PrEP Navigator. Additionally, your involvement in this study will help shape the direction of future research and interventions in the state's response to HIV preventative care.

Are there any risks in participating in this study?
There is always a risk of confidentiality breach, or of revealing personal, sensitive, or identifiable information. However, the researcher will protect participants by deleting highly sensitive personal information from analysis.

How will privacy/confidentiality to protected?
Participants privacy and confidentiality will be protected in various ways. The interview will be conducted in a confidential and safe space, identifiable information will be omitted from the transcripts, and interview materials will be destroyed after they have been analyzed. All data collected will be secured in a safe and secure location that only the study team has access to.

Will there be compensation for participation in the study?
No.
Who to contact with questions?
If you have questions about the research before or after the interview, please contact Mae Tidd at mtidd@wisc.edu or (812)216-6212.

Agreement to participate in this study and permission to use.
I have read this consent and authorization form describing the research procedures, risks, and benefits. I have had a chance to ask questions about the research study, and I have received answers to my questions. By continuing, I agree to participate in this research study, and permit the researcher to use the information I have provided in the interview for their study.

Interview Guide

Intro
[Greeting – Good morning/afternoon/evening]
I want to thank you again for taking the time out of your day to meet with me. To reiterate, I am working with Department of Health Services HIV Prevention Team in evaluating their PrEP Navigation program. The goal of the interview today is to get know more about your experiences

as a Navigator, while also understanding any challenges you may have or continue to face in your role.

Before beginning, I want to make sure you had the chance to review the consent form that I emailed you. Did you have any questions about the information provided in that document?

Just to remind you, I will be recording our discussion today, however I will keep your comments confidential and private. You may skip any question you do not feel comfortable answering and you may also choose to stop participating in the interview at any time. What questions do you have before we begin?

The interview questions are outlined based on core components identified in evaluating public health programs. Again, I am just trying to capture your unique experiences and challenges as a navigator to provide the state with a better idea of where the program needs more attention when considering changes and improvements.

Implementation

1. To start, walk me through your navigation process from beginning to end, Such as your first interaction with a client, what that interaction involves, and then any follow-up communication/interactions you have with them.
    a. Probes: identifying/engaging & educating, referring, linking, starting, adhering (PrEP continuum) - what is their involvement in it?
    b. Essentially, walk me through an initial appointment with you for PrEP, and what I can expect going forward in PrEP care.

Reach (*encompassing of awareness*)

2. Are your navigation services being promoted to the communities of highest risk of HIV, if so, how?
3. How could your recruitment or promotion strategies change to increase PrEP uptake in your agency?

Effectiveness (*Encompassing of Uptake & Adherence*)

4. What are ways you know the program is working, in terms of achieving PrEP uptake goals in the state or at least in the communities your serving?
5. If you could change anything about the program logistics, what would it be and why?
6. Are there any barriers you face as a navigator to ensuring your clients get started on PrEP?
    a. Probes: linking to provide (UW/Vivent), filling prescription (loss of contact), actually starting once picked up
7. What are some things that are helpful to you in ensuring your clients get started on PrEP?
    a. Probes: following up after initial about starting
8. Are there any barriers you face as a navigator in ensuring your clients retain in PrEP care?
    a. Probes: loss of contact, follow-up labs/care,
9. What are some things that are helpful to you in ensuring your clients retain in PrEP care?
    a. Probes: following-up about care (email/text), pre-scheduling labs/visits

Adoption

10. What drove you to become a navigator?
11. What are the reasons you continue to stay with the program as a navigator?
12. How often do you go through trainings as a navigator to stay informed on PrEP care?
    a. Probe: PrEP Workgroup, Annual meetings?
13. What kind of technical support/assistance do you receive from DHS?
    a. Do you receive any from your agency?
14. What are ways DHS can assist/support you as a navigator, in ways that they aren't already?
    a. How can your agency support you more?

Maintenance

14. In what ways have you adapted your navigation services/skills to achieve success in moving clients along in their PrEP care?
    a. Probe: have you changed how you offer care/services since the beginning of acting as a navigator
15. What would be needed for the program to expand in your agency (if capable) and to other agencies/organizations to deliver the program?

Intervention

16. What are the benefits of being a navigator?
17. What are the challenges of being a navigator?
18. Final wrap up question: Do you keep track of your patient demographics, if so, would you be able to share with me a quantifiable number of gender, risk characteristic, and how long they have been involved in PrEP care with you/your agency?

Those were all the questions I had for you today, is there anything you would like to add about your experience as a navigator that has not yet been captured from our conversation?

Demographic Survey

1. In what age range do you fall under?
    a. 18-24
    b. 25-34
    c. 35-44
    d. 45-54
    e. 55-64
    f. 65+
2. What gender do you identify as?
    a. Cis-male
    b. Cis-female
    c. Non-binary
    d. Trans-male
    e. Trans-female
    f. Prefer not to say
3. What is your race?
    a. White
    b. Black or African American
    c. American Indian or Alaska Native

    d. Asian
    e. Native Hawaiian or Pacific Islander
    f. Other
4. Are you of Hispanic, Latino, or Spanish origin?
    a. Yes
    b. No
5. What is your total annual income?
    a. Less than $30,000
    b. $31-60,000
    c. $61-90,000
    d. $91,000+
    e. Prefer not to say
6. What is the highest degree or level of education you have completed?
    a. Some high school
    b. High school
    c. Some college
    d. Bachelor's degree
    e. Master's degree
    f. PhD or higher
    g. Trade school
    h. Prefer not to say
7. If you received a bachelors, masters, or PhD+, what did you receive your degree in?
8. What is the county in which you work/provide PrEP Navigation services in?
9. Do you speak Spanish?
    a. Yes
    b. No
10. Do you speak in Spanish or utilize an interpretation to interact with Spanish speaking clients?
    a. Yes
    b. No
11. Do you help clients access or enroll in health insurance?
    a. Yes
    b. No
12. Do you help clients access or enroll in medication payment assistance programs?
    a. Yes
    b. No
13. Do you help clients with other cost/insurance related issues/concerns?
    a. Yes
    b. No
        a. If yes, what kind of cost/insurance assistance do you provide?
14. Do you help link clients to other support services when necessary?
    a. Yes
    b. No
15. How often are you following up with your clients? (check all that apply)
    a. After first appointment

b. A month after starting PrEP
c. Every 3 months
d. Every 6 months
e. When someone has stopped taking PrEP

16. How long have you been working as a PrEP Navigator?

Navigator Demographics

Table 23. Navigator Self-reported Demographics

Characteristic	**Item**	**Frequency (n=2)** **n (%)**
Age		
	36-45	1 (50.0)
	46-55	1 (50.0)
Gender		
	Cis Female	2 (100.0)
Race/Ethnicity		
	Non-Hispanic White	2 (100.0)
Annual Income		
	$61-90,000	1 (50.0)
	$91,000+	1 (50.0)
Education		
	Bachelors	1 (50.0)
	Masters	1 (50.0)
Degree		
	Nursing	1 (50.0)
	Social Worker	1 (50.0)
County		
	Dane	1 (50.0)
	Milwaukee	1 (50.0)
Average time as a PrEP Navigator (years)		5

Results Supplement Table

Dissemination of PrEP Navigation as Implemented

Table 24. Navigator Quotes to Support their Workflow

Navigator Workflow/Processes	**Illustrative Quotes**	
PrEP Education	"Before they set up an appointment, I sort of give them a once over of how we do our program and the costs for our program and the ways I can help with that. And then if they, with that very kind of bare bones, think that this is something they want to follow through with, they make an appointment and come see me. When they get here, we review everything again with a little bit more detail. I have a folder with information in it that I review with them. I have a worksheet for my clients to fill out who are interested in PrEP, so that I can kind of follow through and manage their care." - Navigator 2	"My first contact is to follow up on a referral, and I usually frame it as you know, I'm Katie, I work at UW Health. I received a referral for PrEP. Sometimes when people get connected, they have a lot of questions, and they're looking for information. And other times, people know what they need to know, and they're ready for an appointment. This is purely anecdotal, but I would say it's about half and half. Sometimes that first conversation is just a bunch of questions, and sometimes they're like, no, I need to schedule. And even if they have a lot of questions many times, people will say, I think I'm ready to schedule now. It's not like they're taking a lot of time to think about it, they just wanted to talk a few things first." -Navigator 1
HIV Testing	"I immediately draw the blood and start the screening. All I need is an HIV test in immediately, and then I'll grab a CMP, among other things, which will come back the next day. Once our rapid HIV test comes back negative, I can hand them a 1 months' supply of PrEP at the end of their first visit." - Navigator 2	"Then I schedule patients in our clinic. We see patients both in person and over video through MyChart. Patients have a choice about how they do that. I talk through the different options for doing labs. If they come in person, they can do labs at the hospital. If they do a video appointment, maybe they prefer to do labs at a [redacted health system name] that's closer to them. Maybe they prefer to do at home labs. We can mail them an at home testing kit. If they are a referral from public health, maybe they've just done labs, and then we can sign the ROI and get your results over." -Navigator 1

Assess Insurance Status & Enroll	N/A	"I always talk about insurance with people in that very first conversation. There's some clarifying of what is realistic when it comes to insurance and Aptitude, even if a patient only wants to do oral PrEP. I typically do a test claim to find out if how PrEP will be are covered by their plans. So, you know, to find out if they're [Descovy and Truvada] covered the same. The one thing that does happen in person is if a person is eligible for Badger Care, then oftentimes, we will do that application together, cause that can be a little bit daunting for folks. In terms of other insurance issues, we just handle that over the phone or over MyChart separately." - Navigator 1
Enroll in Medication Payment Assistance	"If they have insurance, I can sometimes take a copy of their insurance card, and if they don't have insurance, then we talk about the Ready, Set. PrEP program, and I can get them signed up for that pretty much right away." -Navigator 2 "We get them set up with a pharmacy within that month. If I have to set them up with HHS, that gives me time to get that rolling. If there is a weirdness with their insurance, I have time to figure that out. If there's something weird with the co-pay or something, we use Evita as our preferred mail-order pharmacy. At that first visit I might ask them what pharmacy are you going to want to use? With certain insurance policies they have to use like CVS or something like that. If they have a choice, then I recommend Evita to them." - Navigator 2	We have been able in the past couple of years to use grant funding, to provide care for people who don't have insurance. That has been a huge factor that has allowed us to meet people who are at higher risk for HIV infection. The numbers aren't huge, we have less than 20 people who are uninsured, who are coming into our clinic for PrEP care, but those people are overwhelmingly Spanish speaking, and not eligible for insurance in other ways." - Navigator 1
Find a PrEP Provider	"The clinic here are all pretty much all nurses. I think in a lot of other places the navigator might not necessarily be a healthcare clinician necessarily so, therefore, in a lot of other places, maybe they see the navigator and then get set up with the healthcare portion. Here it's all together." - Navigator 2	"Typically, we can see folks within 2 weeks, and we do have more availability for telehealth. If I'm looking at the schedule, and it's like, okay, we can see you in 3 and a half weeks, or, well, what about a video visit? Chances are we can fit that in next week. There's a lot of factors that impact our provider schedules, but we have 2 providers who see most of our PrEP folks. Typically, we're able to get someone in within a couple of weeks." -Navigator 1

Link to Other Support Services	N/A	"If a patient reports not having housing, not having insurance, if they are in need of transportation to the appointments, if they have a lot of questions about PrEP, those are typically like some signals to me that, like, I want to ask more questions, and I want to say, well, would it be helpful to meet in person at your visit? I am only seeing patients in person if they present with higher psychosocial needs. I've talked about accessing recovery programs, I have talked about housing, and I have talked about safety planning." -Navigator 1 "That becomes a time when people talk about other stuff where they're like, well, I was thinking of contacting you because I lost my job last month, and now I don't have insurance, what do I do? Or I'm going on a month-long vacation next week. How do I get enough medication? It becomes a point to check in about other issues that I'm able to assist with." -Navigator 1
Follow Up & Adherence Support		
After 1st Appointment	N/A	"Typically, I check in with the patient about 2 weeks after their appointment. Just to say, how did things go? Have you received medication from the pharmacy? Yet, most of the time, by the time 2 weeks rolls around they've started taking their medication, and they either are feeling queasy or they're not. So, then we can problem solve how they can mitigate that. Sometimes there's issues that come up where, no I never heard from the pharmacy or no, I haven't heard anything, but they were supposed to stop into the lab, so let's make sure you do that first. You know, that has to happen before the prescription will get sent." -Navigator 1
1 Month After	"When they come back in a month, then I kind of run all my tests again. See how they're going, see how they're doing, if they need any supports with like maybe helping remember to take the pill or any weird side effects that sort of thing." -Navigator 2	N/A

3 Months Consecutively	"The first year, it's essentially every 3 months. They only have enough prescription to get them through every 3 months. When I see them, I write out a new prescription, and based on my spreadsheet, I may also contact them ahead of time, saying, "Hey, I can see on my spreadsheet that you know the date is coming up. Just a reminder to come in when you can" After a year on, they'll go wherever for their every 3-month HIV, and then they come to see me every 6 months for HIV, CMP, anything else I might need. Then, every 6 months I will write out a nice big prescription for them." -Navigator 2 "The first year I see them every 3 months, and then once their one-year anniversary shows, then I don't need to see them for PrEP specifically, but every 6 months. I ask that they at least swing through every 3 months, anyway for just like a routine screen which includes an HIV test, but they don't necessarily have to come all the way here for that every 3 month one at that point." - Navigator 2	"Anyone new in our clinic, my goal is to be reaching out to them about every 3 months. To check in about labs to check in about refills. You know, and that becomes a time, I may be calling them because we think they're due for a refill. How would you like to do labs you? Are you planning to come in person? Do you want us to mail you an at home testing kit? And that's at 3, 6, 9, 12 months, like it's not just like one check in at 3 months. About every 3 months, I'm checking in with people." -Navigator 1 "The goal is that I am checking in with every patient every 3 months to make sure that they have what they need. That they have a way to do labs if they want to continue doing that. If they're taking a break, and they don't need that refill, then we can document that. And we know and understand that, and they know how to reach us. So, it is every 3 months." -Navigator 1
If someone stops	*Self-reported in questionnaire that they do, but did not speak about it in the interview*	"So, I think that is the biggest marker of success that patients are staying in care, and we have contact with them, and we know we know when they're leaving." -Navigator 1