Spring 2021

Assessing Pre-Exposure Prophylaxis Screening and Need among Men Who Have Sex with Men and Transgender Persons of Color: A Mixed Methods Case Study of the IMPACT DMV Demonstration Project

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A Dissertation submitted to

The Faculty of
The School of Medicine and Health Sciences, Department of Clinical Research & Leadership
of The George Washington University
in partial fulfillment of the requirements
for the degree of Doctor of Philosophy in Translational Health Sciences

May 16, 2021

Dissertation Directed by
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The School of Medicine and Health Sciences of The George Washington University certifies that Brittany Wilbourn has passed the Final Examination for the degree of Doctor of Philosophy as of February 23, 2021. This is the final and approved form of the dissertation.

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Dedication

I dedicate this work to my SONshine, Bryson Wilbourn, who inspired me to persevere.

Acknowledgments

To my mother, father, and sister, thank you for being my biggest supporters throughout life. Thank you for pushing me to achieve what some thought was unattainable.

To my Cohort 1 peers and friends (especially Cortni Romaine and Kellie Bodeker), thank you for only seeing the best in me even when I doubted myself. To Matthew Levy, thank you for your daily affirmation.

To my amazing Dissertation Chair, Paige McDonald, thank you for guiding me through this process, brainstorming, and troubleshooting as needed along the way. To my committee member Amanda Castel, thank you for your continued mentorship and for serving as a model of success. To my committee member Adam Allston, thank you for your time and expertise. To my Readers, Douglas Krakower and Susanne Doblecki-Lewis, thank you for taking the time to evaluate the quality of my research. I would also like to thank the Rural Center for AIDS/STD Prevention at Indiana University School of Public Health-Bloomington for supporting this research. To my academic advisor, Mary Corcoran, thank you for guiding me through the didactic portion of the program. To the Director of Doctoral Candidacy, Guy Lotrecchiano, thank you for making the transition to doctoral research a seamless one. I would also like to thank DC Health personnel who assisted me with my data collection efforts, specifically Kate Drezner, Kenneth Pettigrew, and Terrance Payton. Lastly, I would like to thank my high school chemistry teacher, Michael Pastirik, who was one of the first people to nurture my love of science.

Abstract

Assessing Pre-Exposure Prophylaxis Screening and Need among Men Who Have Sex with Men and Transgender Persons of Color: A Mixed Methods Case Study of the IMPACT DMV Demonstration Project.

Men who have sex with men (MSM) and transgender persons of color experience disproportionate, multi-level HIV risks. Pre-exposure prophylaxis (PrEP) is an evidence-based HIV prevention strategy; however, access to PrEP has been limited among this population. PrEP demonstration projects that target MSM and transgender persons and test the implementation of PrEP in real-world settings are underway. However, PrEP demonstration projects specific to MSM and transgender persons of color are limited and most demonstration projects do not consider the impact of the implementation process or organization contextual characteristics on PrEP outcomes. The Improve Measurable Participation and Access to Care and Treatment District of Columbia, Maryland, and Virginia (IMPACT DMV) demonstration project was created in response to the high rates of HIV, AIDS, and STIs among MSM and transgender persons of color in the DC, Maryland, Virginia region aimed to provide equitable access to HIV prevention, care and treatment, and support services for those populations. Using a mixed-methods case study design, this study sought to describe PrEP screening and PrEP need in the overall project, understand how the project was implemented at the clinic level with respect to PrEP screening and determination of PrEP need, and describe how the varying contexts and implementation strategies of the clinics impacted PrEP screening and PrEP need in the overall project.

An implementation science framework guided the study's exploration of PrEP

screening and determination of PrEP need. Quantitative data was collected via archival records collected by the project on patients receiving PrEP services from clinics funded by the project. Qualitative data were collected through document review, interviews, and focus groups. Purposeful and snowball sampling were used to identify interview and focus group participants. Descriptive and inferential statistics were used to analyze the quantitative data, and Creswell's spiral method was used to analyze the qualitative data.

To aid the clinic staff in screening for PrEP, the project created an intake form that contained questions meant to assess a patient's or client's risk for HIV and developed a Coalition meant to provide education and updates to partners in the project. Of the 5043 HIV-negative MSM and transgender persons of color enrolled in the project 3803 (75%) were screened for PrEP. Persons not screened for PrEP (n=594) were significantly more likely to have an annual income under $16K (49% vs. 37%, p=.0264) compared to persons screened for PrEP (Table 4). Persons screened for PrEP (n=337) were significantly more likely to have no health insurance (50% vs. 43%, p=.0054) and to be single (77% vs. 72%, p=.0419) compared to persons not screened for PrEP. After adjusting for demographics and site of care, those screened for PrEP had a decreased odds of having an annual income under 16K (aOR 0.512; 0.328-0.800) compared to those not screened (Table 5). The project leadership loosely defined PrEP need as a patient meeting the eligibility criteria outlined in the CDCs clinical practice guidelines as well as having an interest in PrEP. As of March 2019, 3271 (86%) persons were deemed eligible for PrEP of 3803 persons screened for PrEP. Persons deemed eligible for PrEP were significantly more likely to lack insurance (51% vs. 49%, p=.0004) compared to those not deemed eligible for PrEP (Table 6). Those not deemed eligible for PrEP were significantly more likely to identify as male (89% vs. 78%, p=.0355)

compared to those deemed eligible. After adjusting for demographics and site of care, those deemed eligible for PrEP had a decreased odds of identifying as male (aOR=.333; .113-.980) compared those deemed not eligible for PrEP (Table 7). Staff at 9 of the 10 clinics funded by the project provided information related to their mission and vision, their staff and patient populations, their motivations for joining the project, their implementation of the project with respect to PrEP screening and determination of PrEP need; and perceived barriers and facilitators at multiple levels to PrEP screening and determination of PrEP need. There was variation between the project leadership and the clinic and among the clinics. The clinics varied most notably in their organizational contexts, specifically their organizational characteristics (i.e., age, type, location, size), their networks and communication (i.e., degree of collaboration within and among clinics), and their cultures (i.e., the priority populations at the center of their mission and vision). While there was often overlap between the barriers and facilitators identified by project leadership and the clinic staff, there were also differences between the barriers and facilitators identified by project leadership and clinic staff and among clinics based on type and size. The barriers to PrEP screening and determination of PrEP need identified by project leadership and clinic staff may partially explain the screening and need gaps reflected in the project's PrEP continuum and the continuums for most clinics. In terms of the degrees of adaptation within the project, most clinics made little to no adaptations to the project's recommended processes for PrEP screening or determining PrEP need.

Key recommendations resulting from this study include: 1) Expansion of PrEP indications for MSM in clinical practice guidelines; (2) Conduct of PrEP clinical trials among transgender persons; 3) Inclusion of an HIV risk assessment and PrEP indications for

transgender persons in clinical practice guidelines; 4) Standardization and optimization of data collection with the IMPACT DMV demonstration project; 5) Addressing barriers to PrEP screening and determination of PrEP need within the IMPACT DMV demonstration project; (6) Provision of additional technical assistance and capacity-building, and individualized targets, and; 7) Increased engagement of transgender men in the IMPACT DMV demonstration project.

Keywords: Pre-Exposure Prophylaxis, Men who Have Sex with Men, Transgender Persons, Demonstration Project, Mixed Methods, Implementation Science

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Chapter 1: Introduction

Overview

The Centers for Disease Control and Prevention (CDC, 2019) estimates that approximately 1.1 million people are currently living with HIV in the United States (U.S.) and approximately 380,000 people are estimated to contract the virus each year. HIV diagnoses in the U.S are not evenly distributed across different ages, races/ethnicities, genders, modes of transmission, or geographic locations. The HIV epidemic in the District of Columbia, southern Maryland, and northern Virginia also disproportionally affects certain groups based on age, race/ethnicity, gender, and mode of transmission. Both nationally and locally, MSM of color account for the majority of new HIV diagnoses (CDC, 2017a; District of Columbia Department of Health HIV/AIDS, Hepatitis, STD, and TB Administration [DC Health HAHSTA], 2018a; Maryland Department of Health The Center for HIV Surveillance, Epidemiology and Evaluation [MDH CHSEE], 2019b, 2019c; Virginia Department of Health [VDH], 2019). Gaps in knowledge exist regarding the impact of HIV on transgender persons; however, available evidence suggests that transgender persons are also severely impacted by HIV.

MSM and transgender persons of color experience multi-level HIV risk factors beyond individual-level behaviors such as condom use and partner concurrency: interpersonal (e.g., sexual networks and relationship dynamics), community (e.g., social and cultural norms), institutional (e.g., culturally competent health staff and responsive medical services), and structural (e.g., education, poverty, and policy) factors also contribute to HIV

risk. Pre-exposure prophylaxis (PrEP) is an evidence-based biomedical HIV prevention strategy (CDC, 2018) that could reduce the HIV risk among MSM and transgender persons of color. While the efficacy of PrEP has not been definitively established in transgender persons, it has been established in MSM (Grant et al., 2010) and clinical practice guidelines have been created to aid providers in the prescription of PrEP for MSM (United States Public Health Service [USPHS], 2014, 2018). Demonstration projects targeting MSM and transgender persons are also being conducted to test the implementation of PrEP in real-world settings.

Statement of the Problem

Men who have sex with men (MSM) and transgender persons of color are disproportionately impacted by the HIV epidemic in the U.S.: Black MSM have a 50% chance of being diagnosed with HIV in their lifetime, while Latino MSM have a 25% chance of being diagnosed with HIV in their lifetime (CDC, 2017a). From 2009-2014, 73% of transgender men diagnosed with HIV were Black or Latino and 80% of transgender women diagnosed with HIV were Black or Latino (Clark et al., 2017). HIV prevention strategies have experienced a recent shift from solely behavioral (e.g., condom use) to a combination approach with an emphasis on biomedical prevention strategies. PrEP, an evidence-based biomedical HIV prevention strategy, is more than 90% effective in reducing HIV infection from sexual transmission (CDC, 2018). However, knowledge of, access to, and use of PrEP has been low among MSM and transgender persons of color (McAllaster & Ervin, 2016). Regarding access specifically, providers who are not knowledgeable about PrEP or who hold certain biases regarding patients most likely to benefit from or adhere to PrEP may impede access. Also, different processes may be used to determine whether patients are in need of

PrEP (e.g., a provider-initiated model where PrEP need is determined by the indications outlined in the CDC guidelines versus a shared decision-making model guided by criteria outlined in the CDC guidelines and/or interest in PrEP on the part of the patient). Furthermore, issues such as medical mistrust and PrEP stigma may preclude hypothetical interest in PrEP from translating into real-world interest for MSM and transgender persons of color. While MSM and transgender persons have been the focus of several past, ongoing, and planned PrEP demonstration projects, MSM and transgender persons of color have been the focus of very few PrEP demonstration projects conducted in a geographic area with a severe HIV epidemic. Moreover, most of the demonstration projects have focused strictly on PrEP outcomes such as acceptability, access, uptake, and adherence but not on how the process of PrEP implementation or how the characteristics of the context in which PrEP is implemented (e.g., type of setting, resources, capacity, personnel, etc.) influence those outcomes. Thus, questions remain about the extent to which equitable access to PrEP (which begins with screening and determination of need) can be achieved specifically for MSM and transgender persons of color via a demonstration project. Questions also remain about the impact that variation within a single demonstration project (e.g., contextual variation and variation in the implementation process) has on PrEP access for this population.

Translational Nature of the Study

Translational research occurs on a continuum and the number of distinct phases can range from two to five (Khoury et al., 2007; Schully et al., 2010). Drolet and Lorenzi (2011) identify four phases of translational research progress: the translation of basic science discovery to proposed human application (T1); the translational of proposed human application to proven clinical application (T2); the translation of proven clinical application

to clinical practice (T3); and the translation of clinical practice to public health impact (T4). The demonstration project described in the current study falls in the T3 region of the continuum by implementing PrEP, the efficacy and safety of which has been established in prior clinical trials, in real-world settings. However, findings from the current study have implications for practice improvement that may benefit the larger target population (i.e., the T4 region of the continuum). It is anticipated that the study will culminate in recommendations related to PrEP screening, determination of PrEP need, and infrastructural elements at the clinic level necessary for successful PrEP implementation. These recommendations have the potential to be translated into future protocols and best practice guidelines related to PrEP screening and determination of PrEP need with local benefit.

Purpose Statement and Research Questions

The Improve Measurable Participation and Access to Care and Treatment District of Columbia, Maryland, and Virginia (IMPACT DMV) demonstration project uses the whole-person health system model to address the holistic health and wellness needs of MSM and transgender persons of color and ensure equitable access to culturally competent services related to HIV prevention, HIV care and treatment, behavioral health, employment, and peer support (DC Appleseed, 2017; DC Health HAHSTA, 2016). To facilitate this goal, the regional initiative spanning DC, southern Maryland, and northern Virginia has established the IMPACT DMV Coalition comprised of health department staff from the three jurisdictions, community members, service providers, and private entities that use principles from both high-impact prevention and the HIV care continuum to identify three priority program areas and 24 core services to be offered by the project (DC Health HAHSTA, 2017). To date, 10 organizations have been funded under the project. The purpose of this study is to

describe PrEP screening and PrEP need in the overall project, understand how the project was implemented at the clinic level with respect to PrEP screening and determination of PrEP need, and describe how the varying contexts and implementation strategies of the clinics impacted PrEP screening and PrEP need in the overall project. The proposed research seeks an in-depth understanding of whether and how the IMPACT DMV demonstration project is increasing PrEP access among MSM and transgender persons of color. The research questions (RQs)are as follows:

Research Question 1: What is the current state of PrEP screening and PrEP need in the project?

a. What processes are in place to facilitate PrEP screening and determination of PrEP need?
b. What factors are associated with PrEP screening and determination of PrEP need?

Research Question 2: How is the project being implemented at the clinic level with respect to PrEP screening and determination of PrEP need?

a. What factors at the structural, institutional, and individual level might be influencing PrEP screening and determination of PrEP need?

Research Question 3: What are the sources of variation and degrees of adaptation within the project?

a. What are the different sources of variation among the clinics and between the clinics and the overall project?
b. To what degree did clinics adapt the project's recommended processes related to PrEP screening and determination of PrEP need?

Statement of Potential Impact

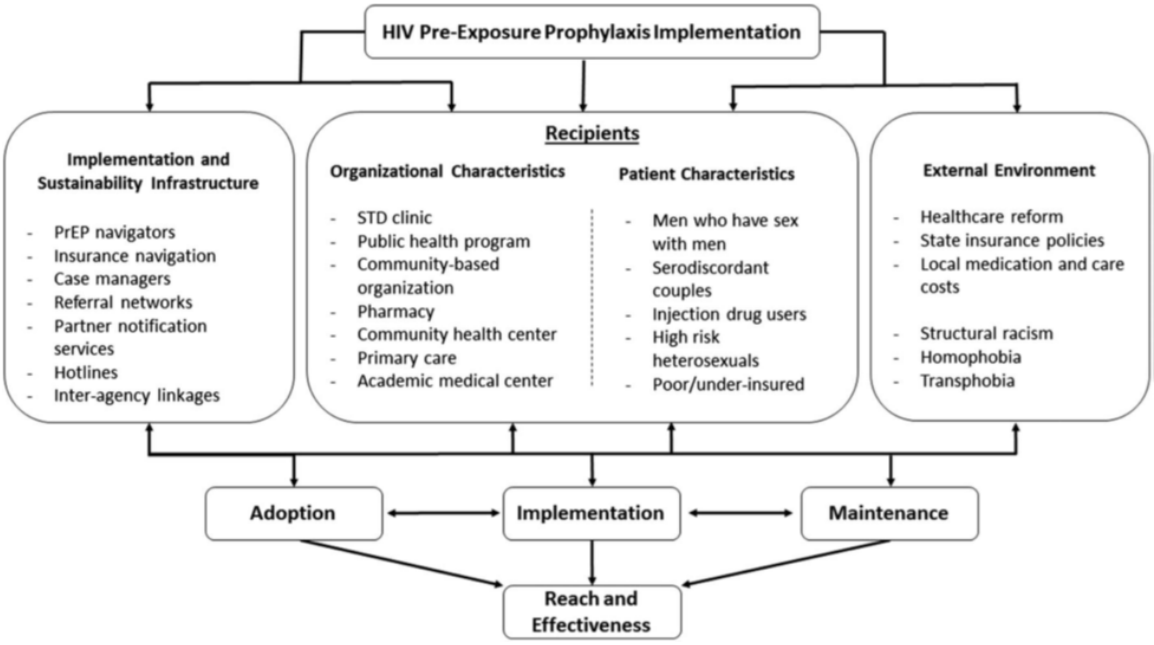
Findings from the study have the potential to inform enhancements to this specific and other similar demonstration projects while also adding to the larger body of knowledge regarding PrEP implementation in real-world settings among key populations. More specifically, findings from the study will highlight implementation processes as well as contextual characteristics (e.g., clinic types and aspects of the clinics' implementation and sustainability infrastructure) that hinder or facilitate PrEP access among MSM and transgender persons of color. Findings from the study may inform future protocols and best practice guidelines related to PrEP screening and determination of PrEP need that will benefit the District of Columbia, Maryland, Virginia area. These future protocols and best practice guidelines may be particularly useful as the current guidelines may exclude some MSM who would benefit from PrEP and do not consider transgender persons at all.

Conceptual Framework

Implementation science is the study of methods to integrate evidence-based strategies and interventions into routine practice (Bauer et al., 2015; Brownson et al., 2012; Eccles et al., 2009; Nilsen, 2015; Schackman, 2010; Thomas et al., 2016). Implementation science can improve our understanding of real-world approaches to increasing PrEP access and subsequent use among MSM and transgender persons of color who are at substantial risk for HIV infection by investigating how the process of implementation, implementation fidelity and adaptation, contextual characteristics, and characteristics of PrEP itself serve as barriers and facilitators to PrEP implementation. Thus, it is appropriate to use an implementation science model to guide this study of the IMPACT DMV demonstration project. The

Practical, Robust Implementation and Sustainability Model (PRISM) is a comprehensive model for translating research into practice and evaluates how the health care program or intervention interacts with the recipients to influence program adoption, implementation, maintenance, reach, and effectiveness, which are outcome measures from the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework (Feldstein & Glasgow, 2008). The PRISM model has recently been adapted to describe elements that specifically influence PrEP implementation (Figure 1). Mayer et al. (2018) recognize that PrEP implementation is influenced by organizational structures, implementation barriers and facilitators, the needs of key populations, and external factors.

Figure *1***.** *Ecosocial Model of Factors Involved in PrEP Implementation*

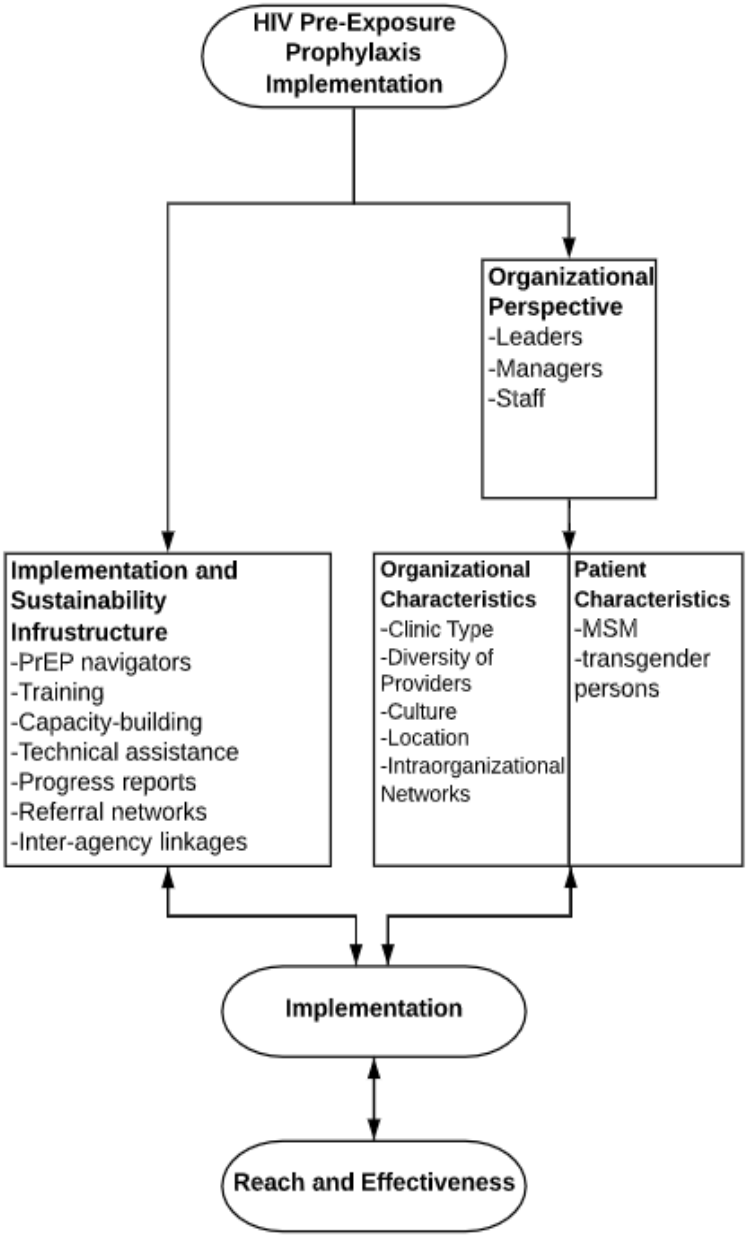


Note. From "Evolving Models and Ongoing Challenges for HIV Preexposure Prophylaxis Implementation in the United States" by K. H. Mayer, P. A. Chan, R. R. Patel, C. A. Flash, & D. S. Krakower, 2018, *Journal of Acquired Immune Deficiency Syndromes,*

77(2), p.17 (https://doi.org/10.1097/QAI.0000000000001579).

This model has been further adapted for the current study to emphasize aspects of the IMPACT DMV demonstration project that will be considered (Figure 2). Research questions were developed with attention to the perspectives of organizations, characteristics of the organizations and their implementation and sustainability infrastructure, as well as characteristics of the key population. Aspects of the external environment will not be explored given the study's focus on organizational characteristics. Pharmacies and academic medical center organizations will not be explored as these types of organizations were not funded by the project. The only patient populations to be considered are MSM and transgender persons of color given the focus of the demonstration project.

Figure *2.* *Adapted Ecosocial Model of Factors Involved in PrEP Implementation in the Context of the IMPACT DMV Project Assessment*



Summary of Methodology

The current study employed a mixed-methods case study design. A mixed-methods design was selected because both quantitative and qualitative methods have limitations and

neither approach alone may be sufficient to fully understand the phenomenon of interest (Creswell & Plano Clark, 2018). A case study approach was selected because the IMPACT DMV demonstration project meets the definition of an unusual or unique case (Yin, 2018) by (a) focusing on a population largely underrepresented in other demonstration projects; (b) using the whole-person health system model to provide prevention, care, and treatment services, inclusive of PrEP services, and (c) forming a regional public, private, and health department collaboration. Quantitative data was collected via archival records collected by the project on patients receiving PrEP services from clinics funded by the project. This included demographic, risk behavior, and PrEP service utilization data collected via REDCap. This data was used to answer research question 1 and sub-question 1b. Descriptive statistics (i.e., frequencies and percentages) were used to construct a PrEP continuum and determine the frequency and percentage of patients captured at each of the following benchmarks: screened for PrEP, in need of PrEP, referred to a PrEP provider, linked to a PrEP provider, prescribed PrEP, and continued on PrEP. Univariate analyses using chi-square for categorical variables, t-tests for continuous variables, and non-parametric tests for count variables were conducted to determine significant differences between patients screened for PrEP and not screened for PrEP as well as significant differences between those deemed in need of PrEP and those not deemed in need of PrEP. In crude logistic regression models, PrEP screening and PrEP need were regressed on each independent variable to examine bivariable, unadjusted associations. A multivariable logistic regression model was then fit to examine the factors associated with PrEP screening and PrEP need. The model was adjusted for covariates and potential confounders. Quantitative data will be analyzed using SAS 9.4.

Three forms of qualitative data were collected to answer the remaining research questions: (a) program documents to understand the project- and clinic-level goals, processes, policies, and procedures that facilitate PrEP screening and determination of PrEP need; (b) interview data from clinic staff to clarify goals and project implementation processes and to understand the contextual characteristics of their clinics and barriers and facilitators to implementation; and (c) focus group data from government officials to clarify goals of the project, implementation processes and to understand barriers and facilitators to implementation. A focus group was conducted with Health Impact Specialists to understand their role and processes in helping patients move through the PrEP continuum and to explore additional perceived barriers and facilitators to implementation. Interviews and focus groups were audio-recorded and transcribed. Document, interview, and focus group analysis included an iterative process of reading, coding, interpreting, and displaying data. All findings were related back to the study's research questions and conceptual framework. Several strategies were utilized to minimize threats to reliability and validity including triangulation, member checking, and use of rich thick descriptions. Findings from the study will be presented to interested stakeholders (i.e., DOH personnel and clinic staff).

Limitations and Delimitations

limitations.

There are several limitations inherent to case study research. First, the rigor of case studies has been questioned, as there are no research methods specific to this design. Unfortunately, it was not possible to pilot the interview and focus group questions due to an inability to identify individuals who were not affiliated with the project but who possessed sufficient knowledge of the project. However, multiple sources of data are collected for case

studies as a way to triangulate the findings. This study collected both qualitative and quantitative data to offset the limitations of each and to fully describe the IMPACT DMV demonstration project as the case. Accepted quantitative and qualitative data collection and analytic techniques were utilized. Additionally, the findings from the case study design used in this study may not be generalizable to other PrEP demonstration projects conducted in other settings or among other populations. However, the thick rich descriptions of the case allow the reader to determine if certain aspects of this case study research are transferable to other settings or populations. Another limitation of case study research relates to reliability. Generally, case studies cannot be (nor should they necessarily be) replicated. However, this study uses three specific techniques to overcome this limitation: development of a case study protocol (i.e., this proposal) which documents all study procedures in great detail, development of a case study database which is an organized collection of all study data, and maintenance of a chain of evidence which allows the reader to understand how the research questions led to the findings and how the findings were derived from the research questions.

While the Health Impact Specialists recruited for this study were from the focus populations of the demonstration project, they could only provide insight into the processes of PrEP screening and determination of PrEP need based on their interactions with PrEP-eligible patients. Thus, another limitation is the lack of input from PrEP-eligible patients themselves, which would provide different insights into the processes of PrEP screening and determination of PrEP need. Additionally, the quantitative data collection was limited to information collected by the project. In trying to assess factors associated with PrEP screening and determination of PrEP need, there was a significant amount of missing data for several sites which limited the analysis.

Due to the lead researcher's existing relationship with DC Health personnel, focus group participants at the local health department level may have felt compelled to participate in the study. Before and during the focus group, the lead researcher reiterated the voluntary and confidential nature of the research. The lead researcher leveraged her existing relationship with DC Health personnel to identify study participants at the clinic level which may have introduced bias into the study sample. Additionally, those who agreed to be interviewed may reflect a limited range of perspectives held within the various organizations. Furthermore, the results presented are based in part on evidence as it was provided to the lead researcher (i.e., documents shared) and, thus, many only selectively reflect the implementation process of the various clinics. However, it was important to limit study participants to those directly involved in the implementation and execution of this specific project at the clinic level and DC Health personnel were aware of the appropriate individuals with the specific knowledge to help answer the study's research questions. Similarly, only clinic members agreeing to be interviewed could identify and provide the necessary documentation needed to help answer the study's research questions. The total number of staff interviews completed was constrained by time, eligibility, and willingness to participate. Lastly, the lead researcher was unable to interview staff at Clinic 10, resulting in an incomplete description of project implementation at the clinic level and sources of variation and adaptation with the project.

delimitations.

This study was purposefully limited in scope to the description of early outcomes of the IMPACT DMV demonstration project related to PrEP screening and determination of PrEP need. Services provided by the demonstration project other than PrEP were not

considered and other demonstration projects were not considered. The focus of the study is on PrEP implementation in a real-world context for a specific population, and the study utilized an implementation science model to describe inputs, outputs, outcomes, and impact.

Definition of Key Terms

Black/African American: "'Black or African American' refers to a person having origins in any of the Black racial groups of Africa. It includes people who indicated their race(s) as 'Black, African Am., or Negro' or reported entries such as African American, Kenyan, Nigerian, or Haitian" (United States Census Bureau, 2011, p. 3; United States Office of Management and Budget, 1997).

Demonstration project: Demonstration projects—also known as effectiveness studies, pragmatic trials, or real-world trials—determine the impact of an intervention, practice, policy, or strategy with proven efficacy under real-world conditions (Brownson et al., 2012).

Evidence-based: Evidence-based interventions, policies, practices, or strategies have proven efficacy, or impact, and effectiveness, or impact under real-world conditions (Brownson et al., 2012).

Framework: Frameworks provide an outline of several constructs and the relationship between the constructs accounts for the phenomenon (Nilsen, 2015).

Hispanic/Latino: "'Hispanic or Latino' refers to a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin regardless of race" (United States Census Bureau, 2011, p. 2; United States Office of Management and Budget, 1997).

HIV/AIDS: Human Immunodeficiency Virus (HIV) is the causative agent of Acquired Immune Deficiency Syndrome (AIDS).

Implementation Science: Implementation science is the study of methods to integrate evidence-based strategies and interventions into routine practice (Bauer et al., 2015; Brownson et al., 2012; Eccles et al., 2009; Nilsen, 2015; Thomas et al., 2016).

Men who have sex with men: Men who have sex with men (MSM) is an etic term coined in 1994 used to describe a subpopulation of men at substantial risk for HIV infection (Glick et al., 1994). Etic terms are created by researchers to describe observable phenomena from a perspective that is outside a particular culture or group (Creswell, 2013). The term MSM is not meant to describe sexual orientation, but rather the behavioral method of HIV transmission through male-to-male sexual contact.

Model: Models describe a phenomenon, typically graphically, in a deliberately simplified fashion (Nilsen, 2015).

Pre-exposure prophylaxis: Pre-exposure prophylaxis (PrEP), an evidence-based HIV prevention strategy, involves the daily use of a pill containing antiretroviral drugs normally used to treat HIV by men who have sex with men, heterosexual men and women, and persons who inject drugs and are at high risk for HIV (CDC, 2018).

Reach: Reach is the extent to which those who participate in the program are representative of the target population, or the percentage of eligible participants who participated in an intervention (Berkel et al., 2011; Durlak & DuPre, 2008; Glasgow et al., 1999; Haynes et al., 2016).

Transgender person: Transgender is "an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with the sex they were assigned at birth" (Gay and Lesbian Alliance Against Defamation, 2007).

Translational research: Translational research occurs along a continuum and involves the application of knowledge from basic science discovery to public health impact (Drolet & Lorenzi, 2011).

Uptake: Uptake refers to the integration of evidence-based interventions, policies, practices, or strategies into routine clinical and public health practice (Brownson et al., 2012).

Summary

Chapter 1 has provided an overview of a proposed mixed-methods case study to explore PrEP screening and PrEP need in the IMPACT DMV demonstration project. The chapter provided background information, explained the purpose of the study and the research questions to be answered, described the approach that will be used, and addressed the study's strengths and weaknesses. Chapter 2 will provide an overview of the current literature and will introduce the conceptual framework that will guide this study. Chapter 3 will go into detail about the study's research design and methodology.

Chapter 2: Literature Review

The first section of Chapter 2 will provide relevant background information necessary for contextualizing this study's research questions and the case of interest. The section will discuss the national and local DC, Maryland, and Virginia HIV/AIDS epidemic; the multi-level HIV risks experienced by MSM and transgender persons of color; the shift in HIV prevention from behavioral to a combination approach (with a focus on oral PrEP); the studies establishing the efficacy and effectiveness of oral PrEP (with a focus on those targeting MSM and transgender persons); and disparities in PrEP knowledge, access, and use among MSM and transgender persons of color. The second section of this chapter will discuss the relevance of Implementation Science to PrEP implementation as well as the conceptual framework that will guide this study. This section will discuss the factors, mechanisms, and processes that may influence the successful implementation of PrEP. Specifically, PrEP implementation processes and characteristics of the different contexts in which PrEP can be implemented that may serve as barriers or facilitators will be outlined in this section.

Introduction: Topic, Purpose, and Methods of the Literature Review

Articles used for this review were compiled from the Himmelfarb Health Sciences Library database, Google Scholar, PubMed, and the CDC. The references of initial articles were also reviewed for additional articles. Keywords and phrases used to identify articles were *HIV, AIDS, HIV risk factors, MSM, men who have sex with men, transgender men,*

transgender women, PrEP, pre-exposure prophylaxis, PrEP clinical trials, PrEP demonstration projects, PrEP knowledge, PrEP awareness, PrEP acceptability, PrEP interest, PrEP barriers, PrEP facilitators, PrEP adoption, PrEP implementation, PrEP access, PrEP screening, PrEP need, PrEP prescription, PrEP uptake, PrEP adherence, PrEP maintenance, PrEP cascade, PrEP continuum, PrEP disparities, Implementation Science, process, and context. The selected articles were published between 1963 and 2020 in English.

Description and Critique of the Scholarly Literature

HIV Epidemic in the United States.

The CDC (2019) estimates that at the end of 2018 approximately 1.2 million people were living with HIV in the U.S., and approximately 38,000 people were diagnosed that year. HIV diagnoses in the United States are not evenly distributed across different ages, races/ethnicities, genders, modes of transmission, or geographic locations. Youth in the U.S. (ages 13-24) are especially impacted by HIV and accounted for 29% of new diagnoses in 2018 (CDC, 2019). Though Blacks comprise only 13% of the U.S. population, they accounted for 42% of new HIV diagnoses in 2018 (CDC, 2019). Similarly, Latinos accounted for approximately 25% of new diagnoses in 2018 despite comprising just 18% of the population (CDC, 2019). Men accounted for 82% of new diagnoses in 2018 (CDC, 2019) and 78% of persons living with HIV in 2018 (CDC, 2019). Between 2000-2014, 84% of transgender persons diagnosed with HIV were transgender women and 15% were transgender men (Clark et al., 2017). The risk of contracting and transmitting HIV varies significantly by sexual behavior, with the risk of HIV transmission during anal sex estimated to be 18 times greater than during vaginal sex (Baggaley et al., 2010). Lastly, the Southern

U.S accounted for 52% of new diagnoses in 2018 despite being home to just 38% of the population (CDC, 2019). To refocus national attention on the continued burden of HIV, The National HIV/AIDS Strategy was created in 2010, updated in 2015, and has three goals: reducing the number of people infected, increasing access to care and improving the health of people living with HIV, and reducing HIV-related disparities (Millett et al., 2010; Morin et al., 2011; United States Office of National AIDS Policy, 2010a, 2010b, 2015). Also, the U.S. Ending the HIV Epidemic (EHE) initiative aims to end the domestic HIV epidemic by 2030 and has four pillars: diagnose all people living with HIV (PLWH) as early as possible; treat PLWH quickly after diagnosis to achieve sustained viral suppression; prevent new HIV infections using proven methods; and rapidly detect and respond to growing HIV clusters to further prevent new infections (United States Department of Health and Human Services [DHHS], 2019).

The District of Columbia specifically has a severe HIV epidemic: as of 2019, 1.8% of the population was living with HIV, a rate that exceeds the World Health Organization (WHO) definition of 1% as a generalized epidemic (DC Health HAHSTA, 2020a). The HIV epidemic in the District also disproportionately affects certain groups based on age, race/ethnicity, gender, and mode of transmission. In 2019, 36% of new diagnoses occurred among individuals under the age of 30, 73% occurred among Blacks, 13% occurred among Latinos, 75% occurred among men, 3% occurred among transgender persons, and 55% occurred among MSM (DC Health HAHSTA, 2020b). In response to the epidemic, Mayor Muriel Bowser, in collaboration with the DC Health HAHSTA and DC Appleseed Center for Law and Justice, developed the 90/90/90/50 Plan to end the epidemic in DC by the year 2020 (DC Health HAHSTA, 2016). The plan outlines the following four goals: 90% of all

residents living with HIV will know their status, 90% of residents living with HIV will be retained in care and treatment, 90% of those in treatment will achieve viral suppression, as well as a 50% reduction in new HIV cases. The DC Health reports similar goals in its *DC Healthy People 2020* Report (DC Health, 2016, 2018).

In addition to all of the District of Columbia, The DC Metropolitan Area includes counties in Maryland, Virginia, and West Virginia (DC Health HAHSTA, 2016). Of the 994 HIV diagnoses reported in Maryland in 2016, 31% occurred in Prince George's county and 12% occurred in Montgomery County, which are two counties in suburban Maryland (MDHCHSEE, 2019a, 2019b, 2019c). In Prince George's county, 68% of new diagnoses in 2018 occurred among men, 85% occurred among Blacks and 8% occurred among Latinos, 41% occurred among those under the age of 30, and 50% occurred among MSM (MDH CHSEE, 2019c). Given the high burden of HIV in the county, the Prince George's County Health Department created an HIV Strategic Plan with the following goals: reduce new HIV diagnoses by 20% by 2020, increase health care access and health outcomes for people living with HIV, reduce HIV-related disparities and inequities, and achieve a more coordinated response to the local epidemic (Prince George's County Health Department, 2017). Additionally, the county has a local EHE plan that builds upon the goals outlined in the national plan and includes the strategies listed in the national plan (Prince George's County Health Department, 2019). In Montgomery County, 65% of new diagnoses in 2018 occurred among men, 61% occurred among Blacks and 18% occurred among Latinos, 30% occurred among those under the age of 30, and 49% occurred among MSM (MDH CHSEE, 2019b).

Northern Virginia includes the following counties: Alexandria (city) County, Arlington County, Fairfax (city) County, Fairfax County, Falls Church (city) county,

Loudoun County, Manassas (city) county, Manassas Park (city) county, and Prince William county (VDH, 2019). Of the 817 new HIV diagnoses that occurred in Virginia in 2017, 27% occurred in Northern Virginia (VDH, 2019). In 2019, males accounted for 75% of new diagnoses in Northern Virginia, Blacks accounted for 56%, Latinos accounted for 26%, those under the age of 30 accounted for 32%, and male-to-male sexual contact accounted for 45% (VDH, 2019). In 2015, a Regional Prevention Group developed the *Northern Virginia HIV Regional Prevention Plan* which identifies priority populations for HIV prevention, outlines deficiencies in HIV prevention efforts at that time, and provides key recommendations to improve HIV prevention (Northern Virginia HIV Consortium, 2015).

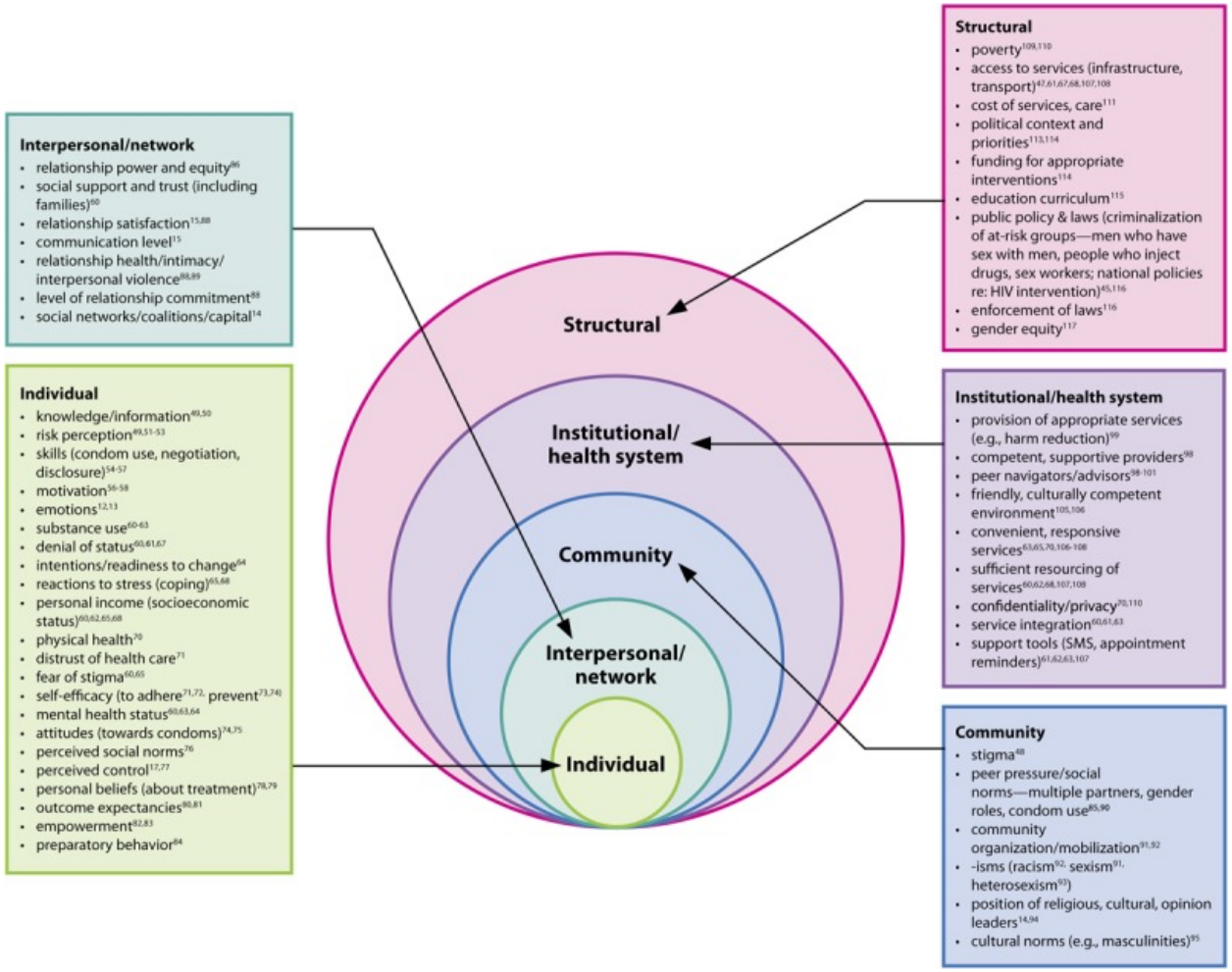
HIV Risk among MSM and Transgender Persons of Color.

As demonstrated above MSM of color in the United States are disproportionately impacted by HIV in an additive fashion: HIV has most significantly affected men, Blacks and Latinos, and those who engage in unprotected anal sex. Thus, Black MSM have a 1 in 2 chance of being diagnosed with HIV in their lifetime, and Latino MSM have a 1 in 4 chance of being diagnosed with HIV in their lifetime (CDC, 2017a). Gaps in knowledge exist regarding the impact of HIV on transgender persons; however, available evidence suggests that transgender persons are also severely impacted by HIV. From 2009-2014, 73% of transgender men diagnosed with HIV were Black or Latino and 80% of transgender women diagnosed with HIV were Black or Latino (Clark et al., 2017). It is important to note that individual behaviors alone do not sufficiently explain the disproportionate impact of HIV among MSM and transgender persons of color. Social determinants are the conditions in which people live, work, and socialize that can impact health outcomes (Berkman, 2009; DHHS, Office of Disease Prevention and Health

Promotion, 2018). One model that describes the relationship between individual risk factors and larger social contexts that impact health is the social ecological model (SEM). SEM evolved from ecological systems theory established by Urie Bronfenbrenner, which states that the entire ecological system in which growth occurs needs to be considered to fully understand human development (Bronfenbrenner, 1986). The system described in the theory contained five subsystems that interact in complex ways to affect and be affected by an individual's development (Bronfenbrenner, 1989, 1995).

In several iterations of SEM, individual behaviors are nested within multiple levels of influence, including social networks, institutions, communities, and policy (Dyson et al., 2018; McLeroy et al., 1988; Poundstone et al., 2004; Scribner et al., 2010). Figure 3 below describes the various influences on HIV-related behavior at each level of the SEM and helps frame the discussion of HIV risk at different levels for MSM and transgender persons of color.

Figure *3. Factors Influencing HIV-Related Behavior and/or Behavior Change at Each Level of the Socio-Ecological Model*



Note. From "Health Behavior Change Models for HIV Prevention and AIDS Care: Practical Recommendations for a Multi-Level Approach," by M. R. Kaufman, F. Cornish, R. S. Zimmerman, & B. T. Johnson, 2014, *Journal of Acquired Immune Deficiency Syndromes, 66*(Suppl 3), p.S251 (https://doi.org/10.1097/QAI.0000000000000236).

individual risks.

Individual risk factors include individual behaviors, perceptions, beliefs, and emotions (Kaufman et al., 2014). As mentioned, HIV is most easily spread via unprotected

anal intercourse. Furthermore, receptive anal sex is riskier than insertive anal sex: the partner receiving the penis, often referred to as a "bottom," is almost 13 times more likely to be infected with HIV than the partner inserting the penis, often referred to as a "top" (Patel et al., 2014). Unprotected anal sex also increases the risk for other sexually transmitted infections, such as syphilis, chlamydia, and gonorrhea, which in turn increase one's risk for HIV (Clottey & Dallabetta, 1993; Cohen, 1998; Flemming & Wasserheit, 1999; Wasserheit, 1992). Injection drug use and sexual activity under the influence of alcohol and drugs has been associated with increased HIV risk (Burcham et al., 1989; CDC, 2015; Gorman et al., 2004; Hess et al., 2015; Mansergh et al., 2006; Page-Shafer et al., 1997). Serosorting is a risk reduction strategy that entails restricting unprotected sex to partners presumed to be of the same HIV status (Eaton et al., 2009; Parsons et al., 2005; Saurez & Miller, 2001), and strategic positioning is a risk reduction strategy that entails assuming the insertive or receptive role during anal sex depending on one's own HIV status (Parsons et al., 2005; Van de Ven et al., 2002). Both of these strategies can impact one's risk for HIV. HIV risk perception, one's perceived risk of contracting HIV, can influence both attitudes toward HIV and engagement in HIV prevention (Gerrard et al., 1996).

The term MSM is not meant to describe sexual orientation but rather the behavioral method of HIV transmission through male-to-male sexual contact. Thus, men categorized as MSM may or may not outwardly identify as gay or bisexual. For Black MSM, the finding that individual behaviors alone do not sufficiently explain the disproportionate burden of HIV among this group may have been documented as early as 1987 in a study that found higher HIV incidence and prevalence rates for Black MSM compared to White MSM despite comparable self-reported risk behaviors (Samuel & Winkelstein, 1987). Several additional

studies have found that compared to White MSM, Black MSM have fewer sex partners and less reported drug use and equivalent levels of lifetime HIV testing and strategic positioning (Maulsby et al., 2014; Millett, et al., 2006; Millett et al., 2007; Millett et al., 2012; Rosenberg et al., 2011; Sullivan et al., 2014). However, studies have also found that compared to White MSM, Black MSM are more likely to contract sexually transmitted diseases that facilitate HIV acquisition (CDC, 2010; Millett et al., 2006; Millett et al., 2007; Su et al., 2011; Sullivan et al., 2014) and are less likely to serosort (Eaton et al., 2010; Marks et al., 2010; Maulsby et al., 2014; Millett et al., 2012). Furthermore, Black MSM living with HIV are less likely to be on antiretroviral therapy and virally suppressed compared to White MSM (Maulsby et al., 2014; Millett et al., 2006; Millett et al., 2007; Millett et al., 2012; Oster et al., 2011b) and are less likely to be aware of their HIV infection (MacKellar et al., 2005; MacKellar et al., 2007; Sifakis et al., 2005).

Compared to other MSM, Latino MSM have the highest rate of unprotected anal intercourse (Remien et al., 2002) and high rates of drug and alcohol use that may contribute to unprotected anal intercourse (Dolezal et al., 2000; Fernandez, 2005; Ramirez-Valles et al., 2008). Low HIV knowledge and low HIV risk perception may also contribute to elevated HIV risk among Latino MSM (Albarracin et al., 2008; Rhodes et al., 2007; Rhodes et al., 2008). Similar to Black MSM, Latino MSM are also less likely to be aware of their HIV infection (MacKellar et al., 2005; MacKellar et al., 2007; Sifakis et al., 2005).

Transgender is “an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with the sex they were assigned at birth” (Gay and Lesbian Alliance Against Defamation, 2007). Transgender women were born male and identify as female. Transgender women are often classified as a sub-population of MSM

due to shared HIV risk factors such as receptive anal intercourse. However, doing so can conceal the unique risks and prevention needs of transgender women and prevent a true understanding of HIV incidence and prevalence in this population (Fiereck, 2015; Grant et al., 2016; Sevelius et al., 2016). Transgender men were born female and identify as male. Transgender men are sometimes assumed to have female partners, and thus, be at low risk for HIV; however, gender identity is separate from sexual orientation with some transgender men identifying as gay and having male partners (Rowniak & Chesla, 2013; Rowniak et al., 2011; Sevelius, 2009). Some transgender people do not identify as either male or female (Lev, 2006).

Many transgender women engage in receptive anal sex, an efficient means of acquiring HIV, with non-transgender men (Baral et al., 2013). Furthermore, some transgender women engage in transactional sex or sex work and may be financially incentivized to engage in unprotected sex. The literature indicates that compared to other transgender women, black and Latina transgender women are more likely to engage in sex work, unprotected sex, and non-hormonal injection drug use (Garofalo et al., 2006; Hwahng & Nuttbrock, 2007; Nemoto et al., 2004).

interpersonal risks.

Interpersonal risk factors include sexual networks, relationship dynamics, and social support (Kaufman et al., 2014). There is evidence to suggest that the sexual networks of Black MSM may help explain their increased HIV risk (Maulsby et al., 2014; Millett et al., 2006). Both high HIV prevalence (Bakeman et al., 1986; Samuel & Winkelstein, 1987) and high rates of unprotected anal intercourse among Black MSM (Peterson et al., 1992) were reported early in the HIV epidemic. While the risk behaviors of Black MSM are comparable

to those of White MSM now, greater rates of unprotected anal intercourse early in the epidemic may have increased the background HIV prevalence among black MSM who are more likely to have black male partners (Bingham et al., 2003; CDC, 2004; Millett et al., 2006). Thus, every act of unprotected sex with a new partner increases the risk of HIV among Black MSM. Furthermore, Black MSM living with HIV are less likely to be on antiretroviral therapy and virally suppressed compared to White MSM (Maulsby et al., 2014; Millett et al., 2012; Millett et al., 2006; Millett et al., 2007; Oster et al., 2011b) and high viral load is associated with HIV transmission to sexual partners (Quinn et al., 2000). Disassortative mixing by age may also explain the elevated HIV risk among Black MSM: young Black MSM with older partners may be at increased risk for HIV infection, as older Black MSM have a high HIV prevalence (Joseph et al., 2011; Maulsby et al., 2014; Oster et al., 2011a).

Similar to Black MSM, the selection of older partners (Joseph et al., 2011) and partners with higher HIV prevalence may increase HIV risk among Latino MSM (Millet et al., 2011). Intimate partner violence is high among Latino MSM and may be associated with high-risk behaviors (Feldman et al., 2007).

Transgender women face high rates of interpersonal violence and lack parental support which contributes to HIV risk (Brennan et al., 2012; Wilson et al., 2012). Transgender men, many of whom have non-transgender men as partners, may be unsure of how to negotiate safe sex and may face increased pressure to engage in risky sex to avoid rejection and receive gender validation (Rowniak et al., 2017).

community risks.

Community risk factors include stigma, social and cultural norms, racism, and heterosexism (Kaufman et al., 2014). "Stigma is a social construction where social devaluation occurs through a process of labeling, stereotyping, separation, status loss, and discrimination" (Eaton et al., 2017, p. 1237; Goffman, 1963). Heterosexism is "the negative regard, inferior status, and relative powerlessness that society collectively accords to any non-heterosexual behavior, identity, relationship, or community" (Herek, 2007, pp. 906–907). Medical mistrust, the distrust of medical institutions including staff and providers who represent the dominant culture, can also influence attitudes toward HIV and engagement in HIV prevention (Ball et al., 2013; Hoyt et al., 2012). Research indicates that Black MSM experience overlapping stigmas due to race, sexual orientation, and gender identity (Maulsby et al., 2014) and that Black MSM experience internalized heterosexism (Glick & Golden, 2010). Furthermore, there is theoretical support for the notion that increased experiences of stigma and discrimination are associated with increased HIV risk among Black MSM (Jones et al., 2010; Wilton, 2009). Medical mistrust is high among Black MSM and may negatively impact engagement in HIV prevention (Hutchinson et al., 2007; Malebranche et al., 2004; Siegel & Raveis, 1997).

Machismo is one socio-cultural value held by some Latino men, including MSM, that masculinity, power, and dominance are achieved through engagement in high-risk behaviors such as unprotected sex and concurrent partnerships (Jarama et al., 2005; Rhodes et al., 2010). Latino MSM may also engage in such high-risk behaviors to overcome discrimination or internalized homophobia (Sandfort et al., 2007). Acculturation is "the acquisition of the cultural elements of the dominant society—language, food choice, dress, music, sports, etc."

(Lara et al., 2005, p. 368). Studies indicate that Latino MSM may begin to engage in high-risk behaviors as a way of becoming socialized to sexual experiences in the United States once they arrive (Bianchi et al., 2007). Familismo, another cultural value held by Latinos, is the strong sense of loyalty to one's family and can create conflict for Latino MSM with family members strongly opposed to homosexuality. Latino MSM may also face rejection from family members which can lead to low self-esteem and engagement in high-risk behaviors (Guarnero, 2007; Ryan et al., 2009).

Transgender women experience transphobia, verbal and physical abuse, social marginalization, all of which contribute to sexual HIV risk (Brennan et al., 2012; Nuttbrock et al., 2013).

institutional risks.

Institutional risk factors include culturally competent staff, convenient and responsive services, and support tools (Kaufman et al., 2014). While on the decline, medical providers still express homophobic attitudes toward MSM (Smith & Mathews, 2007; Téllez et al., 1999) and many healthcare providers also fail to routinely discuss sexual health with patients (Grodensky et al., 2008; Petroll & Mosack, 2011; Tao et al., 2000). Compared to other MSM, Black MSM are less likely to disclose their sexual behavior to a medical provider (Bernstein et al., 2008; Magnus et al., 2010; Petroll & Mosack, 2011) due to fear of discrimination and mistrust (Hutchinson et al., 2007; Malebranche et al., 2004; Nanin et al., 2009). This has implications for HIV prevention because MSM who do disclose their sexual behavior to a medical provider are more likely to discuss HIV, including their own HIV status and risk behaviors, and receive HIV testing (Bernstein et al., 2008; Dorell, et al., 2011; Petroll & Mosack, 2011).

Transgender persons also face discrimination by medical personnel due to a lack of training in the health needs of transgender people (Bauer et al., 2009; Kosenko et al., 2013). The mistreatment that transgender persons experience in the clinical setting hamper HIV prevention efforts, as transgender persons may not feel comfortable discussing their HIV risk behaviors with medical providers (Bauer et al., 2009).

structural risks.

Structural risk factors include education, poverty, access to services, and incarceration (Kaufman et al., 2014). Research suggests that there is lower availability of HIV prevention services in the local neighborhoods of Black MSM (Mashburn et al., 2004; Pierce et al., 2007), contributing to low awareness and utilization of said services. The incarceration rate among Black MSM is disproportionately higher than the incarceration rate among non-Black MSM (Brewer et al., 2014; Jones et al., 2010; Magnus et al., 2010; Millett et al., 2012). While the HIV prevalence rate in prisons is much higher than in the general population (Maruschak & Bronson, 2017; Woodring et al., 2015), that is likely the result of an infection that occurred prior to incarceration (Harawa & Adimora, 2008). Also, support is lacking for an association between incarceration and elevated HIV risk for Black MSM (Brewer et al., 2014; Jones et al., 2010; Magnus et al., 2010). However, HIV testing is not routinely implemented across prisons in the United States (Maruschak & Bronson, 2017), and prisoners do not have regular access to condoms (Harawa et al., 2008).

For Latino MSM, access to healthcare and HIV prevention is greatly impeded by factors such as poverty, homelessness, joblessness, lack of education, English illiteracy, incarceration, lack of insurance coverage, and a lack of familiarity with the US health care system (Mutchler et al., 2011; Pew Hispanic Center, 2010; Warren et al., 2008). Latino MSM

may also avoid seeking HIV prevention services due to fears related to potential detention or deportation (Gilbert et al., 2014; Rhodes et al., 2015).

Because of the stigma experienced in multiple environments, some transgender women are denied access to traditional educational and employment avenues and are forced to turn to sex work or dealing drugs to support themselves (Grant et al., 2011; Poteat et al., 2015) with Black and Latina transgender women comprising the majority of sex workers in the United States (Hwahng & Nuttbrock, 2007).

PrEP Efficacy and Effectiveness.

In recent years, HIV prevention efforts have shifted from solely behavioral to a combination approach with an emphasis on biomedical strategies (Kippax & Stephenson, 2012). One such biomedical approach is PrEP for HIV, an evidence-based HIV prevention strategy that is more than 90% effective in reducing HIV infection from sexual transmission (CDC, 2018). PrEP use entails taking a single pill once daily for as long as one perceives themselves to be at increased risk of HIV infection, and it is recommended that PrEP be used in combination with other prevention strategies (e.g., condoms) as PrEP does not protect against other STIs (CDC, 2018).

clinical trials.

In July 2012, the U.S. Food and Drug Administration (FDA) approved Truvada (emtricitabine/tenofovir disoproxil fumarate [TDF-FTC]) for PrEP use among adult men and women (FDA, 2012). Additionally, the International AIDS Society endorsed the use of Truvada for PrEP in their 2018 recommendations (Sagg et al., 2018), and the U.S. Preventive Services Task Force issued an A recommendation on the use of PrEP for the prevention of HIV (U.S. Preventive Services Task Force, 2019). The FDA approval was informed by the

findings of three clinical trials establishing the efficacy of PrEP. The first, called the Preexposure Prophylaxis Initiative (iPrEX) trial randomly assigned 2,499 HIV-negative adult men and transgender women who have sex with men in Peru, Brazil, Ecuador, the United States, Thailand, and South Africa to daily TDF-FTC or placebo (Grant et al., 2010). The study found that daily use of TDF-FTC reduced HIV risk by 44% compared to the placebo; furthermore, there was a 92% reduction in HIV risk for those with a detectable level of the drug in their blood compared to those without a detectable level of the drug in their blood (Grant et al., 2010). The TDF2 study randomized 1,219 HIV-negative heterosexual men and women between 18-39 years old in Botswana to either daily TDF–FTC or placebo (Thigpen et al., 2012). The study found that daily use of TDF-FTC reduced HIV risk by 62% compared to the placebo (Thigpen et al., 2012). The Partners PrEP study randomized 4,747 heterosexual serodiscordant couples in Kenya and Uganda to daily tenofovir (TDF), TDF-FTC, or placebo (Baeten et al., 2012). The study found that daily use of TDF reduced HIV risk by 67% and TDF-FTC reduced HIV risk by 75% compared to the placebo; furthermore, there was an 86% reduction in HIV risk for those with a detectable level of TDF in their blood and a 90% reduction in HIV risk for those with a detectable level of TDF-FTC in their blood compared to those without a detectable level of either drug in their blood (Baeten et al., 2012). The Bangkok Tenofovir Study randomized 2,413 HIV-negative men and women in Bangkok, Thailand between 20-60 years old who reported injection drug use in the prior year to either daily oral TDF or placebo (Choopanya et al., 2013). The study found that daily use of TDF reduced HIV risk by 49% compared to the placebo; furthermore, there was a 73% reduction in HIV risk for those with a detectable level of the drug in their blood compared to those without a detectable level of the drug in their blood (Choopanya et al., 2013).

Two studies did not find PrEP to be more efficacious than placebo in the prevention of HIV infections. The first study, the Preexposure Prophylaxis Trial for HIV Prevention among African Women (FEM-PrEP), randomized 2,120 HIV-negative women between 18-35 years old in Kenya, South Africa, and Tanzania to daily oral TDF-FTC or placebo (Van Damme et al., 2012). The number of HIV infections in the TDF-FTC and placebo groups was almost equivalent and due to this lack of efficacy, the study was stopped early (Van Damme et al., 2012). Furthermore, the study found the adherence based on drug-level testing to be much lower than adherence based on pill count and participant self-report (Van Damme et al., 2012). Subsequent analyses have confirmed that actual adherence to TDF-FTC was much lower than reported (Corneli et al., 2014; Corneli et al., 2015). The second study, the Vaginal and Oral Interventions to Control the Epidemic (VOICE) trial, randomized 5,029 HIV-negative women in South Africa, Uganda, and Zimbabwe between 18-45 years old to one of five conditions: oral TDF versus TDF-FTC placebo, oral TDF-FTC versus TDF placebo, oral TDF placebo versus oral TDF-FTC placebo, or vaginal1% tenofovir (TFV) gel versus or vaginal placebo gel (Marrazzo et al., 2015). The number of HIV infections across all experimental conditions was almost equivalent, and due to this lack of efficacy, the study was stopped early (Marrazzo et al., 2015). Similar to the FEM-PrEP study, adherence in the VOICE trial based on pill-count and participant self-report was high, yet adherence based on drug-level testing was very low (Marrazzo et al., 2015). These studies underscore the importance of adherence in maximizing the efficacy of PrEP.

In October 2019, the U.S. FDA approved Descovy (emtricitabine and tenofovir alafenamide) for PrEP use among adults and adolescents (FDA, 2019). This approval was informed by the findings from one clinical trial, the DISCOVER trial (AIDS Vaccine

Advocacy Coalition, 2020; Hare et al., 2019). The trial randomly assigned 5,387 HIV-negative adult cisgender men and transgender women who have sex with men in the United States, Canada, and Western Europe to daily Truvada or Descovy. The study found that Descovy reduced the risk of HIV acquisition to a similar degree as Truvada (Hare et al., 2019).

clinical practice guidelines.

In light of the scientific evidence demonstrating the safety and efficacy of PrEP and the FDA's approval of Truvada for PrEP, the CDC developed interim guidance for PrEP use among MSM (CDC, 2011) and full clinical practice guidelines to assist clinicians in identifying MSM, heterosexual men and women, and injection drug users at increased risk of HIV infection (USPHS, 2014). The guidelines summarize the clinical trial evidence for these three groups; provide guiding questions for assessing risk and criteria that indicate PrEP need in these three groups; and provide clinical information of PrEP prescription, monitoring, discontinuation, and adherence. Figures 4 and 5 depict the risk behavior assessment and recommended PrEP indications for MSM, respectively.

Figure *4.* *Risk Behavior Assessment for MSM*

BOX A1: RISK BEHAVIOR ASSESSMENT FOR MSM[36]

In the past 6 months:

- Have you had sex with men, women, or both?
- *(if men or both sexes)* How many men have you had sex with?
- How many times did you have receptive anal sex (you were the bottom) with a man who was not wearing a condom?
- How many of your male sex partners were HIV-positive?
- *(if any positive)* With these HIV-positive male partners, how many times did you have insertive anal sex (you were the top) without you wearing a condom?
- Have you used methamphetamines (such as crystal or speed)?

Note. From *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Practice Guideline,* by United States Public Health Service, 2014 (http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf).

Figure *5.* *Recommended PrEP Indications for MSM*

BOX B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM[2]

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

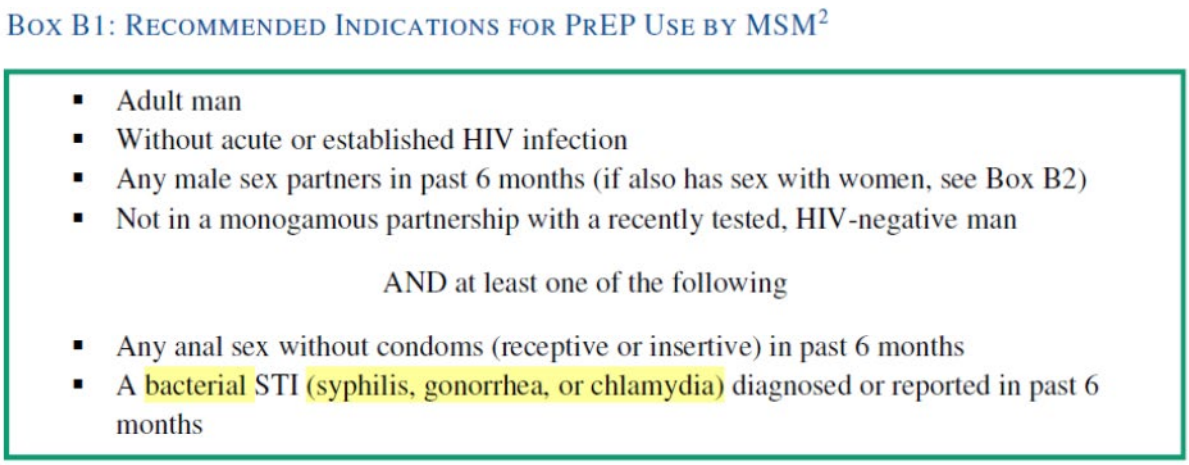
- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

Note. From *Preexposure Prophylaxis for the Prevention of HIV Infection in the*

United States—2014: A Clinical Practice Guideline, by United States Public Health Service, 2014 (http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf).

In 2017, the clinical practice guidelines were updated to include additional scientific evidence on the safety and efficacy of PrEP, as well as additional information on STD, hepatitis, and HIV testing for patients being prescribed PrEP. The recommended PrEP indications for MSM changed slightly to (a) specifically stipulate a diagnosed or reported *bacterial* STI, which increase HIV risk, and (b) no longer include the last criterion regarding having a male partner living with HIV, as the HIV-negative partner may not have access to their partner's relevant medical record data related to HIV medication adherence and viral load (USPHS, 2018). Figure 6 illustrates the updated indications for MSM. Because the effectiveness of PrEP has not been definitively established for transgender women and trials have not yet been conducted among transgender men, the guidelines do not provide a risk assessment or recommended PrEP indications for transgender persons; however, the guidelines do encourage providers to consider PrEP for all persons at risk for HIV infection (USPHS, 2018).

Figure *6.* *Updated Recommended PrEP Indications for MSM*



BOX B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM[2]

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

Note. From *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline,* by United States Public Health Service, 2018, (https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf).

Gilead Sciences, the biopharmaceutical company that manufactures Truvada for PrEP, also lists indications for PrEP on package insert which include having a partner(s) known to be living with HIV ***or*** engaging in sexual activity within a high prevalence area or social network ***and*** inconsistent or condomless sex, STI diagnosis, transactional sex, drug or alcohol use, incarceration, and/or partner(s) of unknown HIV-1 status (Gilead Sciences, 2013).

demonstration projects.

Several PrEP demonstration projects—which determine the impact of an intervention, practice, policy, or strategy with proven efficacy under "real-world" conditions (Brownson et

al., 2012)—have assessed the acceptability, safety, uptake, and adherence of PrEP as well as the correlates of each of those outcomes among MSM and transgender persons in the United States. The iPrEX Open-Label Extension study enrolled MSM and transgender women who were previously enrolled in three randomized PrEP trials, including the iPrEX study, and assessed PrEP uptake, PrEP adherence, sexual practices, and HIV incidence (Grant et al., 2014). Participants either received TDF-FTC free of charge for 18 months or were followed without taking TDF-FTC. Of the 1,603 participants enrolled 76% received PrEP, 8% of whom were Black and 72% of whom were Latino. The study found that PrEP uptake was high when offered free of charge by experienced providers; older, more educated participants with high-risk behaviors were more likely to be adherent; participants with high-risk behaviors were more likely to join the study, choose to take PrEP, and adhere to PrEP; and no infections occurred when drug concentrations indicated use of 4 or more pills per week (Grant et al., 2014). The US PrEP Demonstration Project assessed the feasibility, acceptability, and safety of offering TDF-FTC for 48 weeks to MSM and transgender persons seeking sexual health services at STD clinics in San Francisco and Miami and a community health center in Washington, DC (Cohen et al., 2015). A majority (60%) of the eligible 921 participants enrolled, with 34% being Latino and 7% being Black; furthermore, predictors of enrollment included being from Miami or DC, being self-referred, having prior knowledge of PrEP, and having more than 1 episode of anal sex with a partner living with HIV (Cohen et al., 2015). SPARK Project NYC developed and tested the efficacy of two brief interventions for MSM and transgender women, one that integrates PrEP into sexual health and one that promotes PrEP adherence, against two control interventions at the largest LGBT health center in New York City (Golub et al., 2017b). Adherence to PrEP was high at three months

(92%) and six months (86%) among the mostly White (49%) participants; additionally, participants who received one or both of the interventions had better adherence measured by dried blood spot and self-report at three months (Golub et al., 2017b).

HPTN 073 was an open-label PrEP demonstration project that assessed the initiation, acceptability, safety, and feasibility of PrEP by offering TDF-FTC and client-centered care coordination to Black MSM in Los Angeles, California; Washington, District of Columbia; and Chapel Hill, North Carolina and following them for 12 months (Wheeler & Fields, 2013; Wheeler et al., 2016; Wheeler et al., 2018; Wheeler et al., 2019). A total of 226 participants were enrolled, 79% of whom initiated PrEP and 92% of whom were retained at 12 months (Wheeler et al., 2016; Wheeler et al., 2018; Wheeler et al., 2019). HPTN 073 was uniquely led by Black MSM researchers and incorporated community engagement into all aspects of the study (Wheeler et al., 2018). Project PrEPare (ATN 113) was a demonstration project and phase II safety study that assessed patterns of PrEP use, rates of PrEP adherence, and patterns of sexual risk behavior by providing PrEP, an evidence-based behavioral HIV prevention intervention, and adherence support to young MSM aged 15 to 17 in six cities: Boston, Chicago, Los Angeles, Memphis, New Orleans, and Philadelphia (Hosek et al., 2016a; Hosek et al., 2016b). Of the 78 participants enrolled, 29% of whom were Black and 20% of whom were Latino, most had detectable drug levels in the beginning; however, adherence decreased with visit frequency and HIV incidence was high despite decreasing STIs (Hosek et al., 2016b). Project PrEPare 2 (ATN 110) was a parallel open-label PrEP demonstration project that assessed adherence to PrEP and sexual behavior by providing PrEP and evidence-based behavioral HIV prevention interventions for 48 weeks to young MSM between the ages of 18-22 in 12 urban cities: Baltimore, Boston, Chicago, Denver, Detroit, Houston, Los

Angeles, Memphis, Miami, New Orleans, Philadelphia, and Tampa (Hosek et al., 2017). Of the 200 participants enrolled, 54% of whom were Black and 26 % of whom were Latino, 60% found taking a daily pill to be acceptable and 90% had detectable drug levels in the first 12 weeks. However, adherence decreased with visit frequency and participants had high rates of HIV risk behaviors and STIs at baseline and throughout the study period (Hosek et al., 2017).

The PATH-PrEP study was an open-label demonstration that provided PrEP (TDF-FTC) or PEP to MSM and transgender women in Los Angeles, California based on self-reported risk behaviors (Landovitz et al., 2017). Of the 300 participants enrolled, 11% of whom identified as Black and 28% of whom identified as Latino, 92% were provided PrEP (Landovitz et al., 2017). The majority of participants had drug levels indicative of a protective level of adherence, though high-level adherence declined from 83% at week 4 to 65% at week 48 (Landovitz et al., 2017). Younger and African American participants had lower odds of having drug levels indicative of protection against HIV acquisition (Landovitz et al., 2017). The TAPIR study, a demonstration project, provided cisgender men and transgender women in California with tenofovir diphosphate and randomized participants 1:1 to an intervention or standard of care to test the efficacy of personalized daily test messaging for improving PrEP adherence (Moore et al., 2018). Of the 398 participants enrolled, 28% of whom identified as non-Black Latino and 15% of whom identified as solely Black or multi-racial, 87% had detectable drug levels at 12 weeks. While the intervention did not significantly improve rates of minimally acceptable adherence, it did significantly improve near-perfect adherence. (Moore et al., 2018). The CRUSH demonstration project provided HIV/STI counseling and testing, STI treatment, PrEP (TFV-DP), and PEP to young MSM

ages 18-29 in Alameda County, California, and explored whether structural aspects of participants' lives impacted their PrEP adherence (Myers et al., 2019). Of the 257 participants enrolled, 16% of whom identified as Black and 33% identified as Latino, 93% initiated PrEP. The majority of participants had drug levels indicative of a protective level of adherence, though high-level adherence declined from 87% at week 4 to 77% at week 48 (Myers et al., 2019). African American race, exposure to violence, and having survival needs were associated with significantly lower levels of adherence (Myers et al., 2019).

PrEP Disparities among MSM and Transgender Persons of Color.

McNairy and El-Sadr (2014) were the first to suggest an HIV prevention continuum analogous to the HIV treatment continuum which monitors the progress of people living with HIV. For PrEP specifically, several continuums have been constructed among different populations consisting of several different benchmarks (Davey et al., 2016; Grant et al., 2014; Jenness et al., 2018; Kelley et al., 2015; Parsons et al., 2017). The most common benchmarks are knowledge of PrEP, interest in PrEP, access to PrEP, use of PrEP, and adherence to PrEP. More recent efforts have sought to combine the HIV treatment and prevention continuums in a status-neutral approach (Myers et al., 2018). When the continuum is depicted graphically, it usually cascades downward due to gaps that exist at each stage. Disparities between different groups also occur at each stage, and many of the same factors that contribute to elevated HIV risk for MSM and transgender people of color also contribute to low engagement in PrEP services (Kimball et al., 2020; Meanley et al., 2020; Philbin et al., 2016; Quinn et al., 2019; Sevelius et al., 2016; Wilson et al., 2020). Compared to other MSM, knowledge of PrEP is lowest among Black MSM (Cohen et al.,

2015; Eaton et al., 2015; Fallon et al., 2017; Galindo et al., 2012; Highleyman, 2016; Sanders et al., 2016; Watson et al., 2020), and there is also some indication that PrEP awareness is low among Latino MSM with limited English proficiency (Brooks et al., 2020; Dolezal et al., 2015). For both Black and Latino MSM, age, education, and employment are significantly associated with knowledge of PrEP such that younger Black and Latino MSM with lower educational attainment and lower levels of income are less likely to be knowledgeable about PrEP (Eaton et al., 2015; Garcia & Harris, 2017; Pulsipher et al., 2016). Many studies assessing PrEP knowledge among transgender persons have focused on transgender women recruited alongside MSM. Three studies focused exclusively on transgender women, most of whom were Black or Latino, found low PrEP knowledge (Kuhns et al., 2016; Sevelius et al., 2016; Wilson et al., 2015; Wilson et al., 2016). Other studies exclusive to transgender women have found high knowledge of PrEP (Holder et al., 2019; Rael et al., 2019). One study conducted among transgender men, most of whom were transgender men of color, found PrEP knowledge to be low (Rowniak et al., 2017).

Interest in PrEP has been measured in several different ways including the acceptability of PrEP, willingness to use PrEP, and intentions to use PrEP. Many studies have found that PrEP interest among Black and Latino MSM is as high or higher than that reported by White or other MSM (Brooks et al., 2020; Cohen et al., 2015; Dolezal et al., 2015; Hosek et al., 2017; Mansergh et al., 2012; Patrick et al., 2017; Rolle et al., 2017; Schnarrs et al., 2018). Again, PrEP acceptability studies among transgender women have often included MSM and have failed to report differences between the two groups. Studies focused exclusively on transgender women, most of whom were Black or Latino, found high levels of PrEP interest (Kuhns et al., 2016; Poteat et al., 2019; Restar et al., 2018; Sevelius et

al., 2016; Wilson et al., 2016; Wood et al., 2017). However, it has been recognized that there is an important difference between hypothetical willingness to use PrEP and having immediate intentions to use PrEP (Parsons et al., 2017; Rendina et al., 2017), and that the hypothetical interest does not always translate into real-world interest (Lelutiu-Weinberger & Golub, 2016). Many factors that may preclude real-world interest in PrEP among MSM and transgender persons of color have been identified including cost (Cahill et al., 2017; Wood et al., 2017), concerns about efficacy (Lelutiu-Weinberger & Golub, 2016; Philbin et al., 2016), concerns about side effects (Cahill et al., 2017; Garcia & Harris, 2017; Philbin et al., 2016; Rael et al., 2018; Rolle et al., 2017; Sevelius et al., 2016; Thomann et al., 2018; Wilson et al., 2016; Wood et al., 2017), pill burden (Rael et al., 2018; Sevelius et al., 2016; Wilson et al., 2016), PrEP stigma (Brooks et al., 2019; Cahill et al., 2017; Eaton et al., 2017; Garcia & Harris, 2017; Golub et al., 2017a; Lelutiu-Weinberger & Golub, 2016; Philbin et al., 2016; Rael et al., 2018; Sevelius et al., 2016; Wilson et al., 2016; Wood et al., 2017), medical mistrust (Cahill et al., 2017; D'Avanzo et al., 2019; Garcia & Harris, 2017; Jaiswal & Halkitis, 2019; Philbin et al., 2016; Thomann et al., 2018), and culturally insensitive care (Cahill et al., 2017; Lelutiu-Weinberger & Golub, 2016; Rowniak et al., 2017; Sevelius et al., 2016).

Access to PrEP is a multifaceted concept and includes having a provider who is knowledgeable about PrEP and who does not engage in discriminatory prescription practices, being screened for and deemed eligible for PrEP according to the CDC's or some other guidelines and, being able to afford PrEP and care associated with PrEP. Given that knowledge of PrEP and comfort discussing sexual practices with providers is low among MSM and transgender persons of color (Bernstein et al., 2008; Lelutiu-Weinberger & Golub,

2016; Sevelius et al., 2016), these patients are often reliant on their medical providers for information about PrEP. However, both knowledge of PrEP and comfort discussing sexual behavior can vary by provider type, with HIV providers being more knowledgeable about PrEP and more comfortable discussing sexual behavior compared to non-HIV providers (Blumenthal et al., 2015; Castel et al., 2014; Krakower et al., 2015; Petroll et al., 2017). While the CDC's clinical practice guidelines include an HIV risk assessment for MSM, other tools may be utilized to screen for PrEP including other risk assessments (Wilton et al., 2017), prediction models (Beymer et al., 2017; Hoenig et al., 2015; Marcus et al., 2019; Scott et al., 2020; Smith et al., 2012), and routine sexual histories (The National Association of Community Health Centers & The National LGBT Health Education Center, 2015; Workowski & Bolan, 2015). The CDC's clinical practice guidelines do not include an HIV risk assessment for transgender persons.

Similarly, in addition to the indications provided in the CDC guidelines, PrEP eligibility may be determined by the indications outline by Gilead (2013) as well as risk scores and cutoffs (Beymer et al., 2017; Hoenig et al., 2015; Jones et al., 2017; Marcus et al., 2019; Scott et al., 2020; Smith et al., 2012; Wilton et al., 2017). Furthermore, while the CDC clinical practice guidelines aid providers in determining PrEP eligibility, they may not account for the interpersonal, community, institutional, and structural HIV risk factors experienced by MSM and transgender persons of color. For example, Black MSM may be less likely to have indications for PrEP based on the CDC guidelines compared to other MSM (Hoots et al., 2016; Sullivan et al., 2015) and Black MSM may be less likely to have indications for PrEP when using the CDC guidelines compared to other guidance (Lancki et al., 2018). Because the CDC guidelines do not currently provide PrEP indications for

transgender persons, applying the guidelines for MSM in conjunction with the guidelines for heterosexual men and women or persons who inject drugs may increase the number of transgender persons with indications for PrEP but may also still miss some individuals (Golub et al., 2019; Kuhns et al., 2016; Reisner et al., 2019; Wilson et al., 2015; Wilson et al., 2016). There is also evidence to suggest bias in the prescription of PrEP based on race and sexual orientation (Calabrese et al., 2014; Calabrese et al., 2018).

Because later outcomes along the PrEP continuum (i.e., uptake and adherence) are dependent on initial outcomes along the continuum (i.e., knowledge, interest, and access), it should not be surprising that uptake of and adherence to PrEP among MSM and transgender persons of color lag behind that of other groups (Golub et al., 2019; Huang et al., 2018; Jenness et al., 2018; Reisner et al., 2019; Serota et al., 2020; Snowden et al., 2017; Sullivan et al., 2018).

Inferences for Forthcoming Study

Despite being an effective HIV prevention strategy, it is evident that knowledge of, access to, and use of PrEP remains low among MSM and transgender persons of color. It is also evident that few PrEP demonstration projects have focused on MSM and transgender persons of color, despite the high burden of HIV and the high potential for benefit among these populations. MSM and transgender persons of color in the DC, Maryland, Virginia area specifically have been especially impacted by HIV. Recognizing that individual behaviors alone do not explain the disproportionate impact of HIV among MSM and transgender persons of color, the IMPACT DMV demonstration project uses the whole-person health system model to address the holistic health and wellness needs of the population and provide culturally competent services related to HIV prevention, HIV care and treatment, behavioral

health, employment, and peer support (DC Appleseed, 2017; DC Health HAHSTA, 2016). The current study recognizes that the process of PrEP implementation and characteristics of the context in which PrEP is implemented (including the type of setting, the resources and capacity of the setting to implement PrEP, and the characteristics of the staff and leadership within the setting) are just as, if not more, important than individual-level characteristics of the target population to which PrEP is being marketed. While this study will focus exclusively on services related to PrEP screening and PrEP need provided by the project, a full description of the project is provided in Chapter 3.

Conceptual Framework for Forthcoming Study

implementation science perspective.

It is well documented that the process of translating research into practice is lengthy (Green et al., 2009; Kessler & Glasgow, 2011; Khoury et al., 2007). However, implementation science can help close the research to practice gap and many researchers have called for the adoption of an implementation science framework to improve the efficiency and effectiveness of HIV programs (Dombrowski et al., 2019; Eisinger et al., 2019; Lamdin et al., 2015; Tun et al., 2019). Padin et al. (2011) further explain that the value of implementation science extends beyond improving the effectiveness of a program to "explain what worked, why, and under what circumstances" (p. 199). Regarding the relevance of implementation science to PrEP specifically, a recent Program Announcement for PrEP demonstration projects recognized that implementation science can be used to improve our understanding of real-world approaches that increase PrEP provision (and subsequent use) among MSM and transgender persons who are at substantial risk for HIV infection (US DHHS, 2016). Implementation Science investigates how the process of

implementation, implementation fidelity and adaptation, contextual characteristics, and characteristics of the intervention itself serve as barriers and facilitators to implementation of the intervention.

There are many advocates for a well-planned approach to implementing interventions, though some prefer a linear, stepwise process (Bertram et al., 2015; Golden, 2006; Knapp & Anaya, 2013) while others prefer a more iterative process (Grol & Wensing, 2013a; Lambdin et al., 2015; Northridge & Metcalf, 2016). Regardless of the approach, most implementation efforts begin with identifying a problem or need within an organization and culminate with monitoring and evaluation. Implementation fidelity refers to the extent to which an intervention was delivered as planned (Berkel et al., 2011; Haynes et al., 2016) and adaptation refers to modifications made to an intervention or its delivery during implementation (Berkel et al., 2011; Castro & Barrera, 2011; Castro et al., 2004). Elliot and Mihalic (2004) note that "there is a long history of tension between the need to implement programs as they were designed and delivered in their efficacy and effectiveness trials and the need to make local adaptations to 'fit' the program to local conditions" (p. 50). Regarding the benefits of fidelity, Elliot and Mihalic (2004) emphasize that implementation fidelity is needed to fully realize the effects of an intervention. While Castro and Barrera (2011) acknowledge that in theory a high degree of fidelity is needed to maintain the efficacy of the intervention that has been established, they also concede that often adaptation is needed when the implementation protocol is not aligned with the needs of participants or the setting. It is often the case that characteristics of the current participants (e.g., language, race, class, etc.), intervention delivery staff (e.g., cultural competency), and settings (e.g., rural vs. urban) are different from the participants, intervention delivery staff, and settings used to establish the

efficacy of the intervention (Castro et al., 2004). In such instances, adaptations to the intervention content or methods of delivery are warranted. However, 'misadaptation,' where changes are made to the intervention content and/or delivery with no justification, is not supported (Castro & Barrera, 2011). Implementation fidelity for PrEP screening and determining PrEP need would constitute strict adherence to the CDC guidelines to identify eligible patients. While some researchers have praised the guidelines for being able to accurately identify PrEP candidates (Cornelisse et al., 2018; Jenness et al., 2016), others have argued that many patients who would benefit from PrEP may be missed as the current guidelines do not consider the more nuanced HIV risk factors of some patients (Beymer et al., 2017; Calabrese, 2018; Calabrese et al., 2017; Lancki et al., 2018; Raifman & Sherman, 2018). Thus, consideration of individuals who do not meet the criteria outlined in the current guidelines but who are interested in PrEP (i.e., an adaptation to the implementation of the guidelines) may be warranted.

The concept of 'context' in implementation science can have several meanings ranging from the fixed organization in which an intervention is implemented to the dynamic complex adaptive system into which the intervention is implemented (May et al., 2016; Squires et al., 2015). Pfadenhauer et al. (2017) describe context as a set of characteristics and conditions that surround implementation, with characteristics of context being at the structural, provider, and recipient level and the conditions of context being those that make it ready (or not) for change. Successful implementation of PrEP in real-world settings requires anticipation and mitigation of myriad challenges. Lambdin et al. (2015) elaborate: "In moving from study to real-world environments, the delivery of interventions in service delivery settings is quickly met with the complexities of culture, economics, behavior,

gender, social circumstances, and political environment that must be adequately considered to optimize utilization and continued engagement of services by clients" (p. 244). During his plenary presentation at the 22nd International AIDS Conference, Dr. David Malebranche similarly underscored the need for medical settings to consider the characteristics of their specific context (e.g., services, internal policies, hours of operation, location, staff competency, etc.) when investigating engagement in clinical HIV care instead of blaming patients (Hargreaves, 2018; Malebranche, 2018).

There has been much debate about the type of setting in which PrEP should be implemented and the type of provider that should be prescribing PrEP, a phenomenon known as the "purview paradox" (Hoffman et al., 2016; Krakower et al., 2014). Barriers to PrEP implementation in health departments include lack of staff, limited PrEP knowledge among staff, concerns about cost, and lack of a PrEP protocol while facilitators include the ability to create policies and refer patients to local providers (Weiss et al., 2016; Weiss et al., 2018; Zhang et al., 2018). Barriers to PrEP implementation in primary care clinics include limited PrEP knowledge among staff and discomfort assessing sexual risk while the main facilitator is access to HIV-negative patients (Conniff & Evensen, 2016; Montano et al., 2008; Petroll et al., 2017). Barriers to PrEP implementation in infectious disease clinics include limited access to and experience providing care to HIV-negative patients while the main facilitator is increased knowledge of and support for PrEP among staff (Castel et al., 2014; Krakower & Mayer, 2015; Krakower et al., 2014). The main barrier to PrEP implementation in family planning clinics is limited PrEP knowledge among staff while facilitators include access to women who may benefit from PrEP and the expectation of patients to receive HIV prevention services (Seidman et al., 2016; Seidman et al., 2018). Lastly, the main barrier to

PrEP implementation in pharmacies is limited PrEP knowledge among staff while facilitators include the potential to counsel patients about adherence and monitor side effects (Bruno & Saberi, 2012; Clauson et al., 2009). The argument could be made that PrEP should be implemented in a variety of settings and prescribed by a variety of practitioners as the contextual characteristics preferred by one population may differ from those preferred by another population.

Lastly, characteristics of the intervention itself are important to its successful implementation including its relative advantage to other alternative methods, the complexity of its implementation, its cost, and its risks (Damschroder et al., 2009; Grol & Wensing, 2013b). Unlike other HIV prevention strategies (e.g., condoms), PrEP has been touted as a user-controlled HIV prevention method that can be concealed and does not require the consent and cooperation of a sexual partner (Blackstock et al., 2017; Flash et al., 2014; Hankins & Dybul, 2013; Wheelock et al., 2012). However, providers and researchers have expressed concerns about risk compensation, increased sexual risk-taking due to increased protection against HIV, as a result of PrEP use (Calabrese et al., 2014; Hogben & Liddon, 2008; Hojilla et al., 2016; Holt & Murphy, 2017; Newcomb et al., 2018; Whitfield et al., 2020). Similarly, potential MSM and transgender patients have expressed concerns over the stigma associated with PrEP use. PrEP stigma is associated with perceptions of promiscuity, as many people associate PrEP use with risky sexual behavior, (Brooks et al., 2019; Calabrese, 2020; Calabrese & Underhill, 2015; Eaton et al., 2017; Farhat et al., 2017; Golub, 2018; Haire, 2015); perceptions of sexual identity, as PrEP has often been associated with gay men (Brooks et al., 2019; Haire, 2015; Garcia & Harris, 2017), and perceptions of living with HIV, as the same medication used for PrEP is also used to treat individuals living with

HIV (Brooks et al., 2019; Calabrese, 2020; Eaton et al., 2017; Golub, 2018; Golub et al., 2017a; Golub et al., 2017b; Haire, 2015). Lastly, the cost of PrEP and associated care can be a major barrier to access. Most analyses have concluded that PrEP is cost-effective when targeted to high-risk individuals who are also highly adherent (Hankins, 2014; Hellinger, 2013; Horberg & Raymond, 2013; Schackman & Eggman, 2012); however, the annual per-person cost for PrEP exceeds $10,000, not including associated clinical care (Elion & Coleman, 2016; Mayer et al., 2018; Underhill et al., 2010). Private insurance provides coverage for PrEP, though co-pays and deductibles may be prohibitively high (Castel et al., 2014; Elion & Coleman, 2016; Landovitz, 2015; Mayer et al., 2018). Furthermore, many of the groups most in need of PrEP are less likely to have adequate or any insurance coverage (Mayer et al., 2018; Underhill et al., 2010). While patient assistance programs do exist, through Gilead or city and state programs (Castel et al., 2014; Mayer et al., 2018), navigating the application process is often complicated and requires knowledge of the healthcare system (Elion & Coleman, 2016; Landovitz, 2015). Sentiments from PrEP advocates will need to be considered alongside concerns from potential PrEP users if PrEP implementation is to be successful.

The complexity of implementing an intervention is subjective and often determined by the ratio of implementation facilitators and barriers. As mentioned previously, both barriers and facilitators to PrEP implementation in a variety of settings have been identified. Some of the facilitators to PrEP implementation include staff who are knowledgeable about PrEP, comfortable assessing HIV risk, and willing to prescribe PrEP; integration of PrEP with related services; and infrastructure that supports continuity of PrEP care, (Calabrese et al., 2017; Marcus et al., 2016; Mayer et al., 2018). Frequently cited barriers to PrEP

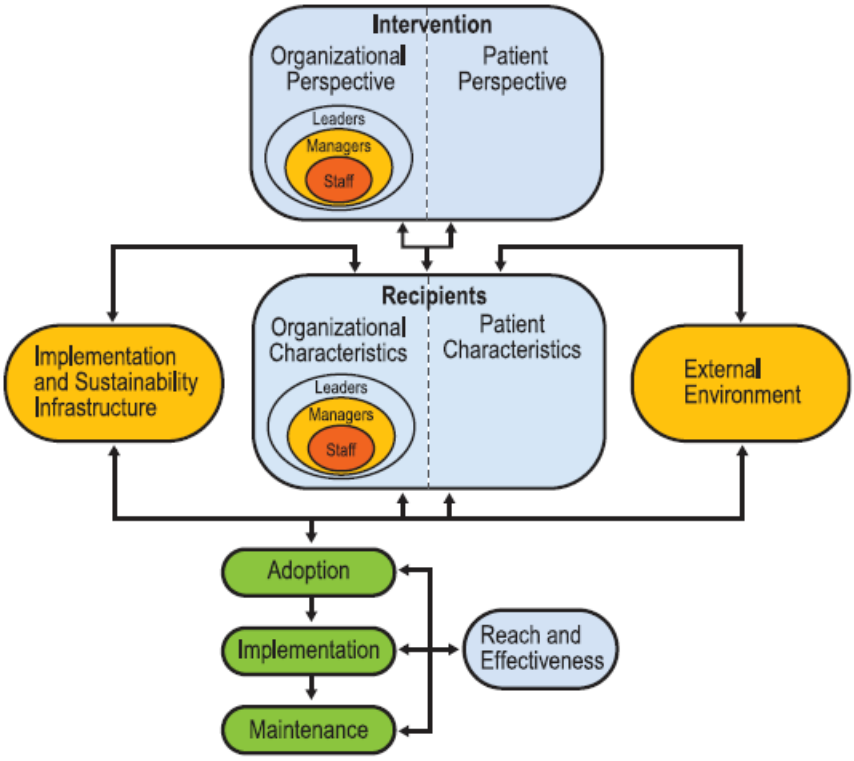
implementation include staff who are less knowledgeable about PrEP, skeptical of its efficacy and safety in the real world, and less comfortable assessing HIV risk; time associated with PrEP screening and monitoring; and cost (Adams et al., 2015; Calabrese et al., 2016; Karris et al., 2014; Krakower et al., 2014). Facilitators will need to be maximized while minimizing barriers, especially cost and risk which have also been cited as barriers by patients, to reduce the perceived complexity associated with PrEP implementation.

There are several theories, models, and frameworks utilized within implementation science. Theories explain why certain relationships lead to certain outcomes; models describe a phenomenon; and frameworks provide an outline of several constructs, with the relationship between the constructs accounting for the phenomenon (Nilsen, 2015). Because implementation science can improve our understanding of real-world approaches to increasing PrEP access among key populations, it is appropriate to use an implementation science model to guide this study of the IMPACT DMV demonstration project. A description of one implementation science model that accounts for implementation processes, organization context, and staff and patient opinions on intervention characteristics is provided below.

PRISM.

The Practical, Robust Implementation and Sustainability Model (PRISM) is a comprehensive model for translating research into practice and for evaluating how the health care program or intervention interacts with the recipients to influence program adoption, implementation, maintenance, reach, and effectiveness (Feldstein & Glasgow, 2008). Figure 7 depicts the components of the model.

Figure *7. PRISM*



Note. From "A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice," by A. C. Feldstein & R. E. Glasgow, 2008, *The Joint Commission Journal on Quality and Patient Safety, 34*(4), p.230 (https://doi.org/10.1016/S1553-7250(08)34030).

The outcome measures in the model are guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework, which aims to help program developers, researchers, and decision-makers who need to evaluate a program focus on five dimensions necessary for success (Glasgow et al., 1999):

Reach: the number, percentage, and representativeness of individuals who participate in a given program.

Effectiveness: the impact of an intervention on important outcomes, such as quality of life and unintended outcomes.

Adoption: the number, percentage, and representativeness of settings and staff willing to participate in a program.

Implementation: the consistency and cost of program delivery as well as any adaptations made.

Maintenance: long-term effects of the program at the individual- and setting-level.

Though all dimensions of the RE-AIM Framework are considered equally important by framework developers, it is not necessary to evaluate all components in every study (Glasgow et al., 1999). Research questions were developed with attention to reach, effectiveness, and implementation dimensions. Adoption was assumed at the point of project implementation, as the current provision of HIV prevention and care services (including PrEP services) was required for organizations seeking funding to expand or enhance those services. Maintenance was not assessed as the IMPACT DMV project is newly implemented and ongoing. Regarding the concept of reach specifically, the number of individuals from the target population who participate in a program (and subsequently benefit from the services provided in the program) increases when more members from the target population have access to the program. A similar concept is that of equity or the extent to which individuals can access services needed (Beauchamp & Walters, 1994). In the context of ethical research, studies should be designed such that everyone from the target population has an equal opportunity to participate. Another concept related to reach is that of distributive justice, or the extent to which the burdens and benefits of society (including research) are distributed fairly (King, 1998; Vaughn, 2010). Historically, some groups such as African Americans

have been subjected to undue burdens in research while being denied benefits. Ethical research should seek to ensure that risks are minimized and that benefits reach those most in need. The IMPACT DMV project seeks to ensure equitable access to HIV prevention, care, and treatment, as well as support services. Equitable access to PrEP services begins with consistent and competent PrEP screening and determination of PrEP need. Thus, the following factors will be considered when describing the reach of the project: (a) the number of eligible patients screened for and determined to be in need of PrEP, (b) the processes used to screen and determine PrEP need, and (c) the reasons why patients might not be screened for or determined to be in need of PrEP.

The PRISM model has recently been adapted to describe elements that specifically influence PrEP implementation (Figure 1). Mayer et al. (2018) recognize that PrEP implementation is influenced by organizational structures, implementation barriers and facilitators, the needs of key populations, and external factors. For this study, the model developed by Mayer et al. (2018) has been further adapted to emphasize aspects of the IMPACT DMV demonstration project that will be considered (Figure 2). Research questions were developed with attention to perspectives of the organizations, characteristics of the organizations and their implementation and sustainability infrastructure, as well as characteristics of the key population. Aspects of the external environment will not be explored given the study's focus on organizational characteristics. The only patient populations to be considered are MSM and transgender persons of color given the focus of the demonstration project.

Summary

The first section of Chapter 2 described the national and local HIV/AIDS epidemic and the multi-level HIV risk factors experienced by MSM and transgender persons of color. The second section of the chapter discussed the studies establishing the efficacy and effectiveness of PrEP, as well as disparities along the PrEP continuum. The last section described the relevance of Implementation Science to the current study as well as the guiding conceptual framework, PRISM. This model was chosen due to its consideration of implementation processes, organization context, and staff opinions on intervention characteristics. The model has been adapted for the study, focusing on aspects relevant to the IMPACT DMV demonstration project. Chapter 3 will describe the methodology and methods to be used in answering the study's research questions described in Chapter 1.

Chapter 3: Methods

The purpose of this study was to describe PrEP screening and PrEP need in the overall project, understand how the project was implemented at the clinic level with respect to PrEP screening and determination of PrEP need, and describe the sources of variation and degrees of adaptation within the project. The research sought an in-depth understanding of whether and how the IMPACT DMV demonstration project is increasing PrEP access among MSM and transgender persons of color.

Overview of Methodology

The research questions were as follows:

Research Question 1: What is the current state of PrEP screening and PrEP need in the project?

a. What processes are in place to facilitate PrEP screening and determination of PrEP need?
b. What factors are associated with PrEP screening and determination of PrEP need?

Research Question 2: How is the project being implemented at the clinic level with respect to PrEP screening and determination of PrEP need?

a. What factors at the structural, institutional, and individual levels might be influencing PrEP screening and determination of PrEP need?

Research Question 3: What are the sources of variation and degrees of adaptation within the project?

a. What are the different sources of variation among the clinics and between the clinics and the overall project?
b. To what degree did clinics adapt the project's recommended processes related to PrEP screening and determination of PrEP need?

Research Procedures

research paradigm.

A mixed methods case study design was used to describe PrEP screening and PrEP need outcomes of the IMPACT DMV demonstration project. A mixed methods approach was selected because both quantitative and qualitative methods have limitations. Creswell and Plano Clark (2018) provide a useful explanation of the value of a mixed methods approach in addressing this issue:

> Hence, the limitations of one method can be offset by the strengths of the other method, and the combination of quantitative and qualitative data provides a more complete understanding of the research problem than either approach by itself. (p. 8).

Brownson et al. (2012) explain that in translational research, which occurs on a continuum from basic science discovery to public health impact (Drolet & Lorenzi, 2011; Woolf, 2008), both quantitative and qualitative techniques should be used to understand a program, the context in which it was delivered, and the extent of limits on generalizability. A mixed methods approach aligns with a pragmatic paradigm, which has a practical ontology (i.e., the nature of reality), an epistemological approach where reality is known through the use of many research tools, and an axiology (i.e., the role of values) that reflects both the

researchers' and the participants' views (Creswell, 2013). A mixed methods approach was appropriate for this study because it sought to quantitatively assess PrEP screening and PrEP need in the project as well as understand the process for each outcome and the various factors impacting PrEP screening and PrEP need at the organization and clinic level via qualitative methods.

study design.

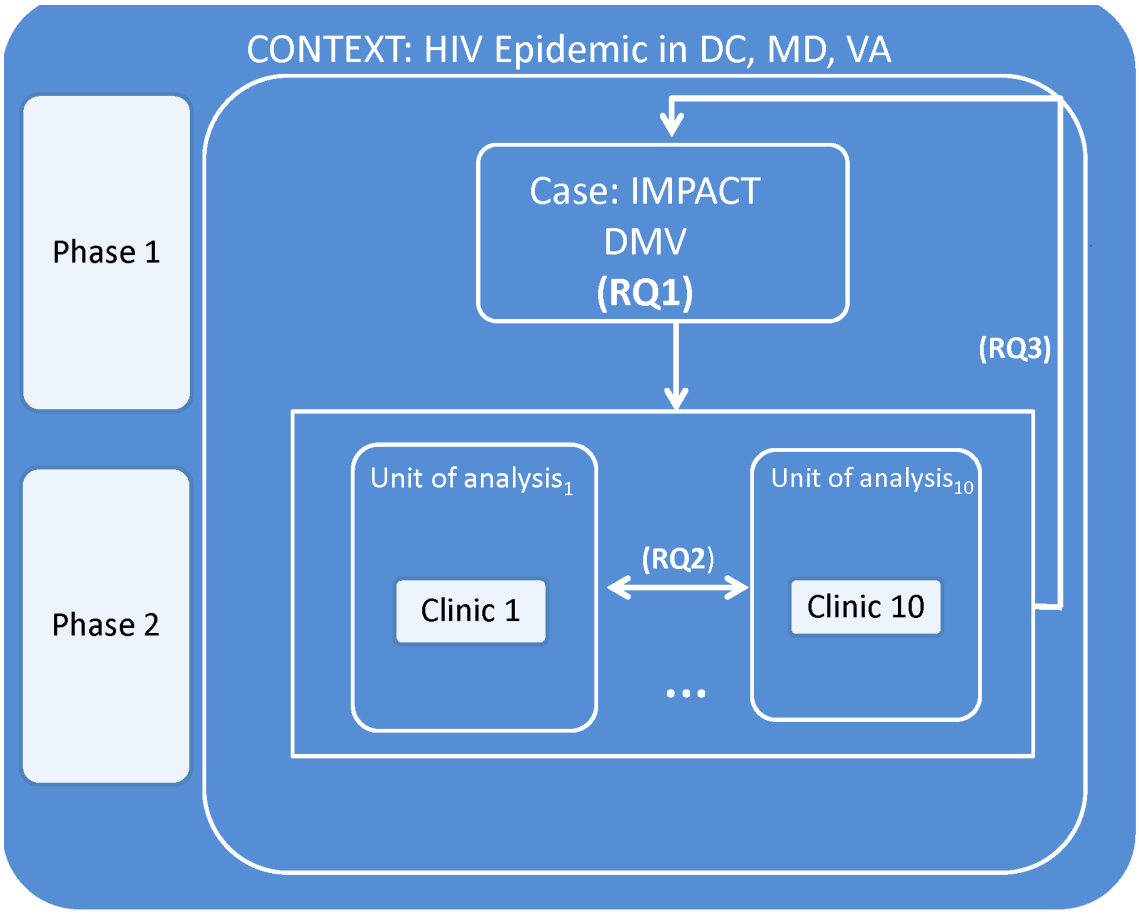
The case study approach was selected for this study based on the characteristics and strengths of case study research that align well with the scope of the research and the type of research questions explored. According to Yin (2018), three conditions should be met when using a case study approach, including: a) type of research question, b) investigator control over behavioral events, and c) the degree of focus on contemporary rather than historical events. For the first condition, Yin (2018) explains that 'how' research questions are conducive to case study research because "such questions deal with the tracing of operational processes over time" (p. 19). The research questions of interest in this study explored whether and how processes related to PrEP screening and determination of PrEP need at the project and clinic level were aligned and how those processes impacted the number of patients screened for and determined to be in need of PrEP. For the second and third conditions, Yin (2018) states that case studies are preferred when examining contemporary events in which behaviors of interest cannot be manipulated. Examining contemporary events is important in case study research because the strategy draws strength from collecting evidence from current events and persons through access to relevant documentation and artifacts, direct observation, and interviews. This contrasts with historical research in which many of these collection methods would not be possible (Yin, 2018). This study relied

heavily upon document review, key informant interviews, and focus groups to assess PrEP screening and PrEP need among the target population. The case study research design is also appropriate when behaviors of interest cannot be manipulated, which is in contrast to experimental or intervention studies that may seek to assess change in one or more groups of interest. This study sought to describe PrEP screening and determination of PrEP need among MSM and transgender persons of color in the project without the intent of intervening to manipulate the behaviors of key stakeholders.

Every case study involves the in-depth investigation of a phenomenon of interest (e.g., person, communities, decisions, programs, etc.) which is bounded by space and time in its real-word context (Yin, 2018). In this study, the phenomenon of interest was the IMPACT DMV project and its impact on PrEP screening and PrEP need among the target population from 2014 – 2019. This definition provided a spatial boundary that focused the study on two specific PrEP outcomes of a particular demonstration project operating in a distinct geographical area. It also provided a temporal boundary that limited the scope of the study to a five-year snapshot in time allowing for an in-depth examination. According to Yin (2018), there are five rationales for a single case study design, as opposed to a multiple case study approach: having a critical, unusual, common, revelatory, or longitudinal case. In this study, the single case design was justified because the IMPACT DMV served as an unusual or unique case for several reasons including: (a) its focus on MSM and transgender persons of color, (b) its use of the whole-person health system model to provide prevention, care, and treatment services, inclusive of PrEP services, and (c) its regional public, private, and health department collaborative structure. When there are multiple units of analysis, called subunits, within a single case of interest an embedded case study design should be used (Yin, 2018).

While the IMPACT DMV project was the overarching case of interest in this study, there were ten clinics within the project that screened and determined the need for PrEP. Figure 8 below graphically depicts the embedded case study design that was used for this study with the identified sub-units of interest for analysis.

Figure *8*. *Mixed Methods Embedded Single Case Study Design*



Creswell (2014) explains that "a mixed methods case study design is a type of mixed methods study in which both quantitative and qualitative data collection, results, and integration are used to provide in-depth evidence for a case" (p. 116). Furthermore, "integration in a mixed methods case study involves the researcher bringing together

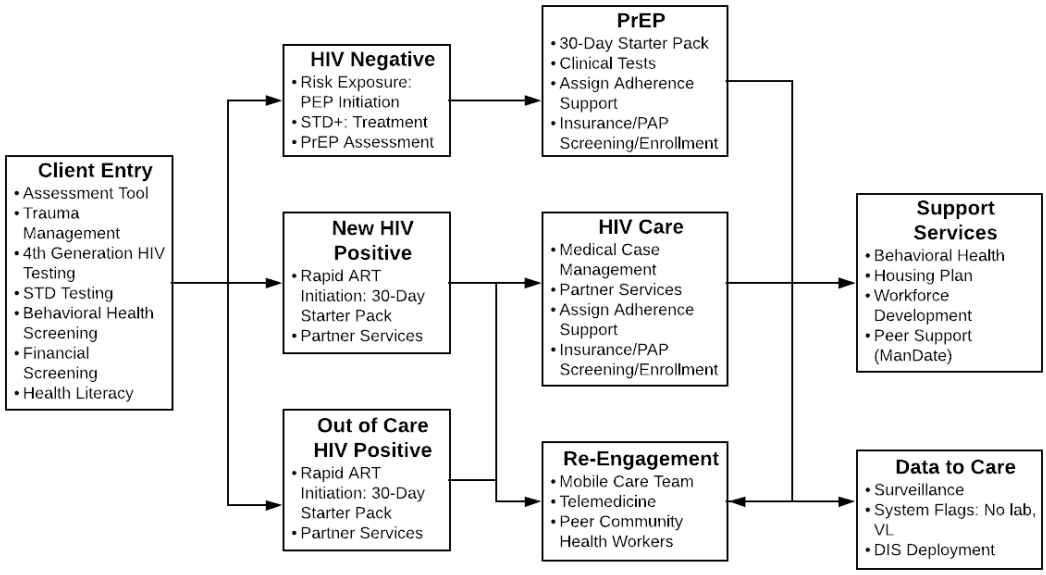
quantitative and qualitative sources of information to describe each case (Creswell, 2014, p. 118). In Phase 1 of the study, both quantitative and qualitative data were collected to fully describe the IMPACT DMV demonstration project as the case, determine the status of PrEP screening and PrEP need in the project, and determine characteristics of the population associated with PrEP screening and PrEP need (i.e., research question 1). In Phase 2 of the study, qualitative data was collected to (a) describe the process of project implementation and factors impacting PrEP screening and determination of PrEP need at the clinics (i.e., research question 2) and (b) describe differences in the contexts of the clinics and differences in the clinic implementation processes compared to the project's recommended implementation processes for PrEP screening and determination of PrEP need (i.e., research question 3). Both quantitative and qualitative data will be integrated to provide a complete picture of PrEP screening and PrEP need in the project.

project description.

The Improve Measurable Participation and Access to Care and Treatment District of Columbia, Maryland, and Virginia (IMPACT DMV) demonstration project used the whole-person health system model to address the holistic health and wellness needs of MSM and transgender persons of color and ensure equitable access to culturally competent services related to prevention, care and treatment, behavioral health, employment, and peer support (DC Appleseed, 2017; DC Health HAHSTA, 2016). Figure 9 depicts the full range of services provided to patients. The project, a regional initiative spanning D.C., southern Maryland, and northern Virginia, was funded through the CDC Targeted Highly-Effective Interventions to Reverse the HIV Epidemic (THRIVE) demonstration grant (CDC, 2017b). To facilitate their goal of ensuring equitable access to services, the project established the

IMPACT DMV Coalition comprised of health department staff from the three jurisdictions, community members, service providers, and private entities that use principles from both high-impact prevention and the HIV care continuum to identify three priority program areas and 24 core services to be offered by the project (DC Health HAHSTA, 2017a). As of December 2018, 7,674 patients were enrolled in the project (inclusive of individuals who were not members of the priority populations and minors), 78% of whom self-identified as MSM, 17% of whom self-identified as transgender, and 73% of whom were HIV-negative (DC Health HAHSTA, 2018). Almost half (49%) of those patients self-identified as non-Hispanic Black and 32% self-identified as Hispanic.

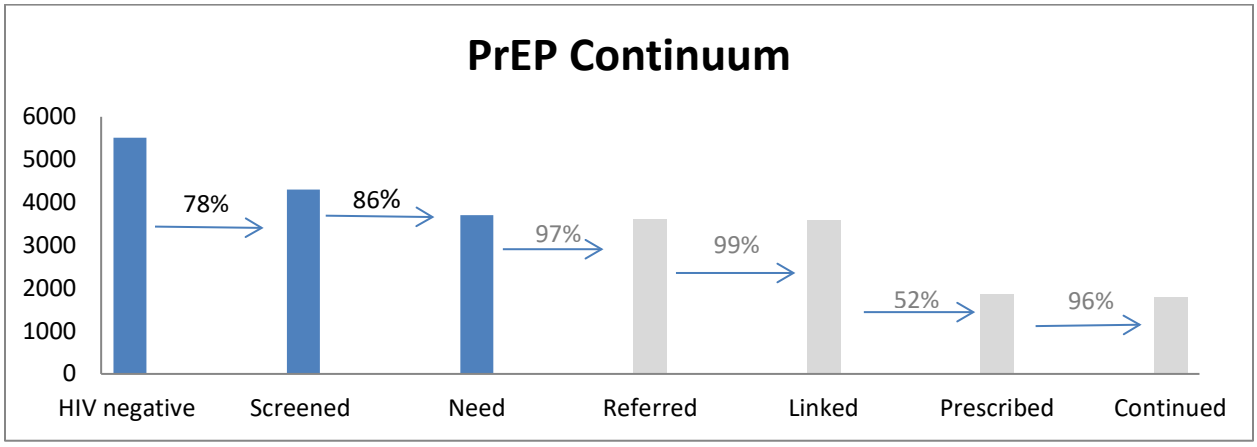
Figure *9.* *Schematic of the IMPACT DMV Demonstration Project*



To document the spectrum of engagement in different PrEP services as of December 2018, the IMPACT DMV project team constructed a PrEP continuum consisting of the following benchmarks: PrEP screening, PrEP need, PrEP referral, PrEP linkage, PrEP prescription, and PrEP continuance (DC Health HAHSTA, 2018). Patients in the project

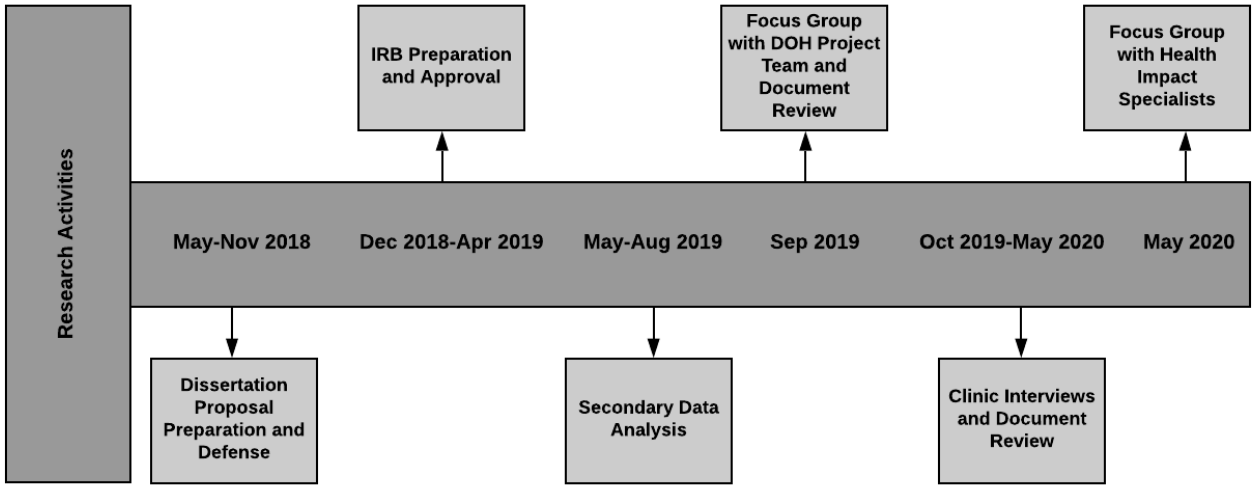
were considered screened for PrEP if they underwent a risk assessment to document behaviors that increase one's risk of HIV infection. Patients in the project were considered to be in need of PrEP if they had elevated HIV risk based on their self-reported behaviors and/or their interest in PrEP. Patients in need of PrEP at one of the eight sites not prescribing PrEP were referred to one of the two prescribing sites. Patients were considered to be linked if they were seen by a PrEP provider at one of the two prescribing sites. Patients in the project were prescribed PrEP if they received a prescription from a PrEP provider at one of the two prescribing sites. Lastly, patients who were still on PrEP at their follow-up visit were considered to have continued PrEP. The project saw large drop-offs in the number of patients screened for PrEP (of those who were HIV-negative) and in the number of patients in need of PrEP (of those screened). These two benchmarks were considered to be vulnerable parts of the continuum that warrant further investigation. However, most of the patients who were determined to be in need of PrEP were referred to a PrEP provider and were linked to a PrEP provider. Again, there was a large drop-off in the number of patients prescribed PrEP (of those linked to a PrEP provider), but most patients who were prescribed PrEP continued on PrEP (Figure 10).

Figure *10. IMPACT DMV PrEP Continuum through December 2018*



A variety of data sources (data triangulation), as well as both quantitative and qualitative methods (methodological triangulation), were used to strengthen the study by corroborating and providing validity for the research findings (Creswell, 2013, 2014; Creswell & Plano Clark, 2018; Maxwell, 2013; Patton, 2015; Yin, 2018). Figure 11 depicts the timeline of data collection.

Figure *11.* *Data Collection Timeline*



Yin (2018) lists six common sources of evidence utilized in case studies: documentation, archival records, interviews, direct observations, participant observation, and physical artifacts. Three of the sources utilized in this study are described below.

quantitative data collection**.**

archival records.

Archival records can take the form of service or organizational records as well as maps and survey data (Yin, 2018). This type of evidence has the same strengths and limitations of documentation, with the additions of often being quantitative and restrictive due to privacy concerns, respectively (Yin, 2018). The IMPACT DMV project collected data on patients accessing services at each step along the PrEP continuum via REDCap, a secure, web-based application designed to support data capture for research studies (Harris et al., 2009). De-identified data from the REDCap form related to patient sociodemographics, risk behaviors, and PrEP service utilization were provided to the researcher in an Excel worksheet

file. Data for adult HIV-negative patients receiving PrEP services as of March 31, 2019 were analyzed for this study. The purposes of the quantitative data analyses were to determine the number and percentage of patients screened for PrEP; to determine the number and percentage of patients determined to be in need of PrEP; to determine the characteristics and any statistically significant differences between patients screened for PrEP and those not screened for PrEP, as well as those determined to be in need of PrEP and those not determined to be in need of PrEP, and; to determine factors associated with PrEP screening and PrEP need.

qualitative data collection.

documentation.

According to Yin (2018), relevant documents of interest include correspondence such as letters or emails; meeting materials such as agendas and minutes; program materials such as proposals, progress reports, or other internal documents; regulatory documents such as policies and procedures; and media materials such as articles or videos. While documentation can be reviewed multiple times, contain specific details, and cover a long period and events, potential disadvantages include difficulty in retrieval and bias of the document author (Yin, 2018). In this study, the purposes of document review were: (a) to understand goals for the project and any formal or informal project implementation procedures created by DC Health personnel to help guide clinic staff and Health Impact Specialists and to help facilitate PrEP screening and determination of PrEP need, (b) to understand goals for the project and any formal or informal project implementation procedures created by clinic staff to help facilitate PrEP screening and determination of PrEP need, and (c) to understand how the goals and

procedures at the project level might align with or differ from those at the clinic level. Documentation collected for this study included:

IMPACT DMV policies and procedures, communications, and program and training materials.

Clinic policies and procedures, communications, and program and training materials.

interviews and focus groups.

Interviews are one of the most important sources of evidence for case studies that provide targeted and insightful information by allowing participants to respond in open-ended ways about the phenomenon of interest (Yin, 2018). However, bias due to poorly articulated questions and social desirability bias where the participant responds in a way that is pleasing to the interviewer are potential weaknesses of interviews (Yin, 2018). In this study, The purposes of the interviews were: (a) to understand the goals for, the context for, and the process for project implementation at each clinic and (b) to explore perceived barriers and facilitators to implementation. Knowledge of the goals for project implementation revealed motivations on the part of clinic leadership for participating in the project. Understanding the context for project implementation revealed the characteristics of each site that might have hindered or facilitated its ability to engage the population of interest in PrEP services. Exploring barriers and facilitators to project implementation highlighted factors related to patients, providers, and the clinic itself that might aid or hinder PrEP screening and determination of PrEP need. This study also utilized focus groups which work well for naturally occurring groups as a method to compare and contrast their activities and viewpoints, recognizing that many decisions are made in a social context (Patton, 2015). In addition to being cost-effective, the participant interactions during focus groups strengthen

the validity of findings by obtaining a variety of perspectives and sparking new ideas, thoughts, and memories from participants based on the responses of other participants (Krueger & Casey, 2009; Patton, 2015). The focus group with DOH personnel served the following purposes: (a) to understand the goals of the demonstration project, (b) to gather perspectives on its implementation, and (c) to explore the perceived barriers and facilitators to implementation. Knowledge of the project goals revealed the intentions and priorities of leadership when developing the project. The second aim was important because the implementation process recommended by DOH personnel differed from the process utilized by clinic staff and provided insight into aspects of the implementation process recommended by DOH personnel that were not communicated to, understood by, or enacted by the clinic staff. The last goal of exploring perceived barriers and facilitators to implementation also revealed differences in perception between the project leadership and the clinic personnel. The focus group with Health Impact Specialists served the following purposes: (a) to understand their role and processes in helping patients move through the PrEP continuum and (b) to explore additional perceived barriers and facilitators to implementation. Table 1 outlines the knowledge gained from the different data sources.

Table 1. *Knowledge to Gained from Data Sources*

Research Question	Data Collection	Knowledge to be Gained	Data Analysis
RQ1: What is the current state of PrEP screening and PrEP need in the project?	Quant: Archival Records	• PrEP screening, PrEP need • Number of patients screened for PrEP • Number of patients determined to be in need of PrEP	• Descriptive statistics (i.e., frequencies and percentages) to determine the number of patients screened for PrEP and in need of PrEP

RQ1a: What processes are in place to facilitate PrEP screening and determination of PrEP need?	Qual: Project-level Document Review	• Goals and process • Formal or informal procedures created by the project leadership	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
	Qual: Focus Group with DC Health Personnel	• Goals, process, barriers, and facilitators • Project development process by leadership • Perspectives on project implementation	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
RQ1b: What factors are associated with PrEP screening and determination of PrEP need?	Quant: Archival Records	• Characteristics and statistically significant differences between patients screened for PrEP and patients not screened for PrEP • Factors associated with PrEP screening	• Initial bivariable analyses to examine sociodemographic and behavioral differences between those screened and not screened for PrEP and between those deemed in need of PrEP and not in need of PrEP • Crude logistic regression to examine bivariable, unadjusted associations • Multivariable logistic regression to examine the factors associated with PrEP screening and factors associated with PrEP need.
RQ2: How is the project being implemented at the clinic level with respect to PrEP screening and determination of PrEP need?	Qual: Clinic-level Document Review	• Goals and process • Formal or informal procedures created by the clinic staff	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
	Qual: Interviews with Clinic Staff	• Goals, context, process, barriers, and facilitators • Actual project implementation process(es) at the clinics	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
RQ2a: What factors at the structural, institutional, and individual levels might be influencing PrEP screening and determination of PrEP need?	Qual: Interviews with Clinic Staff	• Barriers and facilitators	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying

	Qual: Focus Group with Health Impact Specialists	• Goals, process, additional barriers, and facilitators	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
		• Process	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
RQ3: What are the sources of variation and degrees of adaptation within the project?	Qual: Document Review, Focus Group, Interview	• Differences between project goals and processes and clinic goals and processes	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
RQ3a: What are the different sources of variation among the clinics and between the clinics and the overall project?	Qual: Document Review, Focus Group, Interview	• Contextual differences between clinics and influence on PrEP screening and determination of PrEP need	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying
RQ3b: To what degree did clinics adapt the project's recommended processes related to PrEP screening and determination of PrEP need?	Qual: Document Review, Focus Group, Interview	• Process differences between clinics and influence on PrEP screening and determination of PrEP need	• Creswell's spiral method of organizing, reading, coding, interpreting, displaying

participant recruitment.

Purposeful and snowball sampling, two types of non-probability sampling, were used to identify interview and focus group participants. Non-probability sampling methods are appropriate when research aims to elucidate the phenomenon of interest and not to make statistical generalizations (Merriam, 2001). Purposeful sampling should be used when specific individuals can purposefully inform research questions and the phenomenon of interest in great detail. Snowball sampling should be used to identify other people who have information about the phenomenon of interest from initial study participants (Creswell, 2013). In this study, 44 key informants were selected from each of the units of analysis within the case study design. Table 2 outlines the study participants by units of analysis**.**

Table 2. *Study Participants by Sub-Unit Level*

Number of Key Informants	Key Informant Type	Research Question	Data Collection Method
	Phase 1: Local Health Department Representatives		
8	Department of Health Personnel	RQ 1a	Focus Group
	Phase 2: Clinic Staff		
32	Clinic Staff	RQ 2, 2a,	Individual Interviews
4	Health Impact Specialists	RQ 2, 2a	Focus Group

Criteria for selection were determined a priori to identify the minimum sample of key informants that would be able to provide useful information about the phenomenon of interest. The selection criteria and identification of the key informants are described below:

At the *local health department level*, eight project-specific personnel within DC Health HAHSTA were selected for focus group participation. Personnel who held the following positions on the IMPACT DMV team were selected: Senior Deputy Director, Project Manager, Epidemiologist, Transgender Health Coordinator, Impact Health Specialist Coordinator, Data-to-Care Specialist, Public Health Services Specialist, and Disease Intervention Specialist. All personnel had intimate knowledge of and familiarity with programming and policies related to the implementation of the demonstration project.

At the *clinic staff sub-unit level*, 32 leadership and staff members total across the nine clinics participated in individual interviews and a total of 4 Health Impact Specialists were

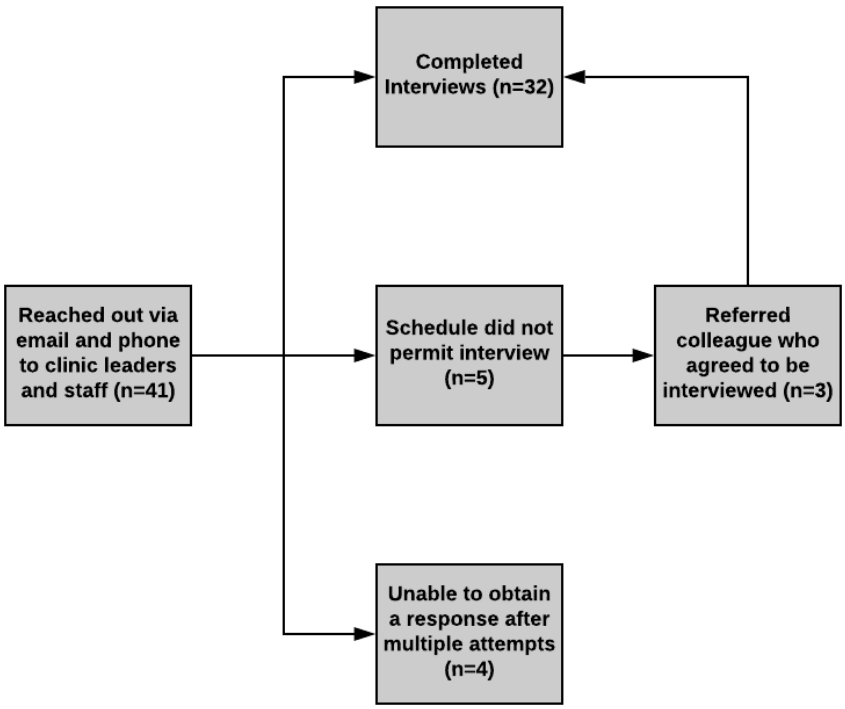
available for focus group participation. Clinic leaders who held the position of Chief Medical Officer, Director, or Manager and clinic staff who held the position of Coordinator, Navigator, Nurse Practitioner, or Medical Provider participated. Clinic participants were contacted based on the position held and recommendations from program personnel. If clinics did not have specific staff for any one of these positions, then the staff person with the most relevant expertise pertaining to the information of interest was selected. Health Impact Specialists were trained and employed by the DC Health and assigned to work within the various clinics funded by the project. Health Impact Specialists were selected based on their involvement with PrEP services and recommendations from the DC government representatives.

To recruit the 44 clinic participants for this study, the lead researcher of this study contacted selected key informants by email or phone and invited them to participate. The invitation described the study and explained what would be asked of the participant as it pertained to scheduling an interview or participating in a focus group. The first step of the recruitment plan was to reach out to selected HAHSTA personnel to notify them of the study. Because the lead researcher of this study has worked with many of these personnel previously, accessing and securing their support for the study was not difficult. This correspondence included a request for document acquisition, their recommendations for identifying key informants at the clinic sites and among Health Impact Specialists, and a request to hold a focus group directly preceding or following one of their regularly scheduled team meetings. This focus group was held after relevant project-level documentation had been received and reviewed so that clarifying questions and questions pertaining to information not contained in the documentation could be asked of HAHSTA personnel. The

second step was to contact staff at each of the clinics to request clinic-level documents and to schedule individual interviews. The last step was to contact Health Impact Specialists to request focus group participation.

The following strategy for follow up with key informant interview and data collection requests was utilized. Each person was given at least seven days to respond before being sent a follow-up email and then another seven days before a phone call inquiry. After 21 days of no response, the lead researcher followed up with a member of the senior leadership staff of DC Health team for further guidance. The invitation correspondence requested that if the individual was unable or unwilling to participate or not the appropriate respondent for the particular questions of interest, to please identify another person in a similar position who might be able to participate. Figure 12 depicts the sampling process among clinic participants.

Figure *12*. *Sampling Process for Clinic Participants*



Semi-structured tools guided the interview and focus group discussions and the domains of interest were derived from the existing literature, the study's research questions, and the conceptual framework for the study. Sample questions can be found in Appendix A. A semi-structured approach allows the wording and sequence of key questions to be determined in advance while also affording the researcher the flexibility to probe interesting topics that emerge (Patton, 2015). Participant interactions during focus groups, critical reflection on the part of participants during interviews, and researcher thoughts about the focus groups and interviews were also be recorded in the form of field notes.

The focus group with the eight DC Health HAHSTA personnel lasted 65 minutes and took place at DC Health after a regularly scheduled team meeting. Interviews with clinic staff lasted between 21-69 minutes. Of the 32 completed interviews, 8 were conducted in person at the clinics, and 24 were conducted via telephone. The focus group with four Health Impact Specialists was conducted virtually via WebEx. Interviews and focus groups were audio-recorded for accurate transcription. All interviews and focus groups were conducted voluntarily. At the time of the interview or focus group, the researcher read a brief description of the study and a statement of informed consent to each key informant. This statement described the study's purpose, procedures, potential risks and benefits, confidentiality statement, and the participant's right to refuse participation. The statement explained that the session would be audio-recorded and transcribed with the consent of the participant. It also explained that every effort would be made to ensure the confidentiality of information. Personal identifiers were removed in the transcription and reporting of the findings. Consent was done verbally to minimize identifying information. Clinic leaders received thank you notes for their time and clinic staff and Health Impact Specialists were compensated with $25 gift cards for their time.

data analysis.

quantitative analysis

descriptive and inferential statistical analyses.

The Impact DMV project provided access to a de-identified Excel worksheet file that includes sociodemographic, risk behavior, and PrEP service utilization data for all adult HIV-negative patients from June 2014 through March 2019. Individuals who did not identify as MSM or transgender and individuals who identified as Non-Hispanic White were excluded

from analysis. Data were cleaned, which included a process of working with project staff to accurately code or fill-in missing data; recoded as necessary to facilitate analysis; and studied through descriptive, bivariable, and multivariable analyses in SAS 9.4 (Cary, NC). Data were analyzed as follows to address research question #1:

Research Question #1. What is the current state of PrEP screening and PrEP need in the project? Frequencies and percentages were used to construct an updated PrEP continuum with emphasis on the PrEP screening and PrEP need benchmarks (Figure 16).

Research Question #1b. What factors are associated with PrEP screening and PrEP need? Initial bivariable analyses examined the sociodemographic and behavioral differences between those screened and not screened for PrEP as well as between those deemed in need of PrEP and not deemed in need of PrEP, using chi-square for categorical variables, t-tests for continuous variables, and non-parametric tests for count variables. In crude logistic regression models, PrEP screening and PrEP need were regressed on each independent variable to examine bivariable, unadjusted associations. Separate multivariable logistic regression models were then fit to examine the factors associated with PrEP screening and PrEP need. Variables were entered into the multivariable models if they were related to PrEP screening and PrEP need in the bivariable analysis ($p < 0.05$). The final models consisted of variables that remained significant throughout the process and did not result in collinearity. The models were adjusted for covariates and potential confounders.

qualitative data analysis.

document, interview, and focus group analysis.

Data were analyzed as follows to address research questions #1a and 2-3: First, Yin (2018) and Creswell (2013) recommend developing a case study database as a means of storing and organizing data collected from the various sources and maintaining a chain of evidence that leads to the study's findings. The NVivo software program used for this study was organized by data collection method: project documents and DC Health focus group data (including field notes and memos), clinic documents (separated by clinic) and clinic interview data (including field notes and memos and separated by clinic), and Health Impact Specialist focus group data (including field notes and memos). Next, Yin (2018) recommends pairing one of four general analytic strategies with one of five more specific analytic techniques. The general technique that was used to guide data analysis was the creation of a descriptive framework, which guided the description of PrEP screening and PrEP need in the project and was appropriate given that the purpose of the study was descriptive. A descriptive case study facilitated the integration of multiple data sources to understand how the project was implemented with respect to PrEP screening and determination of PrEP need. The descriptive framework also illustrated how context—the setting, characteristics, and circumstances in which implementation occurred—impacted implementation at each clinic. The case outline evolved as it was informed by data analysis and Figure 13 illustrates the final outline of the descriptive framework.

Figure *13*. *Outline of Case Descriptive Framework*

I. Current state of PrEP screening and PrEP need in the project
   a. Creation of the project
   b. Initial goals of the project related to PrEP screening and PrEP need
   c. Policies and procedures that facilitate PrEP screening and determination of PrEP need
   d. Perceived barriers and facilitators to PrEP screening and determination of PrEP need

II. Implementation of the project at Clinics 1-9
   a. Background of clinic
   b. Knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need
   c. Actual implementation process for PrEP screening and determination of PrEP need
   d. Perceived barriers and facilitators to PrEP screening and determination of PrEP need

III. Sources of variation and degrees of adaptation within the project
   a. Comparison of variation among clinics
   b. Comparison of variation between clinics and project
   c. Comparison of the degrees of adaptation among clinics

Data analysis was done concurrently with data collection and followed Creswell's (2013) spiral method of iteratively reading, coding, interpreting, and displaying data. For the section focused on the project's impact on PrEP screening and PrEP need, there was first a general reading and review of all the data aligned with that topic (i.e., project-level documents, transcript of the focus group with project leadership, and relevant field notes). The first round of reading was done while listening to the audio recording of the focus group to correct any mistakes in transcription, fill in any information not captured or understood by the transcriptionist, and gain a general understanding of the content of the data. The second round of reading was done to identify phrases and excerpts of the data aligned with the study's conceptual framework and research questions. Memos, or short phrases that convey initial thoughts and ideas about the data (Creswell, 2013; Yin, 2018), were documented by the lead researcher.

Next, the data were coded, which involves aggregating text into categories of information and assigning a label to the code (Creswell, 2013; Saldana, 2016). Coding occurred in two phases: deductive coding followed by inductive coding (Patton, 2015). Deductive coding entails determining a list of codes a priori based on the existing literature, the study's conceptual framework and research questions, and the case descriptive framework (Creswell, 2013; Patton, 2015). To facilitate deductive coding, the student researcher developed a qualitative codebook that contained the list of predetermined codes, a label for each code, a brief definition of each code, a detailed definition of each code, and information about when to apply each code (Creswell, 2014). The codebook evolved and became more refined during analysis and the final version can be found in Appendix B. The second phase, inductive coding, entailed remaining open to emergent codes, including in

vivo codes which are based on the exact words of the participants (Creswell, 2013; Patton, 2015).

The full coding process was used to generate a description of the case based on themes identified, or broad units consisting of several codes that are aggregated to form a common idea (Creswell, 2013, 2014). Thematic analysis has been described as a method for identifying, analyzing, organizing, describing, and reporting themes found in the data and has the advantages of being malleable to the needs of the research and being able to highlight similarities and differences between participants as well as unanticipated insights (Braun & Clarke, 2006; Nowell et al., 2017). Major themes were based on deductive codes (e.g., project development, goals for the project, recommended implementation process, barriers, and facilitators, etc.) while minor or sub-themes were based on inductive codes. Together, the description of the case and the identification of themes within the case are called within-case analysis (Creswell, 2013). The next step in the spiral was data interpretation which moves beyond coding and the identification of themes to identifying the larger meaning of the data (Creswell, 2013). The same general analytic steps of reading, coding, interpreting, and displaying were followed for data associated with the section on the implementation of the project at the clinics (i.e., clinic-level documents, transcripts of individual interviews, transcript of the focus group, and relevant field notes) and data associated with the section on the sources of variation and degrees of adaptation within the project. For the section on the implementation of the project at the clinics, major themes were based on deductive codes (e.g., clinic characteristics, goals for the project, implementation process, etc.), while minor or sub-themes were based on inductive codes. Themes related to screening (i.e., reasons that HIV-negative patients might not be screened from the staff perspective) and need (i.e.,

reasons patients screened for PrEP might not be deemed eligible for PrEP) will be listed on the PrEP continuum (Figure 16j) as a joint display of quantitative and qualitative data (Creswell & Plano Clark, 2018). For the section on the sources of variation and degrees of adaptation within the project, major themes were based on deductive codes (e.g., contextual variation, variation in the implementation process, etc.) while minor or sub-themes were based on inductive codes. The within-case analysis for this section also included comparisons between units (i.e., between the project and the clinic) and between subunits (i.e., between the clinics).

The last step in Creswell's (2013) spiral method, displaying the data, involved the utilization of various tables and figures.

subjectivity statement

This subjectivity statement is provided to be reflexive, or transparent about the biases, values, and experiences that the researcher brings to the study (Creswell, 2013). Creswell (2013) elaborates that reflexivity has two parts: (1) detailing past experiences of the topic being explored and (2) explaining how those past experiences may influence the researcher's interpretation of the study and how they strengthen or limit the study (see *strengths and limitations* section). As a researcher engaged in the study of efforts to increase access to PrEP for MSM and transgender persons of color, I have many life experiences and assumptions that have shaped my view of HIV prevention research which must be bracketed, or set aside, to approach the research from a fresh perspective. I am an African American, middle class, heterosexual, cis-gender woman who is not native to the area where data are being collected. I am currently employed by a school within a university that has a close relationship with DC

Health and I have personally collaborated with several DC Health personnel for various professional projects.

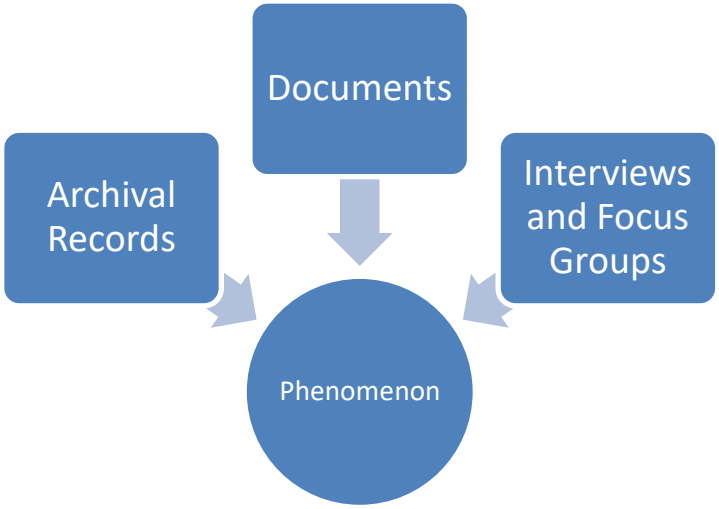
For the entirety of my career, I have worked in the field of HIV prevention and treatment, a desire driven by witnessing family members succumb to AIDS-related illnesses. I have also always been interested in health disparities and health equity research. I have previously worked at a local department of health and a non-profit organization on STI/HIV prevention initiatives. During my time at the health department, I was tasked with eliciting partner information from patients who had recently tested positive for Chlamydia and/or Gonorrhea to refer the partners to testing and treatment. In this role, I was responsible for calling patients to deliver lab test results, administer a risk behavior survey, and elicit information about sexual partners. During my time at the non-profit organization, I worked on the CDC's National HIV Behavioral Surveillance project which collects information on HIV risk behaviors, HIV testing, and prevention utilization from heterosexuals at high risk for HIV infection, persons who inject drugs, and MSM. In this role, I was responsible for conducting formative research (e.g., individual interviews and focus groups with key informants and community key informants) related to the specific population of interest, administering a comprehensive questionnaire, conducting HIV counseling and testing, and analyzing data and summarizing results. In my current role in the Department of Epidemiology in the George Washington University Milken Institute School of Public Health, I coordinate several HIV prevention and treatment studies conducted among recently diagnosed persons living with HIV, youth living with HIV, youth at increased risk for HIV infection, HIV care providers, and MSM and transgender persons. I am heavily involved in all phases of the studies including design (e.g., survey and/or focus group guide

development, securing Institutional Review Board [IRB] approval), implementation (e.g., training of staff, data collection), and dissemination (e.g., data analysis and manuscript and presentation preparation).

Qualitative data analysis aims to meet four criteria of trustworthiness (i.e., accuracy) that also serve as strategies that help bracket previous experiences and biases: credibility (the fit between the participant's views and the researcher's representation of those views), reliability or dependability (the extent to which the research is logical and well documented), transferability (the extent to which the study's findings are transferable to other populations), and confirmability (the extent to which the study's finding are derived from the data) (Lincoln & Guba, 1985; Merrick, 1999). Meeting the criterion of credibility required prolonged engagement with the data (Creswell, 2013) for 15 months: multiple reviews of the interview and focus group transcripts and program documents followed by deductive and inductive coding. Member checking was also utilized by allowing participants to review all transcripts and the summaries of clinic implementation processes and barriers and facilitators for accuracy (Creswell, 2013). To meet the criterion of reliability, the proposal was reviewed and approved by the researcher's Dissertation Committee as well as the George Washington University and DC Health Institutional Review Boards (IRBs) and clearly outlined the steps and procedures taken, as such documentation helps minimize threats to a study's reliability (Yin, 2018). The Dissertation Committee also provided insight into the research processes of the lead researcher as the study was conducted. Transferability requires that readers be provided with sufficient information (Lincoln & Guba, 1985) to determine whether this study's findings are transferable to other populations of MSM and transgender persons of color. Readers were provided thick, rich descriptions of the views and experiences of

participants as well as the settings under study. Confirmability is achieved when credibility, reliability, and transferability have been established (Lincoln & Guba, 1985). As mentioned, data triangulation was utilized as a means of confirming the study's findings in the interpretation stage. Figure 14 depicts the convergence of evidence that was used for the analysis and interpretation of findings in this study.

Figure *14***.** *Convergence of Evidence*



Human Participants and Ethical Precautions

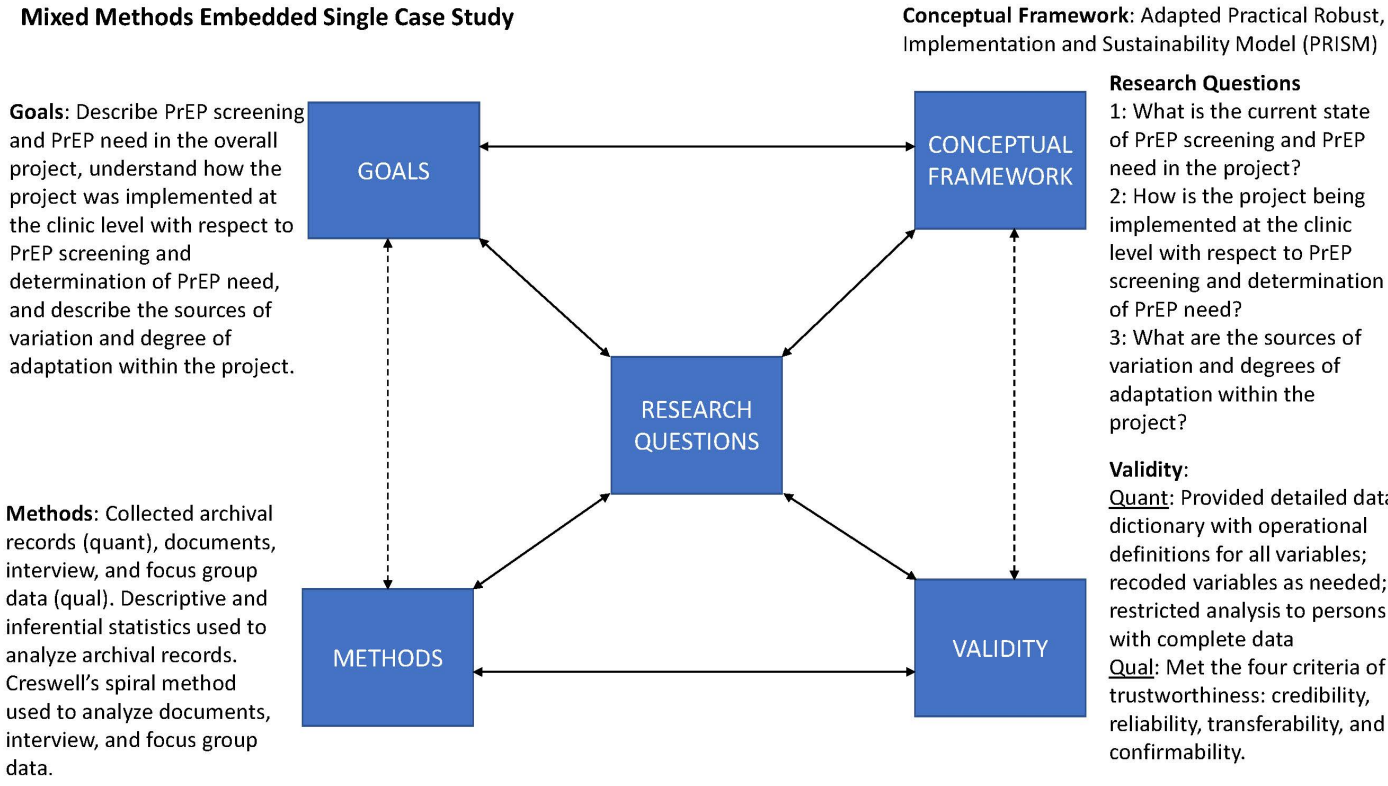
The main ethical risk of this study was the loss of confidentiality. To mitigate this risk, only de-identified patient data was obtained from DC Health. All interviews and focus groups were done voluntarily. At the time of the interview or focus group, the interviewer read a brief description of the study and a statement of informed consent to each key informant. This statement described the study's purpose, procedures, potential risks and benefits, confidentiality statement, and the participant's right to refuse participation. The statement explained that the session would be audio-recorded and transcribed with the

consent of the participant. It also explained that every effort will be made to ensure the confidentiality of information. Personal identifiers were removed in the transcription and reporting of the findings; research records were kept private and were stored in a password-protected file on a password-protected computer. Consent was done verbally to minimize identifying information. Interview recordings were transcribed by a professional transcription service. The audio recordings and transcripts were transmitted through a secure shared drive. All collected data, including archival data, audio recordings, and transcriptions, were saved on the researcher's personal password-protected computer. Prior to the conduct of this study, a protocol for this study was submitted to the George Washington University and DC Health IRBs for review and approval.

Summary

A mixed method embedded single-case study research design was utilized to understand and describe PrEP screening and PrEP need in the IMPACT DMV demonstration project. Data were collected from archival records, documents, interviews, and focus groups. Purposeful, non-probability and snowball sampling were used to identify key informants at the appropriate units of analysis. A variety of strategies were utilized for data analysis including descriptive and inferential statistics for quantitative data and data review, coding, interpreting, and displaying for qualitative data. All findings were related back to the study's research questions and conceptual framework. Several strategies were utilized to minimize threats to reliability and validity including data and methodological triangulation, member checking, and use of rich detail. Figure 15 demonstrates the alignment of the research approach.

Figure *15. Alignment of Research Approach*



Adapted from *Qualitative Research Design: An Interactive Approach* (3rd ed.), by J. Maxwell, 2013.

Chapter 4: Results

The findings outlined in this chapter follow the order of the case descriptive framework to answer the study's research questions and sub-questions. The first section of the chapter will describe the current state of PrEP screening and PrEP need within the project, including the impetus for the project, goals of the project related to PrEP screening and PrEP need, policies and procedures that facilitate PrEP screening and determination of PrEP need, and the quantitative analysis of the PrEP continuum and factors associated with PrEP screening and determination of PrEP need. The second section of the chapter describes the implementation of the project at the clinic level as it relates to PrEP screening and PrEP need, including specific barriers and facilitators associated with PrEP screening and determination of PrEP need. The last section of the chapter describes the sources of variation and degrees of adaptation within the project. Documents and publicly available information were used to create the narrative description of the overall project and quotes from focus groups were used to support the findings. Documents and publicly available information were used to create the narrative description of the individual clinics and quotes from the Health Impact Specialist focus group and staff interviews were integrated and used to support the findings.

Findings

Current state of PrEP screening and PrEP need in the Project (RQ 1)

creation of the project

As detailed in the project narrative included in the CDC THRIVE grant application, the project was created in response to the high rates of HIV, AIDS, and STIs among MSM and transgender persons of color in the DC, Maryland, Virginia region and includes all three localities given the frequent migration of the populations throughout the region for personal and professional reasons. In addition to the need for HIV prevention, care, and treatment services, MSM and transgender persons of color in the area are also in need of behavioral health and social services (e.g., substance use treatment, housing, employment, etc.). To ensure the provision of culturally competent care, the project has established the IMPACT DMV Coalition comprised of health department staff from the three jurisdictions, community members, service providers, and private entities. Thus, by leveraging a regional partnership, the project implemented the 24 services required by CDC's THRIVE funding. The thirteen prevention services include: HIV testing using 4th generation tests; assessments of indications for PrEP and non-occupational post-exposure prophylaxis (nPEP); provision of PrEP and nPEP; adherence interventions for PrEP and nPEP; linkage to care, treatment, and partner services for those diagnosed with acute HIV infection; linkage to care, treatment and partner services for those diagnosed with longstanding HIV infection; STI screening and treatment; behavioral risk reduction interventions; screening for behavioral and social service needs; linkage to behavioral health and social services; navigators to assist accessing HIV

prevention and behavioral health and social services; navigators to assist enrollment in a health plan; and employment/workforce development.

A focus group was conducted with eight project team members (Table 3) to obtain additional information on the project's development.

Table 3. *Description of Project Team Members*

Participant	Race	Gender	Age
Project Team Member 1	Non-Hispanic White	Female	25+
Project Team Member 2	Non-Hispanic Black	Male	35+
Project Team Member 3	Non-Hispanic Black	Female	35+
Project Team Member 4	Non-Hispanic Black	Female	35+
Project Team Member 5	Non-Hispanic Black	Male	35+
Project Team Member 6	Non-Hispanic White	Male	55+
Project Team Member 7	Non-Hispanic Black	Transgender Female	45+
Project Team Member 8	Non-Hispanic Black	Female	35+

Project Team Member 6 expounded on the project:

> The project…was for men who have sex with men of color. We also extended that… to transgender persons of color… And we also intentionally designed it to be a regional project. So, …we…intended to do a project that would involve… our community partners in Northern Virginia and suburban Maryland… The goal was to impact the health of…gay and bisexual, same-gender-loving men of color and transgender persons of color…we had to go one step beyond just services…if we were going to be impactful. We needed to address all of the dimensions of people's lives.

While the project was informed by existing DC Health HAHSTA staff (e.g., Senior Deputy Director, Chief Medical Officer, Chief Epidemiologist), core project team members (e.g., Program Manager, Data Analyst, Transgender Health Coordinator) were hired by DC Health HAHSTA specifically for the project. The project narrative explains that the DC Health HAHSTA project team was primarily responsible for oversight of the Coalition, provision of technical assistance (TA) to Coalition members, development of protocols and data collection tools, and preparation of the Request for Applications (RFA), with strategic input from relevant partners at the Virginia and Maryland Departments of Health to form a 'cross-agency team [that] will serve as a workgroup for regular check-ins on the project progress.' The RFA outlined the rationale for the project's development, the project's purpose and program areas, as well as the application process consisting of a brief written proposal as well as a DC Health site visit. Community-based organizations, educational institutions, other not-for-profit and for-profit organizations in DC, Southern Maryland, and Northern Virginia that provided services to MSM and transgender persons of color were eligible to apply. Potential applicants were provided clear application instructions as well as the evaluation criteria including the organization's infrastructure, sustainability, access to the focus population, cultural competence, and an implementation plan inclusive of a cohesive set of activities and strategies that maximize the health of the focus population. During the focus group, Project Team Member 2 explained:

> We reduced the burden in terms of writing the proposal…So, we did small proposals, but really paid attention to the site visits. So, we gathered folks from around the region and this team to do site visits…The other thing that is unique, we weren't looking for the powerful, we were looking for the folks who wanted to do the work.

> So, that means we had the opportunity to bring in small organizations and big organizations…

Project Team Member 1 elaborated:

> And we created a rubric…of scoring people based on their…written submission and the site visit, which was more of like a discussion of kind of what their practices are now and what their staffing looks like and what they would propose to do…We made sure that each site had…three people…doing the reviewing and one was from Virginia, one from DC, one from Maryland…We tried to make it so that nobody who really like knew the organization did that review to try and make it as…objective as possible…

initial goals of the project related to PrEP screening and PrEP need

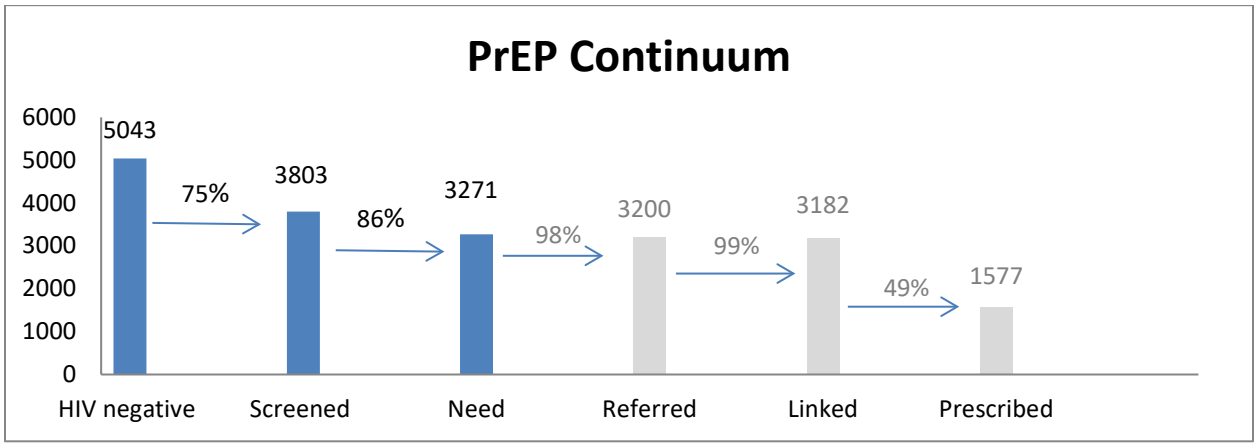
PrEP Screening

PrEP screening is defined by the project team as use of the intake form, or the series of questions assessing one's HIV risk behaviors. The project team did not set any explicit goals related to the desired number of persons screened for PrEP, as they were more focused on increasing access more generally. Project Team Member 1 explains:

> I do think there was probably a number in the original evaluation plan…but I'm not sure that we shared that with the sites. I think with the sites we were basically like screen everyone who comes in who's negative basically to see if they might be a good fit… because everyone should kind of be considered as a potential PrEP client.

Figure 16 depicts the PrEP continuum for the adult MSM and transgender persons of color enrolled in the project as of March 2019. Of the 5043 HIV-negative MSM and transgender persons of color enrolled in the project 3803 (75%) were screened for PrEP.

Figure *16. IMPACT DMV PrEP Continuum through March 2019*



After excluding two clinics due to missing data and incomparable data, data on additional sociodemographic and risk behavior factors of interest were available for 931 persons, who were a median age of 27 (IQR: 23,34) and the majority of whom were cisgender male (77%), Hispanic (55%), and in possession of reliable transportation (79%). Persons not screened for PrEP (n=594) were significantly more likely to have an annual income under $16K (49% vs. 37%, p=.0264) compared to persons screened for PrEP (Table 4). Persons screened for PrEP (n=337) were significantly more likely to have no health insurance (50% vs. 43%, p=.0054) and to be single (77% vs. 72%, p=.0419) compared to persons not screened for PrEP. After adjusting for demographics and site of care, those screened for PrEP had a decreased odds of having an annual income under 16K (aOR 0.512; 0.328-0.800) compared to those not screened (Table 5).

Table 4. *Demographic and HIV Risk Behaviors of a Subset of Patients by Screening Status, N=931**

	Screened[1]	Not Screened[1]	Total	χ^2
Characteristic	**337 (36 %)**	**594 (64%)**	**931**	**p-value[2]**
Age (median, IQR)	27 (23, 33)	27 (23, 34)	27 (23, 34)	.7472
Sex at Birth				
Male	330 (98)	573 (96)	903 (97)	.2106
Female	7 (2)	21 (4)	28 (3)	
Current Gender				
Male	270 (80)	448 (75)	718 (77)	.1010
Transgender	67 (20)	146 (25)	213 (23)	
Race/ethnicity				
Hispanic	202 (60)	314 (53)	516 (55)	.1100
Non-Hispanic Black	117 (35)	245 (41)	362 (39)	
Other/Unknown[4]	18 (5)	35 (6)	53 (6)	
Current Health Insurance Status				
Public	60 (21)	167 (32)	227 (28)	**.0054**
Private	81 (28)	131 (25)	212 (26)	
None	143 (50)	227 (43)	370 (46)	
Current Housing Status				
Stable	257 (76)	417 (70)	674 (72)	.0660
Temporary	72 (21)	167 (28)	239 (26)	
Unknown	8 (2)	10 (2)	18 (2)	
Reliable Transportation				
Yes	267 (80)	460 (78)	727 (79)	.5062
No	68 (20)	131 (22)	199 (21)	
Income				
<16,000	75 (37)	167 (49)	242 (44)	**.0264**
16,000-25,999	51 (25)	59 (17)	110 (20)	
26,000-45,999	41 (20)	50 (14)	91 (17)	
46,000-65,999	21 (10)	42 (12)	63 (11)	
>66,000	13 (33)	26 (67)	39 (7)	
Education				
Less than High School	63 (20)	125 (22)	188 (21)	.8441
High School/GED	152 (47)	255 (46)	407 (46)	

Vocational/Technical School/Some College	49 (15)	87 (16)	136 (15)	
College Graduate	38 (12)	61 (11)	99 (11)	
Some Graduate School/Graduate Degree	20 (6)	29 (5)	49 (6)	
Current Relationship Status				
Single	258 (77)	426 (72)	684 (73)	**.0419**
Dating	13 (4)	55 (9)	68 (7)	
In a relationship	42 (12)	78 (13)	120 (13)	
Divorced/widowed	0 (0)	1 (0)	1 (0)	
Married	15 (4)	17 (3)	32 (3)	
Other	9 (3)	17 (3)	26 (3)	
Gonorrhea Diagnosis in Past 12 Months	18 (5)	22 (4)	40 (4)	.2364
Chlamydia Diagnosis in Past 12 Months	14 (4)	24 (4)	38 (4)	.9327
Syphilis Diagnosis in Past 12 Months	15 (4)	14 (2)	29 (3)	.0771
Other STI Diagnosis in Past 12 Months	1 (0)	4 (1)	5 (1)	.4498
History of Injection Drug Use				
Yes	6 (2)	22 (4)	28 (3)	.0987
No	331 (98)	572 (96)	903 (97)	
History of Condomless Vaginal Sex with Female or Transgender Partner	58 (69)	135 (67)	193 (67)	.7156
History of Condomless Anal Sex with Male, Female, or Transgender Partner	241 (79)	422 (76)	663 (77)	.3210
History of HIV+ Sexual Partner	35 (11)	68 (12)	103 (11)	.7713
History of IDU Partner	7 (2)	20 (3)	27 (3)	.3058

Note. IQR: Interquartile range.
*Clinic 3 and Clinic 7 excluded from analysis due to incomparable data and missing data, respectively
[1]Totals may not sum to N due to missing data.
[2]Chi-square or Wilcoxon test; significant p-values ≤.05 bolded.
[3]Other gender includes intersex, genderqueer, and questioning.
[4]Other race includes mixed race individuals, Asians, Alaska Natives, American Indians, Native Hawaiian, Pacific Islanders, and unknown race.
[5]Other insurance status includes self-pay and unknown health insurance status.

Table 5. *Unadjusted and Adjusted Odds Ratios for Demographic and HIV Risk Behaviors of a Subset of Patients Screened and Not Screened for PrEP (n=931)*

Factor*	OR (95% CI)	*AOR (95%CI)
Insurance		
Public	**.570 (.397-.819)**	1.011 (0.634-1.615)
Private	.982 (.694-1.389)	1.428 (0.888-2.296)
None	Ref	Ref
Income		
<16,000	**.532 (.361-.785)**	**0.512 (0.328-0.800)**
16,000-45,999	Ref	Ref
46+	**.592 (.361-.973)**	0.671 (0.349-1.290)
Current Relationship Status		
Single or Dating	1.127 (0.499-2.543)	2.067 (0.611-6.996)
In a relationship or Married	1.200 (.505-2.850)	2.041 (.581-7.172)
Other	Ref	Ref

Note. $n = 931$.
*Adjusting for age, gender identity, race/ethnicity, education, and site of care.

PrEP Need

PrEP need is defined by the project team as, at a minimum, meeting the CDC guidelines as well as patient interest. When asked if there were any explicit goals related to the desired number of persons deemed eligible for PrEP, Project Team Member 1 responded "I don't think so. I think it was like whatever the need was, we would try to fill it."

In the overall project, 3271 (86%) persons were deemed eligible for PrEP of 3803 persons screened for PrEP (Figure 16). After excluding two clinics due to missing data and incomparable data, data on additional sociodemographic and risk behavior factors of interest

were available for 931 persons. Of the 337 persons screened for PrEP, 265 (79%) were deemed eligible for PrEP with a median age of 27 (IQR: 23, 33) and the majority of whom were Hispanic (60%), stably housed (76%), in possession of reliable transportation (80%), and single (76%). Persons deemed eligible for PrEP were significantly more likely to lack insurance (51% vs. 49%, p=.0004) compared to those not deemed eligible for PrEP (Table 6). Those not deemed eligible for PrEP for significantly more likely to identify as male (89% vs. 78%, p=.0355) compared to those deemed eligible. After adjusting for demographics and site of care, those deemed eligible for PrEP had a decreased odds of identifying as male (aOR=.333; .113-.980) compared those deemed not eligible for PrEP (Table 7).

Table *6. Demographic and HIV Risk Behaviors of a Subset of Patients by Eligibility Status, n=337*

	Eligible[1]	**Not Eligible[1]**	**Total**	**χ^2**
Characteristic	**265 (79%)**	**72 (21%)**	**337***	**p-value[2]**
Age (median, IQR)	27 (23,33)	26 (22,31)	27 (23,33)	.2001
Sex at Birth				
Male	259 (98)	71 (99)	330 (98)	.6442
Female	6 (2)	1 (1)	7 (2)	
Current Gender				
Male	206 (78)	64 (89)	270 (80)	**.0355**
Transgender	59 (22)	8 (11)	68 (18)	
Race/ethnicity				
Hispanic	158 (60)	44 (61)	202 (60)	.9611
Non-Hispanic Black	93 (35)	24 (33)	117 (35)	
Other/Unknown[4]	14 (5)	4 (6)	18 (5)	
Current Health Insurance Status				
Public	56 (25)	4 (6)	60 (21)	**.0004**
Private	53 (24)	28 (45)	81 (28)	

None	113 (51)	30 (48)	143 (50)	
Current Housing Status				
Stable	197 (74)	60 (83)	257 (76)	.1557
Temporary	60 (23)	12 (17)	72 (21)	
Unknown	8 (3)	0 (0)	8 (2)	
Reliable Transportation				
Yes	211 (80)	56 (78)	267 (80)	.6469
No	52 (20)	16 (22)	68 (20)	
Income				
<16,000	62 (39)	13 (30)	75 (37)	.1418
16,000-25,999	38 (24)	13 (30)	51 (25)	
26,000-45,999	29 (18)	12 (28)	41 (20)	
46,000-65,999	20 (13)	1 (2)	21 (10)	
>66,000	9 (6)	4 (9)	13 (6)	
Education				
Less than High School	54 (21)	9 (13)	63 (20)	.1633
High School/GED	117 (46)	35 (52)	152 (47)	
Vocational/Technical School/Some College	35 (14)	14 (21)	49 (15)	
College Graduate	34 (13)	4 (6)	38 (12)	
Some Graduate School/Graduate Degree	15 (6)	5 (7)	20 (6)	
Current Relationship Status				
Single	208 (79)	50 (69)	258 (76)	.1125
Dating	12 (4)	1 (1)	13 (4)	
In a relationship	30 (11)	12 (17)	42 (12)	
Divorced/widowed	0 (0)	0 (0)	0 (0)	
Married	10 (4)	5 (7)	15 (4)	
Other	5 (2)	4 (6)	9 (3)	
Gonorrhea Diagnosed in Past 12 Months	16 (6)	2 (3)	18 (5)	.2753
Chlamydia Diagnosed in Past 12 Months	12 (4)	2 (3)	14 (4)	.5092
Syphilis Diagnosed in Past 12 Months	12 (4)	3 (4)	15 (4)	.8950
Other Diagnosed in Past 12 Months	1 (0)	0 (0)	1 (0)	.6017
History of Injection Drug Use				
Yes	6 (2)	0 (0)	6 (2)	.1976
No	259 (98)	72 (100)	331 (98)	
History of Condomless Vaginal Sex with Female or Transgender Partner	44 (69)	14 (70)	58 (69)	.9159
History of Condomless Anal Sex with Male, Female, or Transgender Partner	189 (79)	52 (80)	241 (79)	.8710
History of HIV+ Sexual Partner	28 (11)	7 (10)	35 (11)	.8166

History of IDU Partner	6 (2)	1 (1)	7 (2)	.6349

Note. IQR: Interquartile range.
*Limited to those screened for PrEP.
[1]Totals may not sum to N due to missing data.
[2]Chi-square or Wilcoxon test; significant p-values ≤.05 bolded.
[3]Other gender includes intersex, genderqueer, and questioning.
[4]Other race includes mixed race individuals, Whites, Asians, Alaska Natives, American Indians, Native Hawaiian, Pacific Islanders, and unknown race.
[5]Other insurance status includes self-pay and unknown health insurance status.

Table 7. *Unadjusted and Adjusted Odds Ratios for Demographic and HIV Risk Behaviors of a Subset of Patients Eligible and Not Eligible for PrEP (n=337)*

Factor*		OR (95% CI)	*AOR (95%CI)
Current gender			
	Male	**.436 (.198-.962)**	**.333 (.113-.980)**
	Trans	Ref	Ref
Insurance			
	Public	3.717 (1.248-11.070)	3.316 (0.994-11.067)
	Private	**.503 (.273-.925**	.582 (.257-1.319)
	None	Ref	Ref

Note. $n = 337$.
*Adjusting for age, gender, race/ethnicity, education, and site of care

policies and procedures that facilitate PrEP screening and determination of PrEP need

PrEP Screening

The project's policies and procedures related to PrEP screening were adapted from the CDC's PrEP guidelines. Information related to the clinical efficacy of PrEP, as well as PrEP screening, need, prescription, monitoring, and payment, was provided in the form of a

presentation as well as a protocol. Regarding PrEP screening, both documents contain a workflow for the initial as well as subsequent PrEP visits (a brief outline is provided in the presentation and detailed procedures are provided in the protocol), and both documents advise providers to begin the initial visit with a medical and sexual risk assessment and 4th generation HIV testing. However, sites were not expected to rigidly follow these policies. Project Team Member 1 explains:

> With that being said, all the sites were kind of given flexibility to kind of use their normal practices…you know there weren't really strict guidelines of like, you should be screened for PrEP versus you shouldn't…

The presentation includes sample questions that providers could use to assess HIV risk (e.g., What type of sex are you having? What type of sex would you like to have? Do you have a provider you can talk to about your sexual orientation and health?) and places an emphasis cultural competency and sex-positive conversations by including a list of LGBTQ-friendly terms and reminding providers to manage their discomfort and biases during discussions with patients. The protocol references a separate intake form that providers should use to assess HIV risk. There are two versions of the intake form referenced in the protocol, both of which include questions about sexual risk behaviors. However, the actual questions differ between the two versions, and the questions in the version used by one site ask about behaviors in the past 3 months while the questions in the version used by the other 9 sites ask about lifetime behaviors. When asked about the different versions of the intake form, Project Team Member 1 clarified “So that's the beginning. Yeah. They all use the intake form and then they are allowed to add other questions that they may have for their

own intake." When asked specifically about the different time periods of the questions in the intake forms, Project Team Member 1 responded:

> … I think we talked about the time periods a bunch when we were making this and… three months I think we were thinking was just like an easier time period to remember versus six months…because a lot of the sexual health behavior ones are kind of specific about…like what your partners are like and how often did you talk to them about certain things. And so, we thought in three months we might get better… recollection. And then the, 'have you ever?'…we wanted to allow for people to kind of change their practices because we deal with a lot of people who make choices at certain times that are different from their choices at other times. And we talk about season of [risk] and like, you know, they may not have done something in the last year, but that doesn't mean that's not part of their potential activity. So, we kinda wanted to get an idea of their full sexual history.

To assist the sites with PrEP screening, the Coalition provided education for providers who delivered PrEP services at any point along the continuum in several ways. A Provider Work Group was established to foster an exchange of information related to best practices for the provision of PrEP. Periodic technical assistance was also provided to increase the cultural competency of providers as well as their capacity to conduct comprehensive risk assessments. Sites were also given quarterly report cards that showed the PrEP continuum for their organization as well as the overall project. The report cards helped to identify potential gaps in screening among HIV-negative persons.

PrEP Need

Regarding PrEP need, the project's policies and procedures were again adapted from the CDC's PrEP guidelines. The training presentation includes indications from the 2017 CDC guidelines for the three populations for whom the agency recommends PrEP: MSM, heterosexual men and women, and persons who inject drugs. For MSM, the protocol contains

those same indications, as well as additional indications not listed in the CDC guidelines (e.g., prescription of nPEP and continued high-risk behavior or multiple courses of nPEP). The protocol also provides a list of indications for transgender persons by combining indications listed for the other populations (e.g., the presence of other risk factors that increase HIV risk, including transactional sex). In reference to the additional PrEP indications for MSM in the protocol, Project Team Member 1 clarified:

> I mean for MSM, it looks like they added, you know, being prescribed PEP, which I think just makes sense because we've talked about that a lot at the clinic and at other sites where it's like if they are on PEP, like they might be in a situation where yeah, they only need PEP like once every three years. But it also might be an ongoing thing that's not really sustainable and so it might make more sense for them to be on PrEP as a safer option.

When asked about the inclusion of PrEP indications for transgender persons in the protocol, Project Team Member 1 replied:

> I mean, because they're part of our project and a lot of the biological risk factors [between MSM and transgender women] remain the same. And I know our clinic staff feel strongly about that…

Project Team Member 2 added, "and just not to be assumptive…you want to be explicit about this community and that community, not to sort of lump them together."

To assist the sites with determining PrEP need, periodic technical assistance was also provided to increase the capacity of providers to determine PrEP candidates. Sites were also given report cards that showed the PrEP continuum for their organization as well as the overall project. The report cards helped to identify potential gaps in PrEP need among persons who had been screened. Project Team Member 2 explained:

> Our goal is to put people on PrEP and when it's appropriate, when they need it and when they ask for it rather than you just sending folks over to the clinic and or saying they should be on PrEP. Because it really still should be a client-centered event, right? So, there was a period of time that we needed to do some technical assistance around ensuring that we're being client-centered and that our program was not numbers-driven. It really is about the appropriateness of PrEP.

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Project team members identified barriers to PrEP screening and determining PrEP need at the structural, institutional, and individual levels.

PrEP Screening

Regarding barriers to PrEP screening at the structural level, Project Team Member 5 posited:

> I oftentimes wonder if we are doing a really great job in…making sure that there is enough providers to supply the need. So, once we've done a lot of community engagement and education, do we have, um, an appropriate number of providers?…And we do have a project, a part of the project where we are, um, doing academic detailing to reach out to providers to inform them about different tools. But I don't know that we've yet reached a level to where it is enough to make sure that there's this balance of community need and provider offering. Um, so that's something that we're always working toward to make sure that, you know, people have a place to go once they know they want to go to a place.

The biggest structural facilitator to PrEP screening identified by the project team was the whole-person health system model that the project utilizes. Project Team Member 8 elaborated:

> I would say it makes it easier…that we were able to provide, so to speak, wrap-around services and services that were not just centered around sex. So, [for] people who come to the clinic, ‘yes, I'm presenting here for chlamydia. Yes, I'm here for gonorrhea, but that's the last thing on my mind. I have housing, I have, you know,

> um, education, I have food, other things that are on my mind that are more pressing than my sexual escapades last night and what bought me…here.' So, the fact that we were able to link them to resources and connect them to, um, some of their more prominent needs…I think that's probably one of our selling points in itself. The fact that [they're] here… for sex, but that may be the last thing we get to…when you sit in the seat. I want to know about everything.

Project Team Member 2 also described that "sort of dismantling old school ideas around sex and [describing] sex as normal, good fun" helps to facilitate the PrEP screening process at the structural level by normalizing the conversation.

At the institutional level, Project Team Member 7 explained that the reputation of an organization can be a barrier to PrEP screening:

> I know one of the things that that comes from certain communit[ies] is…the reputation of the organization coming in, so it's a hesitancy to engage because I'm going to have this experience…whether it's the language, whether it's the… facility. You know, it's not a warm and welcoming facility.

In reference to staff, Project Team Member 3 identified "the bias that the provider brings into the room" as another barrier while Project Team Member 1 mentioned "the uncomfortableness on both sides," or the discomfort that both providers and patients may feel about the risk assessment as a barrier. No facilitators to PrEP screening were identified by project team members at the institutional level.

No barriers or facilitators to PrEP screening were identified by project team members at the individual level.

PrEP Need

Regarding determining PrEP need, no barriers were identified by project team members at the structural level. As a facilitator to the process of determining PrEP need at the structural level, Project Team Member 5 described DC Health's PrEP campaigns:

> One thing I think is…the campaigns that…DC Health shares with the community. And I think at best what they do is begin to integrate people's sexual journeys as they journey. And it tries its best as they can collectively to remove [the sentiment of] 'this is for me, this is not for me.'…And there was an attempt also to make sure that there was images of different communities…So thinking about our dominant campaign…both for African American and Latinx, um, transgender women, looking at what does it mean to have an image of me or someone like me to say that 'Hey, this is okay to at least consider.'

One barrier to determining PrEP need identified at the institutional level was the perception among providers that patients need to be perfect to undertake PrEP. Project Team Member 2 explains:

> I think that we have to create a new narrative that people can do multiple things at one time, that I can have a challenge and still be on PrEP. I think we've created the idea that until I get rid of all my other issues, I'm not available for PrEP …So I think for our providers it's just understanding that people can handle multiple things at one time, including a crisis and taking care of themselves.

Project Team Member 1 explained that the main facilitator to the determination of PrEP need at the institutional level was the availability of "culturally sensitive, open, nonjudgmental peer navigators."

At the individual level, Project Team Member 8 discussed the low perception of risk and medical mistrust as barriers to determining PrEP need:

> I would probably say getting to a space where some populations recognize, uh, normalized behavior as a risk. And so, we engage…people who come in, they may be eligible for prep and it's like, 'well, that's not for me because, you know, I have this

> under control. I feel like I'm not at risk because I don't like the word risk. So now I feel like, you know, you're pushing me away.*'* Um, and you know, you just have medical mistrust in certain populations.

Participant 2 also discussed low risk perception and fatalism among young people as barriers to determining PrEP need:

> Well for me there are a couple of things. I think one, there is this perception of risk. I think that…with the advent [of] ARTs we have really sort of diminished the look of HIV…But also thinking about people like young folks, 'why do I protect myself if I can't even envision a future 60 years from now?'…And if you [ask] a 20-year-old, 'what do you think you'll be doing in 40 years?'…they say, 'probably dead.'… And I think that for some of our young folks…it's like, 'what am I protecting if…there's nothing to think about for tomorrow?'…There's no incentive for taking the pill every day.

No facilitators to determining PrEP need were identified by project team members at the individual level.

Implementation of the project at Clinic 1-9 (RQ 2)

To date, 10 organizations have been funded by the project to provide PrEP, and Table 8 displays characteristics for those clinics. The project was implemented to different degrees, as evidenced by the variable number of HIV-negative persons, persons screened for PrEP, and persons determined to be in need of PrEP across the clinics. Table 9 displays the characteristics of participants at each clinic.

Table 8. *Clinic PrEP Characteristics*

Clinic	Location	Health Impact Specialists	Number HIV-Negative[1]	Number Screened for PrEP (%)[1]	Number in Need of PrEP (%)[1]	PrEP-Related Resources		
						HIV/STI Testing	Referral	Prescription
1	MD	1	66	22 (33)	9 (41)	X		X
2	DC	3	268	111 (41)	84 (76)	X	X	
3	DC	1	76	7 (9)	7 (100)	X		X
4	VA	3	95	38 (40)	31 (82)	X		X
5	DC	4	32	17 (53)	16 (94)	X	X	
6	DC	3	85	23 (27)	19 (83)	X	X	
7	DC	0	3797	3151 (83)	2711 (86)	X		X
8	DC	1	315	315 (100)	295 (94)	X		X
9	VA	1	251	101 (40)	83 (82)	X	X	
10*	DC	0	58	18 (31)	16 (89)	X	X	

*Clinic 10 was not included in the qualitative interviews and focus groups.
[1]Enrolled in the project through March 2019

Table 9. *Description of Clinic Staff*

Participants	Title	Race	Gender
		Clinic 1	
Participant 1.1	Deputy Director	Non-Hispanic Black	Female
Participant 1.2	Medical Assistant	Non-Hispanic Black	Female
Participant 1.3	Manager	Non-Hispanic Black	Female
Participant 1.4	Former Health Impact Specialist	Non-Hispanic Black	Transgender Female
		Clinic 2	
Participant 2.1	Program Manager	Hispanic	Female
Participant 2.2	Chief Medical Officer	Hispanic	Male

Participant 2.3	Former Health Impact Specialist	Hispanic	Transgender Female
	Clinic 3		
Participant 3.1	Manager	Non-Hispanic Black	Male
Participant 3.2	Outreach Specialist	Non-Hispanic Black	Female
Participant 3.3	Coordinator	Non-Hispanic Black	Transgender Female
	Clinic 4		
Participant 4.1	Program Manager	Non-Hispanic Black	Male
Participant 4.2	PrEP Coordinator	Non-Hispanic Black	Male
Participant 4.3	Health Educator	Asian	Female
Participant 4.4	Health Impact Specialist	Non-Hispanic Black	Male
	Clinic 5		
Participant 5.1	Program Director	Non-Hispanic Black	Male
Participant 5.2	Health Impact Specialist	Hispanic	Male
Participant 4.3	Prevention Coordinator	Non-Hispanic Black	Female
Participant 5.4	Director	Non-Hispanic Black	Transgender Female
	Clinic 6		
Participant 6.1	Program Director	Non-Hispanic Black	Female
Participant 6.2	Manager	Non-Hispanic Black	Male
Participant 6.3	Manager	Asian	Female
Participant 6.4	Researcher	Non-Hispanic Black	Male
Participant 6.5	Health Impact Specialist	Non-Hispanic Black	Male
	Clinic 7		
Participant 7.1	Director	Hispanic	Male
Participant 7.2	PrEP Navigator	Hispanic	Male
Participant 7.3	Director	Non-Hispanic White	Female

Participant 7.4	Manager	Non-Hispanic White	Female
Clinic 8			
Participant 8.1	Medical Director	Non-Hispanic White	Male
Participant 8.2	Nurse Practitioner	Non-Hispanic White	Male
Participant 8.3	Epidemiologist	Non-Hispanic White	Male
Participant 8.4	Coordinator	Hispanic	Female
Participant 8.5	Health Impact Specialist	Non-Hispanic Black	Male
Clinic 9			
Participant 9.1	Executive Director	Hispanic	Male
Participant 9.2	Prevention Counselor	Non-Hispanic Black	Male
Participant 9.3	Health Educator	Hispanic	Transgender Female
Participant 9.4	Program Manager	Hispanic	Male

Clinic 1

background

Clinic 1 is a non-profit community-based organization located on the 4th floor of a large office building in Southern Maryland. For 21 years, the organization has provided supportive services to persons living with HIV and other sexually transmitted infections (STIs), as well prevention services including HIV and STI testing and sexual health education. Regarding the vision and mission of the organization, Participant 1.1, the Deputy Director, stated:

> So, the mission, the vision of [clinic 1] is an empowered community where folks are self-reliant and can make the best choices about their healthcare… The way that we do that is to provide support, education, and resources that promote healthy lifestyles

> in an effort to decrease the health disparities in our region and increase the access to quality healthcare. We were founded by two cisgender Black women who …were working with women who were positive and saw how a lot of Black women were falling through the cracks….We understand that although we have our roots in HIV, HIV has so many layers and we want to be able to address those layers…And so we're still one of the very few community-based organizations in the county that does offer HIV, STI care, treatment, and supportive services for anyone in the county who is eligible.

Participant 1.4, a former Health Impact Specialist, added:

> We have a doctor, we have a pharmacy, we have a clinic, we have different psychosocial support groups so we're kind of like a mini [clinic 7] in [Southern Maryland].

When describing the staff of clinic 1, Participant 1.3 explained:

> Well, we do have a very diverse staff… I think…the age range would be anywhere from… 22 to about 60 years of age….a lot of us come with social work backgrounds, case management backgrounds,…community educator backgrounds…a lot of public health people here…We have a…heavy African American presence here, heavy African American female presence here. I would say probably about 90%. The black girl magic is strong at [clinic 1]!

When asked to describe the clients of clinic 1, Participant 1.1 explained:

> …we're really about half and half serving men and women…I would say at least two-thirds of the men that we serve identify as men who have sex with men or who have had sex with men…the majority of the women that we serve identify as cisgender, mostly African American. We do serve some African-born and Latinx. And then we also do have of course services available for transgender men and women as well.

Participant 1.3 went on to specifically describe the clients receiving HIV prevention services including PrEP:

> Their age range and gender would be… between age 20 and 30, and the bulk [are] African American MSM… I haven't seen any transgender men; however, we have quite a few transgender women…[most clients are] minimally educated and it's about 50/50 in reference to the insurance…Most are employed.

Participant 1.1 shared the clinic's motivation for wanting to participate in the demonstration project:

> You know what really drew us to this project is the opportunity to offer the support of services. So, I love that the project was about…figuring out how do we fill in the gaps so the folks can get access to care… And so, I can say it's allowed us to really grow. Our services, our staff, our culture which is a big deal particularly for [this] county. And so, in terms of services, it's allowed us to really focus on what services do we have available for men who have sex with men and for Transgender women and men of color….And so we were able to do innovative things like our Transgender support group…Likewise for our MSM population…So it's been some really, really good work that has come out of the 1509 … And so, we've been able to do a lot of education internally with our staff…We've been able to change our policies, our forms, kind of our systems so that we can be more affirming and more supportive of the MSM community and also the Transgender community…So yeah it's really, really served as a catalyst for a lot of the great things that we're doing.

Participant 1.4 described her motivation for joining the project as a Health Impact Specialist:

> I was just looking for a job at first but once I started, I got very deep into it because I have a lot of friends that are positive….And then I want to help my community because my community is known for sex work so I'm a big advocate on that…

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

The project's recommended process for PrEP screening, according to Participant 1.1:

> Follows the general CDC recommended screening process for PrEP. So, in assessing folks for risks, their willingness and making sure they're understanding what it means to get on PrEP. It's not a morning-after pill, it's not a sometimes pill, it is a commitment to your health. And then making sure they also understand the contraindications and the side effects and all that good stuff …

Participant 1.1 also described support provided by the project team around PrEP screening:

> Yeah. So we've gotten lots of guidance from [Project Team Member 8], she has been awesome…so [clinic 8] has been great in us being able to refer people there whether

> its PrEP or PEP…And then also in just sending us sample guidance, sample protocols and connecting us with other resources in the community that can help us create those protocols…A lot of either virtual or over the phone [support] and then probably maybe about three or four times a year…it'll be somebody from the Health Department that's out here.

PrEP need

Regarding the project's recommended process for determining PrEP need, Participant 1.1 shared:

> …so, one of the things…is…at-risk behaviors. So, we're looking at like I said 'frequent flyers' to the STI clinic for example, serodiscordant relationships, someone who engages in sex work. So those activities or behaviors that put them at high risk.

Participant 1.1 explained, that similar to the support provided by the project for PrEP screening, the support provided for determining PrEP need is:

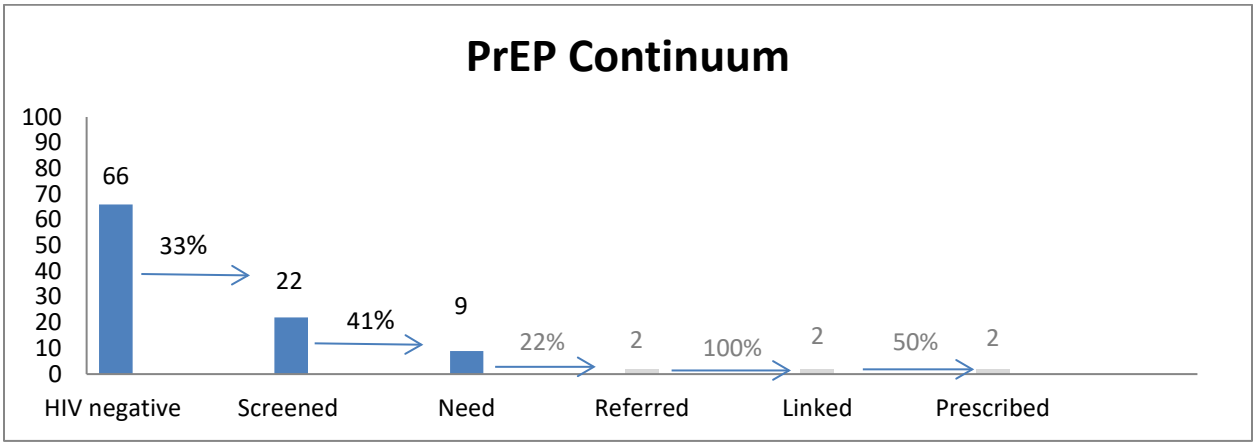
> …mostly over the phone and virtual. And like I said they'll come out. There hasn't been like shoulder-to-shoulder TA but that's okay [because] we've really not even requested that… One of the things I really appreciate is they're really trying to be intentional and making sure that there is some space in [this] county where these services are available and where there's a clear relationship and a clear path of communication And then lately they're kind of like "Okay you guys are good?" And so, if we need something, we can reach back [out].

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16a depicts the PrEP continuum for clinic 1 as of March 2019. Of the 66 HIV-negative persons enrolled in the project at clinic 1, 22 (33%) were screened for PrEP.

Figure 16a. *Clinic 1 PrEP Continuum through March 2019*



When asked how the project's recommended screening process informs the process of PrEP screening at clinic 1, Participant 1.1 commented:

> So, it informs our practice in a couple of ways: one, in terms of outreach and our linkage to care and navigation work that we do in the community…It informs how we talk to people and making sure that we infuse it into every step [when] we talk to people. So, either during testing, tabling, making sure that we talk about it… It also created a door within…our infectious disease practice…for folks who do come in and to get screened for STI's and then we have our "frequent flyers" being able to say 'okay it's the third time. Remember we talked about PrEP the first two times? What are you thinking now?' So really creating those doors within our practice and within our organization.

Participant 1.2, a medical assistant who is currently solely responsible for PrEP screening in the clinic, explained that she screens for PrEP by having an informal conversation that primarily occurs in conjunction with STI screening:

> Usually, the people that have come to [clinic 1] for PrEP screening are people that…do come in often for STI screening. So, when they come in I start a conversation with them about what do they know about PrEP? Have they heard about PrEP?...I don't have a printout of questions that I make them fill out, but I just ask questions out of my head like, 'What…are some of the risk behaviors that you are involved in?' I ask them, 'How…often are you having sex unprotected? Is your partner HIV positive? What do you know about your past sexual partners?'… So, this

> is just a conversation. Like when you go to your doctor's office for your annual check-up somebody will have a conversation with you. That's what I do with them, but we actually don't have a questionnaire…that we can actually attach onto people's profile…So we're actually coming up with a questionnaire that will be on paper [so] we can actually have a record of people.

Participant 1.1 shared that once the medical assistant refers a patient to the provider, he takes a social history using a questionnaire built into the electronic health record. The questionnaire includes sociodemographic questions as well as questions assessing HIV risk (e.g., Sexually active? Sexual partner has HIV? History of inconsistent/no condom use?). When asked about whether clinic 1 uses the 1509 intake form, Participant 1.1 clarified "I want to say we used that [the 1509 intake form] as the template when we built that [the social history questionnaire]." In addition to developing a questionnaire specific to PrEP screening, Participant 1.2 also explained that clinic 1 was in the process of developing a protocol to conduct screening in the field:

> I'm the only one that do PrEP right now, as I'm attached with the clinic… however I just had a conversation with our outreach team…So right now when they go out in the community not only are they doing HIV testing but they're going to be talking to people about PrEP so we're trying to come up with a protocol on how they can get people outside to come in. What is the steps that they have to go through? Let's say for instance if they go out in the community and they find somebody that's interested in PrEP how do they go by to bring them? What is the process? So that's something that we're trying to come up with and let them know, 'Okay this is what they need to come in, this is how you do it' and that kind of stuff. So, we're all working on that.

Participant 1.3 explained how HIV testing is conducted in the field and the clinic by members of the Linkage to Care Department and how PrEP education is currently integrated:

> To screen someone for PrEP basically… means to provide a HIV screening… here at [clinic 1], HIV screening and what we call HERR, which is Health Education Risk Reduction, goes hand and hand….So we like to educate and empower the individual… and then we move into the screening… we use what's called an EIS

> form, which is Early Intervention Services, and that form basically [asks]… when and if you are sexually active. What type of sex are you having? Or who are you having sex with? Is this a man who sleeps with a man? If it's a person who considers themselves or identifies as bi-sexual…? The whole mission is for us to identify the type of sex that's being had, so that it would allow us to better counsel the individual on a more customized basis…

PrEP need

Figure 16a depicts the PrEP continuum for clinic 1 as of March 2019. Of the 22 persons screened for PrEP at clinic 1, 9 (41%) were determined to be in need of PrEP. The determination of PrEP need at clinic 1 is largely driven by the patients' perceived risk and interest. Participant 1.2 expounds:

> So, I usually don't tell people that 'Hey you are eligible because you're gay or you're this or that.'…I go into details by educating them, giving them information about PrEP and at that point somebody can say, 'Oh I'm interested, how do I do it?' So, these are patients that actually…say '…Okay because of my high-risk life I just feel like I need extra support…'… Another person can say, 'Okay, I'm a go think about it and come back.'… I think maybe three out of five might say I want to go home and think about it. And then it's so funny that the ones that go home and think about it they end up coming back again and say that 'Okay I'm ready, I want to make an appointment.'

When asked about specific behaviors that might trigger a determination of PrEP need while conducting the screening, Participant 1.2 shared:

> …people that are sleeping around with anybody not knowing the person's past history. People that do these sex parties and all that anybody that…. Sex workers for instance you don't know who you are coming across. And if that is the kind of behavior that you are in it would be better for you to protect yourself from HIV because you don't know who you are getting in contact with.

Participant 1.2 also clarified that she would not discourage someone who didn't have high-risk behaviors from using PrEP:

> I mean…let's say for instance if someone has a headache and they want to take Tylenol, you can't tell them not to take Tylenol. So, if somebody comes in and…they only have one partner and they still want to get on PrEP I don't have any reason for telling them, "No you can't do it."…So sometimes you have to let patients make their own decisions.

Participant 1.3 equally emphasized that clinic 1 did not use a list of specific behaviors to determine PrEP need:

> Not a set list…because we deal with everything from a holistic approach. And so, with that in mind,…it's about meeting people where they are, each case is customized… if that individual tests negative for HIV then that makes them eligible for PrEP initially…If there's multiple partners, that's what we hone in on. If there's any admission of any IV drugs use, we definitely hone in on that. If an individual is experiencing homelessness… we hone in on that. As well as sex work. When those type of things come out of the counseling with the individual, then those are the things that we pick up on…it's not written down anywhere that I can recall…like there's no check list.…

Participant 1.4 added "[this] county is number one in new [HIV] diagnoses…[it] is very bad… If you're negative we're going to inform you about PrEP."

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 1 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

<u>PrEP screening</u>

At the structural level, Participant 1.4 explained that [clinic 1]'s lack of visibility can serve as a barrier to screening:

> I kind of want to say like the location because a lot of people really don't know that we offer everything that we offer there. So, we have been getting out in the community and doing a lot more outreach…so people can get more familiar. Because

> a lot of people go to DC for everything and they don't realize that it's sitting right there in their backyard basically.

However, Participant 1.1 described how the ability to provide transportation to the clinic can help to facilitate the screening process by stating, "And the accessibility, being able to get here, the fact that we can offer transportation as we can has been a big deal…."

Participant 1.1 revealed that at the institutional level, the lack of staff who could focus specifically on the PrEP program had been a barrier to PrEP screening:

> I can say PrEP is probably the slowest thing that we've been able to do and not for lack of trying or anything. It's really been bandwidth, our ability to identify [a] PrEP coordinator that will be here and to get it done… And so being able to have more feet on the ground. It's also going to help us.

However, Participant 1.1 described how the atmosphere and appearance of the clinic help to facilitate the screening process:

> I think that the patients that we serve feel safe here…or are not shy about letting us know if they do not feel safe. And…we're in this building for a reason…When you're outside, it could look like…you're coming in here and going to the ATM machine, a lawyer's office, or whatever. So, a lot of clients have appreciated that piece.

Participant 1.2 echoed this sentiment, and explained how the nondescript building in which clinic 1 is housed helps to facilitate patient engagement with the PrEP screening process:

> …we are like a one-stop-shop…And due to that a lot of people like to come here because everything is kept I'm a say on the down-low because nobody knows your business. And [clinic 1] doesn't have anything that says, 'boom this is what they do in here,' it's more like an office building. So…that might be a reason why some people like to come here.

Participant 1.3 explained that the relatability of staff was another institutional facilitator:

> I would say that the Linkage to Care staff shows up as very, very relatable age-wise and…We look like the people that we serve….We've even hired some clients who are on the Linkage to Care team. That move…was initiated to be used as an asset

> because if we're out on the front lines, who best to tell that person who was newly diagnosed that living with HIV does not mean dying with AIDS other than a client/employee who knows that for fact and that's their reality on a daily basis…I would say…that's our greatest asset… we even have transgender individuals on our staff. So, like when we go into different communities, you can pick out someone from our team and say, 'Hey, that's just like me!' So, it makes us very relatable; it opens up conversations that are not always easy to be had.

Participant 1.1 also described the cultural competency of the staff:

> …we worked on the cultural competency piece... [the co-founder] and I both came into 1509 at a certain level, but we were also open to learning and expanding and pushing ourselves and modeling that for the staff. And so…introducing myself using pronouns and knowing when to do that. Modeling how to be humble, if you've misgendered someone inadvertently… and learning the lesson and understanding the value in understanding the seriousness of it. And…I would like to say that…we've moved leaps and bounds in terms of cultural competency and mirroring our [patients]…. It is important…that we make sure that we look like the 'who' we want to serve.

At the individual level, the biggest barrier to PrEP screening identified by staff was the lack of patient familiarity with PrEP. Participant 1.1 explained:

> … there is a lot of hesitation in this county kind of in general. In DC you could be at a bus stop and you'll see the ad for HIV and you've kind of had a conversation with a total stranger…And…the stranger ain't going to fall off the bench, right. Baltimore City, the same thing. [This] county, not so much. And so, we've really got to move the conversation. So, it does take us a little bit longer to move folks along so…kind of accepting and letting PrEP sink in. And so, I would say that the general characteristics of our population is that it takes a little, probably about two more steps longer for them to actually engage where I think that in DC and Baltimore people know about it…but we have to really talk it up…we've got to move the conversation about PrEP and just about sexual health and being sex-positive.

However, Participant 1.2 shared that patient transparency during STI screening helps to facilitate the PrEP screening process:

> …I don't think that they're not [truthful] at all. And the reason why I say that they're truthful is because sometimes they'll come in and they're like, 'I know I have this' and when you screen and…you give them a positive result they're not surprised

> 'cause it's like, 'Okay, I was expecting this.' As far as with the STI screening: 'Okay, I knew this was coming.'

Participant1.3 agreed, explaining that transparency among patients encountered in the field may require a few interactions:

> I would say probably about 75% [are transparent]. Once the initial rapport is made, I find that after the first follow up call, if the individual was not comfortable at the time of screening by that follow up call, then they're more comfortable and that leads to them being more open and truthful about the behaviors that they are experiencing or exercising.

PrEP need

No barriers or facilitators to determining PrEP need at the structural level were identified by clinic 1 staff.

At the institutional level, the staff at clinic 1 identified the lack of a standardized protocol for PrEP as a barrier to determining PrEP need. Participant 1.2 expounded:

> …we're trying to come up with some eligibility questionnaires…that can also determine who is eligible and who is not…we just want to know what everybody's standpoint is. Maybe it will let us know a person more better. Just like how when people come in to do HIV testing we ask them questions like, When was the last time you got tested? What was the result?' You know like certain questions that we ask, the same thing I feel like we can ask because I know that there's been people that's been on PrEP before and might have stopped after a couple of years and want to get back on it. But if you don't ask them you would not know that they've been on PrEP before.

Participant 1.3 shared that the organization's individualized, customized approach to PrEP eligibility and the organization's safe space helps to facilitate the process of determining PrEP need:

> The mere fact that we meet people where they are… there's nothing too big or too small for us to handle…. We actually create and hold that space for each individual that we encounter.

Participant 1.3 also explained how the personality and non-judgmental approach of the staff helps to facilitate the process of determining PrEP need:

> I think that the outgoing-ness of the team actually, it pulls people in…the skills to show up transparent really is a plus on our end. We make it very clear that we're coming from a judgment-free zone.

Participant 1.1 explained how the organization's increasing visibility and normalization of PrEP help to facilitate the process of determining PrEP need:

> Our ability to identify more people, our ability to push the conversation more, our ability to show up in…spaces, so online and real spaces too. It's really about pushing the conversation and kind of pulling stigma back.

At the individual level, the main barriers to determining PrEP need identified by clinic 1 staff were lack of PrEP knowledge, medical mistrust, and side effect concerns.

Participant 1.1 elaborated on the lack of knowledge medical mistrust among patients:

> So, I think again it has to sink in, it has to sink in because it could be… the first time they've really been able to talk about how you show up and how you have sex in a non-judgmental space and so maybe have time to sink in. [Then] there's always the part about, 'You want me to take a pill and I'm not sick? Why would I do that?' Especially for the patients who don't see themselves at risk in the first place: 'So now you want me to take a pill and I'm not sick?' And so, the distrust of that whole process…that exists in some of the patients that we come across.

Participant 1.3 corroborated the medical mistrust among patients as a barrier to determining PrEP need:

> The lack of trust…trust in PrEP…affects it a little negatively…and I can tie that to the lack of knowledge, not being able to pinpoint a person that the individual knows personally who's utilizing PrEP.

Participant 1.2 described patient concerns about side effects, stating "they'll tell you that they read about it and the side effect is kidney failure and they're not interested." Participant 1.3

echoed these concerns among patients, explaining "some have expressed being concerned of the side effects and they are a little reluctant to move forward because of that." Staff at clinic 1 did not identify any individual-level facilitators to determining PrEP need.

Clinic 2

background

Clinic 2, a non-profit organization and a Federally Qualified Health Center founded in 1983, has a main medical clinic and community center located in Northwest DC as well as an additional medical clinic, community center, and school-based program located in Southern Maryland. The main location is a tan building on a residential street that includes a church, school, and community center. Clinic 2 providers a range of primary care, mental health, and substance use services as well as health promotion, reproductive health, sexual health, and LGBTQ health services. Participant 2.1, a Program Manager, elaborates:

> …So [clinic 2] has been around like I think for thirty-five years. It started…as a volunteer organization providing services. It opened because of overall migration waves from Central America due to earthquakes and the wars that happened years ago….Currently, we have five sites. The main one is here in DC. We also have another clinical site in [Southern] Maryland…And also we have three community centers, so we have one that's…located in [Northwest DC]…a [LGBTQ health] program…that takes place for the LGBTQ Latinx community. We also have a community-based program in a school in [Southern Maryland]…. That program basically provides services to…newly arrived youth. And also, we have another [LGBTQ health program] site in [Southern Maryland] that also has support groups and activities, HIV testing, STI testing for the LGBTQ community [and] also serves as a safe space. So … it's easier to understand [clinic 2] as divided as two: so, we have the clinical services and the community services.

Participant 2.2, the Chief Medical Officer, defines the mission of the organization:

> Our mission is to provide culturally appropriate medical services… to our patients without regard to ability to pay and are focus historically is on…the immigrant community from Central America. Although…we have other types of patients…our strength is culturally appropriate services for that population.

Participant 2.2 goes on to describe the clinical staff at the main medical site in Northwest DC as well as the staff at the community center in Northwest DC:

> The clinical staff…there are three family physicians, three internal medicine providers… two family nurse practitioners… one volunteer pediatrician, part-time…. Our ages are variable … ranging from 32 to 53…And the training is mostly as I said, family medicine or internal medicine, and some of us have additional experience treating HIV… so there's some familiarity with the medications used for PrEP…. And then aside from the clinical staff, we have a community-focused part of the agency which is focused on HIV prevention in the community. They do a lot of screening tests, rapid testing for HIV and also STI's and the focus is on the Latinx immigrant community…They're…mostly native Spanish speakers, but some are U.S.-born, non-Latinx. They're mostly men, but there are…some women. And they are overall younger than the clinical staff. Some are in their 20's, 30's.

Participant 2.3, a former Health Impact Specialist, added:

> I think in the [Maryland] site, I was the only trans-woman or trans-person in general…in that time… But after I left I think they hired a non-binary interpreter and… in DC also in the LGBT health program, they have a trans-woman as well. So, I will say they only have…in the entire organization a hundred and something people, they had just one trans person…they need to hire more.

Regarding the patients served by clinic 2, Participant 2.1 explained:

> Well, I can fairly say that 90% of people we serve here at [clinic 2] it's Latinx community, low income Latinx, so monolingual as well. So, most of our clients do not speak English. In terms of age, I think it's all across the board. As I was mentioning, we have a sexual health team, that's the one I oversee. And basically, we see all the community; we are not focused on just one area of the community. But…the other program we have, that is the LGBTQ health program…is more focused or geared towards youth, LGBTQ youth... We here at sexual health we see basically everyone in the community. I would say like sixty percent [of PrEP patients] is part of the LGBTQ community and maybe forty, general [heterosexual] Latinx population.

Participant 2.2 elaborated by describing the clients seen by the clinical staff:

> We serve approximately 4000 individual patients… Mostly younger, Latinx immigrants, and I would say it's… mostly 20 to 30… A lot of them are recent immigrants…Most are male; a handful are female. And in terms of their, like, income level, I would say…the vast majority of our clients are under 200% of the federal poverty limit… And most are either uninsured or have some type of public assistance, insurance like the DC alliance or on Medicaid.

Participant 2.1 also described the motivation of the organization to participate in the demonstration project:

> …basically, to expand our services, also this project was a great opportunity to build infrastructure around our PrEP services, HIV testing, sexual health, and also substance use. So, it was a great opportunity and platform for us to provide the services but not only one program....So, it helped a lot to synchronize both programs in terms of services and protocols and the manner in which we provide PrEP services and HIV testing. So basically, it enhanced all our services across the board, not only in one program but in the whole department of community services.

Participant 2.2 commented on the impact of clinic 2's participation in the project on PrEP access specifically:

> …well, it's a focus, you know nationwide and worldwide, preventing new infections. And the…community health… team has always been focused on that. And we have had…issues with access to care. We've seen patients that were interested in PrEP but couldn't get the medical appointment right away, [and] they ended up with HIV. So, it's been a priority lately to try to reduce the barriers to starting…patients on PrEP as quickly as possible.

Knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

As Participant 2.1 explained, the staff at clinic 2 were aware that "…basically this [project] is for MSM and the transgender community of color" and that they were

encouraged to use the intake form provided by the project team to screen for PrEP.

Participant 2.2 added:

> …I think we're involved in more than one initiative or funding streams that focuses on PrEP [but] I guess the focus [of this project] is on identifying high risk negative patients and navigating them to medical care so they can be [given] PrEP and diagnosing HIV as quickly as possible to…[prevent] new infections.

PrEP need

When asked about the project's recommended process for determining PrEP need, Participant 2.1 explained that certain risk behaviors indicate PrEP eligibility:

> So basically, if we for example test a person and it is negative…[and] if we perceive it's a high risk for HIV. So that could be either multiple partners, having unprotected sex, discordant couples, anal sex with a transgender woman, etcetera. So, if we perceived there's a high risk.

Participant 2.2 added:

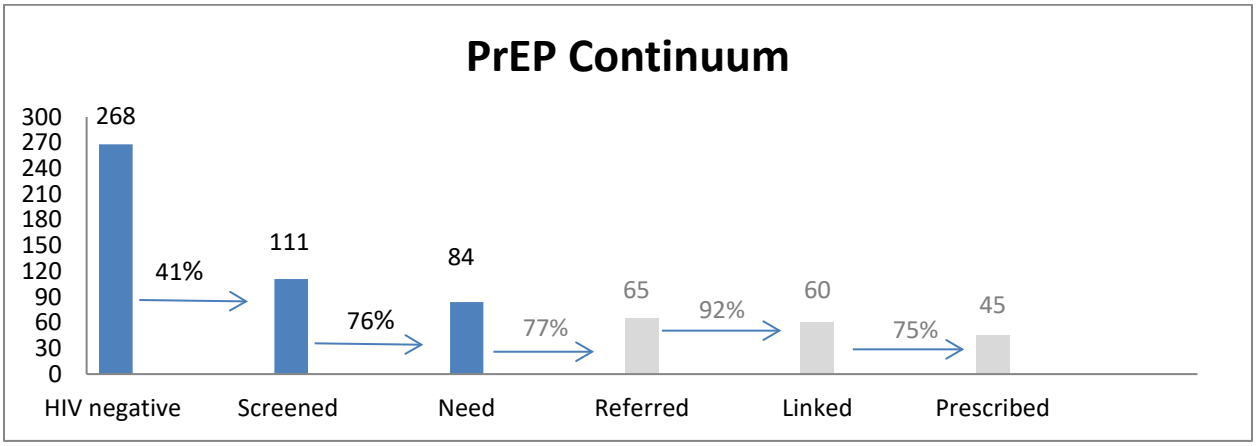
> Well… I don't have the project definition but I would assume it was individuals who have had a documented STI, who have sex without condoms and potentially will have an HIV positive partner or possible contact with people with unknown HIV status.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16b depicts the PrEP continuum for clinic 2 as of March 2019. Of the 268 HIV-negative persons enrolled in the project at clinic 2, 111 (41%) were screened for PrEP.

Figure 16b. *Clinic 2 PrEP Continuum through March 2019*



PrEP screening conducted by the community health team is done in conjunction with HIV testing and involves the use of both the project's intake form and an internal HIV risk assessment. Participant 2.1 expounded:

> We have risk assessments and we fill out every time we do HIV testing or counseling, we do risk assessments. And for example, if people qualify for the Impact DMV Project we use the documentation they provide us, that is pretty similar… So, we have an intake form provided by DOH which helps us guide our conversation with our clients…. We are using it exactly as they gave us although it is kind of challenging sometimes and lengthy but yeah we use it as it is… We have just the English form but all of our health educators and testers are bilingual, so they do the translation at the moment… And so, we make the risk assessment which includes questions about their sexual practices…multiple partners questions, unprotected sex, discordant couples.

Participant 2.2 explained that the clinical team lacked a standard approach to screening for PrEP:

> So, I think that from the perspective of the community health…team… they may feel that their role is do the screening and navigate the patients to medical care… what's lacking in the clinical team is a standard approach to screening and risk assessment… I think that…would be a goal…to have that at the point of care in the electronic record to prompt certain questions… we have a standard… medical intake questionnaire but I think that's not enough…my impression is that [the providers

> are]…targeting patients that they believe are at risk with certain questions. I may be wrong, but I think that as a clinician there can be a tendency to not ask questions of people you… may assume are not at risk, like about the sexual activity…Because I don't know exactly what providers are asking…patients and with what frequency… So, I do believe that we could be better about asking about sexual practices in general… We're a small practice…we don't have a formal clinical protocol. And so, we're developing a clinical protocol for…PrEP… What I have so far is…based on the CDC guidelines for PrEP. You know, the clinical indications and recommendations.

PrEP need

Figure 16b depicts the PrEP continuum for clinic 2 as of March 2019. Of the 111 persons screened for PrEP, 84 (76%) were determined to be in need of PrEP. At clinic 2, PrEP need is determined by the community health team based on responses to the risk assessments utilized during HIV testing. Participant 2.1 explained:

> …because of the risk assessments, if we perceive the client has a risk just only once then he's eligible for PrEP… so that [would] be drug use, recent STI, multiple partners, unprotected sex, sex with HIV positive partner or unknown partner…. And also, we always, if the client's negative, we always try to inform them about PrEP regardless of their risk because it's an option they have…. And based on that we inform people about their PrEP eligibility and how they can access it and that we could help access the PrEP medication…. If the client is a patient of [clinic 2] the provider can prescribe the PrEP. But if they are not clients of [clinic 2] what we do is we have a good relationship with the people at [clinic 8] and then we refer directly to them.

Participant 2.3 agreed that PrEP was discussed with anyone whose HIV test result was negative:

"and if they do the test, and it was negative…they were candidates [for] the PREP talk."

Much like the PrEP screening process, Participant 2.2 shared that there was no standard approach for determining PrEP need utilized by the clinical team:

> I guess we all just do it based on our clinical judgment. You know, someone who's had STI's or has had… unprotected sex and is MSM or transgender. Those are

> potential flags for risk that might prompt a recommendation for PrEP… contact with sex workers is another risk flag that I didn't mention. And then… sexual activity while under the influence of alcohol or drugs.

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 2 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

No barriers to PrEP screening were identified by staff at clinic 2 at the structural level. Participant 2.1 explained that clinic 2's affordable services help to facilitate the PrEP screening process:

> And also, I think that is something that helps eliminate the barriers to either testing, PrEP, and sexual healthcare overall… All of our community services are actually non-billable, so all of them are free. Any navigation service we do, any counseling service, any testing services, they are non-billable. So, the way we provide this it's through grants and our fee-for-service model from the DOH…so we can provide our services at no cost.

Participant 2.3 added that the clinic was transit-accessible, which helps to facilitate the screening process stating, "And it's not far from the Metro Station in DC or [MD]… like…it's very accessible."

At the institutional level, the internal processes of clinic 2 were identified as a barrier to PrEP screening. Participant 2.2 explained that lack of time and a lack of accommodating services on the clinical side may serve as a barrier to PrEP screening:

> On the medical side we are a family practice, we…focus on, you know, multiple different…chronic diseases and other things, so sometimes there's lack of time during a routine visit to discuss… in detail people's sexual history and risk factors if it

> doesn't come up spontaneously…. I guess [another] barrier there is that since [the medical intake questionnaire] is an electronic questionnaire and since some of the patients have challenges with technology or they have a language barrier…typically our staff fill it out with them. And so that's another thing,…[the] space where a lot of people are doing [the] intake is not necessarily that quiet or as private as we would like. We can't expect I think to get a lot of information specific to PrEP…on the medical intake questionnaire.

Regarding staff, Participant 2.2 explained how the beliefs and biases among the clinical staff may serve as a barrier to PrEP screening:

> One might be attitudes about sexual behavior or…reticence about asking in detail about sexual practices. And among the support staff, there are some people who for personal or religious reasons…weren't asking questions about behavior. That's something we've tried to address upon through training and discussions with the entire clinic staff you know. Attitudes about people who are transgender, potential sort of just systemic discrimination or homophobia, transphobia that may not be overt…but it's sort of there, you know. There's also…in the culture in general in Latin America, Central America, you know… there's a lot of … importance of religion, Christianity and people brought up with beliefs about sexual behavior or homosexuality and so…you know, a lot of the staff are from the community as well, so.

Participant 2.3 also mentioned that while the staff are all Latino and Spanish speaking, most of the staff are cisgender men and women who are not familiar with the sexual behaviors of transgender women:

> Like everyone else out there [clinic 2] doesn't have a trans staff; they don't know how to screen or interact with trans community, especially with trans women. Because…in the screening we ask questions like 'Have you had sex?' and like it's difficult…[because] normally only men penetrate…But when a trans person comes to the office and there's a cis-male or a cis-person doing the screening and a trans-woman says 'Well I penetrated a few clients and I think that maybe I'm at risk' they [are] just shocked by that statement. And they're like 'But you're trans; and you're a woman, so what are you doing then?!' All the judgment [comes] out… and that's a real thing…a barrier not only…with [clinic 2], but overall. Unless they have…a trans health promoter or you have…staff that…reflect the community… that way we feel comfortable to come to you to do the screening and they will have the proper

> services… So many trans women just go away because they are ashamed to say whatever they have to say to get PREP… many people have moved to another clinic. Even when the language barrier exists, they are willing to go to another service because they don't know how to treat trans-women.

While the internal clinical processes were cited as a barrier to the PrEP screening process, Participant 2.1 stated that the culturally competent and convenient services provided by the community health team help facilitate the PrEP screening:

> I think in terms of [clinic 2] something that could be positive is…we provide cultural appropriate care. That means talking to clients in Spanish…. Also…our services are walk-in services…. They don't need to make an appointment; they don't need to talk with anyone they can just come in and see us.

Participant 2.1 explained how the relatability of staff in other ways, their training, and non-judgmental approach help to facilitate PrEP screening:

> Also, our health educators they come from the community so they are trusted people around the community. I also think that something positive is that of course we have trained our health educators to provide this risk assessment and acknowledging to clients, that is not always easy and we know it's not easy to talk about this topic, specifically in the Latin community. But just acknowledging that and being open and not judgmental with clients I think is one of our biggest skills we have with our community.

At the individual level, Participant 2.2 shared that the medical mistrust patients feel when speaking with certain medical providers and internalized homophobia and transphobia can hinder the PrEP screening process:

> Let's just say someone's whose MSM or transgender, was not confident necessarily that they could go to any provider… and feel accepted or… you know… [that] they won't be judged. They weren't necessarily comfortable talking about this. A lot of people would be closed about their sexuality… not open about their sexual practices…. Yeah, medical mistrust and just general… stigma they feel…. You know, not everybody is open about…their sexual orientation or gender identity and they

> may be reticent to reveal that to a medical provider unless they…[feel] comfort and confident that it's a friendly place for them… that it's an accepting environment. And sometimes they get clues from the, you know, from the first contact on the phone or… when they come in… they get the feeling that [this is] not the kind of place that they want to be open.

However, Participant 2.2 went on to explain how the high level of PrEP awareness among patients can help to facilitate screening:

> There's a lot of awareness of PrEP availability. We get patients now who ask about it, who say that they're interested in it, they've heard about it and…. I think people in the community are talking about [it]. There's the media, there's advertisements… for PREP medication on TV. So, there's quite a bit of awareness, and now there are people who are soliciting PrEP…and…in general, and there's a lot of word of mouth in the community. A lot people talk about it, people know about it, in… MSM and transgender, Latinx community, I think everybody, pretty much knows about it.

PrEP need

No structural barriers to determining PrEP need were identified by staff at clinic 2. When asked about facilitators, Participant 2.1 referred back to the ability of patients to access services at no cost.

At the institutional level, Participant 2.2 explained that the "lack of a standard…approach" poses a barrier to determining PrEP need. In reference to staff, Participant 2.2 again described how the beliefs and attitudes of bias among the clinical staff can hinder the process of determining PrEP need:

> There may be pre-existing beliefs and attitudes… about sexual activity, sexual behavior, and reluctance to probe routinely…about, you know, questions about sexual practices.

When asked about facilitators to the process of determining PrEP need at the institutional level, Participant 2.1 referred back to the provision of culturally appropriate care. Participant

2.1, again, also explained that the ongoing training of staff serves as a facilitator to determining PrEP need:

> We have regular trainings that are not only for the community services but the clinical services. We have trainings that both staff are part of. And actually, the last one we had was around sexual health and PrEP. So…we try to enhance not only one factor of the services we have but all of them. So, it's constant training to [both] clinical and community services. And I think that has helped a lot doing those, actually determining and being confident and feel good doing…with our clients.

At the individual level, side effect concerns, PrEP stigma, and pill burden were the most common barriers to determining PrEP need identified by staff. Participant 2.1 explained:

> So, I think the side effects are something people are concerned about. And also, another thing we have seen is that for example many of our clients they live with multiple people or they share a house or they are couch surfing. So, they are afraid of people or roommates or whoever they live with to find out about their taking PrEP. So, they are afraid and they kind of try to hide their medication, and if there is a pill they need to take every day is a challenge also for them.

Participant 2.3 echoed those sentiments:

> I think the…trans community and not having all the questions answered can be an issue. 'Is it something that'll affect my hormone treatment while I'm taking PREP?'…that's not studied about PREP and hormone interaction…. Yeah, there's a lot of stigma around PREP. So, people might… hide the medication…for their partner… finds out… or other social determinants, like use of alcohol, like 'Oh, I drink too much today… I was not able to take a pill'… [or] when people who are using other substance, they forget to take a pill.

Participant 2.2 discussed how positive perceptions of PrEP can facilitate the process of determining PrEP need:

> I think… there's an issue with you know, condom use or not wanting to use condoms during sex. So… it's seen as a positive for that reason, you know, fortunately or unfortunately. Because the patients are thinking 'Okay, if we're taking PREP, we

> don't have to use condoms….' And so, I think patients in the community have heard that this is kind of like… a good thing…condoms are seen as a downer.

Clinic 3

background

Clinic 3 is a non-profit health clinic founded in 1988 under a different name and is located on the seventh floor of an office building in Northwest DC. Clinic 3 provides primary care, behavioral health, and nutrition services in addition to PrEP. The mission and vision of clinic 3 are to "build healthier communities… by providing high-quality health services." Participant 3.1, a Manager, added:

> We started as an [AIDS Service Organization] ASO in the eighties and we've gone through a couple different periods of change…we also became a primary care medical home…Our mission statement or vision entails seeing to the holistic care of the individual which includes… removal of barriers to care for food, clothing, shelter, helping connect to dental care, and mental health and other behavioral services. So, we also provide support groups and a lot of referral and linkage… often through nonmedical case management but often through other programs like IMPACT which has that focus on… the MSM and transgender populations of color in DC…. [clinic 3] has two different locations. Our main location which is here [in Northwest DC] where the majority of the staff is….[and] our other location which is located [in SE DC].

Participant 3.2, an Outreach Specialist, stated "our outreach department, we go out into the community to several locations and do HIV testing and screening." Participant 3.1 described the staff at clinic 3 by saying:

> So, in general… we have one employee who would be considered not of color. The majority of the people who work here are African American or Black…. So, we have… some people are Black from DC and then some people are Black not even from the country. So, we have a good mix of the 'of color' population. So [the] outreach team…we have two Black MSM…one…. That runs sort of the outreach team and then another one that provides more direct services. We also have a transgender individual, male to female…she does the majority of the direct services

> with IMPACT clients. But we also have a cisgender female…she does some IMPACT work but she really does more nonmedical. And we also have two other individuals who mostly do psychosocial groups.

Participant 3.3, a Coordinator, described the patients receiving HIV prevention services from the outreach team, stating "…most of those are roughly are in their twenties, thirties, yes they're around that age. The gender breakdown is more male, MSM…Mostly all African American…." Participant 3.1 added, "the majority of the clients that my team deals with are…of color and probably eighty percent of them fall somewhere under the non-heteronormative umbrella."

When asked what motivated the organization to participate in the demonstration project, Participant 3.1 shared:

> The project…was a no brainer for me. Once it was announced, I knew that it was vital for us to get involved with, because [of] the proven methods to ensure linkages to prevention and treatment.

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

When asked about the project's recommended process for PrEP screening Participant 3.1 responded, "So we were actually given an intake form for the Impact Project and we were told that that could serve as our risk assessment." Participant 3.1 also commented on support for PrEP screening provided by the project:

> That was a PowerPoint training. And they talked about the whole IMPACT program and things of that nature. And the screening process, and PrEP and the different types of, they referred to it as "treatment as prevention." And that was really good, the training with the DOH was really good.

PrEP need

When asked about the project's eligibility criteria for PrEP, Participant 3.1 explained:

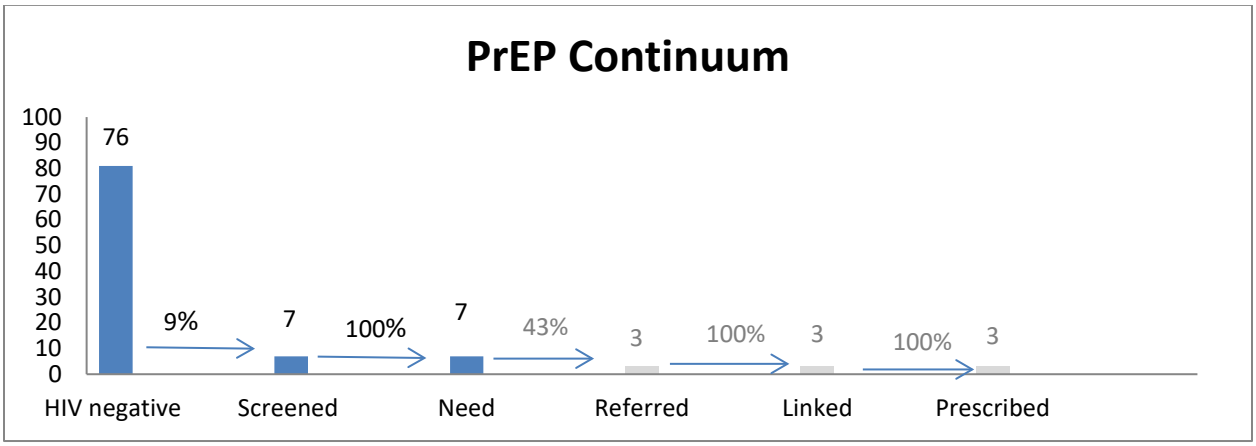
> They need to be sexually active and they need to be HIV negative and they need to be…at risk for contracting HIV…that's kind of a broad umbrella…. I'm not sure if I know the exact parameters that IMPACT DMV is using.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16c depicts the PrEP continuum for clinic 3 as of March 2019. Of the 76 HIV-negative persons enrolled in the project at clinic 3, 7 (9%) were screened for PrEP.

Figure 16c. *Clinic 3 PrEP Continuum through March 2019*



PrEP screening at clinic 3 entails using a modified version of the project's intake form and an internal HIV testing form. Participant 3.1 explained:

> So, we've been using that [intake form] on intake and periodically thereafter to determine the need for PrEP. So…we sort of ascribed a point value to the things that are on the list…. So, we do have another risk assessment form that we use…we often do HIV screening in conjunction with risk assessment so we collect information on… both forms…. So, we have a mobile unit that we use for [HIV] screening and when we come across people who fit the target population for IMPACT then we'll add in that IMPACT form to do as well because it doubles as an IMPACT enrollment form.

The HIV testing form asks about the number of sexual partners, past STIs, receptive and insertive condomless sex, sex with someone living with HIV, injection drug use, and sex under the influence of alcohol and drugs. Participant 3.1 explained that HIV testing and PrEP screening mostly happen in the field:

> We have a mobile unit that has two small rooms in it so that's one of the places that we do it. There are several places where we go to that have like either an apartment building or a small…community room…sometimes we do presentations on the science of HIV and how it works and what things you need to avoid contracting it and then we'll offer screenings after that. Or we just go to a place and set up and offer screenings. So, when we do the setup and offer screenings we do the HIV and PrEP education, but it's like a one-on-one basis as opposed to telling everybody in the town.

Participants 3.1, 3.2, and 3.3 are primarily responsible for PrEP screening at clinic 3, however, Participant 1 clarified "although the vast majority of them are done by [Participant 3.3]. She does a lot of the direct services…." Participant 3.2 discussed the length of time associated with conducting the screening:

> …probably about a good ten to fifteen minutes because… some clients may have a lot of questions… and most people don't know what PREP is, so I have to explain. And then the others, they're knowledgeable of PREP and they're just like 'ok.'

PrEP need

Figure 16c depicts the PrEP continuum for clinic 3 as of March 2019. All of the 7 persons screened for PrEP were determined to be in need of PrEP. PrEP need at clinic 3 is determined in several ways. For example, responses to questions on the project's intake form are given a point value and a higher score indicates a need for PrEP. However, clinic 3 also takes a broader approach to determining PrEP need. Participant 3.1 explained:

> If you've reached a certain point value then we would recommend PrEP to you. One thing that we've unofficially sort of been doing is looking at the overall numbers for the city and applying that as a concept to inform our PrEP recommendations....Because…the lifetime risk of contracting HIV for MSM of color in the District of Columbia is like one in two. The recommendation is always that, from our perspective, if you're not positive we're going to recommend that you get on PrEP if you are a sexually active MSM individual or transgender individual.

Participant 3.3 elaborated on the types of behaviors that would lead to an elevated score:

> If you're Black and live in DC, your sexual orientation, if you use drugs or alcohol, if you're homeless. And your sexual practices: if you have multiple sex partners in a year or if you inject needles, anything of that nature.

Participant 3.3 also clarified that someone at 'low risk' risk for HIV would not be turned away:

> I have had, like, clients that [say] 'Oh hey, I'm married but still interested in it' and I'm like 'Okay, absolutely!' And I sign them up!

Because Participants 3.1, 3.2 3.3 are primarily responsible for screening clients for PrEP, they are also primarily responsible for determining PrEP need. In reference to how long it takes to determine PrEP need, Participant 3.3 shared "Once you get the factors…after one minute…I'm like 'yeah PrEP, you need PrEP.' So, one minute is sufficient."

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 3 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

At the structural level, Participant 3.1 described the inaccessibility of clinic 3 to some DC residents as a barrier to PrEP screening:

> So, it would be helpful if we had a brick-and-mortar location that was in Ward 7 and 8 because that's where the epidemic has the most hold…. We do have a mobile unit…but not being there any time, all the time is less effective than if we were…. So, it would be helpful to be more entrenched in Wards 7 and 8 but we're working on it.

No facilitators to PrEP screening were identified by staff at clinic 3 at the structural level.

At the institutional level, Participant 3.3 described the atmosphere of clinic 3 as a barrier to the screening process:

> Yes, the location is a bit posh; it's a bit bourgeoisie…and so with the clients that we deal with, the population that we deal with, it is a deterrent, it is…. When I say bourgeoisie and posh, I'm speaking about a lot of Caucasian clients that come in, you know just, it's not the same demographic. So sometimes when you go into an atmosphere like that sometimes you might have a moment or you feel like you have to keep up appearances. So, anything that would be leaning towards something negative a lot of people don't share it because like 'Oh, I'm supposed to look good in this environment so I don't want to make myself look bad so I won't share this information.'

Participant 3.1 commented on the prior negative experiences that patients have had with the clinical staff and the differences that patients perceived between the clinical and outreach teams:

> I will say that we have recently had some patients mention that while they engage in some of the outreach-related services like support groups and health literacy groups, they don't engage with the clinical team for various reasons relating to their previous engagements with the clinical team… So, there's…a perceived difference between the interactions with one side of the house and another side of the house.

However, Participant 3.1 also explained how the use of the social networking strategy (SNS) model to reach people and incentivizing the screening helps to facilitate the screening process at the institutional level:

> When I first came to manage this IMPACT program…we had three people enrolled. So, I created an SNS program where I would find people in the community… And it's got to be somebody that fits the bill of the CDC's…popular opinion leader. So, I bring them in and train them…and then send them into the field…. So just being able to use the SNS model and sending people out into the field to work on screening…first their peer network and then the peer networks that are offshoots…. that grew our IMPACT population very quickly from three to a hundred and seventy-three in about two maybe three months…. It's [also] helpful that the initial intake…we incentivize that survey so we really haven't had pushback on that at all.

Participant 3.1 spoke to the relatability and skillset of the staff as a facilitator to the PrEP screening process:

> It's helpful that we have people on our staff that reflect the population to whom we are speaking. So, I make sure that we have both transgender and MSM individuals on the team, kind of at all times…Um, we also have a mix of people that are skilled in talking to different populations. So, like we have members who are really great at speaking to people whose social environment is deeply entrenched in deep Southeast…And then we have people who are able to effectively communicate with people in other areas of DC. So, I think that we have a good solid mix of relatable people almost no matter who you are or from where you're coming in DC.

At the individual level, Participant 3.1 explained that the lack of transparency among patients can serve as an initial barrier to the PrEP screening process:

> We have had—and this may speak to the incentivization not necessarily being the best way to do it—but we've had people that we initially engage with the intake [who] give us one answer and then later give us another answer. So, we may not be

> getting upfront the exact right information…people are just giving us something to be quick but then we continue to engage so we always get to that other answer.

Participant 3.3 agreed that patients "eventually warm up" to the screening process which serves as a facilitator.

PrEP need

No barriers or facilitators to determining PrEP were identified by staff at clinic 3 at the structural level.

When asked if there were any barriers to determining PrEP need at the institutional level, Participant 3.3 responded "no." When asked if there was buy-in from the organization regarding the broad PrEP eligibility criteria, Participant 3.1 responded affirmatively.

At the individual level, side effect concerns and lack of information among patients were the most commonly identified barriers to determining PrEP need. Participant 3.1 commented on the lack of knowledge:

> There are a lot of misconceptions about PrEP that have been circulating… So, there are some misunderstandings about what…PrEP is for and no matter how much we tell them and show and explain, some people are dead set on believing what they've heard from the community... Some people think that PrEP is for people who are positive. And after they say that whatever I say out my mouth they're not hearing. And the answer could be 'I don't need it; I don't even have sex like that.' Or 'I'm not positive' or 'I don't have HIV so I don't need it…' So, it's the historical thing about like people are used to hearing Prezista®, Truvada®, Norvir® like as a part of a [HIV] regimen… So that's the misunderstanding.

Participant 3.3 commented on the side effect concerns that patients have:

> I have asked a few patients, like 'Okay I see that they're thinking about it. So, I just want to know, like what are your concerns?' And they're like '…does it actually work? And what are the side effects?'

Staff at clinic 3 did not identify any individual-level facilitators to determining PrEP need.

Clinic 4

background

Clinic 4 is a primary care clinic that was founded in 1988, has 7 locations across Northern Virginia, and is the largest provider of HIV care in that area. Clinic 4 offers clinical services (e.g., medical services, mental health services, and support groups), education services (e.g., workshops, seminars, and training sessions for healthcare providers), and prevention programs (e.g., HIV testing, community outreach, and PrEP and PEP). Participant 4.3, a Health Educator, expounded:

> So, we're part of…a large health and…hospital system…in Northern Virginia so we are the dedicated HIV clinic within that…. We have seven different sites across Northern Virginia, so seven different offices. And we serve folks who are primarily HIV positive so we provide their primary care, their medical care, all of that stuff for folks who are HIV positive. We also provide prevention services so…PrEP,…PEP, we offer HIV testing and then…we provide education outreach and all of those things as well.

One specific prevention program within clinic 4, located on the 2nd floor of a large brick office building within a large office complex, focuses on MSM. Participant 4.1, a Program Manager, explained:

> Our organization was founded in 2012 and…was basically created to provide a safe space for gay and bisexual men of color between the ages of eighteen and thirty-four to…receive education of all the…biomedical and behavioral interventions for HIV… We also give the guys education on how to navigate relationships, how to navigate dating, a safe place to talk about familial connections, the coming out experience…. Because the main goal is to make sure that we are empowering the gentlemen that come into this space, that they come in one way but leave a whole lot better. And then of course solidify those relationships through…volunteer opportunities…so that they, in turn, can go back out to the community, disseminate the education that they've

> learned through us as well as bring in…more of their friends to be a part of the project itself… [a] networking structure… We've also had [clinic 4] employees to attend some of our functions because one thing that…we try to facilitate with our program, is…making that relationship visible to the community…that [clinic 4] [and this program]…works together…[to] affirm LGBT specifically…Queer folks of color. We want to put that messaging out there. So, having folks from [clinic 4] come to a few of our events even facilitate a few of our events has been very helpful over the years.

Regarding staff at clinic 4, Participant 4.2 described the diversity of providers who provide clinical services to PrEP patients:

> [Clinic 4] has a dedicated team of providers who could see those [PrEP] patients regularly for appointments. We have about five providers right now …we have a team of nurse case managers and we have therapy and we have our education and prevention team…here on site at the main location…Our providers come from different backgrounds. We have a provider from Asia, a…middle-aged female. We have a provider that's from Africa, another middle-aged female. We have a provider that is from here in the United States, [a] middle-aged female [who] lived in different parts of the country. A middle-aged Black female from California. We have another nurse practitioner, fairly young, early thirties, White female. And another provider, a middle-age…Hispanic female. So, they're all female; all of our providers, and nurse practitioners, and PAs. But we do have the physicians who oversee them. And it's two White females, one White male, and one Middle Eastern male. And as far as our nurse case managers they vary because sometimes we have traveling nurse case managers who come in…for the most part the ones that are permanent; we have one she is from Africa, the middle-aged female. We have another one here born in America, White middle-aged female. And we have another one, Hispanic female, middle age. Those are the permanent ones.

Participant 4.1 described the volunteers who help run the prevention program for MSM:

> For our…group of volunteers… in 2019 we had twelve consistent…members who came to meetings every week to help plan, facilitate a lot of the events that we did as well as our outreach efforts…. And we try to target those popular opinion leaders within the community, those folks who know folks that know them and respect them…. So, most of our…members fall within the age range of…twenty-two…[to] thirty-three…. We have one…member who's originally from Mozambique in Africa so he brings a whole new perspective to what it means to be Black and Gay in America although he's from Africa. We have a couple of…members who identify as

> non-binary so that perspective is now in the space. And we have another…member who's androgynous in terms of their dress and how they express themselves. And then we have some gentlemen who are…just like the average every-day Joe that you would meet walking down the street…. So, it's very diverse in terms of the make-up and I think…that was one of the goals....We want to be able to make sure that our group represents the community as a whole. Because one thing we want to eliminate is the idea of there being a monolith of Black gay men.

Regarding patients at clinic 4, Participant 4.3 stated "from our HIV testing I can tell you that we seem to be testing more men who have sex with men and that is one of our target demographics for our testing grant." Regarding patients participating in the PrEP program at clinic 4, Participant 4.2 stated:

> Most of our patients are Hispanic. And we have some who are Hispanic that are born here in the states and some who are immigrants. We have a few that are of different nationalities and races. So, we see about, I would say overall in the PrEP program we have about, I would say it's about seventy percent Hispanic…it's about fifty-fifty: we have a portion of them that do speak English and we have a portion of them that do only speak Spanish so we have our interpreter services for that.

Participant 4.1 described the participants in the prevention program that he oversees:

> We've reached since 2012 nearly six hundred plus individuals…the majority of folks who come to our space have been gay bisexual men of color…between the ages of eighteen and thirty-four because…that's the age range where HIV is most prevalent in that community…. Through our outreach efforts, we've reached so many different folks who are intrigued by our programming, one community being the Trans community… They've actually lead conversations in our space talking about the issues that Trans women face.

Participant 4.4, a current Health Impact Specialist, described his motivation for wanting to join the project as a Health Impact Specialist:

> Well, I guess for me I've been an advocate in DC for the last past eighteen years now. I have been dealing in the field of HIV/AIDS, STI's, just being a huge advocate for the LGBTQIA plus community.

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

Data were not available for this site.

PrEP need

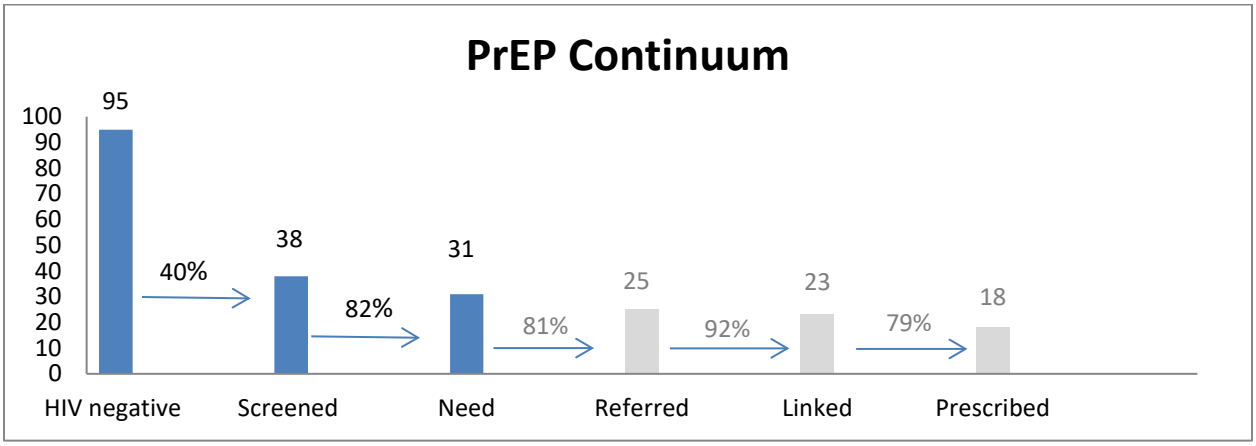
Data were not available for this site.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16d depicts the PrEP continuum for clinic 4 as of March 2019. Of the 95 HIV-negative persons enrolled in the project at clinic 4, 38 (40%) were screened for PrEP.

Figure 16d. *Clinic 4 PrEP Continuum through March 2019*



PrEP screening at clinic 4 entails using a modified version of the HIV testing form provided by the Virginia Department of Health (VDH) and a series of questions built into the electronic medical record (EMR). Participant 4.3 first described the modified HIV testing form:

> So, there are two probably broad methods. So, one would be when we do HIV testing. It's built into our questionnaire for HIV testing which comes right from the Virginia Department of Health since they are the ones funding the testing. So, we do a PrEP screening in there in which we would ask things like 'How many partners do you have?' that kind of thing. And we just evaluate, for lack of a better word, the quote-unquote risk behavior…So what our grant monitor asked us to do is create a duplicate of the form that comes from VDH. So, I was responsible for creating that form…. So, the way I've written out the form, kind of reworded it for our testers is the first thing asking the number of sexual partners that they've had in the last five years…. Then I ask them to check off male partners, female partners, partners of other genders, partners who are HIV positive, any unprotected sex. So yes, no, sometimes. Shared injection drug equipment; yes, no. Sex work; yes, no. Any STI diagnosis in the past five years, I ask them to write out what it is. So again, that mirrors the criteria that VDH has. So, it is a built-in part of the conversation we have with every single person no matter what their background is or what their sexual behaviors are like. We do ask everybody for PrEP because it's part of the grant.

Participant 4.3 went on to describe the second way that PrEP screening is conducted at clinic 4:

> Then the other way would be…we've created a Smart Phrase in our EMR…that takes a sexual history…. 'Who are your partners? Do you use protection? How many partners do you have?'… 'What kind of sex are you actually having? Are you having anal sex, oral sex, vaginal sex? If so are you having receptive anal sex?'…So the Smart Phrase kind of guides them into what questions they need to be asking.

Participant 4.1 shared that in the prevention program specific to MSM, PrEP screening is done by using the modified VDH HIV testing form as well as the project's intake form:

> There's…the traditional 900 forms that VDH has us fill out but [Participant 4.3]…drafted up kind of like a form, like an assessment form that we can actually…fill in all the different questions or information so that we can…determine

> whether the person is high risk and is eligible for PrEP…. We use [the project's intake form] as our onboarding form…. If it's the person's first time coming to a [prevention program] event we'll have them fill out [that] assessment form. Sometimes if time allows I'll go sit with them one-on-one and go over the form with them. Through that we can talk…about PrEP.

At clinic 4, PrEP screening is primarily done by Participant 4.2 or the medical providers. Participant 4.2 explained that "it usually takes about 30 minutes to get through the risk assessment. Within those 30 minutes, we are able to determine if PrEP would be beneficial for them." In the prevention program specifically for MSM, Participant 4.1 explained:

> So, the persons responsible would be…myself and…we may have our Health Impact Specialist [Participant 4.4] do it as well…. And I'll say for the Impact DMV…form…that assessment usually runs anywhere from thirty to forty-five minutes…. It's much longer and more in detail.

PrEP need

Figure 16d depicts the PrEP continuum for clinic 4 as of March 2019. Of the 38 persons screened for PrEP, 31 (82%) were determined to be in need of PrEP. At clinic 4, PrEP need is based on meeting more than one of the criteria outlined by the VDH. Participant 4.3 explained:

> So, to make it easier for testers I took all the criteria that VDH outlined for HIV risks for PrEP eligibility and I have…checkboxes…So again…the criteria that VDH has in terms of if someone is having unprotected sex, if someone has a positive partner who is not undetectable, if someone is sharing IV equipment, if someone is participating in sex work; they're exchanging goods, service, money etcetera for sex or if anyone has had a bacterial STI diagnosis. All of those constitute HIV risks and therefore PrEP eligibility. And then I have devised kind of a system of if you check off more than one thing on the quote-unquote risk behavior then…that should automatically trigger the tester to ask them about PrEP: Have they heard about PrEP? Have they ever been on PrEP? And would they like to learn more about it?

When asked about patients who are "low risk", Participant 4.2 responded:

> If someone comes in and they're telling us that they only have one partner but they're really persistent and they really want to try PrEP then there's a possibility that they're not telling us something. So, we would still try to get them enrolled in the program even if they tell us that they have one partner. Because we've run into that issue before where they would see a nurse case manager and they would tell them one story and then they would see the provider and they would tell him another.

Similarly, Participant 4.1 stated that in the prevention program specific to MSM patients need to meet more than one criterion to be considered in need of PrEP:

> I wouldn't say just one. For example, if they're a man having sex with other men that alone is not enough to say, 'Oh you're high risk.'…So we like to factor those in, in addition to who you're having sex with. So if a person engaged in condomless sex [says] 'I sometimes do, I sometimes don't,' [and] through further processing if it comes out that they never use condoms at all, and they have multiple sex partners, and they like to go to the bathhouses and they like to do a lot of sex parties and a lot of that…That's usually areas…where that exposure could actually happen…Or if they are someone that shares needles regularly for whatever their reasonings may be and if that is done in conjunction with at-risk sex or risky sexual behaviors then of course that's another PrEP referral possibly. So yeah it all depends. It can be one…but I would say more than one to answer your question…. So, then we kind of at least initiate the conversation of PrEP: if they know what PrEP is, if they've heard of PrEP, that's usually where that kind of falls.

When asked if a 'low-risk' patient would be deemed in need of PrEP, Participant 4.1 responded:

> …at that point we're processing what their feelings are, like why do they feel they need PrEP? … But if they're not someone that's really at risk for it we try not to push it, we don't push the envelope with them. But again, at the end of the day, it's patient-centered so if the patient feels that they need it or they want it I'm not going to tell you 'No, don't do it.'

Again, Participant 4.2 is primarily responsible for making determinations about PrEP need at clinic 4. Participant 4.1 shared:

> [Participant 4.2] got hired into the…PrEP navigator...role and he's been phenomenal. So...if we are assessing someone or we screen someone and that person communicates that they're interested in PrEP we no longer have to have a very heavy conversation with them and follow up with them in terms of PrEP we just now refer them to…[Participant 4.2]…and he takes them through the entire process of getting them started with [clinic 4]'s PrEP program.

Perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 4 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

At the structural level, the inaccessibility of clinic 4 was cited as a barrier to the PrEP screening process. Participant 4.1 shared:

> So, if I have to name a barrier in terms of getting folks in for PrEP services I would say that in some cases it is accessibility. So, like transportation…[clinic 4]…is located off of the Metro line so folks can…take the Metro to us and maybe walk like ten minutes or so to get to our office…. I have to speak for us only but I know in times past when it comes to services, getting folks here like transportation-wise, that can be a barrier for some folks especially if they're not comfortable using the Metro.

Participant 4.4 agreed, stating, "Well I know one of the barriers with [clinic 4] because they're located in northern Virginia a lot of people can't get there because of the location." No facilitators to PrEP screening were identified by staff at the structural level.

At the institutional level, Participant 4.3 described how staff turnover can serve as a barrier to the screening process:

> I think potentially a negative influence could be that we've had a lot of staff turnover in the last year. So that can sometimes delay folks from getting appointments and things like that.

In the prevention program for MSM, Participant 4.1 explained that a lack of shared life experience between the volunteer members and the participants can pose a barrier to the screening process:

> I'll say to an extent I feel like…some of our folks…don't have some of the shared life experiences. Like for example if I grew up in a household where my being Gay or being bisexual or being androgynous or whatever was embraced by my family I can't relate to the experience of someone who did not have that…So a lot of times those kinds of exchanges make it awkward even if you're trying to push something like PrEP or safer sex practices, that exchange won't go over easily or smoothly. It won't be like combative but the person may not feel inclined to really hone in on what this person is saying because you're not someone that identifies with me.

Participant 4.2 explained that the positive reputation of clinic 4 helps to facilitate the PrEP screening process:

> I would say the reputation of [clinic 4] and it being like one of the bigger organizations in Northern Virginia. It definitely brings a lot of patients to the organization because a lot of the Northern Virginia residents don't want to leave the area to receive care. I would say most of them, they've heard about [clinic 4] either through word of mouth or looked it up online…. I would say the organization overall…provide[s] a safe space for patients. And if there's anyone who is affecting that safe space then we will pretty much decide that they don't belong here because we want it to continue to be a safe space for our patients. So, most of our PrEP patients feel comfortable because this is a safe space. And I would say that that allows most of the people to open up and share with us things that they wouldn't share with a primary care physician at another facility that didn't specialize in infectious disease.

Participant 4.1 explained that the volunteers in the prevention program for MSM do mirror the participants in other ways that facilitate the PrEP screening process:

> So, I'll say a positive influence, one is we do have members in our group who actually are PrEP users… So actually, in some cases, some of them are working directly with folks in the screening process. So, if a person has a question about PrEP…our crew members could of course share their experience with the person or what their experience with PrEP has been. It kind of helps eliminate some of hesitation or the fears that other folks may have because of things they might have

> heard or something they might have seen…They're not just talking about PrEP from a knowledge standpoint but they can talk about it from an experiential one…. And they're also of the demographic, which is awesome. Because sometimes, I think in some places you'll have folks that don't necessarily align with the demographic you're trying to do outreach with…. And the information can be accurate but the fact that it's coming from someone that doesn't look like me or doesn't share my experience is like 'Why am I listening to you? Why should I listen to you?'… So, in our space it's great that we have folks who actually look like the community sitting and talking to folks about it… I think it gives a more powerful message.

Participant 4.2 commented on the passion, training, and non-judgmental approach of the staff at clinic 4 that helps to facilitate the PrEP screening process:

> [Clinic 4] has a set of providers who are very passionate about infectious disease…And the patients, who I have conversations with, say we try to be personal; we do our best to avoid passing judgment, people are trained on that as well… so we know how to address the situation without passing judgment. And that's what most of these patients like, is to come here and feel like they can be honest and not be judged for their different decisions whether it be their sexuality or their drug use.

At the individual level, lack of transparency during the screening process was the most common barrier identified. Participant 4.1 stated:

> Sometimes they may not want to disclose especially when it becomes about HIV status or whether they're on PrEP or not. Because in our community PrEP sometimes is not met with a grand celebration sometimes. I think in our community there was a point in time where if you…took PrEP people considered you to be one of those 'fast types.' You're one of those that's sleeping around with everybody and that kind of thing. And so…there's a stigma associated with PrEP. So, a lot of folks weren't comfortable disclosing that. They're not feeling comfortable to answer the question, yes that is a barrier… Like the younger generation they seem to be more sex-positive and open to talk about their sexual experiences… but once you go into the thirty-ish range that's when you start seeing a little more resistance sometimes in terms of comfortability… you can kind of see the hesitation or resistance setting in and then the answers start getting short to like none.

Participant 4.3 explained that prior knowledge of PrEP among patients can facilitate the screening process:

> I know I definitely encounter patients who are very well versed and very proactive about their health and reading up about stuff. Or will come in for an HIV test and have read like fourteen papers about it already and they're asking me stuff and even though I've been doing this for a while I cannot answer because it's very like data-driven…. And I think demographics can definitely play a role in that as well. And I'm not sure if this is exactly true…but for example, I might imagine that maybe men who have sex with men may know more about PrEP, because its heavily marketed towards them, right?

PrEP need

At the structural level, Participant 4.3 discussed the referral and insurance issues that may pose a barrier to the process of determining PrEP need:

> ... and this is not like [clinic 4] specific but this is something that is happening in our area, our northern Virginia area…There's been some, not conflict, but some stuff with agencies referring patients; us not being able to get them in right away and there being a little bit of a wait time potentially. And the agency is getting frustrated and sending their patients to DC which is not supposed to happen…Not to say that folks can't go to DC, obviously, they can,… but DC is not accessible for everybody…. The ideal is that if you're a northern Virginia agency you are going to refer them to [clinic 4] and we will figure it out, we'll get them in.... [Another] thing I will say, and it's not particular to [clinic 4] exactly but cost, so insured or uninsured. Even if you're insured kind of regardless of where you go co-pays can be really high and things like that so that could be a factor. If you're uninsured, it's a fair amount of paperwork and documentation that you have to complete…if you're going through the Virginia Department of Health.

No facilitators to determining PrEP need were identified by staff at the structural level.

At the institutional level, Participant 4.1 explained that staff turnover among the volunteers in the prevention program may pose a barrier to the process of determining PrEP need:

> So, one thing I'll talk to is…how transient our area is and a lot of times with our volunteers even with our staff, our coordinators, there's a shift in who's there and who's not there. And then of course with the people that are there some of the folks from the community may semi-relate to one and not really to the other. And so, if a person phases out and a new person comes in and the person of the community that's

> been coming regularly was connected to one person, sometimes that transition you can lose folks in that. Because to build a relationship is work.

Participant 4.1 also shared that the mission and focus of the prevention program can help to facilitate the process of determining PrEP need:

> So, I feel like because our organization has like an empowerment focus, it's all about betterment. Like how do I enhance my quality of life? And I think because our organization has that focus…built into its structure it makes room for a lot of those progressive conversations to actually start taking place. And I think that's regarding PrEP, regarding sexual health, regarding sex-positivity, regarding self-affirmation, a heightened sense of self-esteem, self-worth. Because a lot of those conversations are happening, it makes room for people to really start thinking about 'How do I better my quality of life or enhance my quality of life?' and that can lead to… 'Ok, PrEP. Maybe I should consider PrEP as one of those elements in my life that helps with the heightened sense of quality life.'

The knowledge and passion of the staff at clinic 4 were identified as a facilitator to the process of determining PrEP need. Participant 4.3 shared:

> I would say that in general our staff are very helpful. And especially with [Participant 4.2] on board, he's thrown himself into the program so well that he really knows all the resources. So, like if you have Medicare, Medicaid he'll figure it out for you. If you want to go through Gilead but your income doesn't qualify you for example…he can be like 'Oh then we can do this or we can still go through VDH.' So, I think that's definitely a positive influence in terms of knowing your options, knowing what options are still there, and that it's not one size fits all.

At the individual level, side effect concerns, PrEP stigma, and pill burden were the most commonly identified barriers to the process of determining PrEP need. Participant 4.3 discussed patients' side effect concerns:

> Some have definitely seen the commercials or the Facebook ad about Truvada causing kidney damage in some patients or bone loss in some patients. So, some are like 'Oh well I don't know if I want to do that.'

Participant 4.1 added that the side effect concerns stem from medical mistrust:

> A few guys specifically in the Black community…will go back to Tuskegee…. And so that mistrust with the pharmaceutical companies, that mistrust with the healthcare system because of the issues, the historic controversial issues that arose between the healthcare system and the Black community. A lot of them…even though they're like twenty, thirty-something, they have knowledge of it and they're resistant. So, I've had that a couple of times.

In reference to PrEP stigma, Participant 4.3 shared:

> And certainly, there's stigma around HIV regardless of if you're positive or not. Even someone walking into an HIV clinic or an STI clinic to get their PrEP or pick up their meds, someone sees them and they might make an assumption about them that may or may not be true. So, I think because of the stigma around HIV in general there's still a lot of stigma even around all of the preventative services; PrEP, PEP, testing, all that…

Participant 4.3 also discussed pill burden:

> I'm not saying being on PrEP is a chronic illness or anything like that but I do have a chronic illness and someone who has to take meds either every day or every week and you have to get your blood work done. Periodically, you have to have doctors' appointments…it's a lot. And I think people don't realize that.

Participant 4.2 explained the patients' risk perception can facilitate the process of determining PrEP need:

> I will say knowing that it is a preventative measure for contracting HIV. Many of them like the idea. Like those who are in a [sero]discordant relationship even if their partner is undetectable. A lot of them, they feel more comfortable taking PrEP. Or the ones who are very sexually active and have multiple partners, some of them feel a little bit more comfortable being sexually active with so many partners if they are on PrEP.

Clinic 5

background

Clinic 5, founded in 1987 "to serve the poorest of the poor living with HIV and AIDS," is a faith-based non-profit organization with three different locations. The main site is located in a white two-story house in Northeast DC. The second site is a workforce development program that focuses on the LGBTQ+ community and is located in a large modern office building in NW DC. The third location is also in NW DC. Clinic 5 also has a program specifically for the transgender community. According to the website, the programs offered by clinic 5 are designed to "increase the life expectancy and quality of life for people living with HIV/AIDS (PLWHA)." Participant 5.3, the Prevention Coordinator, described the organization in greater detail:

> The organization I believe began in 1987 as a hospice. It was founded by…a prominent lawyer and he wanted to really figure out how he could help with the HIV epidemic that was happening. Particularly in the District, it really hit hard for of course many people…. And a lot of people were getting turned away, rejected…. And then…the organization expanded to medical case management meaning that a nurse practitioner and or a licensed clinical social worker working in conjunction with that person's physician, just making sure that they have comprehensive all around the clock care in terms of making sure that they not only take their medication but holistically take care of themselves as well. And then we expanded into a food bank…. And then just recently last year we added on a prevention [department] which [provides] community education as well as HIV, STI, and Hep-C testing. And we really just emphasize people knowing what they're talking about and knowing what they're doing. And we emphasize sex education from a sex-positive, a comprehensive fact-based only principle.

In reference to the staff at clinic 5, Participant 5.1, a Program Director, explained "we have about fifteen employees, fifteen to seventeen employees spread across three different sites." Participant 5.3 expounded:

> Our staff is predominantly Black, African American. We do have one individual who is actually…from El Salvador. So, we have a Spanish speaker as well as that representation. And then as far as gender of course the Executive Director, she's a Black woman, well into her sixties…And then we have a licensed clinical social worker and we also have a registered nurse, both Black women. We have a transgender woman who is a non-medical case manager. And then we have another non-medical case manager, a cisgender man. And for the most part, I would say it's split in half; it's cisgender Black men, and then cisgender Black women, and then maybe a quarter of who we work with as far as volunteers and…our non-medical case manager and our receptionist we have transgender women….So the age range as far as the prevention department…so roughly about six to seven of us are between the ages of 25 to 35. The executive director as well as the registered nurse as well as the non-medical case manager and the nutritionist that we also have on staff…they are fifty-five and up. I believe the youngest staff individual that we have is twenty-five, and I believe the oldest I think she's roughly in her seventies.

Participant 5.3 described the clients receiving services at clinic 5 and specifically in the prevention department:

> So generally, they're people that are homeless....or people that necessarily don't have an address, but they may be renting or living with a relative or a friend or squatting…As far as socioeconomic status, I could say most of the individuals that I've come across that I've tested as far as like income mostly prefer not to answer or do not disclose. And if they do disclose it's generally less than thirty thousand including any aid as far as food stamps or Social Security…. We get a lot of people from Ward 5 and Ward 8. Primarily because of where we're located. Sometimes people's medical services from Ward 8 can be a round. So, its [like] 'I can go see my doctor, and then I can go to the food bank, and then I can also try to resolve any housing issues that I need to discuss with my non-medical case manager.' So, it's really trying to meet people where they are. And then also too, a lot of people are recovering addicts… We do work with the elderly… as well as the youth. And the youngest that we have tested is thirteen, yeah thirteen and up we can go. I would say eighty percent Black. And I would breakdown the twenty percent like ten percent White and maybe ten percent Latinx. Rarely do we get anyone else outside of that category…. I would say maybe about fifty percent of people that identify as males; I

> would say maybe a quarter of people that identify as females; and then maybe a quarter that identify as other, gender non-conforming, or non-binary, or transgender.

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

When asked about the project's recommended process for PrEP screening, Participant 5.1 responded:

> It's a different program, status-neutral approach where individuals come in, and regardless of what, they get offered the same level of service. So yeah I've seen the [project's] form, it's an interesting form…. It's…an unnecessarily long form.

Participant 5.1 also described the support that he can get from the project team related to PrEP screening:

> We have a very good relationship with DC Health to call them if we have any problems or to give them suggestions or chew them out for something, there's not a problem…. The coalition meetings…[are] informal discussions, networking type of things. 'Who was in the room? Who's participating in 1509?' Yeah, that's what those are.

PrEP need

When asked about the project's recommended process for determining PrEP need, Participant 5.1 wasn't aware of the project's criteria and preferred to defer to a member of the prevention department. Participant 5.2, a Health Impact Specialist, explained:

> So as far as I know, in order to take PrEP, you have to be negative of course. You have to be able to check-in with the doctor at least every three months. And just make sure that you know what PrEP does. For example, it prevents you from getting HIV but not too many people know that it [doesn't] prevent…STDs. They just see it as a miracle pill sometimes so that as well. And also, just to make sure when applying for PrEP if you're eligible in regards to not having insurance or having insurance.

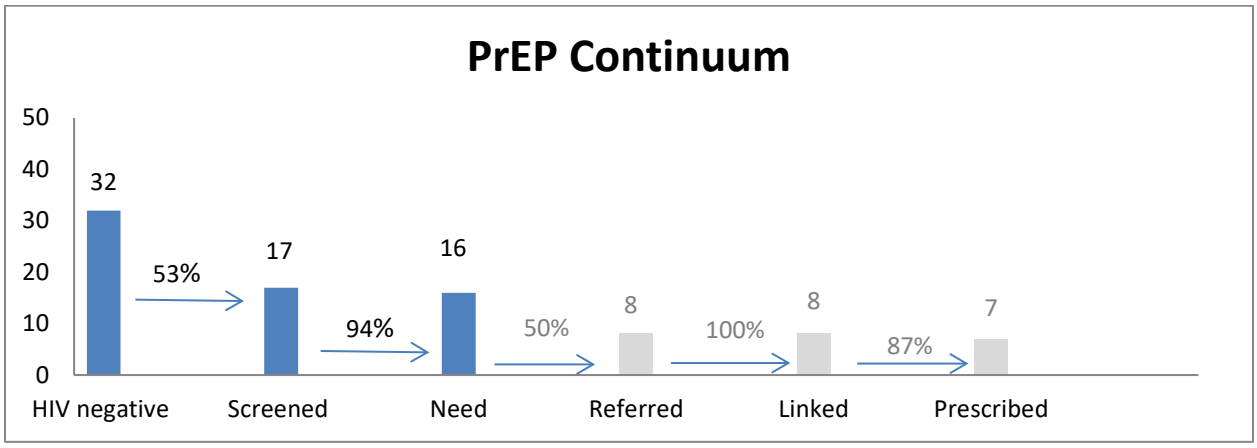
> Depending on the person…they might need either a deductible co-payment card or they're lucky enough to get for free.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16e depicts the PrEP continuum for clinic 5 as of March 2019. Of the 32 HIV-negative persons enrolled in the project at clinic 5, 17 (53%) were screened for PrEP.

Figure 16e. *Clinic 5 PrEP Continuum through March 2019*



PrEP screening at clinic 5 is done via the project's intake form as well as an internal HIV testing form. Participant 5.1 stated the clinic was using the project's form "currently as [it] is" but we're in the process of adapting it. Participant 5.1 added "[Participant 5.2] is actually

revamping the form, putting in other questions to make it more personal to our organization."

Participant 5.2 elaborated:

> I'm the one currently working on the modified version of the intake form with oversight of my supervisor to make sure that the questions are sensible, accurate and of course, they can get the information…for our data uses as well, like when we input into REDCap…. We're trying to update our questionnaire to make it more exact and more straight to the point so the client can feel that we're not asking too much information…We're trying to ask more…questions that actually focus on their sex life and if they were to inject drugs or other stuff…We're using [the project's] form as a basis and keeping some of the questions that we see most clients are more willing to answer…And we're also planning on [re] wording some questions and also just to make sure that it looks more neater on paper instead of clustered.

Participant 5.3 described the PrEP screening that happens in conjunction with HIV testing:

> Well during our intake process for HIV testing we ask their sexual history as well as their current sexual practices… like 'When was the last time they had sex? How many partners do they have at the moment? What method do you use? Do you currently use condoms?'…Another important factor is asking when's the last time they had their annual exam… But the main thing in screening is first making sure that you've seen an actual physician that screened you for other things. So yeah that's pretty much in our intake process, we just see what your sexual practices are, and then from there…I would say [it takes] about roughly a half an hour to forty-five minutes, maybe even an hour because we go over just other nuances when it comes to sex.

Participant 5.3 also described the creation of the internal HIV testing form:

> It's a combination. So, we took some questions from… the CDC. They had like a questionnaire relating to screening people… for PrEP. So, it's actually before I got there. But yeah I believe it's a combination. Because obviously, I enter the information in REDCap and our questions have to match whatever the questions are in REDCap. So generally speaking, in REDCap they ask similar questions of a person's sexual practices just to determine whether or not if PrEP would be appropriate for them.

At clinic 5, Participant 5.2 and Participant 5.3 are primarily responsible for PrEP screening. Participant 5.1 explained that "they are usually the first ones that people see when they come so they'd be the first ones to engage in conversations about PrEP."

PrEP need

Figure 16e depicts the PrEP continuum for clinic 5 as of March 2019. Of the 17 persons screened for PrEP, 16 (94%) were determined to be in need of PrEP. Staff at clinic 5 stressed that PrEP is discussed with all HIV-negative clients. However, the determination of PrEP need is primarily driven by the patients' interest and perception of risk. Participant 5.2 explained:

> We really can't just determine or tell them 'Oh get on PrEP.' We normally give them the option to choose if they're willing to get on PrEP because we don't really want to force it down on them otherwise they'll just see that as oh we're just pushing this drug because we have to…We don't really want to judge them and say that 'Oh just because you have five partners you need to be on PrEP right now.' So instead…we'd rather have them make that decision. But we do ask questions to make sure that they can at least identify that they're outside the norm…I feel like when we keep it more…broad…people have the chance to evaluate where they stand without having someone push them like against the wall and just be like 'Here you need this.'

Participant 5.4, a Director, agreed:

> The way I gauge PrEP eligibility is that a client is informed and interested and having sex. Because if you're having sex, you need to be protected… with all the tools available…I think that anybody who tests negatively, we tell them about PrEP and try to get them to [clinic 8] to be also [be] assessed.

Participant 5.2 further elaborated on why clinic 5 does not have strict PrEP eligibility criteria:

> Yeah. That's silly to me. If this is something that we know can do X, Y and Z why create barriers for people if we're supposed to be helping? [Clinic 5] was founded on the premise of helping the poorest of the poor, the neediest of the needy…So how can

> you help those in need if you have these strict criteria? And we know our population; we know a lot of our population are unemployed, uninsured, struggling with substance use, some of them are engaging in commercial sex work. Why would we create things to prevent them from getting access to this?

Participant 5.3 explained that someone who is low risk would still be deemed in need of PrEP if interested:

> What makes someone eligible for PrEP from our standpoint is the ownership of that individual. If that individual feels that they are eligible. Again, people's behavior, they report one thing and then do another thing…but there's no like 'Oh I'm not going to let you know about PrEP because you're currently abstinent or you're currently, or whatever the case is.' We get a lot of people who say, 'Oh I'm not having sex.' And it's like 'Okay if you decide to, this is what's available.'

Again, Participants 5.2 and 5.3 are primarily responsible for determining PrEP need at clinic 5. Participant 5.3 explained that she makes that determination "immediately, immediately. I always, like I said regardless of their sexual practices, I just say 'Well this is available for you. And this is what it does. This is how it could possibly fit in your life.'" Participant 5.4 agreed, stating,

"You don't want to… give people time to go out, do some risky behaviors and become infected."

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 5 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

At the structural level, Participant 5.2 explained how the inaccessibility of clinic 5 was a potential barrier to the screening process:

> Our location here in Northeast, it's close but…it would be nicer if we were a bit closer…. Most of our people that we do try to reach are mostly in Southeast. So, we're in a good distance from them…Our [mobile] van can only help us reach to a certain degree. It really doesn't put us in the middle where people actually need help. So that's something…that could be changed…and making sure that we can reach more people out in Southeast.

No facilitators to the PrEP screening process at the structural level were identified by staff at clinic 5.

At the institutional level, the reputation of clinic 5 as a faith-based organization was the most commonly identified barrier to PrEP screening. In reference to clinic 5 being a faith-based organization, Participant 5.1 explained:

> One of the things that I think might negatively impact is our name…The Black and Brown Queer community has not been well received in religious institutions and as we expand some of our Queer programming it's kind of like a thing… we realized that would be a barrier to folks…we realized that the name …might scare some people so we created…[the workforce development program] or…[the program] for the Trans community… to help those individuals that might not want to come into [clinic 5]…. And then they realize halfway through that 'Oh hell, this is still [clinic 5]' but by that time they're like 'Oh it's not what I thought.'

However, Participant 5.1 explained how the organization's plan to modify the project's intake form would help to facilitate the PrEP screening process at the institutional level:

> We are steadily changing our intake process so to be more digital and more streamlined in the process so it's not going to be cumbersome… in my mind we want to integrate questions into that so it could be just one smooth thing so right off the bat we have indicators that say 'Okay, yes recommend this person for PrEP.' Or 'No, no need to' depending on whatever.

He also described how clinic 5's reputation as an HIV service provider helps to facilitate the screening process, stating "…because we've been here for so long…thirty years…that folks know… if you want to get any kind of HIV testing, food bank, PrEP, this is a space you can go to."

Another institutional facilitator was the diversity and relatability of the staff, as Participant 5.2 explained:

> Our staff here is very diverse. We have Hispanic, Black, we have transgender, cis. So, I feel when we present ourselves, even at events or out in public, they know they can come up to one of us and say, 'Oh I can identify with you' or 'I feel comfortable speaking to you about either my status or where I stand in regards to taking PrEP.'… So, having people…that…have come from experience of actually…taking…PrEP, know the process of taking PrEP. So, I have never really seen someone too skeptical about our staff members or our credibility…because I feel that the staff here, we are actually going through that stuff as well.

Participant 5.1 agreed:

> So, the community is also innately aware of PrEP…. And a lot of our frontline staff are people from the community that we bring in and train and get them ready to go…and deliver that information back out…. Because in my opinion, and a lot of our opinions here at upper management, is that the best person to share the information with someone is…someone that looks like you, went through similar experiences like you.

At the individual level, the PrEP screening process if often hindered by the more pressing health and social needs of patients. Participant 5.1 explained:

> Substance use is an issue. Opioid use is an issue. Homelessness is an issue for a lot of our clients…We have to address those issues first. Again, if you're homeless and you come in here for food and you're testing really for the Giant gift card, you don't want to hear me talk to you about PrEP because that's not the thing in your mind.

Participant 5.2 explained how the lack of PrEP knowledge among clients can actually facilitate the screening process by allowing the staff to educate them:

> It can be seen as a barrier but at the same time an opportunity. That's how I see it, every time someone comes up and they're like 'Oh I didn't know PrEP exists.'… It is a conversation starter and you can go into more information about PrEP.

PrEP need

No barriers to determining PrEP need were identified by staff at the structural level. As a facilitator to the process of determining PrEP need, Participant 5.1 explained that the organization has mechanisms in place to help patients navigate any insurance concerns or other structural barriers to accessing PrEP:

> Again, one of the things if you're negative we want to keep you negative. So, we want to provide whatever it is that we can do to keep you negative so if its' PrEP we work with you. Then one of things like with our pharmacy… if you can't afford it we work with our pharmacy to see how we can offset some of the cost. But that whole conversation about insurance: who's going to cover it? who's going to pay for it? We do have a program here where we can potentially pay for some co-pays if co-pays might be a barrier for some folks. For some folks, a twenty-dollar co-pay is nothing, but for some people, that's a huge issue. So, we work with individuals to try to alleviate whatever barriers folks may have…And this is where we're trying to do some shifting around next year: you can have their medications delivered to us. If you can't go to pick up your pills or you can't have it delivered to your house you can have it delivered here and then come here and pick it up. Because we also know that some folks don't want people in their house knowing what they're doing. So those are just some of the things that we're doing when we talk about increasing access to PrEP. Not just eligibility because again I feel like anyone if you're engaging in sexual activity you should know about or be on PrEP. But yeah as far as the income and payment pieces, we…are trying to increase ways that we can circumvent…that barrier…for some folks.

No barriers to determining PrEP need were identified by staff at the institutional level. When asked specifically about staff characteristics that may pose a barrier to the

process of determining PrEP need, Participant 5.1 responded "At this time we don't have anyone [who] negatively would impact our process." The organization's process for determining PrEP need and its stance on having broad eligibility criteria were identified as facilitators. Participant 5.2 shared:

> So, I say the characteristics of the organization, like the way they approach…following certain criteria to say, 'Oh you're eligible for PrEP.'…. We really just want the client to know the information. I feel like in order to get more people on PrEP or just to get the word of PrEP out, which is the most important one, we need to help people assess where they are…. Giving out the information about HIV, STIs, giving that information out first; helping them digest that saying, 'Oh I might be at risk but at least I know that PrEP exists.'… We really try to keep an open mind about who should be taking PrEP instead of just the typical, 'Oh a gay male from DC; you need to be taking PrEP.' No, we try to keep it open-minded.

Again, the relatability of the staff was as identified as an institutional facilitator to the process of determining PrEP need. Participant 5.2 explained:

> So, on the staff level I would say that…a little bit our own experiences with PrEP…. So, providing actual experiences is a pro in that regard." Participant 5.1 added 'our diverse staff…our staff lives and works in this community.'

At the individual level, staff explained that patients may not be willing to take a pill every day as they have more pressing health and social needs. Participant 5.3 elaborated:

> We get a lot of people that do not want to take a pill every day. There are a lot of people that have other, multiple issues even in knowing their health status, that's another issue…if you have a patient that is on dialysis and that is in-between housing…we talk to people individually about PrEP and people again are interested and then the issue with them getting on PrEP is 'well I have other issues at hand.'

Participant 5.1 agreed:

> If you test negative great, congratulations. But you're engaging in these other behaviors. What's going on? We're told to just go from one to two…if you test

> negative automatically talk about PrEP… and there's a whole bunch of things in the middle. So again, if I'm homeless and I'm hungry I'm not going to take a pill every day. I'm worried about figuring out what I'm going to do.

Participant 5.3 explained that the low perceived risk of HIV among clients can hinder the process of determining PrEP need:

> I feel like sometimes there are some clients that put up their own barriers in regards to…when they say 'Oh I didn't need that' even though they may need it…We actually have a question on our intake form…about why they don't want to take it or why they feel like they don't need more information about it…. Some of [the] answers that they put [are] either 'I don't need it [or] I don't feel like I'm at risk.'

Participant 5.4 agreed, stating "…some people still think that they're… sex life doesn't make them eligible for infection…." Participant 5.1 also explained that medical mistrust can pose a barrier to the process of determining PrEP need, stating: "Yeah medical mistrust is still big. People still refer back to Tuskegee…like 'Oh no, this is an experiment [on] me. Why you want me to take this pill?'" However, Participant 5.4 also explained the "…willingness, readiness, and desire…" of clients to take PrEP facilitates the process of determining PrEP need.

Clinic 6

background

In 1984, clinic 6 was founded as a non-profit specifically to meet the needs of LGBTQ youth in the DMV area. The main center is located in a brightly colored house in Southeast DC. There is also a housing program in Southeast DC as well as a housing

program in Northeast DC. Participant 6.5, a Health Impact Specialist, described the mission of and services offered by clinic 6:

> At [clinic 5] we primarily focus on supporting and empowering LGBTQ youth in the Washington DC, Maryland, and Virginia area. We do that through youth leadership, in creating opportunities for youth to build self-confidence; critical life skills; advocacy work;…engage with their peers and community; and also commit to social changes, policies, and services that will eventually help them grow into adulthood. Some of the programs we offer, we have weekly drop-in programs for youth…We also have an advocacy program where we teach youth how to be advocates in their school or in the community. The peer health fellowship…where we basically teach youth how to be basically Health Impact Specialists in their communities. We teach cultural competency trainings in schools for teachers…We have a housing program for homeless LGBT youth from eighteen to twenty-four I believe.

In reference to the staff at clinic 6, Participant 6.4, a Researcher, described the spectrum of genders, ages, races, and backgrounds:

> Out of the 15 to 20 staff…it's a mix…There's a fair share of white people…there is a fair share of black people, and [a] fair share of people of color of different nationalities…. We currently have trans staff, gender…non-binary, male-identifying, and female-identifying staff members. As far as age, we have like a lot of younger staff members who work more-so in like…youth-facing roles. We have, like, a lot of management staff that's older, that works more on like…speaking at events and like interfacing with like executive directors of other organizations…I've seen staff members come in with no training because they're coming in as interns or…coming in as…new hires. Like getting acclimated. Recently I've seen new hires [with] social worker or like psychologist kind of backgrounds because they're kind of dealing with like you know, crises management… with LGBT youth. So, yeah, all different kinds of backgrounds.

Participant 6.1, a Program Director, described the youth who participate in programs offered by clinic 6:

> Yeah so most of the clients we serve, let's say eighty percent are youth of color… and this is across all programs…And for in-school work, out of schoolwork, on average most of our young people are like that tenth, eleventh and twelfth-grade range. And I put a grade versus an age because sometimes it takes folks a little bit longer to finish

> school than others or folks that are in nontraditional school settings…It is a good mix of cis, trans and nonbinary, but mostly cis. So, when we talk about the cis aspect of it, it's mostly cis men and not cis women.

Participant 6.4 described the clients specifically in the IMPACT DMV project:

> Yeah, so the IMPACT Project, because the objective is totally different, we have clients that are between the ages of eighteen to upwards to like 40-50 years old…The age was concentrated in the 18-24 and 18-30 kind of like age group…Almost all of our clients are African American or people of color. We have a lot more MSM clients and transgender clients. That's just, you know… the way that the recruiting went…A lot of them are employed. Even people who kind of like go through periods of temporary unemployment, they kind of tend they have a job more than they don't. With education, it's very mixed. They're people who have like master's degrees, some people have like no degree at all. People who have income that's like above $70,000 that have no degree, people who have like bachelors, master's degrees and like under $50,000, so…it's all like sprinkled in here… And…it just speaks to the diversity of like the region.

Participant 6.4 also discussed his thoughts on clinic 6's decision to participate in the demonstration project:

> You know… our mission as an organization versus like the mission of the of the IMPACT DMV Program, they differ slightly. I think that like [clinic 6] was a very interesting site awardee… Like…the reason why it was awarded made a lot more sense than like the implementation of…the program. Just because, from [a] strategic, public health standpoint yes…. Awarding, you know, the grant to an organization that interacts with youth on a regular basis makes sense, right? But like, in terms of like reducing risks at the 18 to, you know, 24 or 29 level. When you get into the weeds of like what that group looks like… how easy or hard it is for that group to maintain access to a space, to make it across the city that's like not…inexpensive, it got very, very tricky very, very quickly. And like we had to expand our program from the onset in order to make it to a target number, like within the first three or four months of receiving the grant…I would say that like in terms of that 18 to 24 population, it was not as effective as we had planned for it to be…And… it wasn't…the…fault…[of] the people who were collecting the data. I think it was more so…the location where [clinic 6] is, you know. The kind of the attention that [clinic 6] receives publicly, you know…So it kind of like shifted how we had to like navigate that group…I don't think…hardly if any of the people in the [MPACT DMV program] who are 18 to 24, 18 to 29, actually are youth who come to [clinic 6].

Participant 6.5 also discussed his motivation for wanting to join the project as a Health Impact Specialist:

> Ideally I wanted to be able to help people and my dream job was to be a therapist. And when a friend of mine introduced me into the Health Impact Specialist program I realized that I can get kind of my feet wet into being able to help youth. And…not only [be] the kind of person that I needed when I was young, but also be able to put smiles on people's faces.

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

When asked about the project's recommended process for PrEP screening Participant 6.1 responded:

> So, from my understanding,…it's really about reducing barriers for folks to be able to get tested, have their PrEP referrals and things and it really be a very seamless process so that folks won't have to… go through so many things to go get tested and then have to go through so many additional things to get on PrEP. Like it can really be: you get tested and you want a PrEP referral we can red carpet you, if you will, directly into this process to get whatever needs to be done.

Participant 6.4 added:

> To my understanding… the questionnaire… guided you know conversations with PREP…around like…why people want PREP and why people don't. And like who's taking PREP and who's not.

Participant 6.1 also described support provided by the project team around PrEP screening:

> So [the interactions are] mostly via phone or via e-mail. There are meetings that are set up maybe on a quarterly basis…set up for folks to be able to come all together in a space that are all working on the 1509 Project…To look at the data, to see what's been reported. Also, to be able to get a better understanding of what work additionally still needs to be done and what places and things needs to be targeted and then also what pieces we can celebrate in the work that's been done.

PrEP need

Participant 6.4 shared his understanding of the project's recommended process for determining PrEP need:

> I was instructed to determine PREP eligibility based off of... current [HIV] status…[and] sexual behavioral patterns…[such as] intravenous drug use, multiple sex partners or multiple unprotected sex partners, unprotected sex often with an HIV+ partner, previously or recently contracted an STI. All of these were like kind of included…I think that, you know, the project is a little too broad as far as like PrEP eligibility. Because everybody [who is] like HIV negative doesn't necessarily want PREP and doesn't really have to have reason to like not want PREP.

Participant 6.1 explained that support provided by the project around determining PrEP need:

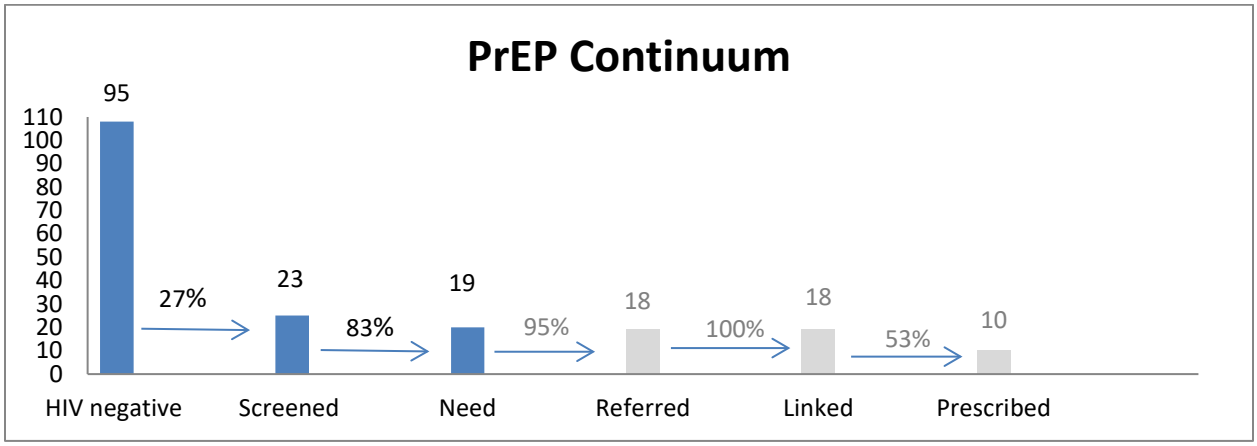
> Meetings [and] e-mail. At the beginning of the project…they went through the scope of work and talked about the goals of the project; what folks needed to accomplish and…the purpose [of] community partners…. All of that was communicated then.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16f depicts the PrEP continuum for clinic 6 as of March 2019. Of the 85 HIV-negative persons enrolled in the project at clinic 6, 23 (27%) were screened for PrEP.

Figure 16f. *Clinic 6 PrEP Continuum through March 2019*



Those participating in the IMPACT DMV project are screened for PrEP using the project's intake form. Participant 6.3, a Manager, shared:

> Yes. So, we have monthly conversations usually over the phone but sometimes in person checking up on…their health status, general well-being, stuff like that…I would say about ninety percent of mine are via phone at this point. A lot of my clients are not near our drop-in center or have transportation barriers so we have started doing phone calls I think about six months ago to try and lower those barriers…And we run through the survey that IMPACT DMV DOH gives us to run through which talks about mental health needs, substance abuse needs, it covers a whole wide range of stuff. And then in there is a question about whether or not the client is interested in obtaining PrEP or PEP. And typically, it's just a 'Hey is this something you're interested in? Have you heard about it? Do you think that it's something that you might be interested in taking?'…talking about the pros and cons of that.

Participant 6.4 added:

> People come in, I would say specifically to discuss PREP and discuss like, the entire survey…I primarily like to do them in person…If a client needs to meet over the phone, then I'll do that. Or [if] it just works easier for both of us. But most of the time, it's been in person…. We kind of market the entire survey, that it's like a snapshot [of] you're like…you know kind of like well-being. So, kind of like PREP is not I guess the only advertisement… I… kind of like know [the intake form] so well that I kind of like don't rely on it…it's more of a conversation anyway like during the sessions…So it kind of makes it easier for that kind of conversation to happen organically. And then for me to get like an organic answer from them; like why they do or don't…use PrEP…So yeah, like we were kind of instructed when we started

> doing it…to use physical forms…in case we didn't have online access. But like even if we did a physical form, we'd have to convert that over electronically anyway because that's how the information is being counted. So, like yeah, we just…kind of skipped the physical form…and make the electronic form the default.

Participants 6.3 and 6.4 are primarily responsible for screening clients in the demonstration project for PrEP. Participant 6.3 explained that the time it takes to screen someone for PrEP varies depending on the client's needs:

> If the client has no other needs or referrals that they're looking for…I'd say the average amount is like twenty-five [minutes]. If they really are just here to get the incentive and leave. But it depends, sometimes our conversations go up to like forty, fifty minutes.

Participant 6.4 agreed:

> Intake probably takes around 20 to 25 minutes… if the person…sought out the mental health services or they need those health services, or different kinds of…service kind of pieces, it can get longer. I think the longest I would say a session would go [is] about an hour.

PrEP need

Figure 16f depicts the PrEP continuum for clinic 6 as of March 2019. Of the 23 persons screened for PrEP, 19 (83%) were determined to be in need of PrEP. Participant 6.3 described the criteria used to determine PrEP need for clients participating in the demonstration project:

> Yeah. So typically, we say folks who are…like men who have sex with men, engaging in condomless sex acts, or people who may or may not use condoms consistently. Folks who might have STDs, rectal-specific STDs, and again maybe not using condoms. Folks who have one or more HIV-positive sex partners. And then folks who may be using drugs. And all of that includes Trans women of color also…if they are having sex with male-identified folks with penises.

When asked if someone who did not report any of those behaviors would be deemed in need of PrEP, Participant 6.3 stated "Yes if they're…interested." Again, Participants 6.3 and 6.4 are primarily responsible for determining PrEP need for clients participating in the demonstration project. Participant 6.4 shared that he thought the criteria he and Participant 6.3 used mirrored the project's criteria "pretty well." He added that he makes the determination of PrEP need "the same day [I'm] speaking with the client." Participant 6.3 described the next step in the process, explaining "and then if they are interested we actually cannot get them hooked up to PrEP in our space, but we do refer them to typically [clinic 7].

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 6 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

At the structural level, participant 6.4 explained how the inaccessibility of Clinic 6 can pose a barrier to the PrEP screening process:

> And I also think that the location of [clinic 6] makes the whole IMPACT…program harder to run a little bit. Just because it is kind of like out of the way in terms of like, in my opinion,…a central location for like people to kind of like access. Yes, it's along the metro line…[but] because of the way that DC is gentrified, it's kind of harder for people who are, you know, more economically sensitive or you know economically challenged to like make it to…like come to see us.

Participant 6.3 explained that subsidizing transportation for clients in the program helps facilitate the screening process:

> Yes, we will provide them with Ubers to and from…any IMPACT meetings including ours or meetings outside of the space,…referrals…[to] [clinic 7] or anything else.

While Participant 6.4 agreed that subsidizing transportation can help facilitate the screening process, he clarified:

> It wasn't brought in as a feature of the program until, like, much later. And like a lot of people…probably needed it… over the like two and a half [to] three years that we've had this program.

As another structural facilitator to the PrEP screening process, Participant 6.3 explained, "If clients were interested we do offer to go out and meet them in the city as well. No one has really taken us up on that since I've come on. They just prefer the phone calls."

At the institutional level, the appearance of clinic 6 and its focus on youth was the most common barrier to PrEP screening for MSM and transgender persons of color. Participant 6.3 explained:

> Given that spatial things are going to [effect] the way you're feeling comfortable…[and] given that we are a youth org and typically its older folks coming into the space, that can be awkward…It's a youth space…a little townhouse that's been converted. We're full of bright colors and comfy seating arrangements…So…some clients…come in…and then they try to hang out and we're like 'Ah, it's program time, we have thirteen-year-olds in the space, you have to leave now.' It can be a little awkward because they are aware that they're much older.

Participant 6.4 added "…the focus of youth, I think negatively can effect of the PrEP screening process." Participant 6.3 also described some of her personal demographic and professional attributes that may pose a barrier to the PrEP screening process:

> I am a young woman of color [but]…. I'm not Black or African American…and I do not identify as Trans and so I'm sure that affects it as well…. [Also], this is my pretty much the one connection I have to the health work that [clinic 6] does in my day-to-day work with the organization. So, because I'm not steeped in the health and

> wellness world of DC it definitely I think that impacts the process…it is not necessarily as sm. h as my coworkers who are in this world day in and day out.

However, Participant 6.4 explained that the staff's "openness and…willingness to engage new people" helps to facilitate the PrEP screening process.

At the individual level, the PrEP screening process can be hindered by the more pressing health and social needs of patients. Participant 6.3 explained:

> Often times the survey and the questions aren't necessarily top on their list when they come in. If there are clients who do come into the space, typically they're also looking for things sort of a little bit more outside the purview of the IMPACT grant, other kinds of support.

Participant 6.4 agreed:

> …just patient behavior. Like so, when you're like having somebody that has an obvious mental health issue, something like that. Or like you know someone who has…just like red flags. They would like kind of like…make that a priority [rather] than like 'Okay, do you want to have a conversation about risk?', you know…And so yeah, it's all very like I don't want to say, 'go with the flow', but it's [not] like a static formula. You have to have like a little bit of flexibility.

Participants 6.3 and 6.4 both identified knowledge of PrEP as a facilitator to the screening process at the individual level. Participant 6.3 shared "Often folks know what PrEP is already and have been on it at least once before so there's not often a ton of the initial education to do around PrEP…" Participant 6.4 agreed, stating "Most of them come in knowledgeable about PREP."

PrEP need

No barriers or facilitators to determining PrEP need at the structural level were identified by staff.

No barriers to determining PrEP need were identified by staff at the institutional level. When asked about staff characteristics that might pose a barrier to the process of determining PrEP need, Participant 6.1 responded "No, I don't think so." Participant 6.1 also explained that the organization's sex-positive approach and willingness to advocate for clients facilitates the process of determining PrEP need:

> I would say, one, that we're a sex-positive organization. I would say, two, that we always seek to look at the holistic approach of a person… I would say also from an organizational perspective… because advocacy is a part of what we do, being willing to advocate for the rights of people and being willing to speak out and speak up against systems and things that are not supportive of specifically LGBTQ folks is…So I think things like that are super important because sometimes it's about system change versus other pieces.

Participant 6.1 also explained that the non-judgmental approach of staff facilitates the process:

> We're a very nonjudgmental staff, there's not too much of anything that our staff would be like '(Gasp), what!?' We're pretty, pretty, pretty, pretty, pretty easygoing when it comes to a whole lot of things.

Participant 6.3 added that the organization's stance on PrEP eligibility helps facilitate the process of determining PrEP need:

> But regardless, if a client is interested we'll always refer them whether or not they meet the criteria just so that they get connected to more care in the city. And then even if they don't go on PrEP when they get to [clinic 7] or wherever we refer them to they might get some other care, so we see it as a positive just trying to get them into as many doors as possible.

At the individual level, both Participants 6.3 and 6.4 agreed that the low-risk perception among clients can pose a barrier to determining PrEP need. Participant 6.3 explained:

> A lot of the clients that I see right now are not sexually active so they're just not interested. So, I actually haven't given a PrEP referral in about a year. They're all like 'We're pretty much celibate.'… Yeah. So, a lot of them aren't currently sexually active or they have long-term partners who they know don't have HIV, [who] they know that they don't have STIs. They get tested regularly or have been fluid bonded for like decades. So often times folks are pretty clear on like this is not applicable to my life.

Participant 6.4 added:

> I think like the client pool that we have isn't doing a whole lot…. They're like … 'I'm not putting myself at higher levels of risk beyond like you know a normal-esque lifestyle…therefore I don't need to take a pill you know… what are my real chances of getting infected with HIV based on my behaviors right now?'

Participant 6.4 also explained that the majority of clients had a positive view of PrEP which can facilitate the process of determining PrEP need, stating "I think most patients… like 60% of patients have like a positive view."

Clinic 7

background

Founded in 1973, clinic 7 is a nonprofit and Federally Qualified Health Center with four sites: a youth services site located in a small building alongside other businesses in Southeast DC, a clinical site located in a brightly colored building in Southeast DC, a clinical site located in a large modern office building in Northwest DC, and an administrative site located in a large modern office building in Northwest DC. Clinic 7 also houses a PrEP clinic in one of its Northwest locations. According to the website, the mission of clinic 7 is "to offer affirming community-based health and wellness services to all with a special expertise in LGBTQ and HIV care." Clinic 7 also provides "stigma-free care to anyone who walks

through our doors." Participant 7.2, a PrEP navigator and former Health Impact Specialist, elaborated:

> I would say compared to other organizations that are participating in the IMPACT Demonstration Project, it's very big…A big medical team. We see a lot of patients. We also do a lot of community outreach and a lot of community events, a lot of rapid HIV tests, and a lot of STD testing. We were primarily known for providing HIV services but we're expanding beyond that as we offer primary care as well as part of our medical services. And its mission and vision has always been to help disenfranchised communities. The agency started working in the eighties with HIV patients and providing HIV care but now it's moving beyond that…to just a regular health clinic and now moving into community health and wellness…And we have this slogan called 'We see you' which just means that we acknowledge you, we see our patients but we see the person in them first.

Participant 7.4, a Nurse Practitioner and Manager of the sexual health clinic on which clinic 7 was founded, describes the sexual health clinic in greater detail:

> The STI clinic is actually the foundation of [clinic 7]. It started in 1973 as a…volunteer-run clinic to serve the community. And then [clinic 7] was founded a couple of years after… and it's been going ever since then….[Clinic 7] has a particular focus on the LGBTQ community and people living with or affected by HIV, although we see everybody…And [the STI clinic], it's always been primarily volunteer-run. It is a free service that we offer to everybody regardless of whether they have insurance, regardless of whether they're a [clinic 7] patient…We offer free testing for Chlamydia, Gonorrhea, Syphilis, Hepatitis C and HIV…And of course, if we have any newly diagnosed HIV or Hepatitis C cases we link them to care within the main part of [clinic 7].

Regarding the staff at clinic 7, Participant 7.3, a Nurse Practitioner and Director, explained "we are an organization around four hundred staff which [has] seen periods of somewhat rapid growth actually through the IMPACT DMV time." Participant 7.4 described the volunteer staff at the STI clinic in detail:

> We have volunteers working at every step along the way. So, we have volunteers who register the patients when they come in, we have volunteer phlebotomist, volunteer

> HIV testers, volunteer health educators and screeners, and even volunteer providers so volunteer physicians and nurse practitioners…We have some volunteers who have been with us for quite a long time, more than ten, twenty years. And then we also have a fair amount of young volunteers who are early twenties kind of just passionate about what [clinic 7] does…I would say the majority of the volunteers are White…I would say it's pretty split [between] men and women. We have a couple of nonbinary volunteers as well. But I would say right now the majority are early twenties, White, kind of split between cis men and cis women…I would say the majority of them are in either some health-related or human rights related field…Like we have volunteers who are social workers, nurses but they don't have to have that background to volunteer…They don't have to be in the health field to do this because we train them on how to talk to patients. And we train them on STI's and Truvada and PrEP.

Participant 7.2 described the socioeconomic status, race, and gender of clients accessing free HIV and STI testing services:

> For our walk-ins we have a large population of individuals who are uninsured or in-between insurances…So we see a split between African American community, our Latinx community and we also, of course, see a lot of Caucasian individuals here given our location here in Northwest. But it's a very diverse population that comes in to test with us for rapid HIV testing and STI testing as well…We see mostly men who have sex with men…that's part of our target population for many different grants which we are funded to, to provide preventative services…And of course, we also serve a lot of Transgender individuals…It's very interesting because…we see people all the way from Germantown, Maryland all the way down to Richmond, Virginia.

Participant 7.3 described the patients seeking medical services at clinic 7, including those on PrEP:

> So, patients that seek our services for medical visits, about probably six to eight thousand HIV negative individuals and about thirty-five hundred individuals living with HIV…We're in the development of integrating PrEP into primary care…Our PrEP patient population…we do fifty to seventy-five new PrEP starts a month which was increased since 2012 where we had about twenty patients on Truvada for PrEP and that was mostly our serodiscordant couples. In the beginning, our patients tended to be older, White, MSM and as our partnership and engagement and evaluation efforts have continued we've seen an expansion in [race] and age to more closely…represent the key populations at risk of HIV in the city…It's about fifty percent under the age of thirty…About sixty percent have private insurance, about thirty percent have public insurance…And then about forty percent represent

> populations of color; Around sixty percent identify as White. Self-reported, it's predominately MSM. There are some, I think about six percent identify as across the gender spectrum. About six to eight percent identify as Trans.

When asked what motivated the organization to want to participate in the demonstration project, Participant 7.1, a Director, shared:

> Well [clinic 7] was one of the pioneers that started PrEP the city with [a different PrEP demonstration] study. And I think…after our experience with [that] study and looking at our mission as an organization to serve our community…particularly in HIV prevention…definitely we thought that it would be a great opportunity for us to enhance our services particularly as it relates to PrEP navigation. Before 1509, we didn't really have a PrEP navigator. And I find that's helped us to introduce a PrEP Navigator to our organization…I think 1509 was a great program. I think it had a lot of changes…. So, the project is almost over…I think we are looking at now [as] we are moving out of 1509, I want to keep the same concept but I want to look at the screening tool and modify it for our own purpose... like I don't know if you have seen it…[it's] like twenty pages…I think they were very helpful in creating this coalition… the…referral system.

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

When asked about the project's recommended process for PrEP screening Participant 7.1 responded:

> Well, it has been so long, more than four years. And it has changed a couple of times…[But] basically…our…priority population which are people of color…And they could have come from different entryway for us from HIV testing, from medical service, from public benefits. And…after the questionnaire provided by them, they will enroll into the program…It was like a pretty extensive questionnaire to identify the needs of the individual from housing, from transportation, job-related, security, food, all of those.

Participant 7.1 also commented on support for PrEP screening provided by the project:

> Well, we do have, as a part of IMPACT DMV, we created this IMPACT coalition…that used to meet once a month. I think after that it changed to quarterly. In those, it's kind of like the scenarios where they provide different topics of continuing education as it relates to PrEP, not just PrEP but also HIV. And there were different topics discussed in those meetings.

PrEP need

When asked about the project's recommended process for determining PrEP need, Participant 7.1 explained:

> Once again this has changed a couple of times. As of the last time, I think was last year actually, they shared with us what their…requirements for that. It was a chart that was coming from [clinic 8] and it was actually broad...Like if you are the priority population [and] you are sexually active we'll definitely talk to you about PrEP.

Participant 7.2 described support that the project provides for determining PrEP need:

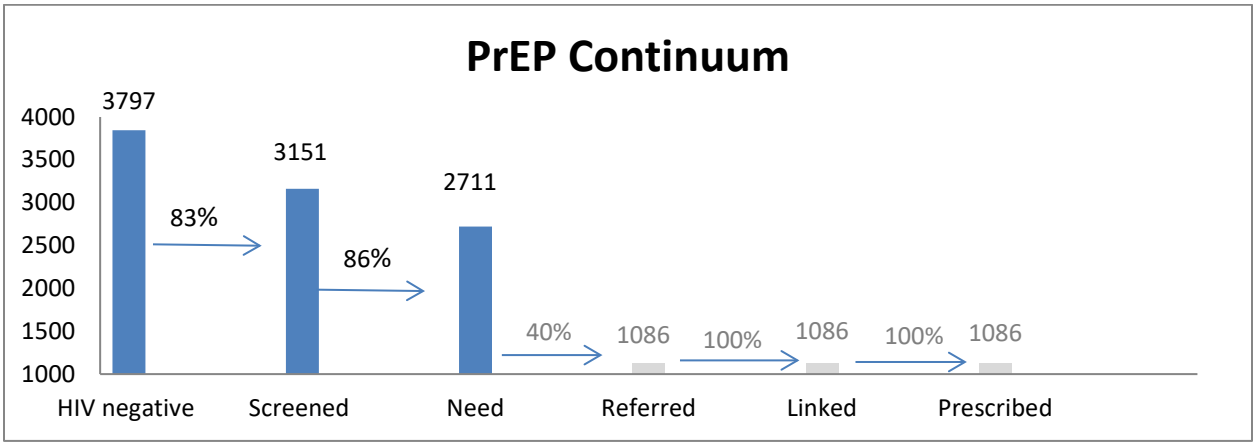
> I have attended many of their trainings…and coalition meetings and there's always a training component which is wonderful and they provide a lot of technical assistance and support and guidance. So, we're able to see what the DC Health…looks like and how we can adopt some of those strategies and things that we get from their trainings into what we're doing to provide more comprehensive services and kind of like strengthen already what we're doing.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16g depicts the PrEP continuum for clinic 7 as of March 2019. Of the 3797 HIV-negative persons enrolled in the project at clinic 7, 3151 (83%) were screened for PrEP.

Figure 16g. *Clinic 7 PrEP Continuum through March 2019*



PrEP screening at clinic 7 occurs in multiple ways. In the Community Health department, PrEP screening occurs in conjunction with HIV testing. In addition to the project's intake form, staff conducting rapid HIV testing and STI testing also use an internal testing form. Participant 7.1 described the use of the two forms:

> We kept that way [of] enrolling into the IMPACT project. Mostly how we were identifying those were through our daytime HIV testing or our evening STI clinic…So anyone that met that demographic…they were definitely pulled into that program… [Also] through our walk-in patient HIV testing or STI testing. We utilize [a] risk assessment and that's kind of like the point of conversation for us.

The internal form includes questions on client demographics (i.e., age, sex, gender, race/ethnicity, sexual orientation), history of HIV testing, drug use, sexual activity (ever and in the prior 12 months), and condom use in the past 12 months. Participant 7.2 elaborated:

> It's…like a form that everybody has to fill out when they're coming in to get tested for HIV or for STDs. And there's questions in there about substance abuse, questions about how many sexual partners, when was the last time you got tested for HIV and STDs…. We have a question about condom usage which I know a lot of people might not feel comfortable answering…but it's our role as testing counselors to ask those questions and go over them…We have a question that asks when was the last date of possible HIV exposure and I think that question has been key for a lot of us who are

> doing counseling and during our testing shifts because it lets us know if a person would be more appropriate for post-exposure prophylaxis rather than pre-exposure prophylaxis…And that's how we screen for PrEP and PEP.

Participant 7.3 described the universal PrEP screening process utilized in the clinical setting:

> We do not use a risk assessment tool…We do universal PrEP screening and talk about PrEP [with] every person in an effort to destigmatize and normalize the conversation so part of primary care is screening for PrEP…So all new patients get a sexual health history. As part of that sexual health history, people are screened for how they actively prevent HIV infection just as we talk about how patients actively prevent pregnancy. And so that is frequently the conversation that we'll have around the idea of PrEP…Patients that have a positive STI, and most specifically rectal or vaginal Gonorrhea, Chlamydia, or Syphilis, get actively screened [for] PrEP.

Similarly, Participant 7.4 described the PrEP screening process in the STI clinic:

> So, for everybody who comes through we have like a template, like an [History of Present Illness] HPI template built into our EMR that asks a series of questions including sexual health history questions, risk questions…like 'Do you know about PrEP?' And… 'Are you familiar with PrEP? Have you ever been on PrEP? Are you interested in PrEP?' And then our screeners offer information on PrEP.

Participant 7.2 explained that while he may have the title of PrEP navigator, in the Community Health department "anybody who [is] providing those direct services to patients is screening patients for PrEP… we're all asking those same questions about risk and exposure to HIV." In the clinical setting, Participant 7.3 explained that PrEP screening is conducted by "the primary care providers." In the STI clinic, Participant 7.4 explained:

> So often times it's not staff who's screening at all it's the volunteers who we train to screen to them. But staff will fill in if we're low on volunteers…So in terms of staff… myself… and then we have an MA, a medical assistant who helps with the treatment, [and] we have our AmeriCorps fellow who is our PrEP educator.

PrEP need

Figure 16g depicts the PrEP continuum for clinic 7 as of March 2019. Of the 3151 persons screened for PrEP, 2711 (86%) were determined to be in need of PrEP. Participant 7.1 explained that for clients in the IMPACT project, the process of determining PrEP need went from meeting specific criteria to a broader approach:

> In the beginning I think yes we were using like more CDC guidelines… if they were definitely actively sexual[ly] with multiple sex partners, one at least STI within six months we would definitely enrolling into a program…After taking into consideration the epidemic, what's happening in the city, like incident rates and all of that, we decided that [if] you are among this…priority population, [if] you are sexually active with sex partners, we will talk to you about PrEP. So, we just decided…that not so much as let's check all these boxes…So we did start it very conservative in terms…per CDC guidelines, but I think they were not too broad and it needed to, for us, to change…[So] once again [if] you are sexually active, [if] you have multiple partners…and you live in the city…you are a candidate for PrEP.

Participant 7.2 also discussed how PrEP need is determined for "low-risk" clients:

> So, if a person walked in and they want to be on PrEP they are given information, an overview about pre-exposure prophylaxis and how that works. And for some people they've definitely told us that for them it's like a relief in a way, kind of like a backup. Because…ultimately…we know that we can't always know what our significant other is doing twenty-four seven. So, it's kind of having like that relief. And as well as letting them know that PrEP is something that you can start and you don't have to be on it for the rest of your life. It's something that you can stop taking if anything changes in your life, so it's not a lifetime commitment…But if they want to be on PrEP they can get on PrEP. We're not going to tell them they can't get on PrEP although their risk might be significantly lower than other populations or other individuals.

Likewise, in the clinical setting, Participant 7.3 explained that patients were deemed eligible if "they want it." She elaborated:

> For specific eligibility, I think we…[look at] prevalence rates. So, by living and being socially and sexually active in Washington DC places an individual at increased risk of HIV infection and so therefore it's someone that should know…[about] PrEP if

> that's an option for them. We have some conversations around repeat PEP patients…So that's another entry point that we have from a PEP to PrEP transition…So I think it's just overall we saw early on that we had a low bar and a low threshold for PrEP eligibility and that for health promotion efforts it was the best way forward. So being HIV negative and interested in PrEP.

As Participant 7.4 explained, a broad approach to determining PrEP need is also utilized in the STI clinic:

> So honestly the way we think of it, I mean…we're an STI clinic right? So, anybody who's coming to us almost by default is eligible for PrEP. And that's kind of the way we think about it…So we talk about it with everybody who doesn't check off that they're already positive. We're automatically assuming everyone's eligible unless they have HIV.

Regarding the responsibility for determining PrEP need in the Community Health Department, Participant 7.2 explained:

> My role as the PrEP navigator is to identify candidates for PrEP…I am the one that pulls out a list of patients who have come into our services. And there's a question if they're interested in PrEP, if they're taking PrEP, if they would like to be on PrEP…I'm pulling the list of those people and compiling a list and then following up with those patients and just having a conversation about PrEP…And I think a lot of it is giving out information but also just listening to them…But to answer your question I guess that would be me for the purpose of the grant and the program and the effort to identify candidates.

In the clinical setting, Participant 7.3 stated that the determination of PrEP need is made by "our providers." She added:

> We mostly do same day PrEP starts. So, if a person is interested in PrEP and wants to start that day, we start that process and send the prescription down that day and usually see them back in thirty days and follow up with a one-week phone call. We found that the reduction in wait time to medication initiation improved uptake and retention especially at that one-month and six-month visit.

In the STI clinic, Participant 7.4 shared "I do notice…we get more referrals from some screeners than others so I think there's always room for improvement."

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 7 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

No barriers or facilitators to PrEP screening were identified by staff at the structural level.

At the institutional level, all four participants identified a lack of time as the biggest barrier to PrEP screening in the Community Health department, in the clinical setting, and the STI clinic. Participant 7.3 described the barrier in the clinical context:

> A barrier to PrEP screening is the short visits and the primary health indicators that are also required as part of an annual medical exam. So, the time is a barrier where not everyone may…have a full sexual health screening or have the discussion around sexual health that would possibly allow for a full PrEP screening. Because we have twenty-minute visits which means about ten minutes with the patient, maybe fifteen…if we need to.

Similarly, Participant 7.4 described the lack of time in the STI clinic:

> We see a lot of people in a short amount of time…On the patient end, they might be wanting to get in and get out, they've been waiting in the waiting room, maybe they don't want to go and get as far deep into a PrEP conversation in the screening process. And similarly, on the screener end, they're conscious of time and not keeping people waiting. So that's the first thing that comes to mind… that's like the biggest thing.

In reference to staff, the lack of diversity and relatability was the most commonly identified barrier to the PrEP screening process. Participant 7.2 elaborated:

> …kind of like going back to representation because we have a lot of Caucasian doctors, we have a lot of Cisgender doctors who are providing medical care to our

> Transgender patients. And kind of like one of the workarounds in that…has been getting Trans care navigators and has been getting more medical providers of color that are representative of the population that we're serving. But I guess like one thing that negatively affects, like some patients might not feel confident in telling everything to their medical doctor because of…not feeling represented sometimes.

Participant 7.3 agreed:

> I think that we have an underrepresentation as in no representation of Trans women or Trans providers in general which I think is a huge gap. We have an underrepresentation of providers of color. And we have an underrepresentation of especially MSM of color. And I think that's a barrier, I know that's a barrier.

However, the reputation of clinic 7 overall as a safe space was the most commonly identified facilitators to the PrEP screening process. Participant 7.1 shared:

> We were a part of [a different PrEP demonstration] study so a lot of people in the community, they knew that we were doing PrEP…And so I think the community trusts us…Even if patients have established care in other places they usually land here either for those routine testing or…for PrEP…. Sometimes they do not feel comfortable talking [to] their providers [about] prescribing PrEP.

Participant 7.4 agreed:

> Well, we have PrEP materials everywhere, like promotional materials everywhere. People come to us because they feel safe and comfortable coming to [clinic 7] and talking about sex. I have plenty of patients in both my primary care and in the evening clinics that will say 'Oh yeah I have a primary care provider but I don't want to talk to them about this.' And so, I think because of [clinic 7]'s reputation, because of the PrEP posters all over the place, it brings up the dialogue just by walking in the doors.

Provider comfort discussing sexual health and interacting with LGBTQ patients was also cited as a facilitator to the PrEP screening process. Participant 7.1 explained "…we have a very strong mission and vision and I think most of those providers that come here, they come prepared knowing this is what we serve…" Participant 7.3 added:

> For the most part clinicians that seek employment at a LGBTQ health organization are usually open to discussing sexual health. And that part is mostly discussed [during] an interview process. It is a big part of what we do so I think our bar is a little bit [higher]…We don' have the same…issues that other clinical sites we have.

At the individual level, Participant 7.1 explained that a lack of PrEP knowledge, specifically among transgender patients, may pose a barrier to the PrEP screening process:

> We do have a large number of Transgender people so we did have as a part of 1509 that subset of internal research project for interviewing our trans cohort…We did it first with the individual interviews and then we did group interviews…What fascinated [us] 'cause some of them didn't know what PrEP was so we had to spend a little bit more time educating. We understand that the individual will have that issue, but we didn't think that the focus group would have that issue and they actually had that issue. So, it was kind of challenging.

Participant 7.3 explained that medical mistrust among patients my keep them from being fully transparent during the screening process:

> We know that it's a fair amount of medical mistrust and other barriers that exist. And patients may feel more comfortable discussing and disclosing their situation that may have them be at increased vulnerability to HIV infection…[if] we seek to build that support and trust by helping them through that process.

As a facilitator to the PrEP screening process, Participant 7.2 explained that many patients are proactive about their health and receptive to the process:

> So, I think that positively we have a lot of patients who are just very proactive about their health and they're very understanding of different processes such as if a…person like they only come in for medical services then we have this conversation about PrEP and prevention…And they're very understanding, everybody is very receptive.

PrEP need

At the structural level, the inability to help patients navigate insurance and payment concerns was cited as the biggest barrier to determining PrEP need. Participant 7.2 explained:

> And a lot of people will be strong candidates for PrEP but their concern is once again insurance and paying for it…One of the big barriers are people who are over income for our sliding fee scale and they're not eligible for Medicaid and they have to pay full medical fee for their follow-up. So we're able to find coverage for say for the medication but then we have nothing in place for individuals who are unable to get insurance or are not Medicaid-eligible who fall out of our sliding fee scale and have to pay full fee for labs and medical appointments…Finding coverage for the rest of the medical appointments and the labs that can be costly and that's a big turn off for individuals…What we've been doing is refer those individuals to [clinic 8] but it's one of those things where it's unfortunate when patients can't come back for their follow-up because they can't pay for their medical appointment or for the labs.

No facilitators to determining PrEP need were identified by staff at the structural level.

At the institutional level, provider bias was identified as the biggest barrier to determining PrEP need. Participant 7.3 explained:

> …because we don't have specific eligibility criteria…I guess…there exists the potential for providers to have their own bias on eligibility and not discuss…eligibility with…all patients since it is left somewhat to provider discretion by having universal eligibility criteria. I think that's a barrier.

Participant 7.4 agreed:

> In terms of bias coming from the provider, we know that bias exists so I'm sure something's happening there. I don't know whether that is bias of like pushing towards one population versus the other…I mean yeah bias exists everywhere so I'm sure there's bias there.

The existence of services such as the PrEP clinic, onsite pharmacy, and STI clinic—which can reduce wait times and payment issues for patients—was cited as the biggest facilitator to determining PrEP need. Participant 7.1 explained how the PrEP clinic and onsite pharmacy served as facilitators:

> Our PrEP clinic is something that is innovative that we created and it's basically to expedite the process since it was overwhelming some patients. Other things that we have done which also are very helpful is there's a lot of issues when after you are prescribed PrEP you will encounter most of the time issues and how to obtain your

> medication. If you go to a pharmacy that does not understand how to apply the patient assistance program you will have some issues there. So, having our pharmacy understand that, communicates with other providers, with other PrEP navigator, that's pretty helpful.

Participant 7.3 described how having patients initially interact with the STI clinic helps to facilitate the process of determining PrEP need in the clinical setting:

> And so, I think that helped, having the community health team and the STI testing team almost prescreen patients for PrEP. Also, it's really helpful because by the time they come in and talk to a provider the system has already kind of given them an awareness of PrEP and supported the uptake and eligibility discussion to make it an easier conversation for providers to have. And by easier it's usually like 'Yeah I want PrEP, this is why' because they've already had the first round of discussions with the HIV and STI testing team.

Participant 7.3 also discussed buy-in across the organization regarding PrEP eligibility:

> And then so facilitating I think is that early on we had leadership buy-in that was supportive of the low threshold for eligibility for PrEP and supported the PrEP uptake and PrEP awareness for all.

Participant 7.4 explained that providers are dedicated to the mission of clinic 7, which facilitates the process of determining of PrEP need:

> I think people come to [clinic 7] because they believe in it…On the provider level like doctors and PAs, they could make a lot more money going literally anywhere else. They come to [clinic 7] because they believe in the mission and they believe in what we do. And I think when it comes to PrEP that is kind of a helpful thing because you already have people who are invested in preventing HIV.

Participant 7.1 also stated that "I think our providers are pretty well [informed] about PrEP", which facilitates the process of determining PrEP need.

At the individual level, many barriers to determining PrEP need were identified with the most common being side effect concerns. Participant 7.1 explained:

> The side effect situation is getting a little worse. There's a lot of lawsuits that's been making the social media. It started very small but it's very large now. And it's so many firms advertising, making this a case…It's frustrating when I see that 'cause it's taking away all of our efforts…I don't know if it's going to change with Descovy but there is a thing there…People are like 'oh what about this lawsuit?'

Participant 7.4 agreed:

> People usually come to me and say… either they heard from so and so it made them sick or it hurt their kidneys…'cause there's a lot of Truvada lawsuits ads and Facebook [ads] and whatnot. And people will be like 'Oh everyone is suing [this] company; it's a dangerous drug.'

Staff also discussed how medical mistrust and misinformation among patients can pose a barrier to the process of determining PrEP need. Participant 7.1 stated:

> [When] we talk about education…it depends like…in priority populations [such] as Black or Latinx community they have…their own education in their network…So they mistrust the healthcare system, they come with a mistrust and [that] adds…to…what type of education they came with, like what PrEP is…So yeah that is a big challenge that we are still working on. We are trying, it's not part of the 1509, but we're trying to do more; different types of outreach [and] education through social media outreach…Like different ways to educate the community with non-traditional posting and stuff. It's just more like how you engage the priority population through social media. But yeah there is a limitation there with education and how you break those barriers.

Participant 7.3 added:

> We have some patients who don't trust the medical system and have not had the best interactions with the medical system, so it may take many touches with different aspects of the medical system to increase that trust and provide a space where people feel safe to take recommendations for new medications. There is some misinformation in the community around PrEP, in many communities around PrEP. I've heard people tell me that Truvada has HIV in it and so I feel like that's an area…where misinformation is definitely damaging.

Conversely, Participant 7.3 explained that patient knowledge of and interest in PrEP facilitates the process of determining PrEP need:

> So, I think facilitating eligibility is being aware of PrEP, having an idea that PrEP is for them, that they're eligible, that they may benefit from it, and wanting to take it…I would say that overall, the biggest thing is that patients ask for it. And so, patients who have the agency to ask for PrEP are the ones that around the country will get it. And so, I think the biggest thing that impacts one's eligibility for PrEP is the patient's own advocacy.

Clinic 8

background

Clinic 8, located in a modern brick office building in Northeast DC, is a public health clinic that was formed only a few years ago after combining two separate clinics. Participant 8.2, a Nurse Practitioner and Supervisor, elaborated:

> The STD clinic was…located over in Southeast DC…And about three and a half years ago…the STD clinic came here to…Northeast…. And about eight months ago the TB clinic, formerly…located in Southeast DC, moved in…Now it's the STD and TB clinics co-located and rebranded as [clinic 8].

Participant 8.2 went on to describe the services offered at clinic 8:

> So, we provide STD and TB testing and treatment services for anyone who lives, works, or plays here in Washington, DC at little to no out-of-pocket expense to the patient. On the STD side of things, we do categorical STD testing [and] treatment for Gonorrhea, Chlamydia, Syphilis. Hepatitis screening. We do HIV screening…We do PrEP…and post-exposure prophylaxis…And we do rapid ART induction for new HIV positive patients or patients who have been out of care and need reconnection to care.

Clinic 8 also has a PrEP clinic, which Participant 8.3, an Epidemiologist, described as "interesting because it's actually a PrEP clinic within a…free-standing STD clinic."

Participant 8.3 also described the staff at clinic 8:

> So right now, there is [Participant 8.1] who is the…medical [director]. And then there's [Participant 8.2] who is the nurse practitioner. And they oversee the clinical aspects of the clinic. There's… the clinic coordinator and she oversees most of the non-clinical aspects of the clinic…. There are two physician assistants...that do most

> of the work. There are several what we call medical assistants or health techs…We also have a contract nurse…she basically goes between TB and STD. There are three front office staff that do registration and a bunch of other things…There's also a disease intervention specialist, and an investigator…and they also are forward-facing or they also deal with the public. And those are pretty much the individuals that work at the clinic who the public may or may not interact with. And then in the back of the clinic are…everybody from disease intervention specialists to pregnancy or family planning coordinators. Some of the TB staff folks are back there that do administrative work.

Participant 8.4, a Coordinator, added:

> I think overall we have about close to thirty people…I would say the majority of the staff is female. So, in terms of orientation…the females will be heterosexual…Then with males, we have a variety; so, we have Gay people and we have also heterosexual people. And then we have a Transgender person as part of the staff…I would say the majority of the staff is Black [or] African American. But we have some of us, like I'm Latina, so we have a couple…and a couple of White people. So, age range, I would say the majority of the people are in their forties and above. But there are…some young people in the staff too, some people in their thirties. I don't think we have anybody in their twenties.

Participant 8.1, the Medical Director of clinic 8, described the general patient population of the clinic:

> So [clinic 8]…sees anyone who walks through our door regardless of where their state of residence is, or country of origin, or their willingness to pay. In terms of our most common clients…it's about a 60/40 male to female split. It's about eighty percent African American or Latino patients. And...of the three hundred male patients it's about seventy percent men who have sex with men. We see probably about five percent of…patients who are Transgender.

Participant 8.3 added that "the clinic in general predominantly serves lower socioeconomic status individuals, a lot of people of color predominantly from Wards 7, 8, and 5."

When asked what motivated the organization to want to participate in the demonstration project, Participant 8.1 shared:

> I think our…being involved with the demonstration project was…really…[about] using [the] Health Impact Specialist as well as…PrEP navigation. So…sort of like a workflow in terms of how we were able to…reduce cost barriers for patients…through PrEP navigation services as well as…clinical services.

Participant 8.3 added:

> It was very clear that we had a mission to try and get PrEP to those that would most benefit from it. And some of those populations that are highest risk in Washington, DC happen to be MSM of color, Transgender females of color…And so there was definitely an impetus and a push to really serve that underserved population if you will. And that goes all the way from educating to actually implementing the PrEP and then maintaining the PrEP…So because…I have a little bit of a national view on some of these things…I just want to be very clear that I am very proud of the DMV program, unbelievably proud. I think that we are one of the few programs and places in the country that are getting PrEP to the people who most need it. And so even though…[there are] problems and issues…I can't express how…good that I think that we're doing, both at the individual and the population level.

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

When asked about the project's recommended process for PrEP screening Participant 8.1 responded "So at least [from] my [understanding] in terms of PrEP screening, it's a pretty broader screening." Participant 8.2 explained that having Project Team Member 8 embedded in the clinic was the biggest support provided by the project:

> [Project Team Member 8] who's the PrEP coordinator…she's also often embedded in the clinic and often forward-facing or dealing with patients. But that's really one of…the things that she does really well is she helps patients [with] PrEP.

PrEP need

When asked about the project's recommended process for determining PrEP need, Participant 8.2 explained:

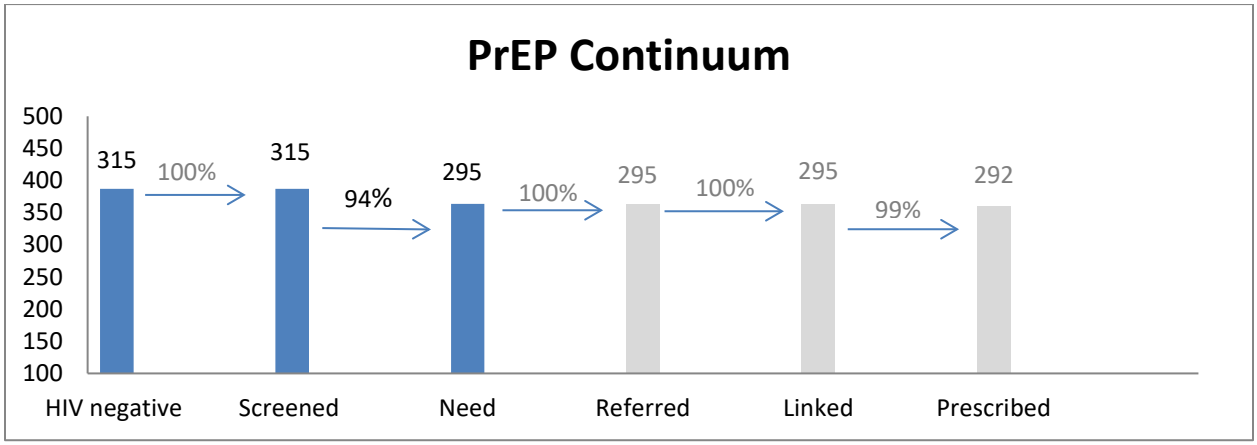
> So again, my understanding is that we don't want any barriers. So, any MSM of color or Transgender female of color who sought out…services to start PrEP or maintain on PrEP should have been allowed or implemented on PrEP and maintained at low or no cost to them.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16h depicts the PrEP continuum for clinic 8 as of March 2019. All of the 315 HIV-negative persons enrolled in the project at clinic 8 were screened for PrEP.

Figure 16h. *Clinic 8 PrEP Continuum through March 2019*



At clinic 8, providers conduct a sexual history with every patient using a template that doubles as an informal PrEP screening. Participant 8.1 stated:

> We have universal PrEP screening for basically every patient who comes in for it… In terms of our routine templates or our sexual history…I think that was developed…I believe in 2016 by my predecessor in consultation with I believe [Participant 8.3]. And I'm pretty sure that's modeled off the Fenway model of how to ask a sexual history.

Participant 8.3 added:

> So, we have our own risk assessment tool that we're using…We have templates within…our electronic health record…It [is] a way of us gathering very important information…to really guide what we do clinically with this person above and beyond the…provision of PrEP.

Participant 8.2 described the questions in the sexual history template in detail:

> We do a fairly detailed sexual health history on all our patients, even ones coming in for asymptomatic [STI] screening…It starts out with 'What sex were you assigned at birth? Which gender do you identify now? What's your sexual orientation? Are you currently sexually active? If so, when was your last exposure? Do you currently use drugs or alcohol? Have you ever used drugs or alcohol when you had sex? What is the gender and quantity of your sex partners in the last three months? What is the gender and quantity of sex partners in the last twelve months? Were any of them anonymous or pseudo-anonymous? What type of sex have you had in the last three months; insertive oral, receptive oral, insertive vaginal, receptive vaginal, insertive anal, receptive anal? How often was a condom used for each of those activities?' Always, frequently, occasionally, and never are the choices there…And then the last question is about PrEP knowledge and whether you want to talk about starting PrEP. So that's actually really much off the top of my head, the memory of the form. Clearly, we do it all day, every day…And based on their…response to the PrEP specific questions about whether they've heard of it [and] whether they want to start today, we talk about the provider's assessment of the HIV risk and try to get…an idea of what the patient's… assessment for HIV risk is and then talk about PrEP based on those risk assessments. So, it's both a specific and an organic process when it comes to PrEP screening. And so, the good part about that, it's sort of fold[ed] into any STD visit.

Participant 8.1 explained that additional PrEP screening is done by the PrEP Navigators using the project's intake form:

> And so, our PrEP navigators…provide additional screening on top of the screening that we're currently doing. But that's usually after…a sexual history has already been taken. So, it's some degree of redundancy and usually when they're sent to…the PrEP navigator or Health Impact Specialist it's usually done after the decision has been made to already start the patients on PrEP.

Participant 8.3 added:

> So [the project's intake form] is a form that we don't fill out as providers in the clinic, I believe that's an intake form that [Project Team Member 8] and the other PrEP navigators use. I believe they fill it out in REDCap.

PrEP need

Figure 16h depicts the PrEP continuum for clinic 8 as of March 2019. Of the 315 persons screened for PrEP, 295 (94%) were determined to be in need of PrEP. Regarding determining PrEP need at clinic 8, Participant 8.3 shared:

> We're supposed to look at the CDC risk factors…Things like: Have they had a bacterial or some sort of sexually transmitted infection within a certain amount of time?... Are they in a discordant relationship? Do they have a lot of receptive anal intercourse…with people of unknown HIV status? That kind of stuff. That being said, we have started several people on PrEP who just really didn't meet CDC's criteria but wanted to be on PrEP for their own peace of mind or for their own reasons…We have several patients on PrEP who has never had a sexually transmitted infection.

Participant 8.1 explained that the process of determining PrEP need is ultimately driven by the patient's interest in PrEP and/or perceived risk of HIV infection:

> Within a clinical context…basically, anyone who asks for it or they determine themselves at high risk, then we are open to providing that individual PrEP…Generally, that kind of trumps all else…Overall, we trust our patients…They might be at a different stage historically compared to where they might be going into the future…Even if they're currently in a monogamous relationship, [if] they say 'I

> think that my potential risk for HIV, it's potentially high'…they essentially don't feel comfortable…telling us about something or they're expecting that their situation in terms of potential HIV risk and acquisition might change and…that's why they're bringing it up that they're wanting to get on PrEP. So yeah again, there's no kind of hard and fast for us. If you don't meet any of these specific CDC risks, we're not going to *not* provide you with PrEP. We understand that life and relationships and sexual practices change. And…if you want to insulate yourself [from] this potential change in the future, we'll try to make that happen as much as we can.

Participant 8.2 discussed the decision to have broad PrEP eligibility criteria:

> Almost anyone who comes here potentially is PrEP eligible. It's really more do they want PrEP? Is there any sort of contraindication in their medical history that makes them ineligible for PrEP? So, a history of very poor kidney function, already being HIV positive, or not being sexually active. Those are really the only exclusion criteria if you will. So, the inclusion criteria [are] pretty broad…[and] the prevalence of HIV in this area is one of the main factors...And given the prevalence of HIV in our area and the high [risk] nature of many of our patients….You have to remember that patients that are coming to the STD clinic are different than the patients going to see a primary care provider for a physical. These people are coming to the STD clinic because they perceive themselves as being at risk for STDs. So, we're starting out with a group that's in a risk category that's different than your run of the mill family practice clinic…And the idea that CDC guidelines are not regulation set in stone. They're designed to be just that: guidelines for practice…And so I don't think it was probably ever the intention to restrict who gets PrEP just to those people identified in the risk stratification provided by those guidelines. I don't think that was ever the intention.

In reference to who is responsible for determining PrEP need, Participant 8.2 stated "typically…providers…make that determination when they're seeing the patient…So the PAs, me as the NP, or the volunteer or contracted NP's." Participant 8.4 added:

> Yeah, we do it the same day. And most of the time what they will do if the patient says yes for PrEP, they will have already ordered the lab test that is needed for PrEP…The patient will leave here with seven days [of] pills. And then the PrEP navigator…will start the application…with Gilead. And then…when they come back…everything will be ready and they will give them a prescription.

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 8 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

No barriers to PrEP screening were identified by staff at the structural level. Participant 8.1 stated that the affordability of services facilitates the PrEP screening process at the structural level:

> Yeah I mean I think…[having] no financial barriers is probably the largest one that facilitates PrEP screening. The fact that… the clinic is walk-in or is openly available for individuals. And it could be a potential positive factor that they're free to come in and it's free of charge to them.

At the institutional level, the most commonly identified barriers to the PrEP screening process were a lack of time to conduct the screening and the affiliation that clinic 8 has with DC Health. Participant 8.3 explained how limited time hinders PrEP screening:

> It's the providers being overworked, it's double booking of patients, it's not having enough time…When we were a free-standing STD clinic we were very problem-focused. So, what I mean by that [is] someone came into the clinic and they…had a very specific problem and so we basically addressed that very specific problem. It was very problem-focused. When we moved to doing PrEP, we became what I call pseudo primary care…And so the time that it takes to do the conversations, counseling, education and screening for PrEP was something new and different and more time consuming than what a problem-focused clinic was normally all about…So now…we were asking PA's, the volunteer providers to fit into their busy STD schedules some of these things like screening for PrEP and counseling and education which takes longer than the normal fifteen to twenty-minute visit that problem-focused patients can take…It's just sometimes it gets to be a crazy, busy clinic. And I think that for a crazy, busy clinic that predominantly is problem-focused sometimes non-problem-focused issues fall off the radar. That's probably the best way I can put it.

Participant 8.2 explained how the clinic's affiliation with the DC government negatively affects its reputation and can pose a barrier to the PrEP screening process:

> I think a possible negative to our structure is that we are a government agency. So, because of the current political climate and people's understandably distrustful attitude towards the government [it] is a negative. Even though we're not the federal government, we're a local government and we certainly don't share those [attitudes of the] current federal government…That could potentially be a negative if people just see us as part of the government instead of recognizing us as the safe place for being able to access care.

In reference to staff, Participant 8.2 explained that provider bias stemming from age and outdated prevention strategies pose a barrier to the screening process:

> Because we're not twenty-something or thirty-something providers…So we have lived through a time in medicine where we didn't have [a] good preventive strategy for HIV and certainly during the time when HIV was a terminal illness, a scary disease for which there wasn't good treatment…We have to let go of the messages around sex that we learned over time are not helpful. So, moving into a sex-positive attitude about sexual behaviors…not just "Don't have sex" or "Only have sex with a condom." But identifying other ways people reduce risk or potential harm from sex and PrEP is part of that…And so what I think potentially could be negative is how that influences our ability to approach patients with an open mind when it comes to sexual behaviors and whether or not they are traditionally considered high-risk behaviors for HIV.

Participant 8.3 stated that he thought it was actually a lack of cultural humility posing a barrier to the PrEP screening process at the staff level:

> I think, and no one really wants to talk about this, but I also think that there are differences in the comfort level of providers when dealing with our priority population. What I'm really talking about is the dealing with MSM of color and Transgender females of color. So, it not only takes in their identity and who they are, but also what they do. And the reason I know this…is because [Project Team Member 8] and I have identified more than one…unfortunate incidents that have occurred where a PrEP patient has asked to never see a certain provider again based on their experiences. And to be honest with you this gets much more to cultural humility education and not so much PrEP screening.

Participant 8.2 also explained that one facilitator to PrEP screening at the institutional level was the integrated approach:

> Well, I think that a positive factor to our structure is that we are conducting…sexual health histories on virtually everyone who comes through the door. So that sort of repetition, just sort of universal approach towards getting detailed patient health histories is just part of our process.

Participant 8.2 explained that staff are diverse and do mirror patients demographically:

> So, we do have a diverse staff, that's helpful…We have a pretty good racial and gender diversity mix in providers as well as at least two openly gay providers so that's helpful. We also have the PrEP navigators… a cisgender African American woman,…an African American MSM who does PrEP navigation, and a Hispanic Transgender woman who does PrEP navigation.

Participant 8.3 also discussed the willingness of providers to help each other as a facilitator to the screening process at the institutional level:

> I will tell you that some of the better providers—and what I mean by better providers, the ones who are comfortable admitting that they don't know something which in the provider world is uncommon—those providers…ask to shadow before they actually see their own patients. And the other thing I'll say…there's a lot of communication and there's a lot of mentoring…For some of the providers that may not have the same amount of experience that some of us do…So there's a lot of teamwork, if you will, to make sure that things get done appropriately.

At the individual level, Participant 8.2 explained that internalized beliefs and stigma can preclude some patients from being transparent during the screening process:

> Well, I mean because we're talking about groups that have been marginalized…And how it influences the screening for PrEP, I say patients' beliefs about sex and same sex behaviors and stigma associated with HIV may cause people not to bring up PrEP…so that could influence whether or not they're screened.

Participant 8.3 elaborated that for some patients internalized beliefs caused a lack of transparency while for others medical mistrust caused a lack of transparency:

> So, I think the number one is comfort with their provider…and to take that a step further it's comfort talking about these things with a provider. And that's especially difficult among Transgender individuals because a lot of them have had very bad interactions or experiences in the medical community…Because if I'm a Transgender female and I'm sitting in the waiting room and I've had bad experiences with the medical community, if I don't see that there are gender-neutral bathrooms, if I don't see that there are signs asking about preferred pronouns and preferred names, if I don't see that then I'm already going to have defenses up…. So…[another] thing…I have, off the top of my head, I have like five to seven MSM who are all African…[and] a couple of them say to me with tears in their eyes that they have never been honest with a doctor or a provider before in their entire life…And this gets to the stigma and the shame that's not only associated with sex but its associated about being a man who has sex with men or transitioning, all that kind of stuff.

As a facilitator the screening process at the individual level, Participant 8.2 explained "they've done this sort of internal, informal self-screen if you will for PrEP."

PrEP need

No barriers to determining PrEP need were identified by staff at the structural level. The main facilitator was the ability to assist patients in navigating insurance any payment. Participant 8.1 shared:

> I mean it's not like we consider insurance status before we determine eligibility or anything like that. It's a pretty firm mandate that we've been provided that we should provide PrEP to all people who seek it at no cost. So yeah, we make that happen as much as we can…We provide PrEP free on hand. So, when patients start up, we give them seven days of medication and send them over to the PrEP navigator who either gets them on Advancing Access, or PrEP DAP, or gives them a co-pay assistance card. So essentially it's costless for the patient.

At the institutional level, Participant 8.1 explained that there may be some variability in how strongly providers recommend PrEP to certain populations:

> I mean our regular providers who work in the clinic have at least…5, sometimes 10-15 years of experience in terms of diagnosing HIV and diagnosing STIs. So, they've been pretty aware of sort of the patient-level of factors that are associated with HIV infections. So, I think that if they're seeing certain characteristics…that sort of raise their concern for potential higher risk for HIV infection they will make a stronger, firmer recommendation for PrEP within the clinical encounter…Yes it might be some variability in terms of how strongly they're recommending to different groups and that's provider-dependent based off of certain criteria.

Participant 8.3 explained that the main institutional facilitator was the existence of the PrEP clinic:

> In some cases, there's no time and there's no distance between when we identify somebody as being high risk and when we can actually link them to a provider to start PrEP…Some of those patients get started on PrEP that exact same day; [For] some, it's the next day. But that's one of the benefits of having a PrEP clinic in a STD clinic: we're able to identify high-risk individuals easily and very seamlessly link them to PrEP care versus community-based organizations which may be out in a van or out in the community. And…then when they identify somebody who's eligible for PrEP and interested in starting PrEP then they actually have to refer them to care and link them to care and that can be problematic especially in Washington, DC.

Participant 8.4 explained that the knowledge of PrEP and training among providers also facilitates the process of determining PrEP need:

> We started the program with only one clinician doing PrEP and everybody else kind of like didn't know exactly what was going on…And at that time it was only him and we only put the PrEP patients when he was in clinic and the rest of the clinicians didn't know. But then they generalized the training and everybody went through it and now anybody can do PrEP.

At the individual level, all 5 participants cited side effect concerns among patients as a barrier to the process of determining PrEP need, and several indicated that it stemmed from a lack of knowledge of PrEP. Participant 8.5, a Health Impact Specialist, explained:

> Usually, the White people are already on PrEP. And they had already knew what it was and they had been on it since like 2012. But it was the little Black and Brown people that weren't aware of it, were afraid of the side effects.

Participant 8.3 added:

> And I think that this whole, the side effect profile of Truvada has been blown way out of proportion. And I have had several patients and friends who have not started PrEP because of Truvada but are now going to start PrEP because of Descovy. And I think part of that is Gilead's fault itself because I think they're really, really pushing for this Descovy for obvious financial reasons for themselves…But I think that there's a lot of [m]isinformation…I've had several patients…assume that most patients get side effects. And so then [I] educate them and tell them that 'No most of our patients don't get side effects. And for those few that do, if they take the pill the same time every day and they take it with food in their stomach—and not only food but food that has protein and fat in it—their side effects disappear within the first week of starting Truvada.'

The second most common barrier at the individual level was PrEP stigma. Participant 8.4

shared:

> Sometimes people don't want to show the pill because they don't want [other people] to get confused that they are taking the pill because they are in fact HIV positive. But that also goes the other way: I have heard of people that are HIV positive…say that …they're…Truvada for PrEP…. Like patients know that in the street and then they are afraid that people are going to think that 'Oh I'm one of them, I'm one of the ones that said that I'm taking PrEP but in fact is HIV positive.' I have those conversations with patients.

Participant 8.3 added:

> There have been a significant number who have…felt…shame…[from] others…because of being on PrEP…It's…[a] misconception in the community that people on PrEP are sluts or irresponsible and those kinds of things. And I know that for those of us that are intimately involved in all aspects of PrEP provision that we find that ridiculous. But it's pervasive and it's out there…I think it's more pervasive amongst certain subpopulations of individuals…And to be very clear I think that that's more of a problem in the Latinx community.

As an individual-level facilitator to the process of determining PrEP need, Participant 8.2 explained:

> Well, I mean…baseline knowledge about PrEP…[is] dramatically different for different groups. So…our patients…who are MSM or Trans women, they start out at a pretty advanced level of knowledge about PrEP typically.

Clinic 9

background

Founded in 2009, Clinic 9 is a non-profit community-based organization located on the third floor of a tall brick office building in Northern Virginia that provides STI education and testing as well as support groups for persons living with and at risk for HIV, at no cost. In terms of its mission, Participant 9.3, a Health Educator and former Health Impact Specialist, explains:

> [Clinic 9] is established by and for the community [and the] mission is to improve and strengthen the health and well-being of our diverse Northern Virginia community through culturally competent and language-appropriate HIV/AIDS services including HIV testing and prevention education, free of charge to all. And then with that [clinic 9] has many programs. One of them is HIV testing; Hepatitis-C testing; also, a program…for the MSM; the PrEP referral that I'm in charge [of]; the regional status neutral approach [to] services; the [program for transgender women] that I'm the coordinator for.

Participant 9.1, the Executive Director, added: "…so this organization I opened in 2009 because there was a big need especially for the Spanish community in terms of HIV and STD prevention and care."

Regarding the staff, Participant 9.1 shared:

> We started with two employees but now we have more than twenty. This is full-time, also volunteer. So, the majority are health educators, community health worker. Also, we have…[a] therapist for the mental health services.

Participant 9.4, a Program Manager, added "we are very multicultural. We have African American, Latino, Transgender women, we have Asian…. And we have young and older people also." In terms of the clients receiving HIV prevention services including PrEP, Participant 9.1 explained:

> I can say sixty percent, the majority of our clients is Spanish clients since all this funding we received is used to serve the Latino community. I can say thirty percent is African American and the rest is other race, it's mixed. Maybe seventy percent is male. And so, the other is females. Also, we included transgender. I think this is a great percent, I think at least ten percent of the transgender population. At least eighty percent of our [male] clients [are] MSM because all the services are very targeted.

Participant 9.2, a Prevention Counselor and former Health Impact Specialist, added:

> Most of the time…they don't have insurance or they're in-between insurances because they're in-between jobs but most of the times they do need some kind of financial assistance for PrEP…I've had people that came from I'll say like Dale City, Woodbridge area. Then I have a majority of people that come from the area where we're located...Then I have a lot of people [from] DC.

When asked what motivated the organization to want to participate in the demonstration project, Participant 9.1 shared:

> Yeah, I think this is a great opportunity for collaboration… the idea is…all the services should go to the community, not the community coming for your services…So, when this opportunity coming with HAHSTA to collaborate…This is just a great opportunity to…expand our services, also our referrals…So, if your client is not qualified for PrEP so we try to connect [them to] all their services so it can be maybe housing, mental health, or work development. So, we try to not necessarily put it in PrEP but it can be beneficial for all their services as well…It has also external referrals with [clinic 7], [clinic 2]…that's organizations that we work close. Also…[clinic 4].

knowledge of recommended IMPACT DMV processes for PrEP screening and determination of PrEP need

PrEP screening

When asked about the project's recommended process for PrEP screening Participant 9.1 responded:

> I think with the 1509 it was the first initiation for PrEP here in Northern Virginia. The process was clear because they provided all this training and plus we have all these tools, materials that [DC] DOH provide through all these meetings, trainings…Our meaningful relationship with the DOH was strong…I think the [DC] DOH, they organize several, they have some coalition, different coalition so that we meet for several months…it was several organizations that participated.

Participant 9.3 commented on support for PrEP screening provided by the project:

> [DC] DOH… They are wonderful. When they have something new like a training or something updated with PrEP…they will call me.

PrEP need

When asked about the project's recommended process for determining PrEP need,

Participant 9.1 explained that the focus of the project was MSM and transgender persons:

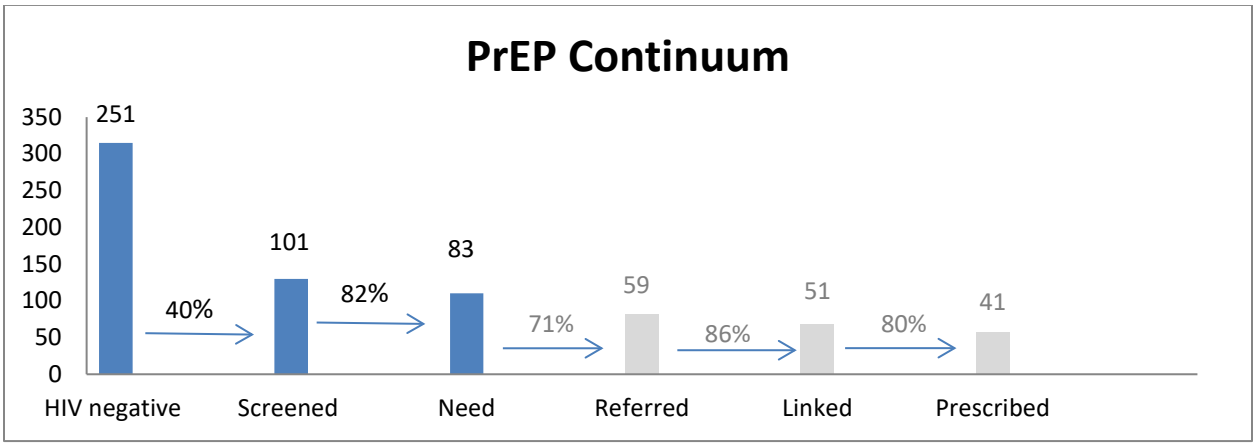
> First clients…to be part of this program it has to be high risk, men who have sex with men, that's number one…Also they ask [us] to engage in the Transgender community, that was very beneficial for the Transgender community to get on PrEP…. When we're talking about high risk it can be an injection drug user…have sex with multiple partners with unknown HIV status. So, we reach a lot of homeless, substance abuse for alcohol and drug abuse, and Transgender individuals.

actual implementation processes for PrEP screening and determination of PrEP need

PrEP screening

Figure 16i depicts the PrEP continuum for clinic 9 as of March 2019. Of the 251 HIV-negative persons enrolled in the project at clinic 9, 101 (40%) were screened for PrEP.

Figure 16i. *Clinic 9 PrEP Continuum through March 2019.*



Screening for PrEP at clinic 9 is done in conjunction with HIV and STI testing. When clients present for testing either at the clinic or at community events, they complete an initial assessment that asks about the number of sexual partners they have had in their lifetime, any condomless sex (oral, anal, and/or vaginal), the types of partners with whom they have had condomless sex (male and/or female), and any anonymous sex. This initial intake form is administered by any clinic 9 staff member conducting the HIV or STI testing. Participant 9.3 elaborates:

> The first one, the rapid testing…risk assessment tool where we ask: 'when was the last time you were tested for HIV? When was the last time you got tested for Syphilis, Hepatitis-C, Chlamydia, Gonorrhea? What were the results?' And then we go into more detail. 'When was the last time you had unprotected vaginal sex? When was the last time you had unprotected anal sex? Was that with a male? Was that with a female? Was that with a Trans woman?' And then we go to. "When was the last you had unprotected oral sex?' The same thing 'Trans, male, female?" And then we go "How many sexual partners have you had?"…. 'When was the last time you had sex under the influence of alcohol or any other substance? When was the last time you shared or used needles? When was the last time you used or shared other drug…paraphernalia like pipes, straws? When was the last time you exchanged sex for drug, money, or something you needed?'

If patients are deemed high risk based on their responses to this initial assessment, then they are screened for PrEP using a PrEP risk assessment form. Participant 9.3 explains:

> That's where we go to the risk assessment evaluation for PrEP… the questions are based on, 'how old are you today? In the last six months, how many partners? Have you had sexual encounters? In the last six months, how many times have you had receptive anal sex where you were the bottom partner without a condom? In the last six months how many of your partners were HIV positive? In the last six months, how many times did you have insertive anal intercourse? In the last six months have you frequently used drugs or alcohol before or after sex?'

The PrEP risk assessment form contains just 6 questions, the majority of which mirror the Risk Behavior Assessment for MSM contained in the CDC's Clinical Practice Guidelines. Participant 9.1 explained that the PrEP risk assessment form is "a combination…[of]…the current risk assessment from [clinic 9] [in] combination with the CDC… screening for PrEP. Also, HAHSTA...provide some tools."

When asked about the time associated with screening clients for PrEP, Participant 9.3 explains that after conducting the initial assessment taken during HIV or STI testing, "So then…we talk about PrEP and then they'll be like 'okay you know what yeah I'm interested

in PrEP. What do I need to do?' And that's when we do the risk assessment as well…that's an extra five to ten more minutes to be like okay let me get your [PrEP] risk assessment evaluation."

Participants 9.2 and Participant 9.3 are primarily responsible for screening clients for PrEP using the PrEP risk assessment form.

PrEP need

Figure 16i depicts the PrEP continuum for clinic 9 as of March 2019. Of the 101 persons screened for PrEP, 83 (82%) were determined to be in need of PrEP. Responses to each question on the PrEP risk assessment form utilized by clinic 9 are given a score. For example, the first question inquires about the client's age. If the client is between the ages of 18-28, then they are given a score of 8. If the total score from all 6 questions is greater than 10, then the client is eligible for PrEP. Participant 9.3 elaborates:

> So yeah we go through an assessment of the questions…Then we add those scores, and then if they hit over 10 …we talk about PrEP….And the message I'm saying about PrEP is if you use a condom and if you use PrEP you're a mixture of Wonder Woman and Superman. And if you only use PrEP you're only like Clark Kent and Linda [Carter] before turning into Superman [and Wonder Woman]…So if a score is 10 or greater, evaluate for intensive HIV prevention services included with PrEP. If a score is below 10, provide indicated standard HIV prevention services.

However, the staff at clinic 9 made it clear that clients who show interest in PrEP are eligible even if their PrEP risk assessment score is less than 10. Participant 9.4 explained:

> Sometimes people don't tell the truth and when we see that they are asking for it is because they maybe are getting into a high-risk situation but they don't want to share sometimes. Some people lie and they say, 'I'm not [at] high risk but I want to be on PrEP.' We have many cases like that and we refer them.

Participant 9.3 elaborated:

> At [clinic 9] everybody who wants it is eligible…. I mean because you only need one time to sleep with somebody without using a condom. And to be honest, HIV is like Russian roulette, you don't know when it's going to be your turn. So that's what I normally tell all of my clients, if you want to try PrEP, try PrEP for three months, see how it goes, see if it's for you. Because every three months you have to come back to us and see how high risk you are…So then they will be able to determine if they want to keep on using PrEP because PrEP is not a long-term…It all depends on which stage the client that walks into [clinic 9] they are…So we always leave the door open for whoever wants to be on PrEP, wants to leave PrEP, or they want to come back to PrEP.

Because Participant 9.2 and Participant 9.3 are primarily responsible for screening clients for PrEP, they are also primarily responsible for determining PrEP need. Participant 9.2 shared:

> Usually, it gets made kind of right then and there. Like after talking to the client, doing the evaluation. I just basically look over everything and I'm like 'okay you definitely do need PrEP' and then I'll assign PrEP. 'Cause…usually you can tell if they're at high risk, [whether] they really need PrEP, [whether] it be beneficial for somebody…usually…me or [Participant 9.3]…we are usually the ones to actually make the final call and set up the appointment.

Participant 9.4 elaborated that "we usually do when the client is in there…It's more easy because later on if you call them they don't answer or their interest goes down."

Regarding training specific to determining PrEP need, Participant 9.2 shared:

> We've had training where we've been certified. We go to different conferences. We network. We're just very much in the culture of it. So that's kind of how we've been trained to…refer for PrEP…. Certifications like…the HIV Fundamentals trainings. And there are also certifications in PrEP navigation and also social network strategies and stuff like that, all of these initiatives for HIV prevention. And then a lot of these classes and courses they overlap…it's kind of like cross training...So it just gives us a more well-rounded view.

perceived barriers and facilitators to PrEP screening and determination of PrEP need

Staff at clinic 9 identified barriers and facilitators to PrEP screening and determining PrEP need at the structural, institutional, and individual level.

PrEP screening

Regarding barriers to PrEP screening at the structural level, Participant 9.2 shared:

> Our challenge is the location because a lot of people that are interested in PrEP and coming…[from] a lot of areas that aren't necessarily our home. So that can be a problem sometimes.

Participant 9.1 explained that "we are the organization who provides all the services for free, we don't charge" which facilitates the PrEP screening process at the structural level.

When asked if there were any barriers to PrEP screening at the institutional level, Participant 9.1 responded "Actually, no…" The culturally competent services offered at Clinic 9 help to facilitate the PrEP screening process at the institutional level. Participant 9.4 explained:

> …because we target the minorities, for the Latino community sometimes it's very difficult to access these services. And what we at [clinic 9] are trying to do is have information in Spanish and sometimes the health educators do like social media campaigns talking about PrEP and the benefits and all those things and that's how we can influence people to come in and get PrEP in [clinic 9]. And also, we have a lot of posters and information in the testing room in the waiting area in both languages, English and Spanish.

Participant 9.1 commented on the positive reputation of the organization in the community as a facilitator to the screening process at the institutional level:

> [Clinic 9] in the last ten years increased our visibility in terms of the services we provide. And we appear in several campaigns in awareness…That's also helping a lot

> with the community, they can trust about PrEP…I think that the community now trusts how serious [clinic 9] is…And plus [Clinic 9] is around the community, so we reach out to the community constantly.

Another facilitator was the diversity and relatability of the staff, as Participant 9.3 explained:

> We are very diverse, very diverse. We have the…Black African American…And then we have the Trans…And then we have the White MSM…And then we have the Hispanic MSM…We are very diverse like where they are like 'okay, you know what? I see a familiar face, I just don't see White people, or I don't [just] see Black people, I don't [just] see Latinos.'

Participant 9.2 elaborated on the diversity, passion, relatability, and comprehensive approach of the staff:

> We all come from different walks of life, so diversity. We all care about our clients, we're all very passionate…we all are from the community…we all can relate to our clients…. [And] that probably has to affect our clientele, seeing people of color of all different skin tones and shades and hues and cultures and backgrounds. I think that really makes our clients feel more at home as well…The screening process is easy for us…We are really thorough when we have conversations, we really ask in-depth questions. We ask questions that the client probably wouldn't even think that we would ask. Because we really do want to know in the back of our minds, if we send you out here is this really going to benefit you. It's not just a numbers game. So, when they come and everybody here speaks Spanish, everybody here [speaks] English.

At the individual level, the biggest barrier to PrEP screening identified by staff was the lack of transparency of some patients during the screening process. Participant 9.4 explained:

> That's one of the main ones yeah; some clients are not honest. And sometimes you can see it when you're asking them the questions that they're not being honest and then …the process cannot be really done good because people are not honest. But we inform them anyway of the benefits of being on PrEP and all those things. And…we have a lot of Arabic people, Middle Eastern, coming and because of their religion…they're not open that much. But we know it's a lot of MSM activity within the Middle Eastern people and we invite them but just really have to get them into PrEP.

Participant 9.2 echoed those sentiments:

> Sometimes clients are afraid to be transparent with us. And I'll tell them 'listen I'm not your wife or cousin or anything, I'm here to help…so I can best direct you to services.' So, if they're being transparent it just makes it a lot easier…Because I really can't assess your risk…if you're not being transparent, if you're not really telling me what you're sexually doing…Are you having sex in all three sites? Are you having sex with just men or just women? If you're not telling me these things I'm like, do you need PrEP? 'Cause you're giving me the assumption that you're not at high risk.

Participant 9.3 explained that the main individual-level facilitator of PrEP screening was the fact that patients are "really interested in getting more information about PrEP." Participant 9.2 added: "So I think any client that's open to knowledge and open to education it's a lot smoother for all."

PrEP need

As a barrier to determining PrEP need at the structural level, Participant 9.4 explained that after determining that someone was eligible for PrEP:

> We were having a lot of challenges finding places to refer clients for PrEP eligibility especially when people don't have insurance. It was really, really hard at first. but we've been finding now some places like [clinic 4] or we send people also to [clinic 7] and those are the two main places.

Participant 9.2 elaborated:

> Also, barriers like cross state things. Like for instance for our clients it's a lot easier for us to send them to [Clinic 8] because it's a faster process, they leave with PrEP within the first visit and all that good stuff. [But], because of the policies and stuff like that, DC would prefer our clients [be sent] to Virginia providers. But the thing is with Virginia providers…it's not same-day PrEP and the financial co-pays are different and just the process of their screening for PrEP and prescribing PrEP is different and may be potentially slower than [clinic 8]. So those are usually kind of issues that we found referring people to PrEP.

No facilitators to determining PrEP need were identified by staff at the structural level.

No barriers to determining PrEP need were identified by staff at the institutional level. Regarding facilitators Participant 9.2 explained:

> Our internal structure is really great when it comes to it…. There's no process here that would be a burden as far as PrEP navigation here from my experience. It's easy, you come in to get tested, we screen you, we'll evaluate you for a few minutes, we'll have a conversation with you, and then we'll help set you up.

Participant 9.4 reiterated that by saying, "I think the process is very clear and we don't have any negative experiences."

Similar to PrEP screening, the diversity and relatability of the staff were other institutional facilitators to the process of determining PrEP need. Participant 9.2 explained:

> The positive characteristics of the staff is just being diverse, coming from the same community, being passionate. Being literally 'for the people by the people." That saying, that's what we are. Literally, we walk what we talk. What the clients tell me, stories that the clients have had are stories that I had when I was younger. So, it just really is like the community made us, and now we're here to help the community.

At the individual level, the main barriers to determining PrEP need were side effect concerns and PrEP stigma. Participant 9.4 talked about the side effect concerns and PrEP stigma:

> It was a big campaign on Facebook and also on one of the main Spanish TV [channels] about PrEP and the secondary effect, people did not want to get it because the side effects…And it was influencing very much. But I would say especially with the Hispanic also with the LGBTQ Latino community… that's what maybe influences people, for people not to get into PrEP.

Participant 9.2 elaborated on the side effect concerns:

> But other things are, that really affect people not wanting to have PrEP in the first place, we can thank the infomercials now [for] the whole 'If you've used PrEP in the past year, go and get a lawsuit' or something.

Participant 9.3 also spoke about PrEP stigma:

> Somebody that I know he got fired from a job because they assumed that the pill that he was taking was for HIV. So that's one of the things that I have heard: people assuming that because it's Truvada, it's an HIV medication…We always try to give them the little pill thing; Gilead gives us the little key chains where you can put your pill there. But yeah, there's always assumptions though; we live in an environment where people assume everything.

Participant 9.4 agreed:

> In some cases, family found the medication and they thought they were HIV positive. And then they were coming, 'Oh my god my family found this and they think now I'm HIV positive even that I told them it's to prevent.' That happens with a couple of the clients.

The main facilitator to determining PrEP need at the individual level was the risk perception of the clients. Participant 9.1 explained "…so definitely the clients and their perception that they are at risk, that is the reason they're willing to take care of themselves, take care of their partner."

Variation and adaptation within the project (RQ 3)

Sources of variation within the project

As can be expected, there was variation among the clinics and between the clinics and the project leadership. Most notably, there was variation in the organizational contexts of the clinics and in the perceived barriers and facilitators to PrEP screening and determining PrEP need identified by the project leadership and clinic staff.

organizational context

Within the organizational context, clinics varied in their organizational characteristics; their networks and communication within the project; and their culture.

organizational characteristics

Table 10 displays the organizational characteristics of clinics. With respect to organizational age, only clinics 8 and 9 are less than 20 years old. With the exception of clinics 4 and 8, all other clinics are nonprofits. While clinic 1 is located in Maryland and clinics 4 and 9 are located in Virginia, all other clinics are located in DC. Clinics 1, 8, and 9 only have one clinic location while the remainder of clinics have 2 or more locations. While the number of locations doesn't necessarily correlate with the size of the organization (e.g., clinics 4,5, and 6 are relatively small with three or more sites), it does appear that the size of the organization correlates with having screened and determined a higher proportion of patients to be in need of PrEP than smaller clinics (Table 8).

Table 10. *Organizational Characteristics of Clinics*

Characteristics	Clinic(s)
Organizational Age	
≤20 years old	8,9
>20 years old	1,2,3,4,5,6,7
Type of Organization	
Non-profit	1,2,3,5,6,7,9

Primary Care	4
Public Health Clinic	8
Location	
DC	2,3,5,6,7,8
MD	1
VA	4,9
Number of Sites	
1	1, 8,9
2	3
3+	2,4,5,6,7

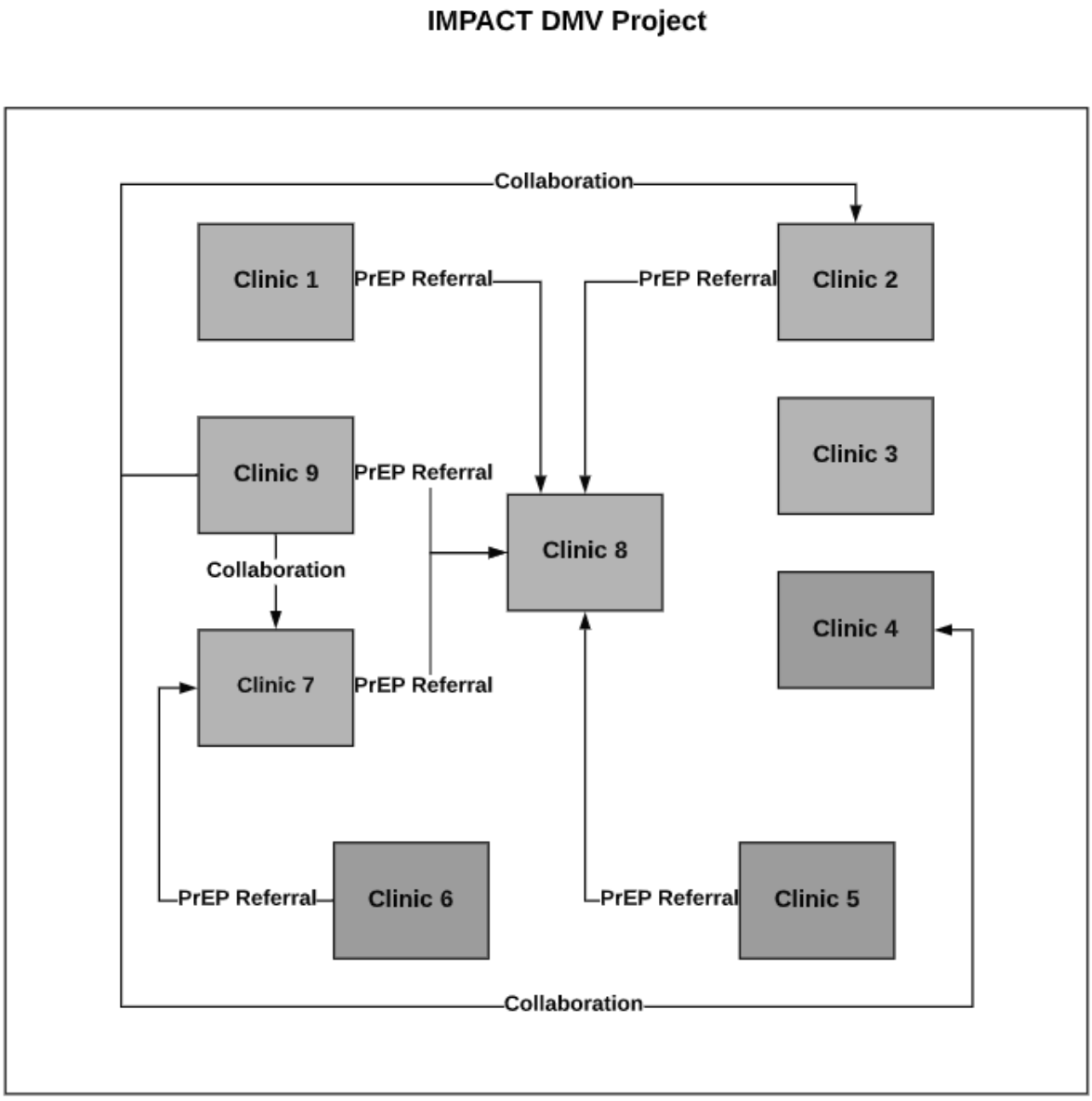
networks and communication

With respect to intra-organizational networks and communication, clinic 7 demonstrated the highest degree of connectivity and communication by screening for PrEP and determining PrEP need across three different departments: the Community Health Department, the clinical setting, and the STI clinic. The existence of multiple PrEP access points at clinic 7, a relatively large organization, may have partially contributed to the high proportion of HIV-negative project participants being screened for and determined to be in need of PrEP (Table 8). Conversely, clinics 1, 3, 5, and 9—all relatively small organizations—have a designated department or team responsible for PrEP screening which may partially explain the lower proportions of HIV-negative project participants being

screened for PrEP at those clinics (Table 8). Interestingly, clinics 3, 5, and 9 had high proportions of persons deemed eligible for PrEP of those screened.

Figure 17 depicts the inter-organizational networks and communication in the project. Staff at clinics 3 and 4 did not explicitly reference collaborating with or referring potential PrEP patients to other clinics participating in the project during interviews or focus groups. Conversely, clinic 9, a relatively small organization, mentioned collaborating with two other organizations and referring potential PrEP patients to one other organization in the IMPACT DMV network. Clinic 8 served as the PrEP referral site for five organizations which may partially explain the high proportion of HIV-negative project participants being screened for PrEP (Table 8).

Figure *17.* *Networks and Communication Between Clinics*



culture

The culture of an organization can be defined by its norms, values, and mission. For most of the clinics in the project, specific populations or groups of people are specified in the

mission and vision statements (Table 11). Clinic 6 is the only organization with a specific focus on youth. Clinic 6, along with clinics 4 and 7, also has a specific focus on the LGBTQ+ population. Clinics 1 and 5, both of which have primarily African American patient populations, have a specific focus on disenfranchised persons. Clinics 2 and 9, both of which have primarily Hispanic patient populations, have a specific focus on the Latinx community.

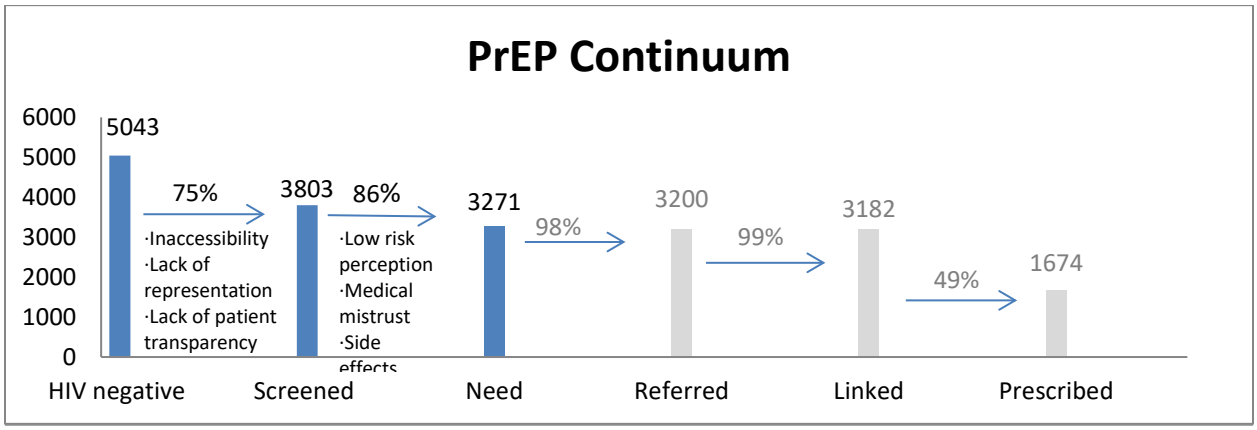
Table 11. *Cultural Characteristics of Clinics*

Characteristics	Clinic(s)
Priority Population(s)	
Disenfranchised Persons	1, 5
Latinx Community	2, 9
Persons Living with HIV	4, 5
Youth	6
LGBTQ+ Community	4, 6, 7
Everyone	3, 7, 8, 9

barriers and facilitators

The three most commonly reported barriers to PrEP screening across the project leadership and clinic staff and across the structural, institutional, and individual levels are listed in Figure 16j.

Figure 16j. *IMPACT DMV PrEP Continuum with Barriers through March 2019*

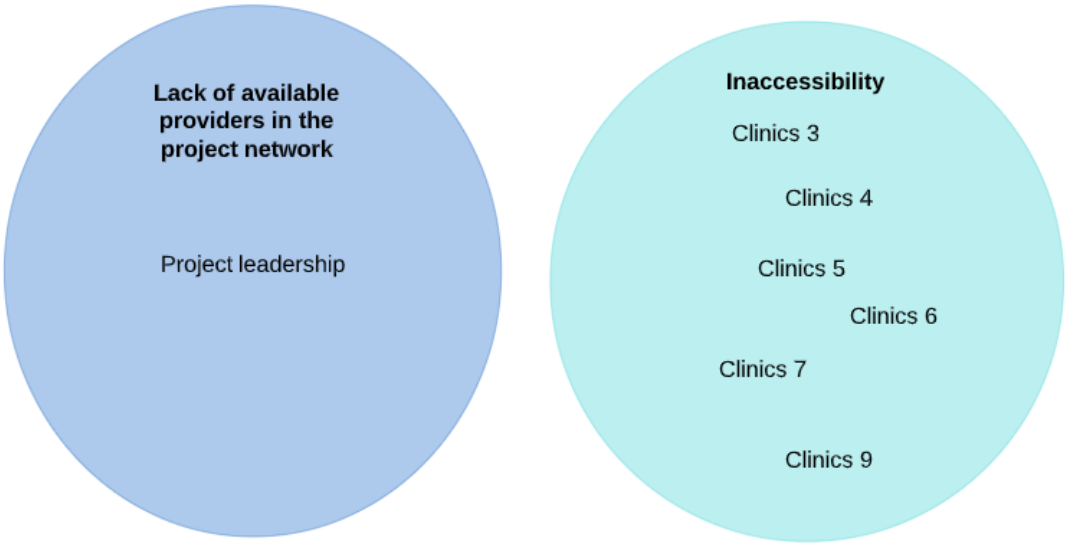


PrEP screening

structural

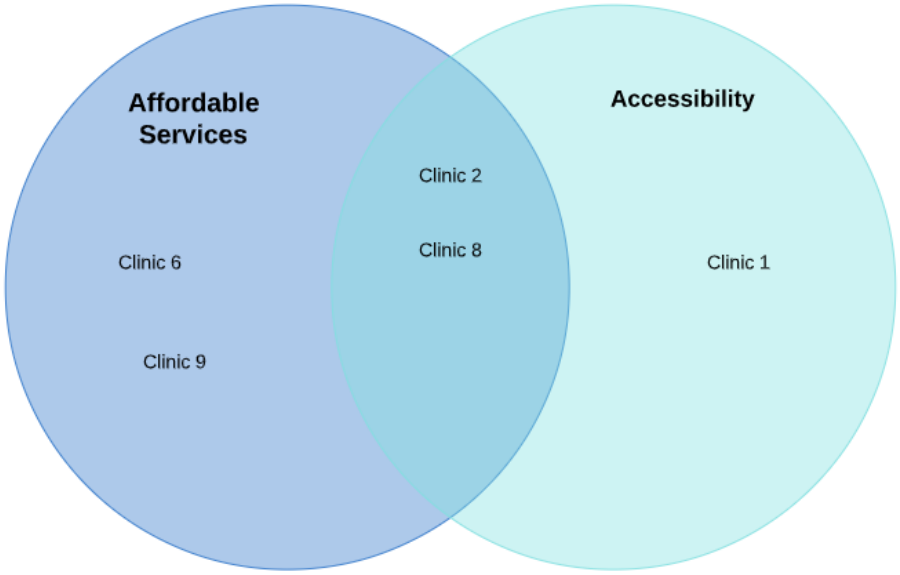
At the structural level, there was no overlap between barriers reported at the project and clinic level (Figure 18). While the project leadership saw the lack of available providers in the IMPACT network as the biggest structural impediment to PrEP screening, the staff at the clinics (with the exception of clinics 1, 2, and 8) saw the inaccessibility of the clinics to patients due to their location as the biggest structural barrier to PrEP screening. The difference in structural barriers reported at the project and clinic levels may be partially explained by the different levels of interaction that project leadership and clinic staff have with patients.

Figure *18*. *Structural Barriers to PrEP Screening*



Across the project, the most commonly reported facilitators to PrEP screening at the structural level were the affordable services (i.e., free of charge) offered by the clinics as well as their accessibility (i.e., the clinics are transit-accessible or subsidize transportation), reported by staff at relatively small clinics Three clinics (2,6, and 9) where staff cited affordable services as a structural facilitator to PrEP screening are non-profit organizations, as are two clinics (1 and 2) where staff cited the accessibility of the clinic as a structural facilitator to PrEP screening (Figure 19).

Figure *19***.** *Structural Facilitators to PrEP Screening*

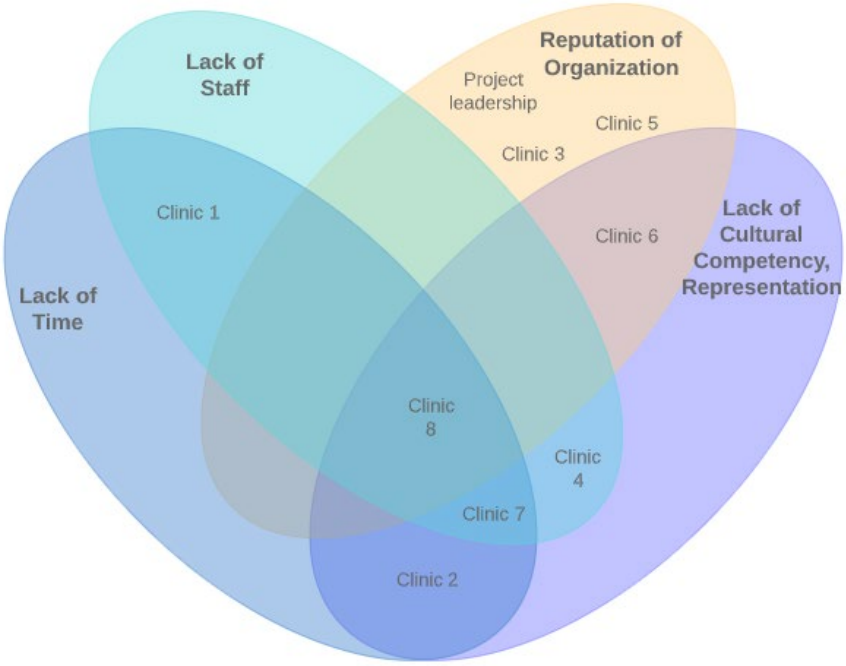


institutional

At the institutional level, lack of time, lack staff, the organization's negative reputation, and the lack of representation and/or cultural competency among staff were the most commonly reported barriers across the project. Lack of time, lack of staff, and lack of representation and/or cultural competency among staff were reported as barriers by staff at clinics of all sizes (e.g., clinic 2 is relatively small while clinic 7 is relatively large). However, the negative reputation of organizations was reported as a barrier primarily by staff at smaller clinics as well as the project's leadership. Staff at clinics of all three types (i.e., non-profit, primary care, and public health) reported lack of staff and lack of cultural

competency and /or representation among staff as institutional barriers to the screening process (Figure 20).

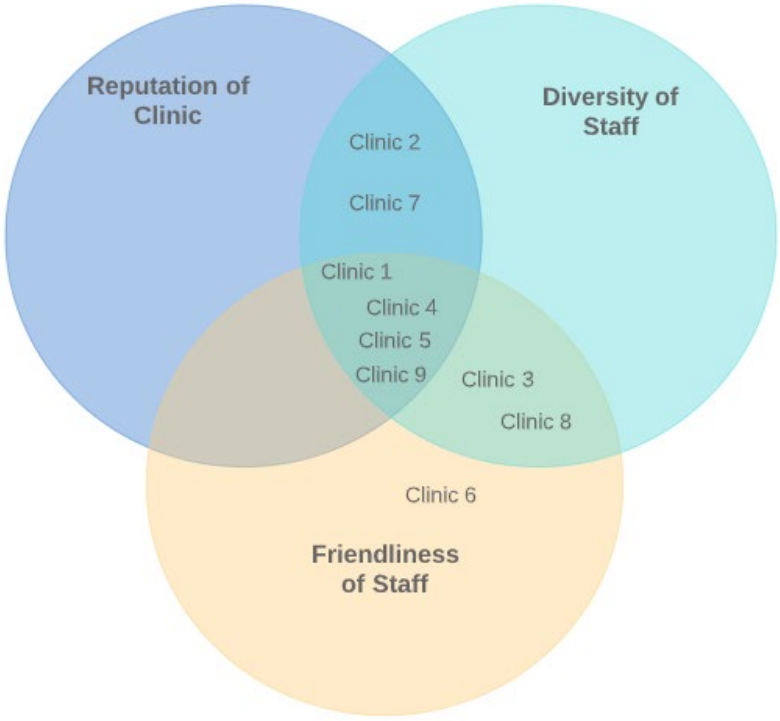
Figure *20***.** *Institutional Barriers to PrEP Screening*



Across the project, the most commonly reported facilitators of PrEP screening at the institutional level were the positive reputation of the clinics, the diversity and relatability of the staff, and the friendliness of the staff. While staff at relatively small clinics reported the

diversity of staff and/or the friendliness of the staff as facilitators, all three facilitators were reported by staff at clinics of varying sizes. Staff at all three clinics types (i.e., non-profit, primary care, and public health reported the diversity and friendliness of staff as institutional facilitators to the screening process (Figure 21).

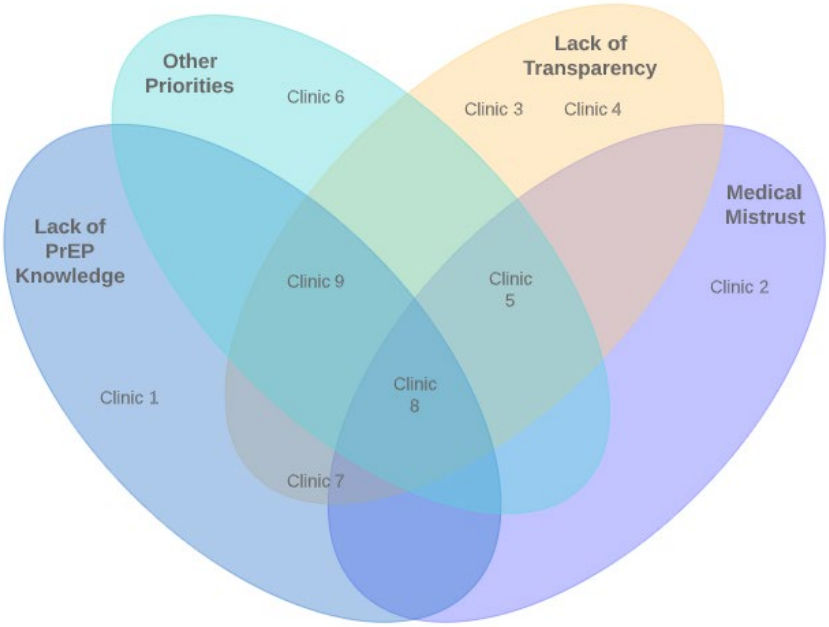
Figure *21***.** *Institutional Facilitators to PrEP Screening*



individual

At the individual level, lack of PrEP knowledge, competing priorities, lack of transparency during the screening process, and medical mistrust were the most commonly reported barriers across the project, all of which were reported by staff at clinics of varying sizes. Staff at all three clinic types (e.g., non-profit, primary care, and public health) reported lack of patient transparency during the screening process as an individual barrier (Figure 22).

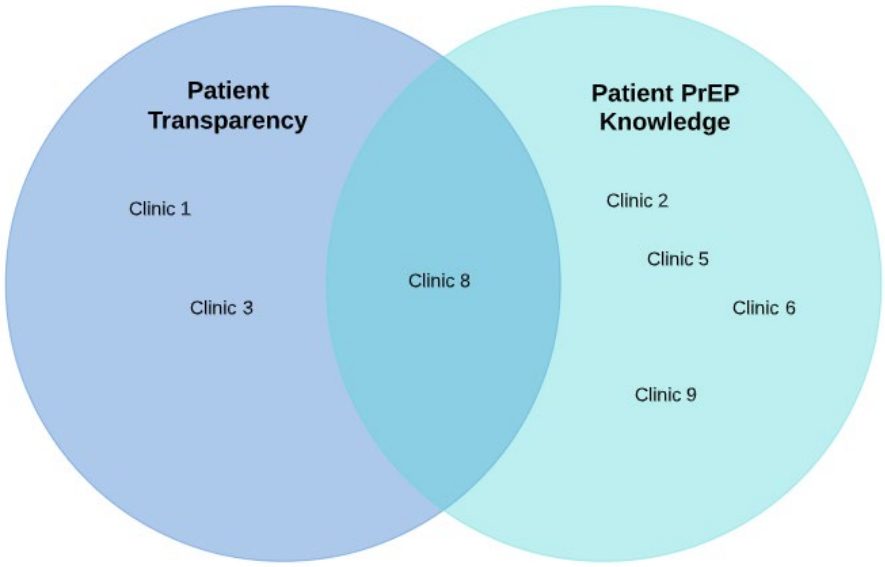
Figure *22***.** *Individual Barriers to PrEP Screening*



Across the project, patient transparency and knowledge of PrEP were the most commonly reported individual level facilitators, all of which were reported by staff mostly

working in small clinics. Two of the clinics (1 and 3) were staff reported patient transparency as an individual facilitator to the screening process are non-profits, as are four clinics where staff reported patient knowledge of PrEP as an individual facilitator to the screening process (Figure 23).

Figure *23***.** *Individual Facilitators to PrEP Screening*



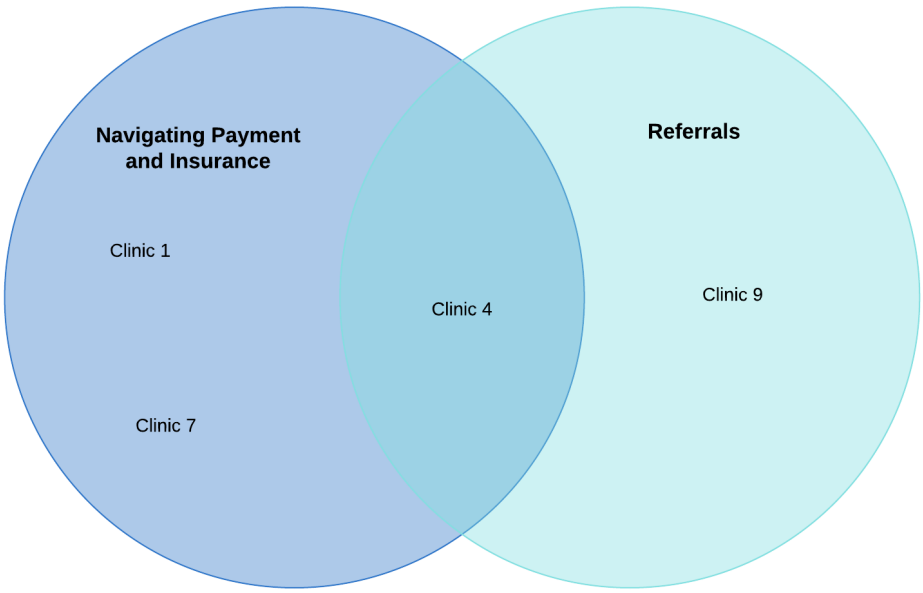
PrEP need

The three most commonly reported barriers to determining PrEP need screening across the project leadership and clinic staff and across the structural, institutional, and individual levels are listed in Figure 16j.

structural

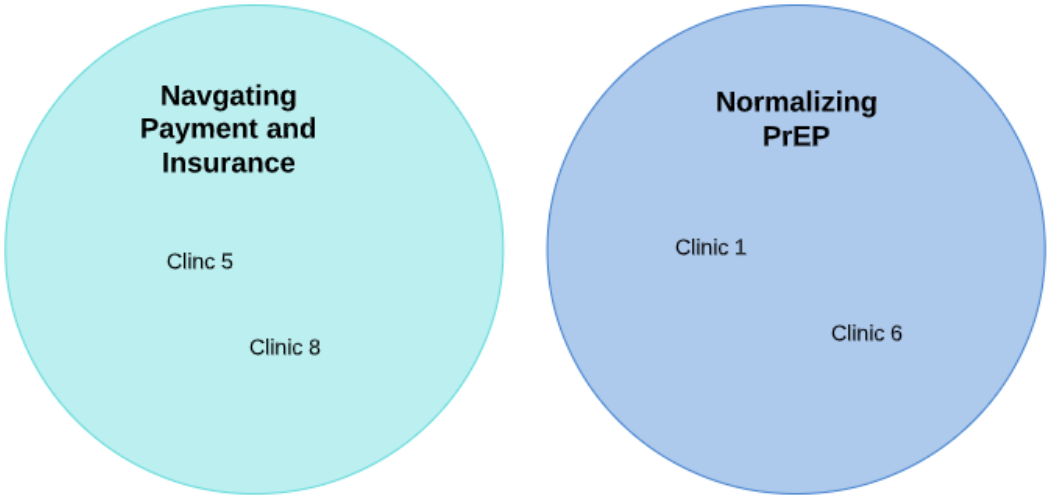
Among the project, the most commonly reported structural barriers to determining PrEP need were navigating payment and insurance (clinics 1, 4, and 7) and referrals to other clinics (clinics 4 and 9; Figure 24). These barriers may partially be a result of the inclusion of clinics located in DC, MD, and VA in the IMPACT network and the differential PrEP policies of those states. Two of the clinics (1 and 7) where staff reported navigating insurance and payment for PrEP as a structural barrier to determining PrEP need are non-profits, as is one clinic (9) where staff reported referral to other clinics as a structural barrier to determining PrEP need.

Figure *24*. *Structural Barriers to Determining PrEP Need*



Across the project, the most commonly reported structural facilitators to determining PrEP need were navigating payment and insurance and normalizing PrEP, reported by staff at relatively small clinics. The two clinics (1 and 6) where staff reported normalization of PrEP as a structural facilitator to determining PrEP need are non-profits (Figure 25).

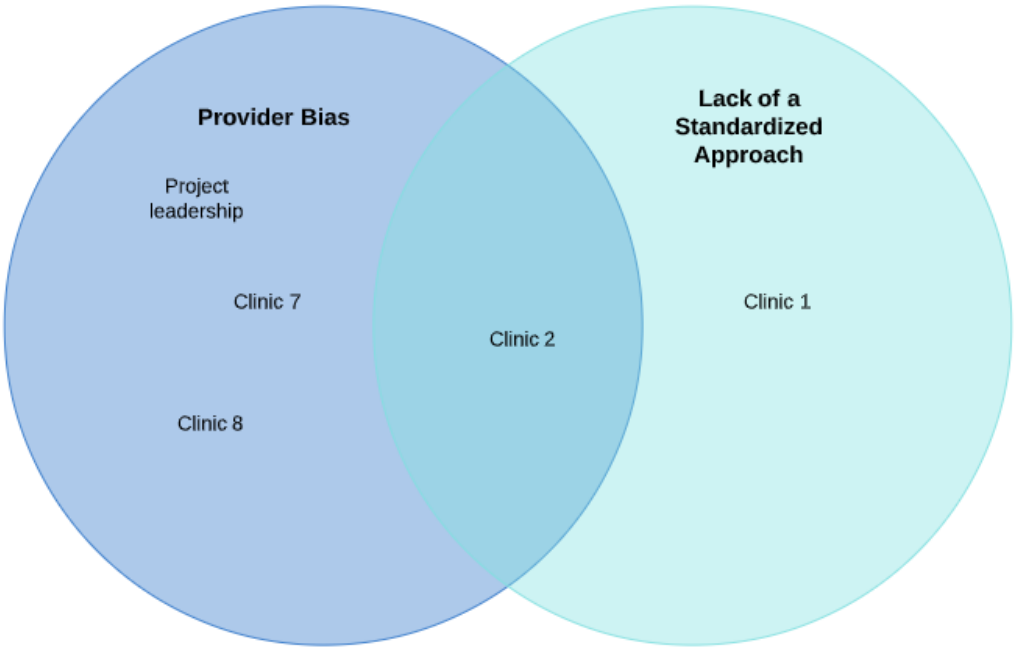
Figure *25*. *Structural Facilitators to Determining PrEP Need*



institutional

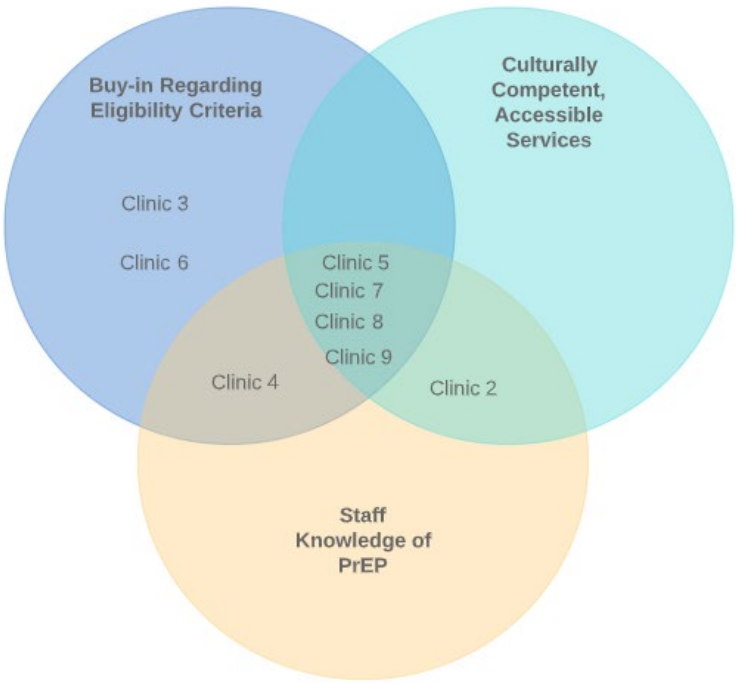
At the institutional level, the most commonly reported barriers to determining PrEP need were provider bias and lack of a standardized approach (Figure 26). While provider bias was reported by staff at clinics of various sizes as well as the project leadership, the lack of a standardized approach was reported by staff at smaller non-profit clinics.

Figure *26. Institutional Barriers to Determining PrEP Need*



Across the project, the most commonly reported facilitators to determining PrEP need at the institutional level were buy-in regarding the eligibility criteria, culturally competent and accessible service, and staff knowledge of PrEP (Figure 27). Staff at clinics of all three types (i.e., non-profit, primary care, and public health) reported buy-in and staff knowledge of PrEP as institutional facilitators of determining PrEP need.

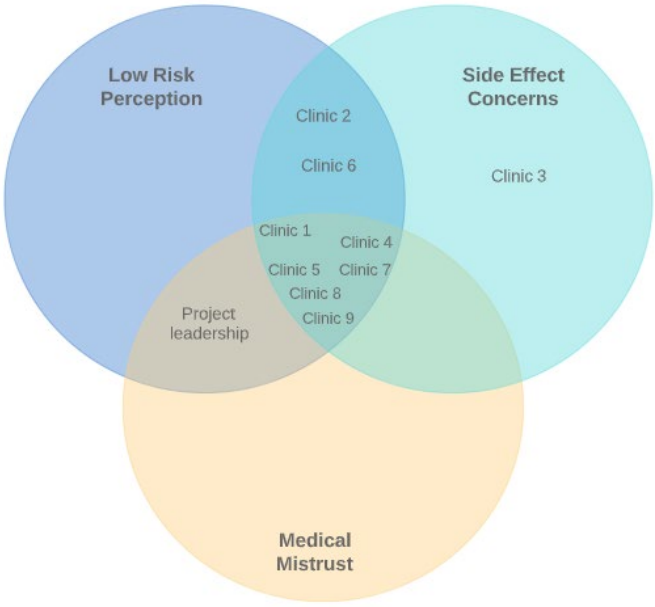
Figure *27***.** *Institutional Facilitators to Determining PrEP Need*



individual

At the individual level, the most commonly reported barriers to determining PrEP need were low risk perception, medical mistrust, and side effect concerns (Figure 28). Staff at clinic 3 reported side effect concerns as the primary individual barrier to determining PrEP need. The project leadership reported low risk perception and medical mistrust as the primary individual barriers. Staff at all other clinics (which vary in size and type) reported all three barriers.

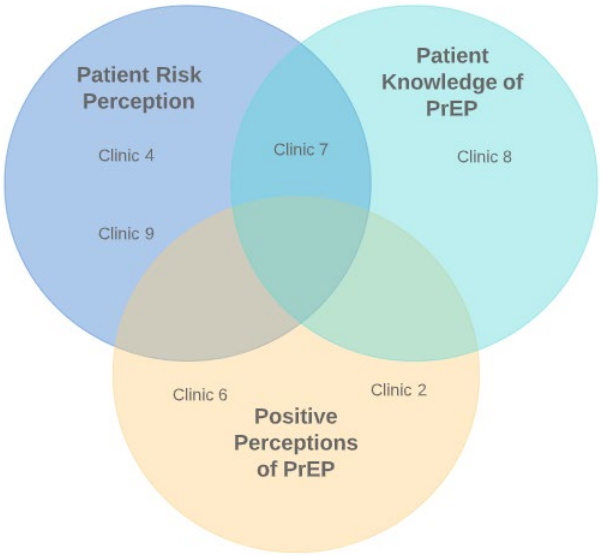
Figure *28***.** *Individual Barriers to Determining PrEP Need*



Across the project, the most commonly reported facilitators to determining PrEP need at the individual level were patient risk perception, patient knowledge of PrEP, and positive

perceptions of PrEP among patients (Figure 29). Clinics of varying sizes reported patient risk perception as an individual facilitator to determining PrEP need, while smaller clinics reported positive perceptions of PrEP as an individual facilitator to determining PrEP need. Two clinics (7 and 9) where staff reported patient risk perception as an individual facilitator to determining PrEP need are non-profits, as are two clinics (2 and 6) where staff reported positive perceptions of PrEP as an individual facilitator to determining PrEP need.

Figure *29***.** *Individual Facilitators to Determining PrEP Need*



Degrees of adaptation within the project

The clinics demonstrated a range of adaptation related to PrEP screening and determining PrEP need, ranging from no adaptation (or complete fidelity to the project's recommended implementation process) to complete adaptation (or no fidelity to the project's recommended implementation process).

PrEP screening

The project leadership recommended, but did not require, the use of the project's intake form for PrEP screening. In turn, clinics either used the project's intake form as it was provided by the project's leadership, made minor modifications to the project intake form, or did not use the project's intake form at all. Most clinics made little to no adaptations to the project's recommended PrEP screening process by incorporating the project's intake form into their regular clinic processes (Table 12). Clinic 3 made slight modifications to the project's intake form by assigning a point value to the questions, representing a medium degree of adaptation to the project's recommended PrEP screening process. Clinics 1 and 9 did not use the project's form at all, representing a high degree of adaptation to the project's recommended screening process. Clinics 7 and 8, which screened the highest proportions of their HIV-negative project participants for PrEP (Table 8), were among the clinics that made little to no adaptations to the project's recommended PrEP screening process.

Table 12. *Degrees of Adaptation among Clinics Related to PrEP Screening*

	Low/No	Medium	High
Clinic 1			·Does not use the project intake form ·In clinic: Informal conversation, social history ·In field: HIV testing form
Clinic 2	·In clinic: Social history ·In field: Project intake form, HIV testing form		
Clinic 3		·In field: Modified version of the project intake form, HIV testing form	
Clinic 4	·In clinic: Social history, HIV testing form ·In field: Project intake form, HIV testing form		
Clinic 5	·In field: Project intake form, HIV testing form		
Clinic 6	·In field: Project intake form		
Clinic 7	·In clinic: Social history ·In field: Project intake form, HIV testing form		
Clinic 8	·In clinic: Social history, project intake form		
Clinic 9			·Do not use the project intake form ·Internal HIV/STI form, Internal PrEP form

PrEP need

The project leadership recommended, but did not require, that interest in PrEP and the self-report of at least one risk behavior be used as criteria for PrEP need. In turn, clinics

either used the project's recommended criteria, made slight modifications to the project's recommended criteria, or developed their own criteria for PrEP need. Most clinics made no adaptations to the project's recommended process by using the project's criteria for PrEP need (Table 13). Clinic 2 used the self-report of at least one risk behavior as the only criterion; clinic 3 added a high score on the modified project intake form to the project's recommended criteria; and clinics 5 and 8 used interest in PrEP as the only criterion, all changes representing a medium degree of adaptation to the project's recommended process for determining PrEP need. The only criterion for PrEP need at clinic 9 was a high score on the internal risk assessment used by staff, representing a high degree of adaptation to the project's recommended process for determining PrEP need. While PrEP need rates were generally high among clinics (Table 8), clinics with the highest PrEP need rates (clinics 3, 5, and 8) were among those that made a medium degree of adaptation to the project's recommended process for determining PrEP need.

Table 13. *Degrees of Adaptation among Clinics Related to Determining PrEP Need*

	Low/No	Medium	High
Clinic 1	· Interest · ≥1 risk behavior		
Clinic 2		·≥1 risk behavior	
Clinic 3		·High score on project intake form ·≥1 risk behavior ·Interest	
Clinic 4	· ≥1 risk behavior		

	· Interest		
Clinic 5		·Interest	
Clinic 6	· ≥1 risk behavior · Interest		
Clinic 7	· ≥1 risk behavior · Interest		
Clinic 8		·Interest	
Clinic 9			·High score on internal intake form ·Interest

Summary

This chapter described the current state of PrEP screening and PrEP need in the overall project; the implementation of the project at the clinic level with respect to PrEP screening and determination of PrEP need; and the sources of variation and degrees of adaption within the project.

The project was created in response to the high rates of HIV, AIDS, and STIs among MSM and transgender persons of color in the DC, Maryland, Virginia region and includes all three localities given the frequent migration of the populations throughout the region for personal and professional reasons. To aid the clinic staff in screening for PrEP, the project created an intake form that contained questions meant to assess a patient's or client's risk for HIV and developed a Coalition meant to provide education and updates to partners in the project. Clinics were not required by the project leadership to use the intake form. As of March 2019, 5043 HIV-negative persons had been enrolled in the project and 3,935 (74%) had been screened for PrEP. After excluding two clinics due to missing data and

incomparable data, data on additional sociodemographic and risk behavior factors of interest were available for 931 persons, who were a median age of 27 (IQR: 23,34) and the majority of whom were cisgender male (77%), Hispanic (55%), and in possession of reliable transportation (79%). Persons not screened for PrEP (n=594) were significantly more likely to have an annual income under $16K (49% vs. 37%, p=.0264) compared to persons screened for PrEP (Table 4). Persons screened for PrEP (n=337) were significantly more likely to have no health insurance (50% vs. 43%, p=.0054) and to be single (77% vs. 72%, p=.0419) compared to persons not screened for PrEP. After adjusting for demographics and site of care, those screened for PrEP had a decreased odds of having an annual income under 16K (aOR 0.512; 0.328-0.800) compared to those not screened (Table 5).

The project leadership loosely defined PrEP need as meeting the eligibility criteria outlined in the CDCs clinical practice guidelines as well as having an interest in PrEP. As of March 2019, 3271 (86%) persons were deemed eligible for PrEP of 3803 persons screened for PrEP. After excluding two clinics due to missing data and incomparable data, data on additional sociodemographic and risk behavior factors of interest were available for 931 persons. Of the 337 persons screened for PrEP, 265 (79%) were deemed eligible for PrEP with a median age of 27 (IQR: 23, 33) and the majority of whom were Hispanic (60%), stably housed (76%), in possession of reliable transportation (80%), and single (76%). Persons deemed eligible for PrEP were significantly more likely to lack insurance (51% vs. 49%, p=.0004) compared to those not deemed eligible for PrEP (Table 6). Those not deemed eligible for PrEP for significantly more likely to identify as male (89% vs. 78%, p=.0355)

compared to those deemed eligible. After adjusting for demographics and site of care, those deemed eligible for PrEP had a decreased odds of identifying as male (aOR=.333; .113-.980) compared those deemed not eligible for PrEP (Table 7).

Staff at 9 of the 10 clinics funded by the project provided information related to their mission and vision, their staff and patient populations, their motivations for joining the project, their implementation processes with respect to PrEP screening and determination of PrEP need; and perceived barriers and facilitators at multiple levels to PrEP screening and determination of PrEP need. There was variation between the project leadership and the clinic and among the clinics. The clinics varied most notably in their organizational contexts, specifically in their organizational characteristics (i.e., age, type, location, size), their networks and communication (i.e., degree of collaboration within and among clinics), and their cultures (i.e., the priority populations at the center of their mission and vision). While there was often overlap between the barriers and facilitators identified by project leadership and the clinic staff, there were also differences between the barriers and facilitators identified by project leadership and clinic staff and among clinics based on size. In terms of the degrees of adaptation within the project, most clinics made little to no adaptations to the project's recommended processes for PrEP screening or determining PrEP need.

Chapter 5: Conclusion

The purpose of this mixed methods embedded single case study was to describe PrEP screening and PrEP need in the overall project, understand how the project was implemented at the clinic level with respect to PrEP screening and determination of PrEP need, and describe the sources of variation and degrees of adaptation within the project. This chapter will provide a summary of the results presented in Chapter 4 and will discuss them within the context of this study's research questions and the existing literature. The chapter will also identify implications for theory, practice, and future research as well as policy and programmatic recommendations. The chapter will conclude with identification of the strengths and limitations of this study and a closing summary.

Summary and Synthesis of Findings

RQ 1: Current state of PrEP screening and PrEP need in the Project

Like the HPTN 073 demonstration project (Wheeler & Fields, 2013; Wheeler et al., 2016; Wheeler et al., 2018; Wheeler et al., 2019), the IMPACT DMV demonstration project was developed specifically for MSM of color in the DMV region. Additionally, the IMPACT DMV project extended its services to include transgender persons of color, given the high rates of and risk for HIV among this population. In addition to the provision of HIV prevention, care, and treatment services, the project also provided behavioral health and social services (e.g., substance use treatment, housing, employment, etc.) "to address all of the dimensions of people's lives."

Also similar to the leadership team of the HPTN 073 demonstration project (Wheeler et al., 2018), the leadership team of the IMPACT DMV demonstration project recognized the importance of community engagement during the project's implementation, both in establishing the Coalition (comprised of health department staff from the three jurisdictions, community members, service providers, and private entities) and in hiring the Health Impact Specialists (members of the focus populations, hired by DC Health and assigned to one of the clinics). Community engagement has been identified as a core component of efforts aiming to increase PrEP access (Burns et al., 2020; Reza-Paul et al., 2019).

To facilitate the PrEP screening process at the clinic level, the project leadership developed guidance documents including a protocol, a training presentation, and a risk assessment form. While the CDC's risk assessment includes questions about sexual activity, condom use, and drug use in the prior 6 months (USPHS, 2018), the risk assessment created by the project leadership and utilized by most of the sites includes questions about drug use in the past 6 months and lifetime sexual behaviors. The leadership team explained that the timeframe for sexual activity was expanded "to allow for people to kind of change their practices because…people…make choices at certain times that are different from their choices at other times…season of [risk]." The concept of 'season of risk' acknowledges that people may only be at risk for HIV during certain periods, which may impact their decision to initiate or continue on PrEP (Elsesser et al., 2016; Felsher et al., 2018). Despite the provision of documents to guide PrEP screening, clinic staff were not required to use the guidance documents and "were…given flexibility to…use their normal practices." The

project leadership also periodically provided technical assistance to increase the cultural competency of providers as well as their capacity to conduct comprehensive risk assessments. Capacity building, the process by which individuals and organizations improve their knowledge and skills in a particular area, has been identified as a key component to PrEP implementation (Bacon et al., 2017; Golub & Myers, 2019; Zablotska et al., 2018).

To facilitate the determination of PrEP need, the protocol developed by the project leadership included the indications for PrEP from the CDC's guidelines. However, in recognizing that the CDC's guidelines are not all-encompassing (Beymer et al., 2017; Calabrese, 2018; Calabrese et al., 2017; Lancki et al., 2018; Raifman & Sherman, 2018), the protocol for the project does contain additional indications (i.e., having been prescribed multiple courses of PEP and having other risk factors that increase HIV risk). Because the CDC's guidelines do not contain PrEP indications for transgender persons, the project leadership created indications by combining those used for MSM, heterosexual, and injection drug-using populations as other researchers have done (Golub et al., 2019; Kuhns et al., 2016; Reisner et al., 2019; Wilson et al., 2015; Wilson et al., 2016).

Of the 5043 HIV-negative MSM and transgender persons of color enrolled in the project 3803 (75%) were screened for PrEP, and 3271 (86%) persons had been deemed eligible for PrEP (Figure 16). To assess factors associated with PrEP screening, data on additional sociodemographic and risk behavior factors of interest were available for 931 persons. In the bivariable analysis, Persons not screened for PrEP (n=594) were significantly more likely to have an annual income under $16K (49% vs. 37%, p=.0264) compared to

persons screened for PrEP (Table 4). Persons screened for PrEP (n=337) were significantly more likely to have no health insurance (50% vs. 43%, p=.0054) and to be single (77% vs. 72%, p=.0419) compared to persons not screened for PrEP. After adjusting for demographics and site of care, those screened for PrEP had a decreased odds of having an annual income under 16K (aOR 0.512; 0.328-0.800) compared to those not screened (Table 5). This finding may be explained by the fact that PrEP access is more limited for individuals with lower incomes compared to those with higher incomes (Doblecki-Lewis et al., 2017; Okafor et al., 2017). This finding was also supported by the qualitative finding that the competing health and social needs of patients with a lower socioeconomic status can serve as a barrier to the PrEP screening process at the individual level (Figure 22).

To assess factors associated with PrEP need, data on additional sociodemographic and risk behavior factors of interest were available for 931 persons. Of the 337 persons screened for PrEP, 265 (79%) were deemed eligible for PrEP. In the bivariable analysis, Persons deemed eligible for PrEP were significantly more likely to lack insurance (51% vs. 49%, p=.0004) compared to those not deemed eligible for PrEP (Table 6). Those not deemed eligible for PrEP for significantly more likely to identify as male (89% vs. 78%, p=.0355). After adjusting for demographics and site of care, those deemed eligible for PrEP had a decreased odds of identifying as male (aOR=.333; .113-.980) compared those deemed not eligible for PrEP (Table 7). The borderline significance of this finding may be due to the limited sample size.

RQ 2: Implementation of the project at Clinic 1-9

Data via documents, interviews and a focus group were obtained from staff and Health Impact Specialists at 9 of the 10 clinics funded by the project. All clinics had a mission and vision that prioritized HIV prevention and was reflected in the patient populations. Staff at almost all of the clinics were able to articulate their motivations for participating in the project and the importance of removing barriers to PrEP for MSM and transgender persons of color.

The study found that the project had been implemented at all 9 clinics with respect to PrEP screening and determination of PrEP need, though the project had been implemented to different degrees, as evidenced by the variable number of HIV-negative persons enrolled in the project across clinics and the variable proportions of project participants screened for and determined to be in need of PrEP across the clinics (Table 8). This finding is consistent with other multisite PrEP demonstration projects that have found differential enrollment across sites (Cohen et al., 2015; Grant et al., 2014). Staff at all clinics were able to communicate a specific process for conducting the PrEP screening and determining PrEP need at each site. Staff at all clinics were able to identify both barriers and facilitators to the processes of PrEP screening and determining PrEP need at the structural, institutional, and/or individual levels.

RQ 3: Sources of variation and adaptation within the project

This study found that here was variation among the clinics and between the clinics and the project leadership. Most notably, there was variation in the organizational contexts of the clinics and in the perceived barriers and facilitators to PrEP screening and determination

of PrEP need identified by the project leadership and clinic staff. With respect to organizational characteristics, while the majority of clinics were non-profit organizations, other organization types included primary care and public health clinics. The inclusion of a variety of clinic types in the IMPACT DMV demonstration project may have served to increase PrEP access for MSM and transgender persons of color. Regarding intra-organizational networks, this study found that clinic 7 had the highest degree of internal connectivity and communication, defined as multiple PrEP access points, which may have contributed to a higher proportion (82%) of HIV-negative project participants being screened for PrEP compared to clinics 1, 3, 5, and 9, which had a lower degree of internal connectivity and communication (i.e., having a designated department responsible for PrEP screening) and lower screening rates (31%, 9%, 53%, and 41%, respectively). Regarding inter-organizational networks, this study found that clinic 8 served as the PrEP referral site for five organizations (Figure 17) which may partially explain the high proportion (100%) of HIV-negative project participants being screened for PrEP at that clinic. With respect the organizational culture, some clinics listed specific populations in their mission and vision statements while other clinics had mission and vision statements that were broader.

Across the project leadership and clinic staff and across the structural, institutional, and individual levels, the three most common barriers to PrEP screening identified by project leadership and clinic staff were the inaccessibility of the clinics (structural), the lack of representation and/or cultural competency among clinic staff (institutional), and the lack of patient transparency (individual) during the screening process (Figure 16j). Other studies

have documented the negative impact that clinic inaccessibility and lack of transportation can have on PrEP access (Elopre et al., 2017; Rice et al., 2019; Siegler et al., 2018; Siegler et al., 2019). Prior research has also highlighted the importance of having staff that is reflective of the population being served (Magnus et al., 2014; Magnus & Castel, 2016; Wheeler et al., 2018). One study found that HIV testing staff who identified with a sexual and/or racial minority group were more likely to discuss PrEP with clients (Turner et al., 2020). Prior research has also shown that MSM and transgender persons are less likely to disclose risk behaviors in the context of PrEP when patients fear that behaviors will be stigmatized and when such behaviors are actually stigmatized by providers (Brooks et al., 2019; Devarajan et al., 2020; Maloney et al., 2017).

Across the across the project leadership and clinic staff and across the structural, institutional, and individual levels, the three most common barriers to determining PrEP need identified by project leadership and clinic staff were low risk perception, medical mistrust, and side effect concerns among patients and clients, all individual-level barriers. (Figure 16j). Prior research has shown that there may be incongruence between reported risk behaviors and HIV risk perception among MSM and transgender persons of color (Biello et al., 2019; Horvath et al., 2019; Lockard et al., 2019; Parsons et al., 2017), which can pose a barrier to determining PrEP need. Medical mistrust, due to both past and present events, among MSM and transgender persons of color has also been documented in the literature as a potential barrier to PrEP need (Cahill et al., 2017; D'Avanzo et al., 2019; Garcia & Harris, 2017; Kimball et al., 2020; Philbin et al., 2016; Quinn et al., 2019; Sevelius et al., 2016; Thomann

et al., 2018). Lastly, prior research has also shown that side effect concerns among MSM and transgender persons of color exist (Bauermeister et al., 2013; Brooks et al., 2019; Deutsch, 2018; Garcia & Harris, 2017; Holloway et al., 2017; Rael et al., 2018; Sevelius et al., 2016; Wood et al., 2017) and can preclude the determination of PrEP need.

While there was often overlap between the barriers and facilitators identified by project leadership and the clinic staff, there were also differences between the barriers and facilitators identified by project leadership and clinic staff and among clinics based on type and size. The variation in barriers and facilitators among clinics based on clinic type is consistent with prior research that found a difference in the barriers and facilitators reported by staff at primary clinics (Blumenthal et al., 2015; Conniff & Evensen, 2016; Montano et al., 2008; Petroll et al., 2017) compared to those reported by staff at infectious disease clinics (Castel et al., 2014; Krakower & Mayer, 2015; Krakower et al., 2014). The barriers to PrEP screening and determination of PrEP need identified by project leadership and clinic staff may partially explain the screening and need gaps reflected in the project's PrEP continuum (Figure 16j) and the continuums for most clinics (Figures 16a-16i).

Overall, this study found a low degree of adaptation among the clinics with respect to the recommended PrEP screening process (i.e., use of the project's intake form), with staff at most clinics incorporating the project's intake form into their regular clinic processes. However, the staff at one clinic (clinic 5) made modifications to the project intake form, representing a medium degree of adaptation to the project's recommended PrEP screening process. Staff at two clinics did not use the project's intake form at all—representing a high

degree of adaptation to the project's recommended PrEP screening process—with staff at one clinic (clinic 1) assessing HIV risk while taking patient sexual/social histories and staff at the other clinic (clinic 9) utilizing their own risk assessment form (Table 11). Prior research has shown that HIV risk may be assessed with risk assessments other than the one provided in the CDC's clinical practice guidelines (Wilton et al., 2017) and during routine sexual history-taking (The National Association of Community Health Centers & The National LGBT Health Education Center, 2015; Workowski & Bolan, 2015). The two clinics with the highest proportions of HIV-negative project participants screened for PrEP (clinics 7 and 8) were among the clinics that made little to no adaptations to the project's recommended PrEP screening process, suggesting that use of the project's intake form may facilitate PrEP screening.

This study also found a low degree of adaptation among the clinics with respect to the recommended process for determining PrEP need, with most clinics using the project's criteria (i.e., interest and the self-report of at least one risk behavior) to determine PrEP need. However, one clinic (clinic 2) used the self-report of at least one risk behavior as the only criterion; another clinic (clinic 3) added a high score on the modified project intake form to the project's recommended criteria; and two clinics (clinics 5 and 8) used interest in PrEP as the only criterion, all changes representing a medium degree of adaptation to the project's recommended process for determining PrEP need. The one clinic with a high degree of adaptation to the project's recommended process for determining PrEP need (clinic 9) utilized a high score on its internal risk assessment form to determine PrEP need. Other

studies have also used risk scores to determine PrEP need (Beymer et al., 2017; Hoenig et al., 2015; Jones et al., 2017; Marcus et al., 2019; Scott et al., 2020; Smith et al., 2012; Wilton et al., 2017) and WHO (2018) recommends including patient interest in the determination of PrEP need. PrEP need rates were generally high among clinics: the proportion of those screened for PrEP who were determined to be in need of PrEP ranged from 41%-100% and 90% of clinics determined at least 75% of those screened for PrEP to be in need of PrEP (Table 8). Clinics with the highest PrEP need rates (clinics 3, 5, and 8) were among those that made a medium degree of adaptation to the project's recommended process for determining PrEP need, suggesting that the criteria for determining PrEP need should not be prescriptive.

Implications

Implications for theory

The Mayer et al. (2018) model adapted for use in this study proved useful for understanding the elements that may have influenced implementation of the project with respect to PrEP screening and determination of PrEP need. PRISM discusses key elements that influence implementation, which in turn influence reach and effectiveness, including the implementation and sustainability infrastructure, the organizational perspective, organizational characteristics, and patient characteristics. According to Felstein and Glasglow (2018), "successful implementation requires a carefully crafted infrastructure" (p. 237) and includes the provision of routine performance measurement, protocols and procedures that are adaptable, and implementation training and support.

Mayer et al. (2018) also list specific aspects of the implementation and sustainability infrastructure including PrEP navigators, insurance navigation, referral networks, and inter-agency linkages. This study found that the project leadership provided clinics with initial training as well as ongoing capacity building and technical assistance related to PrEP screening and determination of PrEP need. Additionally, the project leadership hired Health Impact Specialists that were embedded in the clinics to assist with PrEP and insurance navigation. The project leadership also created the Coalition which allowed for a referral system and interagency linkages (Figure 17). Lastly, the project provided quarterly report cards to clinic staff to identify gaps along the PrEP continuum. Most of the clinic staff expressed satisfaction with the support that they received from the project leadership.

Feldstein and Glasgow (2008) state that it is important to consider a program from the organizational perspective. The project leadership had already assessed each organization's readiness for the program and the alignment of the project with each clinic's mission by reviewing written proposals and conducting site visits prior to the disbursement of funds. This study found that while staff at most clinics were able to clearly and passionately articulate their motivations for participating in the project, knowledge of the project's recommended processes for conducting PrEP screening and determining PrEP need was variable across clinic staff. This suggests a need for more direct or more frequent communication from the project team as it relates to the recommended processes.

While Mayer et al. (2018) limit organizational characteristics to organization type, Feldstein and Glasgow (2008) recognized that other organizational characteristics can

influence implementation including the organization's history, staff, and culture. This study found that while there were similarities among the clinics with respect to organizational characteristics, each clinic was unique with respect to its mission and vision, staff, and patient populations. Both Feldstein and Glasglow (2008) and Mayer et al. (2018) recognize that patient characteristics (e.g., age, race, socioeconomic factors, etc.) can influence implementation. This study found that those screened for PrEP had a decreased odds of having an annual income under 16K, which has implications for future outreach efforts needed to low-income MSM and transgender persons of color.

While PRISM proved useful for understanding the elements that may have influenced implementation of the project with respect to PrEP screening and determination of PrEP need, there were some limitations identified as well. First, the Feldstein and Glasglow (2008) version of the model emphasizes the importance of considering the intervention from the perspective of organizational staff who will implement the intervention. However, this study found that it was also necessary to consider the perspectives of staff from organizations making implementation recommendations and guidance (i.e., DC Health). Second, while both the Feldstein and Glasglow (2008) and Mayer et al. (2018) versions of the model account for organizational characteristics (e.g., organization type, culture, staff, etc.), neither version accounts for the physical location of an organization, a barrier to the process of PrEP screening cited by staff at the majority of clinics in this study. Furthermore, alternative theoretical applications may have provided an additional explanation of the data. For example, the study found that the organizational contexts varied among the clinics and may

help explain the differential implementation processes. Thus, a dual application of PRISM and a framework with a greater emphasis on organizational context could provide additional insight into the implementation of PrEP screening and determination of PrEP need at the clinic level. In the Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework, context is one of the four main constructs accounting for successful implementation and is described at three distinct levels: local, organizational, and external (Harvey & Kitson, 2015).

Implications for practice

This study found that the clinic with the highest degree of internal connectivity and communication screened a higher proportion of HIV-negative project participants compared to clinics with a lower degree of internal connectivity and communication. This suggests that creating multiple PrEP access points within a clinic may have greater reach than having a dedicated PrEP department. Similarly, clinics with the highest PrEP screening rates were among those that made little to no adaptations to the project's recommended PrEP screening process by integrating it with their normal clinic processes. The integration of PrEP with existing and related services has been supported by other studies (Calabrese et al., 2017; Marcus et al., 2016; Mayer et al., 2018). Regarding the PrEP screening process specifically, the staff at five clinics cited a lack of cultural competency and/or representation among staff as a barrier. Thus, clinic efforts to provide cultural competency training should be continued and efforts to hire staff representative of the patient populations should be intensified. Similarly, the negative reputation of the organization in the community was cited as a barrier

to the PrEP screening process by staff at four clinics. This underscores a need to increase outreach efforts to the communities served by these clinics.

Implications for Implementation Science

Findings from this study provided an understanding of the processes related to PrEP screening and determination of PrEP need utilized by the clinics. Understanding organizational processes is a core component to implementation science because organizational processes impact the uptake and sustainment of evidence-based practices such as PrEP (Brownson et al., 2012). Findings from this study also provided and understanding of the perceived barriers and facilitators among staff as it related to PrEP screening and determination of PrEP. Understanding perceived barriers and facilitators is also an important component of implementation science because they impact the uptake and sustainment of evidence-based practices (Brownson et al., 2012). Lastly, findings from this study also described project fidelity at the clinic level with respect to PrEP screening and determination of PrEP need. Fidelity is an outcome often studied in implementation science research to assess whether core components of the original intervention were implemented as intended in the real-world setting or if the core components were adapted to the local context (Brownson et al., 2012).

Implications for future research

Future research seeking to describe PrEP screening and PrEP need in the IMPACT DMV project should explore elements of the PRISM framework that were not explored in the current study. While clinic staff did discuss aspects of the external environment that hinder or

facilitate PrEP screening and determination of PrEP need, aspects of the external environment were not an explicit focus of the current study. Prior research has shown that external factors (e.g., state insurance policies, medication costs, racism, homophobia, transphobia) can impact PrEP implementation (Kay & Pinto, 2020; Mayer et al., 2018; Pinto et al., 2018) and should be further explored qualitatively with clinic staff in this project. Future research should also explore maintenance, or the long-term effects of a program, including describing downstream outcomes in the IMPACT DMV project such as PrEP uptake and PrEP adherence among MSM and transgender persons of color. Future demonstration projects could also assess for barriers identified in this study prior to implementation. Future research could utilize a multiple case study design to compare the findings from this study to those of other health departments that received the THRIVE funding for demonstration projects. Also, it is important to note that most of the data for this study was collected prior to the start of the COVID-19 pandemic, and it will be important for future research to explore how clinics adapted (e.g., via telehealth) to screening for PrEP screening and determining PrEP need.

While the current study did include the perspectives of Health Impact Specialists who are MSM and transgender persons of color, the patient perspective—specifically as it relates to their opinions on the processes utilized by clinics to conduct PrEP screening and determine PrEP need as well as their perceived barriers and facilitators to PrEP screening and determination of PrEP need—was not fully explored. Prior research has documented barriers and facilitators to discussing PrEP with a provider (Hubach et al., 2017; Quinn et al., 2019;

Rowniak et al., 2017) and being interested in PrEP (Cahill et al., 2017; Felsher et al., 2018; Rael et al., 2018; Sevelius et al., 2016; Wood et al., 2017) among MSM and transgender persons, and patients in this project could shed additional light on barriers and facilitators as well as the implementation process. Factors at the structural, institutional, and clinic level that hinder or facilitate PrEP screening and determination of PrEP need should also be explored quantitatively (e.g., via a survey) with clinic staff and patients. While this study provided a cross-sectional snapshot of PrEP screening and PrEP need in the IMPACT DMV as of March 2019, future research could utilize a time-based approach to assess clinic-level changes in the implementation process as well as screening and need rates after feedback was provided by project leadership. This study also described the adaptations that clinic staff made to the project's recommended processes for PrEP screening and determining PrEP need, and future research could explore, qualitatively, why clinic staff chose to modify the recommended processes.

Policy Recommendations

The findings from this study underscore the following policy recommendations reflected in prior research:

- **Expansion of clinical practice guidelines for MSM**

As previously mentioned, PrEP indications in the CDC's clinical practice guidelines should be expanded to consider local HIV prevalence as well as the interpersonal, community, institutional, and structural HIV risk factors experienced by MSM of color, who may be less likely to have indications for PrEP based on the current guidelines compared to

other MSM (Beymer et al., 2017; Calabrese, 2018; Calabrese et al., 2017; Hoots et al., 2016; Lancki et al., 2018; Sullivan et al., 2015). The protocol developed by the IMPACT DMV project leadership extends the PrEP indications included in the CDC's clinical practice guidelines and many clinic staff supported making eligibility criteria as broad as possible.

- **Conduct of PrEP clinical trials among transgender persons**

The inclusion of transgender women in PrEP clinical trials has been limited to date (Escudero et al., 2015; Grant et al., 2016; National Center for Innovation in HIV Care, 2015), and PrEP clinical trials have not yet been conducted among transgender men. Thus, questions linger about the efficacy of PrEP in these populations and potential interactions between PrEP and hormone therapy (Cottrell et al., 2019; Mehrotra et al., 2019; Yager & Anderson, 2020). Before risk assessments and PrEP indications for these populations can be developed, the efficacy and safety of PrEP for transgender persons must be established. In this study, the staff at clinic 2 identified concerns about interactions between PrEP and hormone therapy among the transgender community as an individual-level barrier to determining PrEP need.

- **Development and inclusion of an HIV risk assessment and PrEP indications for transgender persons in clinical practice guidelines**

Once the safety and efficacy of PrEP for transgender persons have been established, an HIV risk assessment and PrEP indications for these populations should be included in the CDC's clinical practice guidelines. To facilitate the determination of PrEP need among transgender persons, the IMPACT DMV project leadership combined indications for the other populations, which has advantages and disadvantages.

Programmatic Recommendations

Should the IMPACT DMV demonstration project continue or a similar project be initiated, the findings from this study have resulted in the following programmatic recommendations:

- **Standardization and optimization of data collection**

This study found that the project leadership created two versions of the intake form used by the sites, resulting in project data that did not reflect the same time period. Furthermore, the flexibility afforded to sites regarding the use of the form resulted in a significant amount of missing patient data for some sites. Hence, a more robust quantitative assessment of the factors associated with PrEP screening and determination of PrEP need could not be performed. Thus, project leadership should standardize the intake form meant to be used by all sites and more strongly encourage the use of the form by clinic staff. Alternatively, the project leadership could encourage key questions from the form to be incorporated into existing clinic forms. Because staff at some clinics mentioned future plans to modify the project's intake form, project leadership should also work with clinic staff and clinic patients to determine the optimal length for the intake form and the optimal wording of questions included in the intake form to be more patient-centered, particularly for transgender patients. For example, research has shown that many transgender men prefer the terms 'front sex', 'front hole sex', and 'frontal sex' to 'vaginal sex' (McFarland et al., 2017; Reisner et al., 2019; Sevelius, 2009) and risk behavior questions worded as such may be

better received among this population. Once the form has been modified, project leadership could utilize a stepped wedge cluster design to randomize the clinics to both the intervention and standard practice at different intervals to evaluate the utility of the screening tool (Hemming et al., 2015).

- **Address the barriers to PrEP screening and determination of PrEP need identified by clinic staff**

This study found that staff had variable knowledge of the project's recommended processes for PrEP screening and determining PrEP need, suggesting a need for more direct or more frequent communication from the project leadership as it relates to the recommended processes. This study also identified barriers to PrEP screening and determination of PrEP need spanning multiple levels of the socio-ecological model (Kaufman et al., 2014). Prior to the next iteration of the project, the leadership team should address the most common barriers to PrEP screening identified by staff in this study. For example, to address the structural barrier to PrEP screening of clinic inaccessibility, the project should subsidize transportation to clinics from the outset as prior research has shown that potential PrEP users prefer to access PrEP services at locations near their homes or accessible via public transportation (Smith et al., 2012). However even if travel costs are covered, travel time could still prove to be a barrier to PrEP care as it has been to HIV care (Terzian et al., 2018). Additional recommendations from HIV care and treatment research include clinic-level changes such as mobile clinics in underserved areas and the direct provision of transportation by clinic staff, as well as structural changes such as expanding public transportation to

underserved areas (Evans & Williams, 2013; Goswami et al., 2016; Sagrestano et al., 2014; Sarnquist et al., 2011). To address the institutional barrier of provider bias that may limit determination of PrEP need, the project leadership should more strongly emphasize the integration of PrEP screening into routine care (Calabrese et al., 2017; Marcus et al., 2016; Mayer et al., 2018) and a shared decision-making approach whereby patients and providers can work collaboratively to determine PrEP need (Calabrese et al., 2016; Chin et al., 2016; Krakower et al., 2017). This approach may also help address medical mistrust, cited as an individual barrier to both PrEP screening and determination of PrEP need (Cahill et al., 2017; Calabrese et al., 2019). Another tactic to address medical mistrust and misinformation about PrEP, another individual-level barrier to determining PrEP need identified by clinic staff, would be the scale up of Health Impact Specialists who serve as PrEP champions. Other studies have reported an increase in PrEP access and use via peer educators (Brooks et al., 2019; McMahan et al., 2019). To address the low screening rates of some sites, the project leadership could consider incentivizing the screening process for patients and clients—a strategy utilized by some clinics in the project and supported by other researchers (Cáceres et al., 2015)—while balancing the ethical concern of undue influence (Grant & Sugarman, 2004). The project leadership could also create additional PrEP campaigns, in collaboration with Health Impact Specialists and clinic patients and clients, to address PrEP misinformation. Given that some barriers reported in this study were unique to specific clinics, in addition to addressing the most common barriers reported, project leadership should also utilize an individualized approach to addressing barriers. Furthermore, project

leadership should engage patients and clients to explore barriers to PrEP screening and determination of PrEP need at different levels from their perspective.

- **Provide additional technical assistance and capacity-building, and individualized targets**

Project leadership provided training, technical assistance, and capacity building to staff at partnering clinics, in addition to establishing the Coalition where partners could discuss challenges and best practices. However, some clinics performed better than others in terms of the proportion of HIV-negative project participants screened for and determined to be in need of PrEP. Thus, additional techniques may be warranted. For example, prior research in HIV care and treatment has demonstrated success by developing a community of practice—a group of people with a common passion who improve upon it by interacting regularly (Wenger, 1998)—for a network that moves beyond passive learning to active learning and beyond knowledge transfer to knowledge translation (Gallagher et al., 2017; Wood et al., 2016). Specifically, having interactive training sessions and having seasoned staff at higher-performing clinics mentor staff at lower-performing clinics may prove beneficial for the IMPACT DMV network. Similarly, HIV care and treatment researchers and practitioners have utilized a Delphi method—whereby a group of panel experts reach consensus through an iterative process (Dalkey & Helmer, 1963)—to develop guidelines, recommendations, and best practices (Johnson et al., 2017). Having an expert panel help develop best practices and help set individualized targets could increase enrollment in the IMPACT DMV project as well as screening rates.

- **Increase the engagement of transgender men in the project.**

In both the quantitative and qualitative analysis, this study found very few transgender men represented. As mentioned, transgender men are at risk for HIV and may benefit from PrEP (Golub et al., 2019; Reisner et al., 2019; Sevelius, 2009). Thus, greater outreach efforts are needed to engage this population in PrEP services through this project. Project leadership should work with community organizations primarily serving transgender men, as prior research has shown that incorporating community engagement into HIV prevention research can provide insight into the perspectives and interests of affected stakeholders; assess the acceptability of the research execution plan; offer a strategy for how (or how not to) engage affected stakeholders; and broaden thinking regarding the ethics of HIV prevention research, resulting in more effective implementation (Lavery, 2018). Project leadership should also employ more transgender men as Health Impact Specialists to increase engagement among this population.

Strengths and Limitations

There are several limitations inherent to case study research. First, the rigor of case studies has been questioned, as there are no research methods specific to this design. Unfortunately, it was not possible to pilot the interview and focus group questions due to an inability to identify individuals who were not affiliated with the project but who possessed sufficient knowledge of the project. However, multiple sources of data are collected for case studies as a way to triangulate the findings. This study collected both qualitative and quantitative data to offset the limitations of each and to fully describe the IMPACT DMV

demonstration project as the case. Accepted quantitative and qualitative data collection and analytic techniques were utilized. Additionally, the findings of this case study design may not be generalizable to other PrEP demonstration projects conducted in other settings or among other populations. However, the thick rich descriptions of the case allow the reader to determine if certain aspects of this case study research are transferable to other settings or populations. Another limitation of case study research relates to reliability. Generally, case studies cannot be (nor should they necessarily be) replicated. However, this study uses three specific techniques to overcome this limitation: development of a case study protocol (i.e., the methods chapter) which documents all study procedures in great detail, development of a case study database which is an organized collection of all study data, and maintenance of a chain of evidence which allows the reader to understand how the research questions led to the findings and how the findings were derived from the research questions.

The quantitative data collection was limited to information collected by the project. In trying to assess factors associated with PrEP screening and determination of PrEP need, two clinics were excluded from the analyses due to missing data and incomparable data, which limited the analysis. Also, it is possible that clinic staff screened clients for PrEP but did not have the capacity to track and report data per project guidelines. Thus, the number of patients screened at each site is likely an underrepresentation of the work performed by clinic staff. Furthermore, the lead researcher was unable to obtain the number of patients, specifically the number of HIV-negative patients, served by each clinic to present the screening and need rates in full context. To determine the degrees of adaptation to the project's recommended

processes for PrEP screening and determination of PrEP need, the lead researcher created definitions that might be considered subjective by creating categories based on patterns that emerged from the qualitative findings related to clinic processes.

The lead researcher was unable to obtain information from DC Health regarding the internal review process that guided the selection of participating clinics in the IMPACT DMV project or information on clinics that were not selected. The lead researcher was also unable to obtain information about the prior relationship, if any, between DC Health and the selected clinics. Due to the lead researcher's existing relationship with DC Health personnel, focus group participants at the local health department level may have felt compelled to participate in the study. However, prior to and during the focus group, the lead researcher reiterated the voluntary and confidential nature of the research. The lead researcher leveraged her existing relationship with DC Health personnel to identify study participants at the clinic level which may have introduced bias into the study sample. Additionally, those who agreed to be interviewed may reflect a limited range of perspectives held within the various organizations and some of the participants referred by colleagues lacked knowledge regarding the implementation of the project at their clinic resulting in missing qualitative data. Furthermore, the results presented are based in part on evidence as it was provided to the lead researcher (i.e., documents shared) and, thus, many only selectively reflect the implementation process of the various clinics. However, it was important to limit study participants to those directly involved in the implementation and execution of this specific project at the clinic level and DC Health personnel were aware of the appropriate individuals

with the specific knowledge to help answer the study's research questions. Similarly, only clinic members agreeing to be interviewed could identify and provide the necessary documentation needed to help answer the study's research questions. The total number of staff interviews completed was constrained by time, eligibility, and willingness to participate. Lastly, the lead researcher was unable to interview staff at Clinic 10—a community-based organization providing services to LGBTQ persons of different cultures with an emphasis on transgender populations—resulting in an incomplete description of project implementation at the clinic level and sources of variation and degrees of adaptation with the project.

While the Health Impact Specialists recruited for this study were from the focus populations of the demonstration project, they could only provide insight into the processes of PrEP screening and determination of PrEP need based on their interactions with PrEP-eligible patients. Thus, another limitation is the lack of input from PrEP-eligible patients themselves, which would have provided different insights into the processes of PrEP screening and determination of PrEP need. Furthermore, only four Health Impact Specialists participated in the focus group, thus quotes from this focus group were integrated with quotes from clinic interviews and not presented separately.

Conclusions

Prior research on PrEP demonstration projects has focused strictly on PrEP outcomes such as acceptability, access, uptake, and adherence but not on the influence that PrEP implementation processes or the characteristics of the context in which PrEP is implemented (e.g., type of setting, resources, capacity, personnel, etc.) have on those outcomes. This study

sought to describe PrEP screening and PrEP need in the overall project, understand how the project was implemented at the clinic level with respect to PrEP screening and determination of PrEP need, and describe the sources of variation and degrees of adaptation within the project. In using a mixed methods embedded case study approach, the study's findings were able to provide rich detail regarding the project's recommended policies, practices, and procedures; the actual policies, practices, and procedures of the participating clinics; and sources of variation and degrees of adaptation within the project with respect to PrEP screening and determination of PrEP need. The findings aligned well with the prior literature and with the study's guiding conceptual framework. Multiple stakeholder perspectives revealed a much richer and more nuanced understanding of the overall project, project implementation at the clinic level, and barriers and facilitators to project implementation with respect to PrEP screening and determination of PrEP need than any one stakeholder perspective alone.

This study's identification of possible policy and programmatic solutions will hopefully help to mitigate current challenges faced by clinics in the DMV region as they conduct PrEP screening and determine PrEP need among MSM and transgender persons of color moving forward. More broadly, the study's findings and recommendations may also serve as an illustrative case study that has implications for demonstration projects in other jurisdictions as they move to implement similar processes and face similar challenges. While PrEP screening and determination of PrEP need were the focus of this case study, further research could be conducted to explore elements of PRISM that were not explored in this

study and to describe PrEP uptake and adherence in the IMPACT DMV project. Furthermore, there may also be implications for practice by creating multiple PrEP access points within a clinic rather than tasking one department to be responsible for PrEP; integrating PrEP screening with existing and related clinical services; increasing cultural competency training and the hiring of staff representative of the patient population; and increasing community outreach efforts. Lastly, the findings also highlight the importance of identifying ways for the IMPACT DMV demonstration project to standardize data collection tools and processes, address barriers to PrEP screening and determination of PrEP need identified by clinic staff, and work to provide greater access to PrEP services for transgender men.

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APPENDIX A: Focus Group and Interview Protocols

Focus Group Protocol DOH Personnel

Demographic Survey

1. Please indicate your age group.
18-25
25-35
35-45
45-55
55 and older

2. What is your gender?
Male
Female
Transgender: male to female
Transgender: female to male
Don't know
Refuse to answer

3. Do you consider yourself to be Hispanic or Latino/a?
Yes
No

4. Which racial group or groups do you consider yourself to be in? You may choose more than one option.
Alaska Native or Native American
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White or Caucasian
Don't know
Refuse to answer

5. What is the highest degree you have obtained?
High School Diploma or GED
Bachelor's Degree
Master's Degree

Doctor of Medicine (MD)
Doctor of Osteopathic Medicine (DO)
Doctor of Philosophy (PhD)
Other_____

Team Member Characteristics

- How would you describe your role within the organization and your role on the project?
- PROBE: Have Participants respond one at a time. What are your day-to-day activities related to the project? Who are the people that you interact with at work?
- How was the team created? PROBE: Positions needed, qualifications for those positions

Project Development

- What was the impetus for the project's development? PROBE: Lack of services for the project, siloed/fractured services, lack of structural services, etc.
- What funding supports the project?
- How were the project's program areas and core services decided?
- How were the final 10 sites selected for funding? PROBE: What criteria were used to evaluate applications? How were those criteria prioritized?

Policies and Procedures Related to PrEP Screening and Determining PrEP Need

- What are the project's goals related to PrEP screening? PROBE: How many/What percentage of the target population did you want to be screened for PrEP?
- What policies and procedures are recommended for sites regarding PrEP screening? PROBE: How were those policies and procedures created?
- In what ways are those policies and procedures similar to or different from the 2017 CDC Guidelines for PrEP screening? PROBE: Who do you recommend be screened for PrEP? What questions do you recommend the sites ask? How do these apply to transgender persons?
    - Questions on IMPACT Intake form ask about lifetime activity, questions on DC Health intake form ask about activity in past 3 months, and risk assessment in CDC guidelines ask about activity in past 6 months? Why the difference?
- How familiar do you think clinic staff are with your recommended policies and procedures related to PrEP screening?
- What support does the project provide to the clinics regarding PrEP screening? PROBE: Technical assistance? Training? Guidance? Communication?
- What would the ideal screening process look like? PROBE: What are the various steps involved?

- How does the project define PrEP need? PROBE: What makes someone eligible for PrEP for this project?
- What are the project's goals related to PrEP need?
- What policies and procedures are recommended for sites regarding determining PrEP need? PROBE: How were those policies and procedures created?
- In what ways are those policies and procedures similar to or different from the 2017 CDC Guidelines for PrEP need? PROBE: What indicators do you recommend for determining PrEP need? How do these apply to transgender persons?
- How familiar do you think clinic staff are with your recommended policies and procedures related to determining PrEP need?
- What support does the project provide to the clinics regarding determining PrEP need? PROBE: Technical assistance? Training? Guidance? Communication?
- What would the ideal process for determining PrEP need look like? PROBE: What are the various steps involved?

Barriers and Facilitators

- From your own perspective what would you say are the most challenging issues associated with screening patients for PrEP? PROBE: Why? Are any of these issues specific to certain sites?
- From your own perspective what would you say are the most facilitating factors associated with screening patients for PrEP? PROBE: Why? Are any of these issues specific to certain sites?
- From your own perspective what would you say are the most challenging issues associated with determining PrEP need? PROBE: Why? Are any of these issues specific to certain sites? Why might patients not be interested in PrEP?
- From your own perspective what would you say are the most facilitating factors associated with determining PrEP need? PROBE: Why? Are any of these issues specific to certain sites?

Interview Protocol for Clinic Leadership

Demographic Survey

1. Please indicate your age group.
18-25
25-35
35-45
45-55
55 and older

2. What is your gender?
Male
Female
Transgender: male to female
Transgender: female to male
Don't know
Refuse to answer

3. Do you consider yourself to be Hispanic or Latino/a?
Yes
No

4. Which racial group or groups do you consider yourself to be in? You may choose more than one option.
Alaska Native or Native American
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White or Caucasian
Don't know
Refuse to answer

5. What is the highest degree you have obtained?
High School Diploma or GED
Bachelor's Degree
Master's Degree

Doctor of Medicine (MD)
Doctor of Osteopathic Medicine (DO)
Doctor of Philosophy (PhD)
Other_____

Organization, Provider, and Client Characteristics

- How would you describe your role within the organization?
- How would you describe your organization in terms of size, structure, mission, and the services provided**?**
  PROBE: funding sources, number of employees, leadership, scope of services (HIV versus non-HIV)
- What type of clients/patients do you serve? What type of patients receive HIV prevention services, including PrEP?
  PROBE: From which area of the city do they predominately come from? Are they referred to you? How? And by whom? About how many clients do you serve per day/week/year? What are the general demographics – gender, race, ethnicity, age, socioeconomic status, insurance status.
- What was your organization's motive for wanting to participate in the demonstration project?

Understanding of Recommended Implementation Process

- Are you familiar with HAHSTA's recommended PrEP implementation process for PrEP screening among MSM and transgender persons of color? If so, what does it entail? (If not, interviewer will provide summary).
- Are you familiar with HAHSTA's recommended implementation process for determining PrEP need among MSM and transgender persons of color? If so, what does it entail?
- Do these recommendations inform your practice? Why or why not?
- What support from DC Health does your organization receive for PrEP screening and determining PrEP need?
  PROBE: funding, guidance, technical assistance, training, monitoring and evaluation support, other resources?
- What interactions does your clinic have with DC Health as it relates to PrEP screening and determining PrEP need?

Policies and Procedures Related to PrEP Screening and Determining PrEP Need

- Does this organization have PrEP screening guidelines or policies in place?
  PROBE: If not, is there a specific reason why not? Do you think one will be developed anytime in the future? If so, how would you describe your organization's PrEP screening

guidelines or policy? What form is it in – written, verbal understanding, other? How do you promote/support it? Who is responsible? Any documentation?

- What were the key decision points around the adoption of these guidelines or policy? PROBE: When was it adopted? Who was involved? What evidence or factors were taken into consideration? Did guidance from the CDC, and/or HAHSTA inform your decision to adopt a policy? Does it change over time? How is it implemented or reinforced?
- How would you describe the PrEP screening process?
- Does this organization have guidelines or policies for determining PrEP need in place?
  PROBE: If not, is there a specific reason why not? Do you think one will be developed anytime in the future? If so, how would you describe your organization's guidelines or policy for determining PrEP need? What form is it in – written, verbal understanding, other? How do you promote/support it? Who is responsible? Any documentation?
- What were the key decision points around the adoption of these guidelines or policy? PROBE: When was it adopted? Who was involved? What evidence or factors were taken into consideration? Did guidance from the CDC, and/or HAHSTA inform your decision to adopt a policy? Does it change over time? How is it implemented or reinforced?
- How would you describe the process of determining PrEP need?

Barriers and Facilitators

- From your own perspective what would you say are the most challenging issues associated with screening patients for PrEP? Why?
- From your own perspective what would you say are the most facilitating factors associated with screening patients for PrEP? Why?
- From your own perspective what would you say are the most challenging issues associated with determining PrEP need? Why?
- From your own perspective what would you say are the most facilitating factors associated with determining PrEP need? Why?

Interview Protocol for Clinic Staff

Demographic Survey

1. Please indicate your age group.
18-25
25-35
35-45
45-55
55 and older

2. What is your gender?
Male
Female
Transgender: male to female
Transgender: female to male
Don't know
Refuse to answer

3. Do you consider yourself to be Hispanic or Latino/a?
Yes
No

4. Which racial group or groups do you consider yourself to be in? You may choose more than one option.
Alaska Native or Native American
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White or Caucasian
Don't know
Refuse to answer

5. What is the highest degree you have obtained?
High School Diploma or GED
Bachelor's Degree
Master's Degree

Doctor of Medicine (MD)
Doctor of Osteopathic Medicine (DO)
Doctor of Philosophy (PhD)
Other_____

Organization, Provider, and Client Characteristics

- How would you describe your role within the organization?
- How would you describe your organization in terms of size, structure, mission, and the services provided**?**
  PROBE: funding sources, number of employees, leadership, scope of services (HIV versus non-HIV)
- What type of clients/patients do you serve? What type of patients receive HIV prevention services, including PrEP?
  PROBE: From which area of the city do they predominately come from? Are they referred to you? How? And by whom? About how many clients do you serve per day/week/year? What are the general demographics – gender, race, ethnicity, age, socioeconomic status, insurance status.

Practices for PrEP screening and determining PrEP need

- How would you describe the PrEP screening process at your organization?
- Who on staff is responsible for screening patients for PrEP?
- What technical training is provided to staff to screen patients for PrEP?
  PROBE: Are staff confident in their abilities to screen for PrEP? Are they proficient in their abilities? How are staff evaluated?
- When is PrEP screening offered? Under what circumstances? To whom? By whom? How frequently?
  PROBE: Walk through the entire process of screening. What factors do you consider when deciding whether to screen for PrEP?
- What information is clients/patients provided before and after PrEP screening?
- How would you describe the process of determining PrEP need at your organization?
- Who on staff is responsible for determining the need for PrEP?
- What technical training is provided to staff to determine PrEP need?
  PROBE: Are staff confident in their abilities to determine PrEP need? Are they proficient in their abilities? How are staff evaluated?
- When is the determination of PrEP need made? Under what circumstances? To whom? By whom? How frequently?
  PROBE: Walk through the entire process of determining the need for PrEP. What factors do you consider when deciding whether a patient needs PrEP?
- What information is clients/patients provided before and after the determination regarding PrEP need is made?

Beliefs about Factors Impacting PrEP screening and determining PrEP need

- In your opinion, what organization level characteristics influence PrEP screening for MSM and transgender persons of color?
- In your opinion, what provider level characteristics influence screening for PrEP for MSM and transgender persons of color?
- In your opinion, what client/patient level characteristics influence screening for PrEP for MSM and transgender persons of color?
- In your opinion, what organization level characteristics influence determining PrEP need for MSM and transgender persons of color?
- In your opinion, what provider level characteristics influence determining PrEP need for MSM and transgender persons of color?
- In your opinion, what client/patient level characteristics influence determining PrEP need for MSM and transgender persons of color?

Barriers and Facilitators

- From your own perspective what would you say are the most challenging issues associated with screening patients for PrEP? Why?
- From your own perspective what would you say are the most facilitating factors associated with screening patients for PrEP? Why?
- From your own perspective what would you say are the most challenging issues associated with determining PrEP need? Why?
- From your own perspective what would you say are the most facilitating factors associated with determining PrEP need? Why?

Focus Group Protocol for Health Impact Specialists

Demographic Survey

1. Please indicate your age group.
18-25
25-35
35-45
45-55
55 and older

2. What is your gender?
Male
Female
Transgender: male to female
Transgender: female to male
Don't know
Refuse to answer

3. Do you consider yourself to be Hispanic or Latino/a?
Yes
No

4. Which racial group or groups do you consider yourself to be in? You may choose more than one option.
Alaska Native or Native American
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White or Caucasian
Don't know
Refuse to answer

5. What is the highest degree you have obtained?
High School Diploma or GED
Bachelor's Degree
Master's Degree
Doctor of Medicine (MD)

Doctor of Osteopathic Medicine (DO)
Doctor of Philosophy (PhD)
Other_____

Project Characteristics

- How would you describe your role within the overall project?
  PROBE: Specifically, what was your role in PrEP screening? What was your role after the determination regarding PrEP need had been made?
- What was your motivation for joining the project?
- Did you receive training for your current position? If so, what did the training entail?
- How satisfied were you with the training you received?

Organization, Provider, and Client Characteristics

- How would you describe the clinic in which you work in terms of size, structure, mission, and the services provided**?**
  PROBE: funding sources, number of employees, leadership, scope of services (HIV versus non-HIV)
- What type of clients/patients does the clinic serve? What type of patients receive HIV prevention services, including PrEP?
  PROBE: From which area of the city do they predominately come from? Are they referred to you? How? And by whom? About how many clients do you serve per day/week/year? What are the general demographics – gender, race, ethnicity, age, socioeconomic status, insurance status.

Practices for PrEP screening and determining PrEP need

- How would you describe the PrEP screening process at your organization?
- How would you describe the process of determining PrEP need at your organization?

Beliefs about Factors Impacting PrEP screening and determining PrEP need

- In your opinion, what organization level characteristics influence PrEP screening for MSM and transgender persons of color?
- In your opinion, what provider level characteristics influence screening for PrEP for MSM and transgender persons of color?
- In your opinion, what client/patient level characteristics influence screening for PrEP for MSM and transgender persons of color?
  PROBE: PrEP Stigma, medical mistrust, concerns about side effects or safety, pill burden, cost, low risk perception, etc.?
- In your opinion, what organization level characteristics influence determining PrEP need for MSM and transgender persons of color?

- In your opinion, what provider level characteristics influence determining PrEP need for MSM and transgender persons of color?
- In your opinion, what client/patient level characteristics influence determining PrEP need for MSM and transgender persons of color?

APPENDIX B: Codebooks

Codebook for Project-Level Focus Group and Documents

Name	Description	Files	References
1. Team Characteristics		3	18
1.1 Org Role	Role within organization	2	2
1.2 Project Role	Role within Project	2	9
1.3 Project Team Creation	How the project team was created	3	7
2. Project Development	Why the project was created	2	13
2.1 Reason	Reason project developed	2	2
2.2 Funding	Sources of funding for the project	1	2
2.3 Program Areas and Core Services	How program areas and core services selected	1	4
Clinic Selection	How clinics were selected	1	5
3. PrEP Screening	Screening patients for PrEP	5	70
3.1 Screening Definition		1	2
3.2 Policies and Procedures	PrEP screening policies and procedures recommended to sites	3	12
3.3 Alignment	Alignment with CDC Guidelines	1	8
3.4 Support	Support providing by project to sites regarding PrEP screening	4	35
3.5 Barriers	Challenges associated with PrEP screening	1	9

3.6 Facilitators	Facilitators associated with PrEP screening	1	4
4. PrEP Need	Determining PrEP eligibility	6	82
4.1 Need Definition	How the project defines PrEP need	2	3
4.2 Policies and Procedures	Policies and procedures used to determine PrEP eligibility	3	21
4.3 Alignment	Alignment with CDC guidelines	2	6
4.4 Support	Support providing by project to sites regarding PrEP eligibility	5	35
4.5 Barriers	Challenges associated with determining PrEP eligibility	1	9
4.6 Facilitators	Facilitators associated with determining PrEP eligibility	1	8
5. Miscellaneous		1	9

Codebook for Clinic-Level Interviews, Focus Group, and Documents

Name	Description	Files	References
1. Clinic Characteristics		33	250
1.1 Role of Participant	Role within Organization	32	42
1.2 Organization Description	Organization characteristics (size, structure, mission, services, staff)	32	196
1.2.1 Connections	Connections to other organizations	18	32
1.2.2 Staff	Staff description	27	46
1.2.3 Clients	Type of clients receiving HIV prevention services	32	50
1.3 Motive	Motive for joining IMPACT DMV	10	12
2. IMPACT DMV PrEP Screening		10	30
2.1 Knowledge	Knowledge of 1509's recommended PrEP screening process	9	11
2.2 Inform Practice	How 1509's recommended screening process informs practice	4	5
2.3 PrEP Screening Support	Support received from 1509 team	6	7

	regarding PrEP screening		
2.4 PrEP Screening Interactions	Interactions with 1509 Team regarding PrEP Screening	5	7
3. IMPACT DMV PrEP Need		11	25
3.1 Knowledge	Knowledge of 1509's recommended process for determining PrEP need	10	15
3.2 Inform Practice	How 1509's recommended process for determining PrEP need informs practice	3	5
3.3 PrEP Need Support	Support received from 1509 team regarding PrEP need	2	2
3.4 PrEP Need Interactions	Interactions with 1509 Team regarding PrEP Screening	2	3
4. Clinic PrEP Screening		32	215
4.1 Definition	Clinic's definition of PrEP screening	29	54
4.2 Guidelines	Clinic's PrEP screening guidelines (written, verbal, etc.)	25	37
4.3 PrEP Screening Process	Process of conducting screening (staff involved, under	27	75

	what circumstances, etc.)		
4.3.1 Staff	Staff Responsible for Screening	24	27
4.4 Training	How staff are trained to conduct PrEP screening	27	49
5. Clinic PrEP Need		32	189
5.1 Definition	Clinic's definition of PrEP need	31	75
5.2 Guidelines	Clinic's PrEP need guidelines	27	39
5.3 PrEP Need Process	Process of determining PrEP need (staff involved, under what circumstances, etc.)	23	43
5.3.1 Staff	Staff responsible for determining PrEP eligibility	18	19
5.4 Training	How staff are trained to determine PrEP need	24	32
6. PrEP Screening Characteristics		31	414
6.1 Organization	Characteristics of org that positively or negatively influence PrEP screening	30	141
6.1.1 Positive		28	49
6.1.2 Negative		28	41

6.2 Staff	Staff characteristics that positively or negatively influence PrEP screening	31	144
6.2.1 Positive		31	58
6.2.2 Negative		25	32
6.3 Patient	Patient characteristics that positively or negatively influence PrEP screening	30	129
6.3.1 Positive		24	35
6.3.2 Negative		28	44
7. PrEP Need Characteristics		31	329
7.1 Organization	Characteristics of org that positively or negatively influence PrEP need	29	99
7.1.1 Positive		27	42
7.1.2 Negative		20	23
7.2 Staff	Staff characteristics that positively or negatively influence PrEP need	30	79
7.2.1 Positive		29	34
7.2.2 Negative		13	18
7.3 Patient	Patient characteristics that positively or negatively influence PrEP screening	31	151
7.3.1 Positive		14	14

7.3.2 Negative	29	76
Miscellaneous	13	14