ENHANCING PREP UPTAKE AMONG MSM: FINDINGS FROM INTERVIEWS WITH RESEARCHERS AND PRACTITIONERS

by

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ABSTRACT

BACKGROUND: HIV pre-exposure prophylaxis (PrEP) is a prescription antiretroviral medication that an HIV-negative person who is at high risk for HIV infection takes once per day to prevent infection. The most recent National HIV/AIDS Strategy identifies increasing PrEP uptake among men who have sex with men (MSM) as a pillar of ending the AIDS epidemic. Extant literature suggests that barriers to PrEP uptake among MSM are related to access, stigma, and knowledge/attitudes.

METHODS: From February-March 2016, semi-structured interviews were conducted with researchers and practitioners in the HIV prevention field who work with MSM in Pittsburgh, Pennsylvania (n=11). An interview guide was used that asked about PrEP barriers and ways to mitigate these barriers. Interview recordings were transcribed and analyzed for key themes using ATLAS.ti software.

RESULTS: The original list of 39 codes was condensed into five key themes. The five key themes are that PrEP is empowering; PrEP barriers are multidimensional and overlapping; episodic PrEP is viewed favorably; PrEP needs, access, and perceptions differ by race and age; and risk

compensation is real, but it should not be used to prohibit PrEP uptake. A list of all PrEP barriers identified in the interviews is presented.

PUBLIC HEALTH SIGNIFICANCE: For public health practice, participants in these interviews identified stigma as more significant of a barrier to PrEP uptake for MSM than its discussion in the existing literature would suggest. PrEP enhancement efforts should simultaneously target multiple barriers across constructs for maximum effectiveness, avoid shaming overtones, and be inclusive of black MSM. A table is presented that may serve as a map to intervention design. Research is needed to test the association of PrEP use and STI incidence in US-based samples, to fine-tune local PrEP uptake efforts in other regions, and to monitor unintended consequences of PrEP uptake in the near or distant future.

TABLE OF CONTENTS

LIST OF TABLES

1.0 INTRODUCTION

The pandemic of HIV/AIDS persists around the world despite decades of prevention efforts from multifaceted local, regional, national, and international organizations. In the US, men who have sex with men (MSM) have been disproportionately burdened by the virus since the very beginning of the epidemic. While MSM comprise about 2% of the US population (1), they comprise 54% of people living with HIV/AIDS (2). Each year, 60-65% of total new infections are concentrated among MSM (2), and this number is higher among MSM in some regions of the country.

Many interventions to diminish this disparity have taken a behavioral approach. Assessments of behavioral approaches to prevention intervention design illustrate the need for multifaceted approaches in the fight against HIV. Interventions to reduce HIV transmission among MSM have almost exclusively focused on outcomes such as risk behavior by modifying social factors at individual, group, and community levels (1-3). A meta-analytic review of 58 socio-behavioral interventions concluded these approaches average a 27% reduction in risk behavior (2), and another concluded a 27% to 43% decrease in odds of risk behavior (3). The behavior change associated with behavioral interventions is often insufficient to decrease HIV incidence more than 12 months post-intervention (4). While many of these interventions demonstrated efficacy, these findings evoke the need for additional prevention approaches.

Socio-behavioral approaches may exacerbate the disparity in HIV infection by race/ethnicity among MSM. Socio-behavioral interventions are those that aim to reduce risk for

HIV transmission by measuring behavioral outcomes (e.g., condom use, condom negotiation, and number of sexual partners). The National HIV/AIDS Strategy calls for proportionally allocating resources based on epidemiologic need (5), and the heightened concentration of HIV incidence among Black MSM in the US is well documented. For example, Purcell et al. (6) conducted a meta-analytic review of seven nationally representative surveys in 2012 and estimated that HIV incidence among Black MSM was 6.0 times higher than White MSM, and 2.7 times higher among Latino MSM than White MSM. Furthermore, Millett et al. (7) concluded that Black MSM have three times the odds of testing HIV-positive compared with other MSM. One review of rigorously evaluated socio-behavioral interventions concluded that these interventions are more effective among White MSM than Black MSM (2). Findings that Black MSM do not have significantly different individual sexual behavior from other MSM (8) have forced others to conclude that we need to move beyond focusing on individual sexual behavior among Black MSM (9, 10).

A burgeoning body of evidence supports the augmentation of the socio-behavioral model with combination prevention approaches. Combination approaches incorporate behavioral, biomedical, and structural approaches (11) and target outcomes such as HIV testing and antiretroviral treatment for HIV-positive individuals (treatment as prevention, or TasP) (4). HIV pre-exposure prophylaxis, or PrEP, is a relatively new biomedical prevention method that is used in combination with condoms. PrEP is a prescription medication that an HIV-negative individual at increased risk of HIV infection takes daily to prevent infection (12). When used consistently and together with condoms, it has greatly reduced the risk of HIV transmission among diverse populations in several large-scale clinical trials (13-16). It is described in further detail in the next section. The White House's National HIV/AIDS Strategy 2020, and HIV/AIDS campaigns in New

York state, San Francisco, Washington state, and Pittsburgh have identified expanding PrEP access as a key component to ending the HIV/AIDS epidemic (5, 17-19).

Many people who could benefit from PrEP are not connected to it. Gilead Sciences, Inc., the company that produces the only currently FDA-approved medication, reviewed records from about half of United States pharmacies that dispensed PrEP between January 1, 2012, and March 31, 2014 (20). It found that just over 3,200 people had started the PrEP regimen during that period (20). Meanwhile, the Centers for Disease Control and Prevention (CDC) estimate that 500,000 Americans could benefit from PrEP, including one in four MSM (20, 21). Other researchers have identified reasons for low uptake such as the drug's high cost (22-26), stigma in the community (22, 27-29), and lack of awareness among providers and patients about the medication's potential for preventing HIV (29-37).

This thesis explored barriers and facilitators to PrEP uptake by interviewing employees of HIV-prevention organizations who work with the MSM community in Pittsburgh, Pennsylvania. This project aimed to gather data regarding barriers and facilitators of PrEP uptake, which may be used to inform public health practitioners, researchers, advocates, and policy-makers to better understand how MSM can be connected to PrEP more effectively. First, background information about HIV prevention efforts, about PrEP itself, and conceptual frameworks relevant to the research purpose are presented. Then, a description of the study's methods are described in detail, followed by a presentation of interview results. After that, the results are discussed and consolidated with conceptual frameworks to present implications of these findings for future public health research and practice.

2.0 BACKGROUND

2.1 OVERVIEW OF HIV PREVENTION EFFORTS

This section begins by setting the context for HIV pre-exposure prophylaxis, or PrEP, by presenting a brief overview of HIV prevention efforts in the US. Condom use is the first known HIV prevention method, with the first publications to advocate for condom use to protect against HIV infection being traced to San Francisco in 1982 (38). By the mid-1980s, hundreds of community organizations had formed to care for individuals dying of AIDS and to advocate for more action from politicians, scientists, and doctors (38). In 1987 the World Health Organization established the Special Programme on AIDS (later the Global Programme on AIDS), which widely promoted condom promotion, sex education in schools, simplified treatment of other STIs, syringe exchange programs, and efforts to improve safety of the blood supply (38). Today, other prevention methods include reductions in sexual or needle-sharing partners, male circumcision, and treatment with antiretroviral medications (or PrEP) (11). The future of HIV prevention "*must draw from the successes of existing evidence-based interventions and the expertise of the market sector to integrate preventive innovations and behaviors into everyday routines"* (11).

2.2 WHAT IS PREP?

Pre-exposure prophylaxis, or PrEP, is the use of an antiretroviral medication to prevent HIV infection in HIV-negative individuals. PrEP must be prescribed by a medical provider. Currently,

the only medication that is FDA-approved for use as PrEP is Truvada®. It is a single tablet that contains emtricitabine and tenofovir disoproxil fumarate (FTC-TDF) (13). If an HIV-negative individual is exposed to HIV but has sufficient levels of FTC-TDF in the bloodstream, genital tract, and rectum, the virus is prevented from entering cells and replicating, and the individual remains uninfected (13). It must be taken every day for maximum protection (13), and intracellular levels of FTC-TDF in rectal tissue and blood that are sufficient for protection occur after seven daily doses (39). In vaginal and cervical tissue, this may take up to three weeks (39). Some have called for alternatives to the daily regimen, known as episodic PrEP, because of observations that protection is only necessary during high risk episodes (40).

2.3 EFFICACY OF PREP FOR THE PREVENTION OF HIV INFECTION

Clinical trials have found that PrEP is highly efficacious among people who adhere to its treatment regimen. The iPrEx trial (13) enrolled 1,251 MSM in its PrEP treatment arm, and those who took the drug every day reduced risk of HIV infection by 99% (adherence was confirmed via blood analysis). Those who took it four days per week had a 96% reduction in risk (13). However, eight weeks into the trial, 45% of treatment arm participants had no detectable FTC-TDF in blood analysis (41). This indicates that adherence was a sizable issue.

A less demanding PrEP treatment regimen has demonstrated efficacy for preventing HIV infection, known as episodic PrEP. The IPERGAY trial (40) prescribed episodic PrEP, also known as event-driven or on-demand PrEP, to HIV-negative MSM who reported unprotected anal sex (n=199), and they found an 86% relative reduction in HIV infection compared to placebo control (n=201). The trial's participants were instructed to take two tablets of FTC-TDF or placebo two to

24 hours before sex, then another tablet 24 hours later and a fourth tablet 48 hours later (40). Participants used a median of 14 tablets per month (40).

2.4 IMPLICATIONS OF PREP TO COMBINATION PREVENTION

PrEP is an efficacious bio-behavioral intervention that fills a unique niche in HIV prevention (42). It may be a viable prevention method for MSM who do not use condoms. In a recent sample of HIV-negative Black and Latino MSM in three US cities who were recruited through online, agency, and street/venue outreach efforts (n=605), and were not already taking PrEP, Mansergh et al. (43) found that 52% of the men had anal sex without a condom in the prior three months. Respondents who reported recent sexual risk behavior were more likely than those who did not to prefer PrEP compared with condoms (43).

2.5 CONCEPTUAL FRAMEWORKS

The methods and analysis in this study were guided by theories and models from the fields of public health, health disparities, and psychology. Applicable frameworks were identified through a review of peer-reviewed literature about interventions that focus on medication use and adherence, behavior change, and HIV risk behavior. Frameworks that have been used to inform discussions of medication use include the Theory of Planned Behavior in hypertensive patients (44), the Health Belief Model in hypertensive patients (45) and HIV-positive patients (46), and the Transtheoretical Model in HIV-positive patients (47, 48). The Theory of Planned Behavior, which

has also been used to study gay affirmative behavior (49), posits social pressures and norms as influences to goal-oriented behavior (50). The Theory of Syndemic Production suggests that social marginalization experienced by MSM may manifest in a fear to access health services (51). Because PrEP uptake relies on an interplay of factors at multiple levels of society, the Social Ecological Model (52) was also examined.

These frameworks are instrumental in identifying strategies to connect high-risk MSM to PrEP more effectively. With contextual information about organizational and community strengths and needs derived from interview sessions, examination of existing frameworks will inform recommendations for actions that can be taken by HIV practitioners, researchers, advocates, and policymakers to mitigate barriers to PrEP uptake among MSM.

2.5.1 HEALTH BELIEF MODEL

The Health Belief Model (HBM) delineates a framework for understanding why an individual engages, or does not engage, in behaviors that are beneficial to his health (53). A researcher using the HBM analyzes the association of a given behavior to perceived susceptibility to and perceived severity of disease, perceived benefits of and perceived barriers to behavior change, cues to action, and self-efficacy (53). Practitioners apply the model's key constructs to develop effective interventions that target health behavior through education about risks, for example (54).

HBM's constructs have previously been applied in the context of HIV-protective behavior such as condom use and HIV testing and counseling. Zhao et al. (55) analyzed data from female sex workers and found that perceived benefits and perceived barriers were proximate predictors of condom use ($r=0.23$ and $r=-0.62$, respectively), and that self-efficacy had a direct effect on perceived severity, perceived benefits, and perceived barriers, which was indirectly associated

with condom use (r=0.36). Nöthling and Kagee (56) found that perceived severity of HIV and perceived benefits of and barriers to HIV counseling and testing explained 25.1% of the variances in acceptance of counseling and testing among South African university students. To this author's knowledge, there is currently no research in the peer-reviewed literature that explores HBM constructs among MSM with PrEP uptake as the outcome variable.

2.5.2 SOCIAL ECOLOGICAL PERSPECTIVE

The interplay of personal and environmental factors needs to be considered. The Social Ecological (SE) perspective encourages the examination of factors at five hierarchical levels of individual, interpersonal, community, organizational, and policy (52). Policies that make PrEP accessible, mechanisms that make it known among communities, social norms that make it acceptable, interpersonal interactions with healthcare providers that are productive and with sexual partners who are supportive, and individual factors that support medication adherence all must coalesce. At the individual level, adherence to the PrEP regimen requires a change in behavior, since it requires taking a tablet every day. At the interpersonal level, PrEP enrollment requires a patient who is MSM to disclose sensitive information about gay/bisexual identity and behavior to a healthcare provider. At the community level, social norms may inhibit PrEP uptake and adherence due to stigma (22, 27).

On the organizational and policy levels, accessibility can be increased through organizational and governmental policies that reduce its cost and increase its acceptability. Medicaid plans in some states cover prescription costs for PrEP, and some states have created programs to cover pre-prescription laboratory testing. Additionally, findings from the IPERGAY trial may have implications on the cost of a PrEP prescription. The FDA approved the use of PrEP

with a daily regimen for which the iPrEx trial found strong efficacy (13). However, the IPERGAY trial found efficacy for PrEP with a regimen that prescribes use only during high-risk periods (40). This may be a less costly alternative because fewer tablets are needed; participants in that trial used a median of 14 tablets per month (40). Elsesser et al. (57) found that 74.3% of MSM in a large web-based sample (n=7503) considered a short-term PrEP regimen during high-risk periods to be acceptable, and MSM who engaged in unprotected anal sex while on vacation in the past year were more likely to indicate interest than respondents who did not. Thus, the reasons that the FDA may consider approval of this regimen are twofold: it is less costly and it is easier to adhere to.

2.5.3 THEORY OF SYNDEMIC PRODUCTION

MSM who meet the criteria for PrEP eligibility may be experiencing psychosocial health issues that need to be considered. Stall et al. (58) found that psychosocial health problems including clinical depression, substance abuse, partner violence, and childhood sexual abuse are highly interconnected for MSM living in urban environments and that greater numbers of health problems are positively associated with high-risk sexual behavior. Stall, Friedman, and Catania (51) suggest that while not all MSM experience multiple, or any, of these outcomes, the ones who do may be less likely to seek health services. The Theory of Syndemic Production connects the presence of these health disparities among MSM to experiences of marginalization and stigma associated with gay/bisexual affiliation across the life course (51, 58).

2.5.4 TRANSTHEORETICAL MODEL

The Transtheoretical Model (TTM) proposes five stages of behavior change that individuals experience when changing health behavior (59). Intervention design may be targeted to individuals in a given stage to modify health behavior, with the goal of helping the individual move through the model's stages and lead to sustained behavior change (59). The five stages are precontemplation, contemplation, preparation, action, and maintenance (59). During precontemplation, an individual has no intention to take action, and in contemplation, the individual intends to take action within six months (60). An individual is in the preparation stage when he intends to take action within 30 days and has already taken some steps to do so, and the action stage is when overt behavior change has occurred within six months (60). The final stage, maintenance, signifies that the behavior change has been sustained for at least six months (60).

Ficke and Farris (61) found that from 1995 to 2004, eleven articles in the peer-reviewed literature applied TTM to medication use. Genberg et al. (48) applied TTM to antiretroviral adherence among HIV-positive patients in the New England area. Among the patients in this sample (n=137), those in the action and maintenance stages of change were significantly more likely to adhere to their medication than were the patients in the precontemplation, contemplation, or preparation stages (48). Therefore, the two end stages of the model are ideal; however, an individual most commonly proceeds through the first three to get to that point (60). Public health practitioners who aim to increase PrEP uptake among high-risk MSM might consider including stages of change indicators in needs assessments, goal-setting, intervention design, or outcome evaluations.

2.5.5 THEORY OF PLANNED BEHAVIOR

Originally developed by psychologists to predict goal attainment among college students, the Theory of Planned Behavior (TPB) considers the associations of attitude, perceived behavioral control, and subjective norms to behavior change intentions and execution (50). Subjective norms in the model are measured by normative beliefs about social pressures. Ho and Lee (44) adapted TPB to study medication adherence in hypertensive patients. They found a positive correlation of attitude, perceived behavioral control, and subjective norms with intent to adhere to medication ($r=0.27$, $p=0.00$), and a positive correlation of intent with actual medication adherence ($r=0.49$, $p=0.00$) (44). Andrew, Mullan, and de Wit (62) conducted a meta-analysis of peer-reviewed literature that examined the corrleates between TPB constructs and condom use among MSM. They found that attitude, subjective norm, and perceived behavioral control significantly correlated positively with condom use intention, which in turn accounted for 12.4% of the variance in condom use behavior (62). Interventions to increase PrEP uptake may consider measuring the intent to use PrEP and targeting attitudes and group-level social pressures about PrEP.

2.6 EXISTING BARRIERS AND FACILITATORS TO PREP UPTAKE

With an understanding of how theory informs approaches to increasing PrEP uptake, a review of barriers to PrEP uptake was conducted in peer-reviewed empirical literature. The three barriers of no access, lack of knowledge, and stigma were identified. Additionally, a scan was conducted of existing practices at the organizational or policy level that may mitigate these barriers. These strengths and needs were considered in construction of the interview guide used in this research.

Low access to PrEP is a significant barrier for many who would benefit most, with cost and connections to providers who will prescribe being important factors (22-26). The White House's National HIV/AIDS Strategy documents the correlation between high poverty rates and high risk of HIV infection (5). Truvada's manufacturer, Gilead Sciences, Inc., provides assistance for uninsured populations and co-pays for those who are insured (enrollment forms available at https://start.truvada.com/paying-for-truvada). The Partnership for Prescription Assistance program helps uninsured populations access prescription medications at low to no cost (https://www.pparx.org). Medicaid coverage leverages public assistance for uninsured populations to access a PrEP prescription. For people who are insured, the Patient Access Network Foundation will cover co-pays for any prescription medication, and for PrEP, grants may be up to $7,500 per year (http://panfoundation.org/hiv-treatment-and-prevention). None of these options cover provider visits and laboratory testing that are required for a PrEP prescription, but some states have created additional programs to cover these costs.

Low knowledge of PrEP in both the medical community and MSM communities may also be a barrier. The CDC (21) reported that one in three primary care providers in the US has not heard of PrEP. Among MSM, the numbers may be even lower. Less than 20% of MSM in a sample from Pittsburgh have heard of PrEP (63). However, more recent evidence elsewhere may indicate this is changing. Hood et al. (64) found that 86% of HIV-negative men who reported high-risk sexual behavior in a survey at the 2015 Seattle Gay Pride Parade (n=2168) were aware of PrEP, up from 13% in 2012. The New York City Department of Health and Mental Hygiene (DOHMH) is executing a PrEP education campaign with dual provider and community arms. While this initiative has yet to be evaluated, the campaign is similar to a DOHMH condom campaign from 2007 to 2008 that was considered to be highly effective (65).

Stigma related to PrEP as an HIV-prevention treatment for high-risk populations has also been identified as a barrier. Knight et al. (27) conducted 50 interviews with young men in Vancouver and some of the gay men in the sample expressed views that given its eligibility criteria, PrEP enrollment serves as a signal for one's stigmatized status as sexually promiscuous. Mack et al. (29) identified community-level stigma to be the most significant barrier to PrEP enrollment for MSM, through 20 interviews with HIV prevention experts in Kenya. Community-level stigma may be exacerbated due to conflicting views within the HIV prevention community itself. Some have denounced PrEP due to the perception that rates of sexually transmitted infections (STIs) will increase due to risk compensation (22). However, in a sample of 544 HIV-negative MSM in 13 sexual health clinics in England, McCormack et al. (28) detected no difference in STI incidence between treatment and control.

2.7 HIV IN PITTSBURGH, PENNSYLVANIA

The American Community Survey (66) estimated that the population in Pittsburgh, Pennsylvania, is 306,045, with a density of 5,521 people per square mile. Pittsburgh is the largest population center of Allegheny County, which has a population of 1,229,172 people and population density of 1,676 people per square mile (66).

The HIV epidemic in Allegheny County, Pennsylvania, has remained consistent over the past 12 years (67). Neither the prevalence nor incidence of HIV in the general population has shown a noticeable decline since 2004, and men are disproportionately impacted by the virus (68). In 2013, the most recent year for which county data are reported, the incidence of HIV was 20 per 100,000 males and 3.6 per 100,000 females (68). There were 1,948 total known cases as of the end

of that year, and 1,584 (81.3%) of those individuals were male (68). As is the case nationwide (69), sex with men continues to be the largest driver of HIV transmission among men in Allegheny County, accounting for 87% of transmission among men (68). Nationwide, 60-65% of new yearly HIV infections were among MSM in recent years (69), but in Allegheny County this proportion was 86% in 2013 (68).

3.0 METHODS

3.1 PARTICIPANT RECRUITMENT AND SAMPLING FRAME

This paper presents data collected through interviews conducted with experts who work with HIV/AIDS issues and MSM populations in Pittsburgh, Pennsylvania. Pittsburgh was chosen because its yearly HIV incidence has not significantly decreased over the last decade (9), MSM in Pittsburgh have low knowledge and uptake of PrEP compared to other cities (10), and Pittsburgh is a mid-sized city that is a hub of HIV/AIDS research and practice. Purposive sampling was employed to achieve a sample with maximum variation. Maximum variation is desirable in qualitative research when expertise is sought from different people with different backgrounds who work in different settings (70, 71).

An environmental scan of organizations in Pittsburgh that work in HIV prevention was conducted to compose a recruitment list. The scan identified 11 organizations including clinics, academia, nonprofits, a local health department, and one foundation. Leaders from each organization were contacted via email to be interviewed. See Appendix A for the recruitment email that was used. In some cases, the initial contact agreed to interview, and in others, he or she referred to one of his or her co-workers. During one interview session, a participant recommended three individuals who were later contacted and interviewed. In total, 18 individuals from 10 organizations were contacted, and this yielded a final sample of 11 participants from seven organizations across nine interview sessions.

3.2 INTERVIEW GUIDE DEVELOPMENT

An open-ended interview guide was developed prior to interview facilitation. The guide was designed to inspire discussion with participants without dictating content. The interview questions were about the participant's organization and the community with which he or she works, not about the participant individually. The guide was modified before each interview to reflect differences in the participant's organization. Questions were categorized by organizational characteristics, barriers to PrEP uptake (stigma, knowledge, cost), and inter- and intra-organizational strengths. If needed, the structure was modified *ad hoc* during each interview session depending on the natural flow of conversation.

The interview guide was reviewed by advisors in the University of Pittsburgh Center for LGBT Health Research before implementation to ensure coherence and comprehensiveness. The interview guide appears in Appendix B. Upon consultation with the University of Pittsburgh Institutional Review Board (IRB), it was determined that this study did not constitute Human Subjects Research, and therefore the study protocol did not require IRB submission or approval.

3.3 DATA COLLECTION

Nine semi-structured interviews were conducted by this author during February-March 2016 with 11 participants in Pittsburgh, Pennsylvania. Eight of the interviews were with a single participant, and one interview included three participants at once. Most interviews occurred at the participants' workplaces, and one interview took place at the University of Pittsburgh, Graduate School of Public Health. Each interview took place in a quiet location to ensure clarity for the audio

recording. The highest degrees held by participants are MPH (n=3), MSW (n=3), MD (n=2), MSN (n=1), MBA (n=1), Certified Registered Nurse Practitioner (n=1), BA (n=1), and a high school diploma (n=1) (some participants have more than one degree). See Table 1 for the participants' job roles. The audio recordings were transcribed clean verbatim by a professional transcription service, and transcripts were checked for accuracy by this author with the corresponding audio recordings. Interviews were between 30 to 65 minutes in length. Notes were made immediately following each interview session to summarize important points and record any data that might have not been captured in the audio recording (for example, information from tours of the physical space before or after the interview session).

Table 1. Participant Job Roles.

Participant	Role
P1	Academic researcher; PCP
P2	Program Director
P3	Research Specialist
P4	Program Specialist
P5	Project Manager
P6	Program Director
P7	Program Specialist
P8	Program Specialist
P9	Program Director; PCP
P10	Program Director
P11	Public Health Official

3.4 ANALYSIS

Content analysis as described by Patton (70) was performed on interview transcripts. Common themes were coded and illustrative quotes were identified. Thirty nine primary codes were identified in an initial open coding process on the first six interview transcripts (eight participants total), and these were condensed into five key themes. Data management and analysis were assisted by the use of ATLAS.ti software.

4.0 RESULTS

The open coding process yielded 39 codes, and five key themes emerged from these. See Table 2 for a summary of results. The results and illustrative quotes from this table are expanded upon in the proceeding section.

Table 2. Key Themes from the Interviews.

Key Themes	Illustrative Quotes
PrEP is empowering.	I've heard a lot of really, really positive talk around, "Wow, you're on PrEP. You're doing the things you need to do to take care of yourself and other people."
PrEP barriers are multidimensional and overlapping.	How do you pay for [PrEP]? Do you have culturally competent services? Do you have bus access to get there? Do you trust the pharmaceutical company in the first place that they're not going to be messing with you and have side effects down the line? So a lot of that I think factor[s] in.
Episodic PrEP is viewed favorably.	If you're at a risky time in your life… you can take PrEP for six months and stop taking PrEP… It's not something that you have to take for the rest of your life… It's not forever.
PrEP needs, access and perceptions differ by race and age among MSM.	The "Truvada Whore" conversation is more for middle-age, work-force men. I think that younger people are not calling each other "Truvada Whores." I think that especially in the African-American community, the chances [of HIV infection] are really high. So it's not as much of a joke.
Risk compensation is real, but it should not be used to prohibit PrEP uptake.	We saw [STI] increases go up way before PrEP. I don't believe that PrEP actually was part of it. I think it could potentially contribute to that, but I don't think it was the initial spark for driving it here in the first place.

4.1 PREP IS EMPOWERING.

Participants noted that PrEP empowers MSM in various ways. PrEP was described as empowering because many MSM take PrEP to feel like they are taking care of themselves and/or taking care of sexual partners; it is an opportunity for MSM to advocate for their own health to their providers; and it mitigates fear associated with sex that many MSM have experienced since the onset of the HIV/AIDS epidemic. The view emerged of PrEP as a harm reduction approach that contrasts *"paternalistic"* (Participant 1) approaches to care (to be discussed in a later section).

Several participants explicitly discussed PrEP as a method for individuals to take care of themselves or others. Participant 7 (P7) said that her clients, who are predominantly young Black MSM and Black trans women, have *"really positive talk around, 'Wow, you're on PrEP. You're taking care of yourself.'"* Additionally, given that PrEP enrollment requires a patient to visit a medical setting for testing every three months, P1 pointed out that it keeps individuals engaged in healthcare. P1, a physician who cares for MSM in a PrEP-prescribing medical clinic, said that for this reason many STIs are caught early and treated. P1 also discussed the theme of empowerment in the context of serodiscordant relationships and PrEP:

> *I think the reason why a negative partner might consider going on PrEP is that this is something that he or she can do to protect himself or herself, as opposed to depending on somebody else to maintain undetectable viral load, because we know that while communication should be ideal and should be open ended - things happen. This is something someone can do for himself or herself if he's in a serodiscordant relationship, to protect (P1).*

Other participants offered an empowerment view from a structural standpoint:

> *You can't control what people do. I'm a big proponent of harm reduction. I think you have to give people the tools to make informed decisions and keep themselves safe. At the end of the day, it's up to them. And I think there's that, when you're talking about public health, there's the individual decision-making and risk factors, but I think where we as public health people, as community collaboratives, as healthcare systems, we need to be focusing on environmental change, making the*

> *environment in which individuals live more conducive to healthy decision-making (P5).*

The view of PrEP as a harm reduction approach to HIV prevention emerged in the interviews. While this view is not unique to this sample, several participants expressed positive views about PrEP because it allows them to *"meet the client where they are"* (P4). On the harm reduction perspective and PrEP, P11 said:

> *PrEP is really, in my mind, a harm reduction approach. In the sense that as a healthcare provider, or someone who works with people who are sick or need to have some change in their life, telling people that they should change is really ineffective. I've never had anybody who stopped using drugs or having unprotected sex because I told them it was a good idea, it always takes more than that. It's more of a process and our job as healthcare providers is to keep the people as healthy as we can until they get to the place where they want to be (P11).*

Several other participants described how PrEP is empowering because it may equip their clients and patients with the language to advocate for themselves in a healthcare setting. One participant who is a counselor described how PrEP has enhanced his provider-client relationship and his clients' own health literacy:

> *I don't mind going and maybe advocating for that person. Or, I would ask them like, "Well, what type of information are you looking from your doctor?" I may be able to provide that information [to] them, or I may be able to develop strong questions so that they can go back to their provider that they're used to and ask those questions and advocate for PrEP on their own (P8).*

Several participants discussed how PrEP mitigates the fear that many MSM felt during *"the early cases of HIV in like 1980"* (P9), which was described as an empowering feeling. As one participant said:

> *So I think people have lived under this cloud of fear around their sex and their sexuality for a long time, and to be able to lift that a little bit for people I think is not what PrEP was intended to do, but if it makes people feel better and safer about having sex then I think that's good prevention and it's just good healthcare (P9).*

4.2 PREP BARRIERS ARE MULTIDIMENSIONAL AND OVERLAPPING.

Participants identified various types of barriers to PrEP uptake for MSM. The identified barriers are multidimensional because they can be organized into constructs, and they are overlapping because some barriers may feasibly be categorized into more than one construct. All identified barriers are listed in Table 3, and they are expanded upon below. This list is intended to be extensive but not exhaustive. All of the barriers identified by participants in this sample were placed into three constructs of Access, Stigma, and Knowledge/Attitudes.

Table 3. List of Barriers to PrEP Uptake Identified in the Interviews.

Access	Stigma	Knowledge/Attitudes
• High cost • Lack of insurance • Co-pays above Gilead assistance allotment • Lack of connections to PrEP-prescribing providers • Insufficient capacity among organizations	• Image of the "Truvada Whore" • Image of PrEP as a "party drug" (i.e., assumptions about risk compensation) • Discussions about sex and sexuality are often difficult • Internalized homophobia and self-shame	• Fear of side effects • Lack of awareness in community members and medical providers about what PrEP is and how to get it • Inaccurate self-assessment of HIV risk by community members • Fatalistic attitudes • Distrust of medicine/big pharma

4.2.1 ACCESS-RELATED BARRIERS

Access to PrEP was a primary barrier to uptake that was identified in the interviews. These barriers included PrEP's high cost, insurance issues, and lack of connections to PrEP-prescribing providers. As P5 noted, just because PrEP is legal and FDA-approved, the reality for MSM *"on the ground"*

is more complicated. To elaborate, P5 offered specific examples of access-related barriers that were also echoed by others in the sample:

> *How do you pay for it? Do you have culturally competent services? Do you have bus access to get there? Do you trust the pharmaceutical company in the first place that they're not going to be messing with you and have side effects down the line? So a lot of that I think factor in terms of justice [sic] (P5).*

P5's examples are not an exhaustive list of access-related barriers, but cost and access to a provider/clinic were the two access-related barriers most often discussed by the sample. Participants said that many people do not have a regular provider or they do not feel like they can talk about PrEP with their provider, which may be due to lack of ability to self-advocate in the healthcare setting and/or fear of discrimination. On the provider side, P1 noted that PCPs may not feel comfortable bringing up the topic or that they do not have enough time during appointments, because *"sex is not a three-minute conversation."* Organizational barriers were described as capacity issues in accommodating PrEP's clinical guidelines, including but not limited to comprehensive blood testing pre-prescription and every three months thereafter, and *"red tape"* (P10) that is associated with having a provider who can prescribe PrEP on-site.

Insurance issues came up in several of the interviews. Many participants discussed payment assistance plans for uninsured and underinsured populations, and it was discussed that some plans have paperwork that may be difficult for the layperson to navigate. For example, Gilead's payment assistance plan was identified by P8 as being easier to enroll in than dealing with Medicaid. Additionally, participants noted that they see cost-prohibitive issues commonly among people who are on basic insurance. As noted by P3:

> *I think it's interesting that it's easier to be on PrEP if you're uninsured than it is if you are insured. Unless you have good insurance that covers the majority of your out-of-pocket costs, it's still pretty tough to obtain PrEP. The copay assistance I think only pays about thirty six hundred a year, which is three hundred a month. And so if your co-pay is more than that, then you're out of luck (P3).*

Furthermore, P3 noted that many of his clients who are under 26 and on their parents' health insurance plan are concerned that their parents will know if they enroll in PrEP.

4.2.2 STIGMA-RELATED BARRIERS

Stigma-related barriers emerged in several forms during the interviews. Stigma against PrEP itself, status as MSM or gay/bisexual, and sex in general were identified during the interviews. Some barriers were on the individual level and some were on the community level.

A prominent stigma-related barrier that was discussed was the perception of PrEP as a *"party drug."* This term always carried a negative connotation in the interviews, and it was used differently among the participants. On an individual level, P9 noted that asking about PrEP may be seen as a signal for being sexually promiscuous, and that some MSM fear that label. P9 discussed how some MSM may hesitate asking a PCP in the privacy of a medical visit out of fear of judgment from the provider. However, P8 noted that he did not notice this fear among his clients, who are predominantly young Black MSM and Black transwomen: *"From what I gathered we don't have the whole stigma around, like if you are on PrEP that you're going to go sleep with everyone and everything."*

Additionally, the *"party drug"* stigma had a community-level dimension. Some MSM may forego a PrEP prescription due to the vocalization of "anti-PrEP" views among their peers. One example of "anti-PrEP" views was described by participants as the fear that PrEP is going to cause *"this feeding frenzy of crazy, condomless sex"* (P1), and in turn increase other STIs and drug-resistant HIV. Notably, P1 pointed out that among his patients who are having unprotected sex while on PrEP, most of them were not avidly using condoms before going on PrEP, and also, that

increases in STI rates nationwide began before PrEP was approved by the FDA. P11 speculated on other causes of upticks in STI incidence:

> *The normalization of anonymous and multiple sex partners that I think is rampant right now through social media [sic]. The Tindr's and Grindr's and all the other online hookup apps I think are having a quite an impact on STD risk-taking behavior. The idea that you can GPS a sexual partner just like you can GPS a taxi (P11).*

Additionally, a second "anti-PrEP" view discussed by a participant was the fear among HIV-positive MSM that insurance premiums will increase for HIV medications. However, the participant went on to say this about these "anti-PrEP" views:

> *I could analyze it as being weird like jealousy of why wasn't this around - why didn't people think about this before we contracted the virus? (P2).*

Stigma about sex in general was also cited by participants. P10 explained that some MSM are apprehensive about going on PrEP because *"there is that stigma of sex-shaming"* (P10), and PrEP requires frank conversations about sex. He later expanded on his point:

> *[They] may be embarrassed to ask about it, because they've heard that only sluts take it, or they don't ask about it because - talking about sex in general, we're a very Puritanical society when it comes to that, which is so weird when our movies and TV - we have a very wonderfully slutty pop culture. It's really built around sex, drugs, and rock 'n roll. But you sit down at the dinner table and all of a sudden we are like the Puritans. You don't want to talk about sex. Nobody wants to talk about it because it's embarrassing (P10).*

Fear of discrimination from a provider was cited as a stigma-related barrier by P3, who pointed out that asking about PrEP requires a discussion about sexual behavior, and not all MSM want to *"out themselves"* to their PCP. Input from a health department official (P11) may mitigate this barrier, particularly on his views about how the local health department fills a demand for sexual health services that are anonymous and neutral:

> *I see the health department not only as a traditional care provider, but also because of it's kind of neutrality and anonymity in a way [sic], I think we are - I know we do provide a service to not only the broad community, but for those who again, fall*

through the cracks. Who don't feel comfortable going to your traditional care model, they don't want to go to the Ivory Towers and ride the elevator up past inpatient units and be part of this whole big medical infrastructure. They like the idea of this relatively neutral kind of confidential site (P11).

4.2.3 KNOWLEDGE/ATTITUDE-RELATED BARRIERS

Knowledge- and attitude-related barriers included the lack of awareness of what PrEP is and how to get it, inaccurate self-assessment of HIV risk, fear of side effects, *"fatalistic attitudes,"* and medical distrust.

The lack of awareness about PrEP was discussed as a problem among both patients and PCPs. Some participants articulated that many MSM who know what PrEP is do not know where or how to get a prescription, particularly among those who do not have a PCP, do not want to talk about PrEP with their PCP, or see a PCP who does not know about PrEP. Several participants noted that lack of knowledge about PrEP among providers (e.g., treatment regimen, eligibility criteria, billing codes) is an issue:

Knowing where to get PrEP [is an issue], I think a lot of people have had trouble actually finding providers, and so when people call [around the city] they usually get referred to me… [it] is like, "How do I talk to someone about PrEP?" I think this person was trying to get in touch with me and they called my clinic. And we're like, "We can't call you. We can't have the doctor call you because he's never seen you before." So then what do you do? Like, if they have a question about this, that, and the next thing. So people are kind of like stuck in that particular situation (P1).

Participants recognized that even among their patients and clients who know what PrEP is, they may decide to not seek a prescription because they are self-assessing their risk incorrectly:

They think that they're not at risk. And it could be true for some. Not every individual who comes [here] is sexually active… But it's interesting that we have a lot of people who just don't consider themselves at risk for HIV (P7).

Many participants described a fear of side effects and a fear of interaction with alcohol and other drugs as prevalent barriers among the MSM that they work with. Participants said many of

their clients and patients believe that PrEP will come with burdensome side effects, because it is a medication for HIV:

> *Most question I get [sic], "Is it going to affect my body?" "What are the side effects?" "Does it hurt my lungs?" "Does it hurt my liver?" I think I've heard every organ. "Does it hurt my heart?" So they have these questions because they know that in the past HIV medicines have side effects and they do affect your body long-term (P8).*

Many participants agreed that the most at-risk MSM are not being connected to PrEP, and several discussed the prevalence of "*fatalistic attitudes*" in this context:

> *[When] thinking about populations that may be vulnerable to a number of structural justice factors - if someone is housing insecure, if they don't have food, if they don't have a safe place to be during the day... those are the things that you need to take care of first and PrEP is probably lower down on the list… so if you're just in survival mode day-by-day, PrEP might not be on the radar… I am hearing a lot about people who have fatalistic attitudes, in terms of, "I'm going to get [HIV] anyway," or if they do become HIV-positive, they're not surprised (P5).*

Several participants noted that their patients and clients who are informed about PrEP are usually informed about health-related issues in general, and participants expressed uncertainty about how to reach those who are not:

> *I think that we have a subpopulation that is informed about PrEP, just as we have a subset of our population who is informed about HIV and regularly gets tested. But the question then becomes what percentage is that subset, and how do we reach everyone else with that same information? (P8).*

Distrust of medical and pharmaceutical actors was identified as another barrier related to knowledge/attitudes, for two different subpopulations of MSM. P6 identified that many of her clients have a "*larger distrust of the medical system,*" who are predominantly young Black MSM and Black transwomen. P4, who works primarily with injection drug users of all races, pointed out that many of her patients avoid medical settings in general, because they do not want to undergo blood testing that may show traces of illicit substances and be recorded on their medical records.

4.3 EPISODIC PREP IS VIEWED FAVORABLY.

Participants supported episodic PrEP and said that the communities that they work with view it favorably. It was often described in the context of harm reduction. However, many noted that episodic PrEP is not well known among their clients or patients, with P2 saying *"that message has not been delivered very well to people in the community"* and that many MSM only know of PrEP as a pill that you have to take every day. Participants who see patients or clients said that they speak with their patients about using PrEP during high risk periods of their lives. P8 said that he often emphasizes that it is not a lifetime commitment in client conversations:

> *If you're at a risky time in your life, if you're participating in sex work or if you're at a point where you're in college and you're not in a relationship and you are having lots of sex, you can take PrEP for six months and stop taking PrEP, and then get back on PrEP if you need to… It's not something that you have to take for the rest of your life. And that's what I've been telling people... People know you have to take HIV meds for the rest of your life. So they're thinking, "Oh PrEP, that's one pill a day forever." No, it's not forever. You can utilize it during a high risk stage of your life (P8).*

P1 said that he has made short-term PrEP prescriptions for about a quarter of his patients. In addition to the reasons stated by P8, P1 added that his patients who seek PrEP because they are in serodiscordant relationships typically stop taking PrEP when those relationships end. It should be noted that this list of reasons for taking episodic PrEP is not intended to be exhaustive, and there may be other reasons that were not identified by participants.

4.4 PREP NEEDS, ACCESS AND PERCEPTIONS DIFFER BY RACE AND AGE AMONG MSM.

While participants identified unique characteristics of several subpopulations of MSM, differences by age and race were consistently discussed across the interviews. Specific characteristics about needs, access, and perceptions of PrEP were discussed in particular.

Several participants articulated that focusing efforts on Black MSM and transwomen is important because of their simultaneous higher risk for HIV infection and less engagement with medical care. P9 made a point that expands on this:

> *I think if you're black, there are barriers to accessing healthcare, period. If you're a black gay man, the places you can go and be treated with respect are limited. You're less likely, just demographically, to have insurance or good insurance. If you're not out publicly and feel comfortable and empowered around your sexuality, the likelihood that you're going to say, "I'm going to get PrEP," is probably pretty low. Again, I think there's a stigma that sometimes in the African American community can be stronger around religious prohibition about that kind of stuff (P9).*

P8 described unique attitudes about PrEP among his clients, who are primarily young Black MSM and see PrEP as *"needed for survival"* because of the disparity of HIV by race among MSM. He expanded on his point that the stigma of PrEP as a *"party drug"* is unique to *"middle-aged, work-force men"* (see table 2) and said:

> *I think that especially in the African-American community, the chances [of HIV infection] are really high. Like, even if I have sex for the first time, or if I've only ever had five sexual partners, nine times out of ten I've come across someone who was positive… For a young, black MSM it's not [a joke] (P8).*

Additionally, several participants articulated the importance that health communications about PrEP are inclusive of racial minorities. As P2 said, materials that are not inclusive are *"automatically going to turn people off."*

4.5 RISK COMPENSATION IS REAL, BUT IT SHOULD NOT BE USED TO PROHIBIT PREP UPTAKE.

Several participants spoke about risk compensation, and the two medical providers of the sample spoke specifically about risk compensation among their patients who are on PrEP. When speaking about the stigma of PrEP as a *"party drug,"* P1 said:

> *I don't know that it's going to cause this feeding frenzy of crazy, condomless sex. The reality is, people have lots of condomless sex right now, anyway. I suppose, if you could somehow prove that PrEP was going to take all the people who are using condoms right now, and change their thoughts, then yeah, that would probably constitute risk compensation (P1).*

Thus, P1 indicated that many MSM who are on PrEP and not always using condoms were very likely not using condoms before going on PrEP, either. He called it *"paternalistic"* to tell someone to not go on PrEP because of possible behaviors that he may or may not take:

> *I certainly think that as doctors or medical providers, we don't get to make that decision. This seems very paternalistic to say, "No, you can't have something that can potentially safe your life, because you might have more sex." (P1).*

With that being said, he said that risk compensation does happen:

> *[Risk compensation] is real, it's a question of how real will it be? I sometimes like to ask people, "So, do you feel like, since starting PrEP, you use [condoms] less frequently, or had more condomless sex, or more partners?" A good number of people say, "Well, yeah. I don't need to use condoms anymore" (P1).*

However, risk compensation's effects may be mitigated by PrEP's clinical guidelines, which call for comprehensive blood testing every three months, including STI testing:

> *If you are engaging them in care and are able to screen them for STIs frequently, then you're actually doing a really good thing in terms of at least treating their STIs before they go out and spread it to the entire world (P1).*

P7 echoed this sentiment in stating:

> *PrEP clinics absolutely have to have a very strong role and acknowledgment as STI clinics as well (P7).*

5.0 DISCUSSION

These discussions aimed to uncover and make explicit barriers to PrEP uptake and ways to mitigate these barriers, and in the process some specific attitudes about PrEP emerged. The barriers presented in this paper are intended to be extensive but not exhaustive. Table 3 lists all of the barriers that emerged in the interviews, and this table may serve as a guide to intervention design. These barriers are expanded upon below and are presented from a Social Ecological perspective. The importance of any single barrier or construct over another is not assessed, however, some of the barriers and constructs had more salience among interview participants.

The word "stigma" triggered conversation that extended beyond PrEP itself to include attitudes about sex and MSM identity more generally. Given that the eligibility criteria for PrEP requires an individual to divulge sensitive information about sexual behavior, stigma has formed around PrEP that it is only for "*slutty*" people or only for people who want to use it as a "*party drug."* Thinking about stigma invokes application of the Theory of Planned Behavior and examination of attitudes and subjective norms that emerge when talking about PrEP. While the significance of access-related and knowledge-related barriers cannot be overstated, when thinking about public health practice the particular salience of stigma-related barriers among interview participants calls for pause. For example, MSM who do not have access to PrEP because of financial reasons may be assisted by improving payment assistance mechanisms, but MSM who do not want PrEP because they are embarrassed or ashamed require interventions that are less straightforward. How and where does that conversation begin for someone when PrEP is a nonstarter?

We need the normative consensus among MSM to shift from that of a *"party drug"* that only *"sluts"* take to something that health-conscious people do to keep themselves and their communities safer. As described by participants in this sample, views of PrEP among the community as a *"party drug"* imply that PrEP's sole purpose is to enable MSM to have condomless sex with multiple partners because it significantly reduces fear of HIV infection. The term *"Truvada whore"* emerged in the interviews as a derogatory label ascribed to MSM who use PrEP, a label that pulls from assumptions about sexual promiscuity. A shift in the normative consensus about PrEP represents an empowerment perspective, because it turns PrEP from a signal of sexual promiscuity (which interview participants agreed is stigmatized) to a signal of responsibility and proactive self-care. Building upon attitudes and normative beliefs about PrEP that are positive and empowering may assuage the stigma associated with PrEP uptake and use.

These normative beliefs among MSM may arise from what the literature refers to as "risk compensation." Risk compensation in the context of these interviews and the literature on PrEP describes how individuals may stop or decrease other HIV protective behavior after going on PrEP, compensating one risk for another. HIV protective behavior besides PrEP use may include condom use and number of sexual partners. Informants in this sample said that risk compensation is a reality and important for healthcare providers to talk with their patients about, however, consensus was that the possibility of risk compensation does not warrant prohibiting PrEP among people who need it. Participants pointed out that PrEP is a harm reduction approach, and it may be a viable prevention option for people who are not using condoms in the first place. With that being said, PrEP is FDA-approved as a combination prevention method to be used in conjunction with condoms, and it should not supplant condoms.

Another important point that emerged in the interviews is that the clinical guidelines for PrEP may mitigate the effects of risk compensation. PrEP requires ongoing engagement with healthcare for those who have a prescription. This is especially important in light of findings from research using the Theory of Syndemic Production that find that high-risk MSM may be less likely to engage in health services. To maintain a PrEP prescription an individual must visit their provider for comprehensive blood testing every three months, including STI testing. In the experience of P1, STIs are being detected and treated sooner among his patients who are on PrEP. Thus, as PrEP use increases it is imperative that providers are educated about these guidelines for ongoing PrEP prescriptions.

In viewing PrEP through the lens of harm reduction, PrEP may be seen as an important HIV prevention method that meets people where they are. As P11 said on PrEP and harm reduction, PrEP *"keep[s] people as healthy as we can until they get to the place where they want to be."* This brings to mind the Transtheoretical Model (TTM) and its stages of health behavior change. As found in the literature and these interviews, MSM who never use condoms during sex may deem PrEP to be an acceptable form of HIV prevention. Thus, interventions to increase HIV protective behavior among this population should assess stages of change indicators for both condom use and PrEP use. For example, an individual may be in the precontemplation stage for condom use but in the preparation stage for PrEP use, or vice versa. Since PrEP needs to be used in conjunction with condoms, it is important for PrEP interventions to include condom use. Interventions may do this by applying the TTM to move individuals through the stages of change for both behaviors as long as they are needed.

The Health Belief Model (HBM) may also inform interventions that aim to increase PrEP uptake. Some barriers related to access and knowledge/attitudes in Table 3 are the cost of PrEP,

fear of side effects, and inaccurate self-assessment of HIV risk among MSM. These are textbook examples of the HBM constructs of perceived barriers to change, perceived costs of a behavior, and perceived susceptibility to illness. If an individual's perceived barriers/costs are high, and/or his perceived susceptibility to HIV is low, the HBM predicts that he will not seek HIV protective behavior. Furthermore, the discussion of *"fatalistic attitudes"* in these interviews may call for measures of self-efficacy, another construct of the HBM. As P5 indicated, if an individual believes that "*[he] is going to get [HIV] anyway"* and cannot avoid it, then it may be difficult to engage him in HIV protective behavior in general.

Access-related barriers also need to be addressed in intervention design. Some of these barriers identified in this sample are common in the literature, including cost and insurance issues, but some are not so common. Of particular contribution may be the access-related barrier of insufficient capacity among organizations, because PrEP's clinical guidelines require considerable resources of personnel, time, space, connections to laboratories, equipment, and financial costs associated with these.

Barriers to PrEP described in this sample occur at multiple levels and thus, Social Ecological (SE) perspectives to intervention design are necessary. As discussed in this section, individual decision-making about PrEP use may be influenced at the community level by reframing PrEP as a positive health behavior, and education of the community and providers alike; at the interpersonal level through accurate conversations between providers and patients about actual HIV risk, HIV prevention needs, and the PrEP treatment regimen; and at the individual level by addressing *"fatalistic attitudes"* about HIV risk. At the structural level, PrEP uptake may be facilitated by continued payment assistance mechanisms, expanding Medicaid coverage

nationally, programs that cover pre-prescription laboratory testing, advocating for FDA-approval of episodic PrEP, and organizational capacity building.

5.1 USING THESE FINDINGS FOR INTERVENTION DESIGN

Healthcare navigators and specifically PrEP navigators who serve to answer community inquiries about PrEP may be particularly helpful. As P1 said, his clinic receives phone calls from the community with questions about PrEP, but due to policy constraints, he cannot answer questions from anyone who has not been seen by the clinic. A PrEP navigator may be employed by a local health department or a prominent local nonprofit and may serve as the go-to community resource for all things PrEP. PrEP navigators should have a strong working knowledge about PrEP's eligibility criteria, the breadth of payment assistance options, and the research literature about PrEP; relationships with local providers who are known for fluency in issues related to PrEP, sexual health, and sexual minorities; and a demonstrated ability to communicate scientific health information to lay audiences effectively.

Health communication campaigns that educate the community and reframe PrEP as positive and empowering may also be helpful. Communications should use multiple channels and include messaging that is informative, nonjudgmental, and inclusive of racial minorities. Key information should include PrEP's eligibility criteria, where to get a prescription, payment assistance options, and resources to learn more. Qualitative research may fine-tune any communications product (e.g., posters, social media posts, videos) to greater resonate with the target audience. Given the disparity of HIV experienced by Black MSM, and the lack of focus on

Black MSM in existing PrEP expansion efforts that was identified in these interviews, messaging that targets this community is particularly needed.

Advocating for the FDA-approval of episodic PrEP may be useful, as well. Episodic PrEP may increase PrEP uptake by decreasing costs and promoting adherence. Costs may be decreased because participants in the treatment arm of the IPERGAY trial took a median of 14 tablets per month (40), half of what is needed for a daily regimen. Furthermore, daily adherence is a sizable issue. Forty-five percent of the participants in the original iPrEx trial, who were instructed to take the pill every day, did not have any traces of the drug in their blood (13). Findings from these interviews are congruent with the claim that episodic PrEP may increase PrEP uptake, because participants agreed that episodic PrEP is viewed favorably among MSM that they work with.

6.0 CONCLUSION

The iPrEx and IPERGAY trials demonstrated PrEP's efficacy among MSM, and subsequent work found evidence of its acceptability among high-risk MSM. However, many MSM who could benefit from PrEP are not connected to it. Expanding PrEP access, along with expanding access to testing services and antiretroviral treatment, is a key tenet to ending the HIV/AIDS epidemic. Barriers to PrEP uptake need to be articulated and examined if we are to identify intervention designs and increase PrEP uptake and use. It is with this in mind that I conducted interviews and consolidated my findings with conceptual frameworks and the extant literature to provide recommendations to bolster PrEP uptake among MSM in the United States. It should be noted that these findings represent barriers to PrEP uptake as identified by interview participants in this sample, and qualitative research in other settings may elicit different or additional findings.

PrEP is gaining momentum among public health officials and HIV prevention professionals nationwide. Large-scale clinical trials have demonstrated its efficacy, and HIV/AIDS campaigns at the federal, state, and local levels have identified expanding PrEP access as integral to ending the epidemic. Practitioners, advocates and policymakers should harness this momentum for fighting the epidemic in innovative ways.

6.1 SUMMARY

This study adds to the discussion about PrEP uptake among MSM. First, an overview is presented that described PrEP's context, its efficacy, and current research findings about barriers and facilitators to PrEP uptake. Then, this study's methods are described in detail, followed by the presentation of primary qualitative data that was gathered during individual and group interview sessions with experts in HIV/AIDS research and practice, from February-March 2016, in Pittsburgh, Pennsylvania. The discussion that follows consolidated these data with conceptual frameworks to enlighten or guide practitioners, researchers, and policymakers who seek to enhance PrEP uptake among MSM. While determining absolute importance of any barrier over another is not the goal of this paper, the particular salience of stigma-related barriers among participants was not expected, and the implications of this are discussed. Three specific intervention approaches are identified that target multiple barriers to PrEP uptake that emerged in this study.

6.2 LIMITATIONS

One limitation of this study is the sample is relatively small. Interview participants were purposively sampled because of their employment with HIV-related organizations and their openness to working with MSM populations. All participants live and work in Pittsburgh, Pennsylvania, and their experiences may not be generalizable to areas of vastly different demographics, HIV prevalence, population size, or other important environmental variables. However, this study has several strengths. As a qualitative study it serves an exploratory purpose and generalizability is not necessarily the goal of this research. A group of experts were sampled

who have diverse educational backgrounds, and they represent varying disciplines and roles from multiple levels of organizations across multiple sectors. Study findings and conclusions are further strengthened by the assumption that interview participants have expansive knowledge about the communities that they work with.

6.3 PUBLIC HEALTH SIGNIFICANCE

The complicated stigma that has formed around PrEP use needs to be deconstructed. Views of PrEP that reduce it to a *"party drug"* minimize its innovative contribution to HIV prevention to the detriment of the community. Its ability to empower individuals to take care of themselves and their sexual partners in a new way should not be overlooked. Quantitative research in US-based samples that tests the relationship of PrEP use and STI incidence may enlighten the controversy associated with PrEP use and risk compensation. Given that PrEP is a relatively new prevention method, continued research is needed to better understand any other unintended consequences of PrEP should they arise in the near or distant future.

Stigma-related barriers were highly salient among interview participants, but public health practitioners who aim to increase PrEP uptake should target multiple barriers across constructs for maximum effectiveness. While stigma emerged as more significant for practice than expected, barriers related to access and knowledge/attitudes must be addressed. In this way, Table 3 may serve as a map to intervention design. Local practitioners should create PrEP enhancement efforts that are informed by a strong knowledge of the needs, attitudes, and knowledge of PrEP within their specific community, and further qualitative research can help with that. In general, PrEP

navigators and health communication campaigns are two approaches that may be particularly effective, and episodic PrEP may simultaneously diminish costs and promote adherence.

APPENDIX A: RECRUITMENT EMAIL

Dear [NAME],

You are invited to participate in a research study that I am conducting. I am a Master of Public Health student in Pitt Public Health's Center for LGBT Health Research and a Master of Public Administration student in Pitt's Graduate School of Public and International Affairs. This study aims to understand barriers to PrEP use among men who have sex with men, with a focus on the Pittsburgh region. I hope to interview local experts in the field as a component of this project.

Would you be willing to meet with me for a 30- to 60-minute interview in the next two to three weeks? Your expertise as [PARTICIPANT JOB TITLE] is valuable because I am exploring how HIV-focused nonprofits and clinics are utilizing (or not utilizing) PrEP. This interview will be about [ORGANIZATION NAME], and the community you work with, not about you individually.

If you choose to participate, please let me know as soon as possible. You can send me the dates and times that you are available, and the place you would prefer to meet. I would like to record the interview, so a quiet location would be ideal. I can travel to your workplace for the interview if that is most convenient. Thank you for your time, and I look forward to hearing from you.

APPENDIX B: INTERVIEW GUIDE

Introduction and consent script:

Thank you for taking the time to sit down with me and talk about your thoughts and experiences with HIV pre-exposure prophylaxis in the work that you do. Your input will be valuable in composing my Masters' thesis and finding ways to better connect MSM in Pittsburgh to PrEP.

While PrEP can be used in several populations, I am interested in MSM for this project. I've decided to focus on Pittsburgh because this is a mid-sized city that is a hub of HIV/AIDS research and practice, and there are a number of experts locally, such as yourself, whose insight may be helpful for other regions too. I am aiming to interview a representative group of organizations that work in HIV to get a "big-picture" view.

My questions today will mostly focus on [PARTICIPANT'S ORGANIZATION NAME] and your role within it. Next, I will ask questions about barriers to PrEP uptake. Lastly, I will ask about how barriers might be mitigated. I've typed up some questions ahead of time, but they will serve as a guide more than a hard script. Some of the questions may seem obvious, but this interview is about your experiences and knowledge, and I do not want to impose mine.

Your participation is voluntary, and you may decline to answer any question, for any reason. You may stop the interview at any time if you choose not to continue. Please let me know at any time during the interview if you have any questions or would like me to explain what I mean by any of the terms being used or questions being asked.

As you know, I am recording this interview. The recordings will be transcribed and I will analyze them to write my report. I will not use the recording for any other purpose. Any personally identifying information about you will remain confidential, and I will not use your name or personally identifying information in any reports. The name of your organization may be included. Do you have any questions?

Let's begin.

1. Organization
    a. Tell me about your educational background. How long have you been working in HIV?
    b. Tell me about [organization name].
        i. What is its structure?
            1. How much staff and of what types?
        ii. How are decisions made in [organization name]?
            1. Is there a mission statement?
        iii. What is the organizational culture like?
        iv. How did the clinic start? How long has it been around?
    c. Tell me about your role in this organization.
    d. Tell me about the community you see here.
        i. What are their demographics? Are they mostly homogenous in terms of race, education, age, and income, or are they diverse? How many are positive and negative?
    e. How much is PrEP a part of this organization's operations?

i. Do you do HIV testing? How many people does your agency test? What kind of tests do you provide? What population(s) get tested here?

2. Barriers: stigma, cost, and knowledge
   a. Why might a man who has sex with men in Pittsburgh not be on PrEP?
      i. Differences by race? By age?
   b. What are some PrEP access issues in the community you work with?
      i. Do people know about PrEP?
      ii. Do people know where and how to get PrEP?
      iii. How many people that come here are insured? Medicaid or private insurance? Uninsured?
      iv. Has anyone used payment assistance programs for PrEP? Do people who come here for services know about them?
   c. What have you heard about stigma and PrEP in the community you work with?
      i. Risk compensation fears
      ii. Signaling as sexually promiscuous
      iii. Mixed messages from HIV prevention field
      iv. What might you tell a client who meets the criteria for PrEP but voices these concerns?
   d. How do your patients/clients get connected to your organization?
      i. Do they bring up PrEP, or do you/your providers?
   e. What are some concerns about taking PrEP that you hear from the patients/clients you work with?

3. Mitigating barriers: education, outreach, programs, policies
   a. What might governmental organizations do to help your patients be connected to PrEP? How about nonprofits? Private-sector organizations?
   b. What does your agency do to increase PrEP knowledge among patients who are eligible? Or among the community at large?
   c. How is PrEP different for Black MSM, compared to white MSM? Are there differences in stigma or access? What approaches and practices are needed?
   d. How did your organizational policies change when you started working with PrEP? If they haven't changed, are there ways that you would like them to change?
      i. Continuing education support for providers
      ii. Train and educate front-line staff
      iii. PrEP champion
      iv. Protocol to accommodate testing every 3 months

4. Miscellaneous
   a. What unintended consequences have you noticed PrEP having in your patients?
   b. What do you hope your organization can do with PrEP that it is not already?

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