

MALE PATIENT EXPERIENCE RECEIVING PRE-EXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV THROUGH PRIMARY CARE

Abstract

Objective: The purpose of this study was to examine the experiences of men who seek pre-exposure prophylaxis prevention intervention through their primary care physician, in order to assess access, engagement, effectiveness, and overall satisfaction.

Methods: Data was collected through semi-structured, qualitative, electronic, telephone, and face-to-face interviews. Participants were adult males (n =20) (18 years of age or older), currently residing in the continental United States, and who are currently receiving pre-exposure prophylaxis (PrEP) through their primary care physician (PCP).

Results: The experiences of the subjects in this study indicated variable confidence in primary care providers in both knowledge of and access to PrEP. About half of participants described their access to PrEP solely based on their initiation, sometimes resulting in a delay in and reduced confidence of the intervention prescriber. Participants also described additional barriers to PrEP, including PCP resistance to prescribing, costly co-pays, and variable insurance coverage. Once consistent access was afforded, participants described mostly overwhelming positive experiences in both care and effectiveness of the intervention.

Conclusions: This study of twenty subjects found that while male primary care patients want to have open conversation about their sexual health and access to new and innovative HIV prevention methods, most patients find that they must initiate this conversation with their PCP. Leaving knowledge of and access to prevention interventions up to the patient caused delays or restrictions to PrEP intervention and posed risk to public health HIV elimination efforts.

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MALE PATIENT EXPERIENCE RECEIVING PRE-EXPOSURE PROPHYLAXIS FOR THE
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ABSTRACT

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Objective: The purpose of this study was to examine the experiences of a racially-ethnically diverse cohort of men who seek pre-exposure prophylaxis prevention intervention through their primary care physician, in order to assess access, engagement, effectiveness, and overall satisfaction. It will also be determined what, if any, missed opportunities or changes could be implemented to the roll out of and engagement with nontraditional HIV prevention methods.

Methods: Data was collected through semi-structured, qualitative, electronic, telephone, and face-to-face interviews. Participants were adult males (n =20) (18 years of age or older), currently residing in the continental United States, and who are currently receiving pre-exposure prophylaxis (PrEP) through their primary care physician (PCP). During one week of allotted time during January 2017, participants completed a 30-question survey interview and orientation that examined their lived experience accessing, obtaining, and adhering to PrEP. Participants offered dialogue around how their sense of agency, access to care, and provider relationship could be strengthened based on their experience seeking HIV prevention care.

Results: The experiences of the subjects in this study indicated variable confidence in primary care providers in both knowledge of and access to PrEP. About half of participants described their access to PrEP solely based on their initiation, sometimes resulting in a delay in access and

reduced confidence of the intervention prescriber, if the prescriber was the PCP. Participants also described additional barriers to PrEP, including PCP resistance to prescribing, costly co-pays, and variable insurance coverage. Once consistent access was afforded, participants described mostly overwhelming positive experiences in both care and effectiveness of the intervention. Participants also described a sense of safety and freedom, and a reduction in worry after acclimating to PrEP.

Conclusions: This study of 20 subjects found that while male primary care patients want to have open conversation about their sexual health and access to new and innovative HIV prevention methods, most patients find that they must initiate this conversation with their PCP. Leaving knowledge of and access to prevention interventions up to the patient caused delays or restrictions to PrEP intervention and posed risk to public health HIV elimination efforts. Participants voiced concern with delays in PrEP access due to provider refusal or discomfort in prescribing, lack of provider knowledge of PrEP, and time lapse in care while waiting for provider referral and appointments to outside care providers. Most participants (about one-third) in this cohort learned of PrEP through social/peer environments, suggesting that if your social environment is without PrEP education or accurate information, you are less likely to learn of the intervention and therefore unable to benefit from its proven HIV prevention success. Lastly, missed opportunity to establish trust and a low-level therapeutic alliance between providers and male patients persist.

Table of Contents

Acknowledgements	7
Chapter 1: Introduction	9
Research Question	11
Purpose, Aims, and Goal	11
Literature Review	12
HIV/AIDS in Contemporary America	12
Health Care Access and Disparities for Minority Populations	19
HIV Detection	23
HIV Testing	23
Pre-Exposure Prophylaxis	25
Pre-Exposure Prophylaxis Intervention Concerns	28
Functional Cure and Future HIV Treatment	30
Chapter 2: Methods	33
Background	33
Qualitative Method Research Design	34
Survey Interview Development, Changes, and Adjustments	34
Sampling	35
Sample Size	36
Research Setting	36
Subject Recruitment Strategies	37
Subject Demographics	38
Survey Interview Process: Electronic, Telephonic, and Face-to-Face	40
Subject Data Inventory	40
Institutional Review Board	41
Data Collection	41
Memos	43
Reflexivity	43
Chapter 3: Results	45
Data Analysis	45
Access to PrEP	49
Engagement	50
Effectiveness	52
Overall Satisfaction	54
Findings	55
Chapter 4: Discussion	58
Clinical Recommendations	58
Chapter 5: Conclusion	62
Implications for Further Research	62
Implications for Social Work Practice	62
Limitations of this Study	63
Innovations in Future Pre-Exposure Prophylaxis Prevention Intervention	64
Definitions	65
References	66
Appendix A Interview Survey Questionnaire & Orientation	71

Appendix B Internal Review Board Approval and Mandatory Consent	75
Appendix C Research Poster	77
Appendix D Social Media Call for Participants	78
Appendix E Advertising Tracker	79
Appendix F Subject Demographic Sheet	80
Appendix G Subject Data Collection	81
Appendix H Pre-Exposure Prophylaxis Intervention Resources	82

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Introduction

Shortly after assuming a position as a behavioral medicine specialist in an urban community health center, I made the distinct observation that while it was standard protocol for our team of physicians and nurse practitioners to conduct routine HIV screenings for all adult patients, there was no protocol for educating them about or offering pre-exposure prophylaxis to adult patients, including those men and women who fall in high-risk categories. High-risk behavior is defined as insertive or receptive vaginal or anal sex without a condom, or without being on medicines that prevent or treat HIV, or sharing injection drug equipment with someone who has HIV. Not included in this description are men and women in monogamous sexual relationships, defined as having no more than one sexual partner at a time for an extended period of time. In this clinic, patients are asked limited questions about their sexual health and sexual behavior, but not in every appointment and not in a standardized way.

Ideally, these patients would also see a behavioral medicine specialist, also known as a BMed Specialist, who would conduct a deeper assessment of individual risk behavior. However, in most integrated care models, a BMed Specialist is only pulled in to see a patient if a physician or nurse practitioner requests the service, or if the patient has a previous relationship with the BMed Specialist and the BMed Specialist has identified them on the clinic schedule that day or week. This all leaves too much to chance. How do we make sure each patient is assessed thoroughly and regularly? How do we connect each patient falling into “at-risk” categories to education and preventive intervention, including pre-exposure prophylaxis?

Pre-exposure prophylaxis (PrEP) is a way for people who do not have HIV but who are at substantial risk of exposure to prevent HIV infection by taking a single pill every day. This pill, brand name Truvada, contains two medicines, tenofovir and emtricitabine, that were initially

developed as a drug to treat HIV patients who are living with HIV and are used in combination with other medicines to form what is known as highly active antiretroviral therapy, or HAART (CDC, 2016). Early into my new role at the community health center, I began to engage our physician and nurse practitioners to assess their knowledge about PrEP. I asked our physicians and nurse practitioners if they were aware of the biomedical intervention, and if so, if it is part of their practice to educate and prescribe the intervention to patients that were at substantial risk of HIV exposure. The results of my impromptu survey were concerning. Only two of the 14 physicians were aware of PrEP as an intervention in the prevention of HIV acquisition. All physicians and nurse practitioners had both HIV-positive and HIV-negative patients on their schedules; the latter included many with potential risk for exposure to HIV.

This information was a call to action that led me to seek out more practice information, data, and insight at the biannual National Prevention Conference coordinated by the Centers for Disease Control (CDC) in Atlanta, Georgia, December 2015. During this conference, I sat in several sessions that addressed barriers to care, barriers to prevention interventions, and more specifically, lack of physician uptake in adopting PrEP protocols in primary care clinics. This information backed my assumption that primary care has been extremely slow to integrate education about the delivery of PrEP in their clinical practice, while specialty clinics such as minority health, LGBT health clinics, or certain federally qualified healthcare centers (FQHCs) have been far more ahead of the curve. It is worth noting minority-serving health institutions were slow on the uptake as well. Early on and borne out in the data is that PrEP was largely being offered in private clinics and to affluent gay white male patients largely mobilized by their own demand. It wasn't until after the community pushed for these demonstration projects to recruit in minority populated settings that this began to change. Current clinical trials have

adapted this as well, but access and uptake remain low outside of large metropolitan centers and in minority communities.

Further, there is very little data measuring patient experience receiving PrEP through primary care, with the patient's PCP as the coordinator and educator of the intervention. Surveillance has been largely setup to capture disease transmission and remains an underfunded government-supported service. Very little has been done to survey an individual's experiences in the prevention of disease. That is where my dissertation research comes in. This is an opportunity to begin to assess the needs and barriers of PrEP access in primary care and to start a conversation that will lead to expanded availability, and perhaps later a reduction in HIV incidence rates.

Research Question

What is the experience of male patients who receive pre-exposure prophylaxis (PrEP) through their primary care faculties?

Purpose, Aims, and Goal

The aim of this research is to expand knowledge, assess needs and barriers, and explore overall patient satisfaction of their experience receiving PrEP through primary care by creating an opportunity to engage in research dialogue. The qualitative data and outcomes collected from this research may be used to further inform mainstream HIV prevention work and PrEP uptake in primary care. The goal of this dissertation research is to examine access, engagement, effectiveness of PrEP intervention, and overall satisfaction of primary care administered PrEP.

Literature Review

HIV/AIDS in Contemporary America

Each year since 2012, in the United States alone, there have been about 38,000 new cases of the human immunodeficiency virus (HIV). HIV, a lentivirus (a subgroup of retrovirus), is the virus that is responsible for what is known as acquired immunodeficiency syndrome (AIDS) (www.cdc.gov, 2014). While those with HIV are now living longer and healthier lives with the availability and use of pharmacological treatments, these acquisition rates remain alarmingly high. Medical and public health research have reportedly shown low retention and viral suppression rates among people living with HIV (PLHIV), and the simultaneously emerging data confirms the low transmission risk of virally suppressed PLHIV. High rates of acquisition are especially noticeable in both urban and rural areas of the American South. In July 2012, the Centers for Disease Control (CDC) called for additional methods for the prevention of HIV, including but not limited to the use of pre-exposure prophylaxis (PrEP), stating “additional prevention methods are urgently needed” and “if delivered effectively and targeted to those at highest risk, pre-exposure prophylaxis (PrEP) could play an important role in our response to the HIV epidemic” (2012).

The FDA in 2012 approved Truvada, the drug combination of 300 mg tenofovir and 200 mg emtricitabine, or TDF/FTC (brand name Truvada), as a safe and effective biomedical tool to prevent the acquisition of HIV, also known as a pre-exposure prophylaxis (PrEP), a term used synonymously with Truvada. “Truvada, which has been used to treat HIV-positive individuals since 2004, was approved by the Food and Drug Administration as a tool to prevent HIV in 2012 after studies revealed a 75% success rate in preventing new infections in ¹serodiscordant couples

who used the drug as directed. Another study of gay men showed that 99% of those who took the medication daily as prescribed did not contract HIV (Holpunch, 2014). While Truvada as PrEP has been wildly successful for the vast majority of users, there have been infections that have occurred even when patients have been adherent to their PrEP regimen. Analysis subsequent to their infection have posited that this has come as a result of those patients being exposed to Truvada-resistant strains.

Prevention groups have shown their support for PrEP. “PrEP, a breakthrough in biomedical HIV prevention, reduces the risk of HIV infection by upwards of 90% when taken as directed. The AIDS United Public Policy Committee is committed to raising awareness of and reducing barriers to full scale-up of PrEP as a critically important prevention tool for people faced with substantial risk of HIV infection” (The Urban Coalition for HIV/AIDS Prevention Services, 2014). The progression from HIV to AIDS and eventual death occurs in over 99% of untreated cases. Despite being identified over 20 years ago, AIDS has already taken the lives over 25 million people, and more than 35 million people are currently living with the virus worldwide (Hill, 2014). The World Health Organization (WHO) lists HIV/AIDS as the sixth leading cause of death worldwide. PrEP as a prevention method offers the global community a chance to fight HIV at its source of acquisition. PrEP may also be developed into a cost effective and rigorous prevention method. A recent letter published by the European AIDS Treatment Group states that there are continued demands for ability to manufacture generic Truvada or reduce the cost for broader access. It remains unconscionable that the cost to access an HIV medicine for prevention would be lower than the cost for treatment to save someone’s life, but there has been recognition of the need for broader access to prevention tools globally to turn off the tap in incidental HIV infections. In fact, a recent article in the *New York Times*

introduced the possibility of an intramuscular form of PrEP, where an at-risk patient would potentially be able to receive an injection once every two to three months that would protect him/her from HIV acquisition. The article goes on to say, “Two studies by different laboratory groups each found 100% protection in monkeys that got monthly injections of antiretroviral drugs, and there was evidence that a single shot every three months may work just as well. If the findings can be replicated in humans, they have the potential to overcome a major problem in AIDS prevention: that many people fail to take their antiretroviral pills regularly” (McNeil, 2014). A preliminary human trial is set to start in late 2014 at Columbia University’s Mailman School of Public Health in New York City. However, a larger trial that could lead to an intramuscular injection treatment in humans may still be some years away (McNeil, 2014). If this study is a success, it may mean greater, more thorough protection for populations with significant health care access barriers and/or environmental discord that prevents the ability to remain adherent to current biomedical interventions, which require daily use. An injection once every three months will be especially important for rural populations where a doctor’s visit may only be possible once every three or four months due to access and/or health insurance-related restrictions.

According to the CDC (2011): “...a review of 48 research studies found that about two-thirds of the HIV/STD prevention programs studied had a significant impact on reducing sexual risk behaviors, including a delay in first sexual intercourse, a decline in the number of sex partners, and an increase in condom or contraceptive use. Notably, the HIV prevention programs were not shown to hasten initiation of sexual intercourse among adolescents, even when those curricula encouraged sexually active young people to use condoms” (www.cdc.gov, 2014).

In March 2013, doctors from Mississippi reported that HIV had vanished in a toddler who was infected at birth. Four months later, researchers in Boston reported similar findings in two previously HIV-positive men. All three patients were no longer required to take any antiretroviral drug therapies. In the child known as the “Mississippi baby,” the virus had seemingly vanished for a remarkable 27 months. Media outlets, along with anxiously optimistic HIV researchers, heralded these findings as a potential breakthrough in the cure for HIV/AIDS. The findings of the two Boston men were documented and presented at the International AIDS Society meeting, July 2013, in Washington, D.C. Optimism was short-lived. In December 2013, HIV had returned in both of the Boston men, and then just six months later in the summer of 2014, HIV returned in the “Mississippi baby.” The 27-month off treatment remission experience by the “Mississippi baby” is, in and of itself, a laudable therapeutic goal and is what a cure for HIV may resemble in the foreseeable future, albeit a significantly longer duration. The ability to send the virus into remission and suspend treatment for months or years at a time is an important step because it can spare people living with HIV a lifetime of daily pill-taking, which can be difficult to tolerate and hard to comply with (Johns Hopkins Medicine, 2014). Failure to adhere to the strict pharmaceutical treatment protocols, which occurs often in patients, especially patients in distressed environments, can lead to viral mutations that make HIV resistant to drug therapies (Johns Hopkins Medicine, 2014). In both cases of the Boston men, HIV ultimately rebounded after several months without antiretroviral therapy and following bone marrow transplants for cancer. Both patients received antiretroviral drugs while undergoing transplantation to prevent the donors’ immune cells from becoming infected with HIV. The patients’ own HIV-infected immune cells were destroyed during chemotherapy and by graft-versus-host disease. When antiretroviral treatment stopped, both patients went into HIV

remission for several months (Johns Hopkins Medicine, 2014). In a similar case in Germany, now known in the health science and HIV advocacy communities as “the German patient” or “the Berlin patient,” a male patient’s HIV infection was cured through the use of antiretroviral therapy (ART) drugs and a bone marrow transplant. The patient, who had both HIV infection and leukemia, received a bone marrow transplant in 2007 from a donor who had a genetic mutation known to give patients a natural immunity to the virus. This genetic mutation is a gene known as CCR5-delta32. Nine years after the transplant, the patient remains free of HIV and the virus does not appear to be hiding anywhere in his body, as the HIV virus often does without detection. However, HIV/AIDS researchers have rejected the approach on any kind of scale for patients with HIV. A bone marrow transplant is a last-ditch treatment for cancers such as leukemia (www.reuters.com, 2014). “It's not practical and it can kill people,” said Dr. Robert Gallo of the Institute of Human Virology at the University of Maryland, who helped discover the human immunodeficiency virus that causes AIDS (www.reuters.com, 2014). Still, “the Berlin patient” is an important proof-of-principle case. Most of the latent virus was likely cleared out during the transplant, and even if the virus remained, most strains cannot replicate efficiently given the new cells with the CCR5 mutation. “The Berlin patient” case provides evidence that at least one of the two potential cure methods, sterilizing or functional, or perhaps a combination of both, is effective. The CCR5 gene is an important part of cure theory. Much research has focused on manipulating or “editing” the gene for both use as an HIV cure and an HIV vaccine. From Tebas et al. (2014): “The safety and feasibility of inducing genetic resistance to HIV infection in an attempt to mimic the known inherited resistance displayed by persons with the CCR5-delta32 mutation.”

While HIV researchers continue to make great progress in the goal of providing a

medical cure or remission protocol, no current, practical, and cost effective intervention is available to the public today. What researchers have provided are multiple pharmaceutical therapies that can limit the HIV virus from replication until it is undetectable to most HIV testing procedures. This means that the amount of virus in the person's blood is lower than the amount a blood test can measure. A viral load will be declared “undetectable” if it is under 40 to 75 copies in a blood sample. A study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) titled *Preventing Sexual Transmission of HIV With Anti-HIV Drugs* (2015) looked at 1,763 serodiscordant heterosexual couples in nine countries from April 2005 to May 2015, and measured the rate of infection of HIV negative partners when their HIV positive partner is compliant with ART. The study outcomes indicate that ART consistently suppresses HIV and is highly effective at preventing sexual transmission of the virus in heterosexual couples where one person is HIV-infected and the other is not. In fact, that study found that ART reduces the risk of heterosexual HIV transmission by 93% or more if viral suppression is achieved and maintained. Researchers did not observe any HIV transmission during this study when the HIV-infected partner’s virus was stably suppressed by ART.

When a person living with HIV becomes and remains undetectable, their lifespan can return to that of a person who is not living with HIV with proper medication attention and healthy lifestyle choices. Some doctors even suggest that perhaps an HIV undetectable, medically compliant patient may have a greater lifespan, as these patients engage in an increased number of doctor visits, blood screenings or “labs,” and other preventative medical care. Just as important, once a patient reaches undetectable status, the patient is less likely to pass the virus to their partner(s), as long as the patient remains at an undetectable status and are ART compliant, even without the presence of condoms or PrEP. This is how effective treatment among PLHIV

contributes to secondary HIV prevention.

Some pharmaceutical therapies include a number of once-a-day single-tablet regimens, such as Atripla, Complera, Triumeq, or Stribild, or twice-a-day pills, such as a combination of Truvada and Isentress. While an undetectable viral load or viral suppression is desirable for people living with HIV to extend their life and minimize health events, HIV remains a chronic medical condition that may have multiple complications, particularly towards the later part of the life cycle as frailty, diabetes, high blood pressure, fatigue, and other medical conditions develop or worsen. HIV complications due to a compromised immune system, medical and financial hardships, and social stigma still play a major part in the need for further educational and practical intervention in the area of prevention. However, this is changing. SMART trial results demonstrated that health complications are a function of time of diagnosis and the amount of inflammation. Early treatment may limit the experience of later health events. PrEP is an intervention that can be seamlessly integrated into the primary care clinic flow, aided by decision supports, possibly embedded in electronic health record systems, to optimize identification of primary care patients who could benefit from this form of protection.

In terms of large scale PrEP availability, one barrier is the administrative reticence on the part of primary care stemming from practical and legal considerations when prescribing PrEP. Primary care physicians (PCP) do not universally welcome the educational and additional sexual health assessment requirements necessary to extend access to this relatively new prevention intervention. Data from a 2009–2015 study by Porter and Novelli showed that in 2009, only 20% of PCPs were willing to prescribe PrEP to at-risk patients, in 2012 that rate rose to 45%, and in 2015 to 65%. However, looking at the same years, in 2009, only 1% of physicians actually prescribed PrEP, and in 2015 that number rose to only 7%—a vast difference between

willingness to prescribe and actual prescriptions made. The same study also concluded that 58% of physicians would endorse federal payment for a pharmaceutical prevention intervention.

Future direction might include more targeted investments with federal prevention resources to educate providers in areas where disparities remain pronounced or to offer more incentives for PrEP Continuing Medical Education (CME) and prescriptions.

Another barrier is the conservatism and sex avoidance of American mainstream culture. Large scale PrEP could be seen as an endorsement of casual sex with multiple partners, including those whose HIV status may not be known. We see aspects of this already in urban gay culture where the term “Truvada whore” has become part of the community vernacular. In 2014, Aids Healthcare Foundation (AHF) President Michael Weinstein came out against PrEP, calling it a “party drug,” and launching actions against Truvada manufacturer, Gilead Pharmaceuticals. Later, AHF claimed support of PrEP with co-occurring condom use, as recommended by the FDA. PrEP stigma continues to be a concern for prevention administrators and health care professionals as PrEP uptake remains slow in several key populations, including heterosexual individuals, and black and Latino gay and bisexual men.

Health Care Access and Disparities for Minority Populations

According to the 2010 Census, 42.02 million people, or 13.6% of the total population, reported their race as black or African-American. The state with the largest number of blacks is New York (3.3 million), but more than half (over 20 million people) of the black population lives in the South. It is predicted that the South will experience the largest growth in black population in the coming decades (Campbell, 1996). This is a trend seen now in southern states such as Georgia, which experienced a 27.6% increase in its black population. When it comes to HIV, blacks have been hit the hardest in recent years. Black residents of the District of Columbia

represent three quarters of people living with HIV (75%), but less than half (48%) of the District's population. The rate of black males living with an HIV diagnosis is 5.8 times that of white males in the state of Georgia, showing disproportional rates of HIV acquisition in rural and urban areas alike. Black men who have sex with men (BMSM) are diagnosed with HIV at a rate 6.0 times higher than white MSM, and are 3.8 times more likely to be living with HIV than white MSM (Eaton, et al., 2015). It is estimated that one in two black gay men age 18 today will have HIV by the time they reach 40 if different prevention approaches are not marshalled. HIV/AIDS continue to disproportionately affect minorities in both urban and rural areas at rates that demand that BMSM populations receive specialized and targeted prevention and treatment efforts.

“Racial and ethnic minority populations in the United States, primarily African-Americans and Hispanics, constitute 58% of the more than 928,188 cases of AIDS reported to the Centers for Disease Control and Prevention (CDC) since the epidemic began in 1981. African-Americans make up 50% of all AIDS cases reported in the United States, yet according to the U.S. Census Bureau, they comprise only 12% of the U.S. population. Hispanics represent 15% of all AIDS cases in the United States and are approximately 13% of the U.S. population” (CDC, 2013).

“As of December 2003, African-Americans and Hispanics represented 64% of males living with AIDS and 83% of those in females. As of December 2003, 67% of all women reported with AIDS are African-American and 16% are Hispanic. AIDS is the leading cause of death among African-American men ages 25-44” (CDC, 2013). Homicide is the number one killer of black men between the ages of 15 and 34 in 2011 (CDC, 2014). In 2010, an estimated 134,746 black

men who have sex with men (BMSM) in the U.S. were living with HIV, and this population accounted for more than 20% of new infections (CDC, 2013). Despite advances in HIV prevention methods and access to these resources, black men who have sex with men continue to bear the burden of the HIV.

“Given the impact of HIV among BMSM, there is a considerable need to implement the most effective HIV prevention strategies available for this population. More recently, substantial emphasis has been placed on the use of antiretrovirals as a form of HIV prevention. This strategy holds tremendous promise yet our ability to implement a wide-spread scale-up PrEP for those at-risk for exposure to HIV in the US has been slow” (Eaton, et al., 2015).

In 2012, published data suggested that internalized homophobia may promote acquisition and transmission of HIV infection among BMSM (Jeffries, et al., 2013). “Individual level risk behaviors alone do not explain the cause for the HIV disparity that exists among BMSM, comparable to other similar risk groups. It has been observed that BMSM often engage in less HIV risky behaviors (e.g. drug use and unprotected sex) than non-BMSM population” (Watson, et al., 2014; Millet, et al., 2007).

Additionally, access to and use of preventive primary care services has been limited for black patients in the past due to financial barriers and competing social issues, such as child care, ability to take advantage of employee leave, transportation barriers, and inability to navigate

health care systems, to name a few. Racism and historical oppression have created barriers of mistrust for young men and women of color in health care, government, and corporate systems. Access to preventative medicine may be limited in rural areas, especially in the rural south where HIV rates continue to rise. Missed opportunities to establish trust and a low-level therapeutic alliance between providers and black patients persist.

As with any ethnic group, family social structure and influences, geographic distribution, environmental risks, communication patterns, and lifestyle preferences influence the health beliefs and behaviors of people of color. Generally, people of color still lack overall confidence in the health care system and believe they are less likely to receive the same medications, treatments, or quality of care as their white peers (Henry J. Kaiser Family Foundation, 1999)—a barrier to preventative medicine and public health, particularly when addressing HIV prevention in the community. National surveys have demonstrated that blacks are less likely than their white peers to have a usual source of health care (Collins, et al., 2002). Delayed access to care may contribute to the observed increases in disease morbidity and mortality in low-income and minority groups. Examples include the tendency of blacks to use emergency or urgent care departments when symptoms can no longer be ignored or beared, often late in the course of disease or infliction, and tendency to seek peer, rather than professional, advice about preventive screening such as mammography or HIV testing (Bigby, J., 2003).

HIV Detection

The symptoms of HIV vary, depending on the individual and what stage of the disease the person is in: acute infection, the clinical latency stage, or the late stage of HIV infection, AIDS. During the acute infection stage, there are large amounts of the virus being produced in the body. At early onset, individuals may not experience any symptomology at all. Some individuals may experience flu-like illness within two to four weeks after HIV infection (AIDS.gov, 2015). “Although the symptoms of primary HIV infection may be mild enough to go unnoticed, the amount of virus in the bloodstream (viral load) is particularly high at this time. As a result, HIV infection spreads, more efficiently during primary infection than during the next stage of infection” (mayoclinic.org, 2015). During the clinical latency stage of the disease, HIV reproduces at very low levels, although it is still active. During this period, individuals may not have symptoms. With proper medical care, individuals may live with clinical latency for several decades. Without treatment, this period lasts an average of ten years, although some people progress through the stage faster (AIDS.gov, 2015). As CD4 cells fall below 200, individuals are considered to have progressed to AIDS. Without treatment, people typically survive three years. HIV diagnoses can only be confirmed by blood tests through a medical provider.

HIV Testing

Testing has always been an important part of HIV treatment and prevention. One mechanism by which the CDC hopes to affect the HIV epidemic is through widespread publication and dissemination of its guidelines for HIV counseling, testing, and referral. The guidelines were first published in 1986 and were intended primarily for health policymakers and

service providers in settings such as emergency departments (EDs) that can offer publicly funded HIV counseling, testing, and referrals. The initial guidelines focused on the importance of offering voluntary testing and counseling and maintaining confidentiality (Rothman, 2004). Over time and with treatment and testing advances, guidelines for testing have changed. Several subsequent revisions between 1987, 1994, and 2006 addressed specific issues that the CDC advocated for improving: counseling, testing, and referral (e.g., focus on an interactive personalized approach to HIV prevention counseling) (Rothman, 2004). The guidelines that underpin much of public health effort today are the 2006 guidelines, which were updated to give more flexibility in consent requirements and increase testing. The paperwork had been recognized as an administrative burden, which raised liability concerns. Verbal consent was adapted, resulting in fewer barriers to testing in clinical settings, and opt-out approaches were promoted. We can see many of these changes in HIV and public health work today. With increased access to testing, and streamlines to patient care for those that test positive for HIV, care today is thorough and effective. A particular push by HIV advocates and providers in treatment as prevention has put in place aggressive treatment and early detection protocols in some the hardest hit urban areas. However, many regions, particularly rural areas, lack access to even basic testing and outreach services.

The technology of HIV testing has greatly improved over the last 30 years. Today we have highly sensitive rapid tests, used in many hospitals and clinics, that can detect HIV antibodies from just a swab of saliva in less than three minutes. On July 3, 2012, the Food and Drug Administration (FDA) approved the OraQuick In-Home HIV Test, a home administered version of the saliva test commonly used by testing facilities and clinics, making testing something not just conducted at a clinic or agency, but also at home. The results are concluded

in 20 to 40 minutes and are 99% accurate. This test kit is priced at about \$37.00. Today there are over half a dozen brands of home test kits available at retailers and online sources. HIV testing has also become part of the standard of primary care, where PCPs run HIV testing as part of standard labs or physical exams. Some clinics have gone as far as to run rapid testing through their primary care or internal medicine departments, many of which are free to the public on a walk-in basis.

After undergoing seven clinical trials, a self-injectable HIV antibody, PRO 140, known to have a 98% success rate at reducing HIV, has been approved by the Food and Drug Administration (FDA) for human trials. A study of the intervention concluded that participants were found to have a completely suppressed viral load with full adherence to the once weekly self-injection. This intervention could be available as early as late 2017. Injectable forms of antiretroviral therapy (ART) treatment that provides viral suppression when administered once every 90 days by a health care provider, or once weekly by users, are just some examples of how ART has evolved in recent years.

Pre-Exposure Prophylaxis

When we talk about PrEP, we are really talking about prevention—prevention of the HIV virus from occurrence. We are also talking about identifying the HIV virus in its earliest stage so that the prompt and appropriate management can be initiated, which reduces the impact of the virus. Additionally, through prevention we look to reduce or minimize the consequences of the virus once it has developed, and eliminate, or delay, complications and disability due to the virus (HRSA, 2015). Pre-exposure prophylaxis has been shown to be highly effective in preventing infection with the human immunodeficiency virus (HIV) among persons with sexual behaviors

that place them at substantial risk, including men who have sex with men (MSM). PrEP has shown promise as a safe and effective HIV prevention strategy, but there is limited research on awareness and use, both in the general population and amongst primary care physicians.

On July 16, 2012, Truvada, a pharmaceutical intervention for the treatment of HIV/AIDS with a history dating back to 2004, gained FDA approval for the use in the prevention of HIV. “Truvada is the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners. Truvada, taken daily, is to be used for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection in adults at high risk” (www.fda.gov, 2014).

“In November 2010, the *New England Journal of Medicine* published the results of a three-year clinical trial, funded by the National Institutes of Health (NIH), announcing the arrival of a treatment that could reduce the risk of contracting HIV by more than 90%” (Glazek, 2013). This treatment involved a combination pill form of the drugs emtricitabine and tenofovir. Marketed under the brand name Truvada, the pill was synthesized in 2004 by Gilead Sciences, the world’s largest producer of branded HIV drugs, and has been used in combination with other antiretrovirals as a primary treatment for people living with HIV or AIDS (Glazek, 2013). “The NIH team discovered that a daily dose of Truvada not only suppressed the virus in people who were already infected but also prevented healthy people from contracting HIV” (Glazek, 2013). Shortly after the NIH study, which tracked gay men in Peru, Ecuador, Brazil, South Africa, Thailand, and the United States, additional trials showed the drug to be effective for heterosexual men and women, as well as for injection-drug users; researchers called the treatment “pre-exposure prophylaxis,” or PrEP for short. PrEP came at a time where public health officials

were looking for more effective, more reliable prevention method for protecting the public from HIV, which in turn would lower or eliminate new cases of HIV acquisition. PrEP does just that. HIV advocacy groups and health organizations across the country and around the world have stated their support for PrEP as a prevention method in HIV acquisition. “The Urban Coalition for HIV/AIDS Prevention Services (UCHAPS), the coalition of health department and community HIV planning leaders, and a member of the largest and longest-running national coalition of community-based HIV/AIDS organizations, the AIDS United Public Policy Committee (PPC) joins the call for the scale-up of PrEP” (The Urban Coalition for HIV/AIDS Prevention Services, 2014). They further noted that, “November 23, 2014, marked the four-year anniversary of the iPrEx study, the first randomized controlled trial that found PrEP effective in reducing HIV infection risk” (The Urban Coalition for HIV/AIDS Prevention Services, 2014). The Centers for Disease Control and Prevention (CDC) recommended the use of PrEP for those at substantial risk of HIV infection. Preliminary findings from two ongoing PrEP studies in Europe, PROUD and IPERGAY, that showed growing evidence for the effectiveness of PrEP to provide protection against HIV, added to the authority of the intervention. Shortly after the announcement of the NIH PrEP study results, *Time* magazine put PrEP in the first slot on its list of the year’s top medical innovations. Praise followed from national and international public health and governmental entities. Leaders in HIV prevention and advocacy, infectious disease, and public health have been optimistic in the uptake of PrEP in the prevention as cure directive. Access and use have been slow, particularly in black and Latino communities. A future focus in PrEP access and uptake has recently been directed at primary care. Protocols should encompass strategies to better facilitate understanding of the dynamic factors associated with uptake of, and adherence to, PrEP agents within at-risk populations, and allow for access to intervention and

education in primary care sites. Special efforts should be made to engage men of color, particularly black men who have sex with men (BMSM). Future research should “identify the behavioral and psychosocial factors influencing uptake and adherence within BMSM. The efforts would contextualize current barriers for engaging this population” (Watson, et al. 2014).

Pre-Exposure Prophylaxis Intervention Concerns

Taking Truvada to prevent HIV comes with few risks. In an NIH study (2013), one in 200 people had to temporarily discontinue use owing to kidney issues, but even those subjects were able to resume treatment after a couple of weeks. While bone density loss occasionally occurs in Truvada takers who are already infected with HIV, no significant bone issues have emerged in the PrEP studies. And though about one in 10 PrEP takers suffer from nausea at the onset of treatment, it usually dissipates after a couple of weeks (Glazek, 2013). Truvada for the use of PrEP may have possible side effects that include new or worsening kidney problems, including kidney failure; bone problems, including bone pain or bones getting soft or thin, which may lead to fractures; changes in the user’s immune system; headache; stomach area (abdomen) pain; and decreased weight (www.starttruvada.com, 2016). Many daily users report little to no side effects.

One public health concern has been whether PrEP will replace rather than supplement existing HIV prevention approaches such as condoms. Although condoms are effective at preventing HIV transmission, and perhaps the most widely used method of protection against HIV and other STIs, the rates of condomless anal intercourse among MSM have been increasing since the early 2000s, before PrEP became available, and could rise further with increased uptake of PrEP (Jenness, et. al. 2017). The reduced use of condoms as a prevention for HIV and STIs is

a concern for public health leaders. Some migration away from condoms and toward PrEP is inevitable; these shifts in practice will require public health and primary care providers to redirect education efforts to include safety interventions that meet the needs of PrEP users and continue to include comprehensive information, STI testing, and treatment. Many users of PrEP have been identified as people who don't use condoms anyway.

A final concern is access and awareness of PrEP to the most vulnerable populations. In New York City, public health leaders have geared up efforts to make PrEP available. “A free portable kit with condoms, lubricant, and a section for pills, which health officials hope those at high risk for contracting HIV will use to carry the preventive drug Truvada, will be distributed by the city (and through clinics that receive municipal funds) early next year. Eventually, some of those kits will contain Truvada—a starter dose of it, at least—for those who have first been evaluated by a physician. The city plans to link prospective users to providers who can help them pay for the medication long term, through patient assistance programs and other means” (www.newyorktimes.com, 2015). This comes at a time when primary care facilities are still in the early stages of PrEP education and uptake, and where some HIV/AIDS organizations have criticized the PrEP intervention itself. Michael Weinstein, president of AIDS Healthcare Foundation (AHF), the largest nonprofit global HIV/AIDS organization, has come out against this intervention, stating that only 21,000 of the 1.2 million people that could benefit from the intervention do. That despite “thousands” of articles and two and a half years of availability, that PrEP is a failure. “Any objective observer has to conclude that most patients don't want to take Truvada and doctors are not recommending it” (www.ahf.org, 2015). Research now shows several barriers to PrEP uptake, including lack of physician education on PrEP, PEP, and treatment as prevention (TasP) interventions, low levels of primary care appointments for men

ages 18-24, particularly minority men, lack of public education on PrEP, and physician bias in prescribing PrEP (D. Smith et. al. 2013).

Functional Cure and Future HIV Treatment

A generally new term in the field of HIV treatment is “functional cure.” This term refers to a method that uses genetic modification to cause a specific mutation in the white blood cells of people living with HIV, which mirrors those found in those naturally immune. It has so far shown to be both receptive and long lasting (Dovey, 2015). “This therapy involves taking stem cells from HIV-infected patients and using a gene-editing tool to cause them to form into white blood cells with a specific mutation. The mutation affects a protein known as CCR5, and interferes with the virus’s ability to latch onto blood cells” (Dovey, 2015). “The goal of a functional cure is not necessarily to clear the viral reservoir but to allow a person’s own immune system to control HIV without using medication. These approaches may involve the use of certain experimental drugs or therapeutic vaccines to stimulate the immune system to recognize and control active virus in the body” (www.FDA.gov, 2015). Since the FDA granted approval for further human testing and a Phase 1 safety study, researchers have been optimistic about further progress in the treatment and are hopeful for the eradication of HIV.

HIV treatment and prevention have come a long way since it was formally identified as a retrovirus by research groups led by Dr. Gallo, Dr. Luc Montagnier at the Pasteur Institute in Paris, and Dr. Jay Levy at the University of California, San Francisco, in 1984. Today we have biomedical intervention that is 99.9% effective in the prevention of HIV. PrEP and the effectiveness of current ART treatments have been said to be responsible for the overwhelming

decrease of HIV acquisition in the United States and abroad. However, in the United States alone, roughly 38,000 individuals contract HIV yearly, numbers that demand a deeper look into who is contracting and why. These numbers pose the questions, “Who has access to prevention methods and are they effective?” and “What is the role of primary care in HIV prevention?” These are questions I hope to answer in this dissertation research and analysis. Furthermore, how can integrated care teams meet the HIV prevention needs of patients under the constraints of managed care and a sometimes tumultuous health insurance market? How do we further provider uptake in PrEP access?

Multiple studies have assessed provider attitudes, intentions, and behaviors regarding PrEP, and have identified potential barriers to PrEP implementation. Data on provider reported concerns have largely been gathered from HIV specialists, infectious disease physicians, and other providers in large urban centers. Current understanding of prescriber behavior may be limited by the geographic and specialized nature of those interviewed (Silapaswan, et al., 2017).

Providers have also reported logistical concerns when prescribing PrEP, particularly time constraints, which can make it challenging for PCPs to complete risk behavior assessment and medication adherence counseling during standard brief clinical encounters. Risk behavior assessments are critical, however, to identify appropriate candidates for PrEP. Innovative approaches to assessing risk, including computer-based risk assessments that patients can complete independently and prior to clinician visits, are being explored (Silapaswan, et al., 2017).

In order to achieve provider buy-in, public health officials must make efforts to acknowledge and address their concerns, provide education, and to create simplistic work flows that include

patient behavior and treatment adherence assessments. In some healthcare settings, this looks like simple questions built into the Electronic Medical Record (EMR), questions asked by and recorded by the attending nurse or medical assistant, or communication opportunities embedded into online patient portals. Addressing the provider concerns in PrEP uptake are as important as meeting the patient demand for access to and education of PrEP. This dissertation looks to provide insight and direction for patient concerns based on their had experiences receiving PrEP through their primary care provider.

Methods

Background

This study, which was conducted to examine men's experience accessing and receiving PrEP, a biomedical intervention for the prevention of HIV, began with a comprehensive review of HIV prevention, pre-exposure prophylaxis, and primary care and HIV prevention literature using EBSCO host (University of Pennsylvania), which resulted in 20,300 hits for "HIV Prevention," 1,400 hits for "pre-exposure prophylaxis", and 240 hits for "primary care and HIV." I narrow down these results to a review of approximately 50 articles, which included a final EBSCO host search for "pre-exposure prophylaxis use in primary care," which yielded zero results. Searches on the National Institute of Health (NIH) database and on PubMed yielded a dozen useful articles narrowed to those included in this dissertation.

The aim of this literature review was to explore the research of contemporary HIV issues and concerns, including prevention interventions, as well as the use of primary care as a mechanism for prevention methods rollout. Additionally, because my practice population consists of primarily black and Hispanic/Latino men, because I identify as a gay black man, and because black and Hispanic/Latino men contract HIV at disproportionately larger rates of acquisition than their white and Asian counterparts, "Lifetime HIV incidence rates for African American and Hispanic/Latino MSM are 50 and 25%, respectively" (Centers for Disease Control and Prevention, 2016). I also researched articles that include explanation of HIV prevention methods for minority populations, including methods used to engage minority populations in primary care-based HIV prevention. Although I reviewed all related literature, including studies that explored HIV prevention methods outside of PrEP, i.e. condoms, education, injectable and implant forms of PrEP, I maintained a specific interest in exploring and focusing on the

traditional oral pharmaceutical version of PrEP and its use and accessibility in primary care. I concluded that PrEP uptake has been historically slow in primary care and continues to vary in its availability clinic to clinic, city to city, state to state. I have also concluded that there remain opportunities for cross country, cross cultural, implementation of PrEP education and administration, and further evaluation of the reach and scope of current PrEP programs, which are largely confined to urban areas and specialty clinics but still often miss engaging minority men, especially men who engage in risk behavior but do not identify as a member of an at-risk group/population. Nevertheless, I considered all studies and program evaluations based on their relevance to my research question and for guidance for as to how we have clinicians further the presence and accessibility of PrEP in primary care, nationally.

Qualitative Method Research Design

I chose a qualitative study to explore my topic because my intention for this dissertation research project was to measure patient experience. After creating an interview survey that asked the questions I thought were important, I realized that there were some areas of questioning that would fare more specific responses and thus more specific experience or opinion if asked quantitatively. During interview survey revisions, I added several questions using quantitative inquiry. With these additions, this design seems to have best captured the desired data and narrative to answer my research question.

Survey Interview Development, Changes, and Adjustments

I developed the initial survey interview mid-October 2016 to collect qualitative data. I researched through multiple HIV prevention questionnaires to get a general sense of how the questions were asked/formed. I put together an initial survey of 25 questions. I recruited three

colleagues at the community clinic I worked at to be mock participants in both the survey interview questionnaire and orientation. The mock participants represented both administrative and clinical work within the said community clinic. I had the mock participants examine the material for readability and flow, as well as for question significance. I examined the results to see if the questions were able to ascertain the information I was looking to collect, analyze, and explore; if the questions were able to elicit a true patient narrative. After some minor revisions, spelling and grammar corrections, and the addition of six more questions, some of which were quantitative in nature, I presented the revised version to participant #001, one of the five participants who agreed to be a part of the sample. Upon reviewing and debriefing the results with a peer from my university doctoral cohort, I made some minor revisions to the questions before submitting them to my chair for review. With his recommendations I submitted the final 30-question survey, interview, and orientation as an attachment with my IRB request. Overall, the survey, interview, and orientation went through minimal changes with the most significant changes being the addition of quantitative measure to strengthen the data collection. See [Appendix A. Survey Interview & Orientation](#) for the full and finalized questionnaire.

Sampling

In meeting with my dissertation chair, it was determined that a sample size of five individuals would be sufficient to test my research instrument and method. Because I planned to conduct in-depth survey interviews using an orientation and questionnaire, I recruited a purposive sample of subjects based upon the inclusion and exclusion criteria (see [Appendix A. Interview Survey Questionnaire and Orientation](#)). I developed a running list of all participants that agreed to participate in the study that included name, assigned participant number, age, identified race, residency, and recruitment methods. This running list has been held as a

confidential document. After participants were assigned a participant/subject number, their subject number and collected data was entered into my running data collection Excel spreadsheet.

Sample Size

The total number of subjects for this study was 20. The total number for the initial sample was five. The sample data was added to the overall data analysis. The data collection ceased when responses were similar and the data were saturated (Padgett, 1998); when participant's narrative responses became repetitious or similar.

Research Setting

The research materials were created by myself in my office or at home. The mock questionnaire referred to in the section "Survey Interview Development, Changes, and Adjustments" was administered at my office in Baltimore, Maryland. The sample set of survey interviews and questionnaires and orientations were administered face-to-face and electronically—face-to-face in Washington, District of Columbia, Baltimore, Maryland, and Philadelphia, Pennsylvania; electronically, survey, interview, questionnaires, and orientations were administered in New York, New York. The data collected from the sample was analyzed at my home in Baltimore, Maryland.

The full-scale data collection was administered from my home in Baltimore, Maryland, and from my offices in Baltimore, Maryland, and Washington, District of Columbia. The call for participants was made through paper flyers and social media, described in section "Subject Recruitment Strategies" above, and generated interested from men across the United States, Europe, and New Zealand. Only men living in the United States were selected as participants. The men selected for the full-scale data collection resided at the time of data collection

represented the states of California, Connecticut, District of Columbia, Florida, Maryland, Missouri, New York, Pennsylvania, and Virginia. The full-scale data collection was organized and analyzed at my home in Baltimore, Maryland, and on the campus of the University of Pennsylvania, Philadelphia, Pennsylvania.

I sought out additional data organization and analyzation guidance from my dissertation chair and from a peer from my university doctoral cohort who also was working on his dissertation under the same chair, both conducted on the campus of the University of Pennsylvania, Philadelphia, Pennsylvania.

Subject Recruitment Strategies

Subject recruitment first began with word of mouth recruitment for both the mock participants as well as for the sample set of participants. Once a full-scale data collection was ready to launch, I sent email communication to personal and professional contacts (public health and social work researchers and educators) at Johns Hopkins University, Bloomberg School of Public Health, Baltimore, Maryland, Yale University, School of Medicine, New Haven Connecticut, Us Helping Us People into Living, Washington, District of Columbia, and Whitman-Walker Health Care, Washington, District of Columbia. In the email communication, I attached a poster, (see [Appendix C. Research Poster](#) for posting at said sites). I also generated a social media advertisement for posting in PrEP and PrEP education groups, (see [Appendix D. Social Media Call for Participants](#)). I posted my call for research participants on my personal Facebook page (3,500 followers) and on the Facebook group “Group: PrEP Facts, Rethinking HIV Prevention and Sex” (16,600 followers, globally), (see Figure 1). I developed a spreadsheet to track my recruitment efforts and locations (see [Appendix E. Advertising Tracker](#)).



Figure 1: Social Media Advertisement, Facebook Group

Advertising recruitment and data collection lasted a total of 35 days; 30 days for recruitment, five days for data collection. Between the two methods of recruitment I received about 50 volunteers willing to participate. Of the 50 or so volunteer requests, 21 candidates were chosen in total—just one from the advertisement posters, seven from word of mouth means, and the remaining 13 through social media. One candidate excused himself during the orientation process. Additional candidates volunteered for participation after the cutoff date of January 15, 2017. These candidates were not considered for participation, however, were communicated with in the form of “thank you” emails. The total number of selected subjects for this study who completed the full process was 20. The data collection ceased when responses were similar and the data were saturated (Padgett, 1998); when the information regarding patient experience and patient access that I was examining became similar or identical, and in the presence of an emerging theory.

Subject Demographics

Participants represented men of multiple racial backgrounds and ages. All participants were identified as male, however, were not asked nor volunteered specific preferred gender pronouns. Participants were expected to meet the age criteria of 18 years of age to participate. Participants identified their ages ranging from 26 to 56. The average participant age was 38.2 years of age.

Twenty participants also represented nine out of 50 US states. Participants were not explicitly asked their relationship status, however, 25% of participants volunteered their relationship status, which ranged from single, monogamous, and serodiscordant¹. Participants identified themselves as either black or African-American, white or Caucasian, Latino/Hispanic, Asian American/Indian/Pacific Islander, or other. Ten participants self-identified as black, eight as white, one as Asian, and one as Latino (see Appendix E. Subject Demographic Sheet). This range of racial makeup provided some diversity narrative amongst PrEP users, however, is not necessarily conducive to a national account of who is receiving the prevention intervention.

According to data provided by Gilead, the developers and manufacturers of Truvada, and published by the Food and Drug Administration (2016):

Data on race/ethnicity were available for 44% of PrEP recipients (n = 21,463). White people made up 74% of all those who filled Truvada PrEP prescriptions, with Hispanics (12%), African-Americans (10%) and Asians (4%) accounting for much smaller proportions. Further, the proportion of black people who started PrEP actually dropped, from 12% in 2012 to 10% in 2015.

This raises questions about access to healthcare, HIV prevention methods like PrEP, prevention education outside of condom use, and attitudes and barriers to PrEP use amongst black MSM.

From a socioeconomic standpoint, all participants, because of their access to both primary care and to PrEP, as well as to internet services, were living above the poverty level, \$12,060 for a family of one (<https://aspe.hhs.gov/poverty-guidelines>, 2017). Participants were not explicitly asked about their employment or their health insurance status. All participants confirmed their connection to a primary care physician and access and continued use of PrEP. One participant stated in his narrative that he “temporarily discussed PrEP while he sought out a

new primary care physician.” All participants were engaged in PrEP use at the time of this dissertation research, which suggests access to PrEP at the time I collected data.

Survey Interview Process: Electronic, Telephonic, and Face-to-Face

Face-to-face, phone, and electronic interview surveys and orientations were provided to volunteer participants through an email address created specifically and solely for this project (prepsurvey.socialworkresearch@gmail.com), after participants were screened against the inclusion/exclusion criteria. Screening took place in person, over the phone, and by email. The interview surveys and orientations ranged from approximately 30 to 50 minutes in length. Prior to beginning each interview, I reviewed the Penn Consent Form (see Appendix B: Internal Review Board Approval and Mandatory Consent) with each subject, answered any questions, and obtained the subject’s signature. All participants retained an electronic copy of the signed consent form and completed interview survey and orientation. Only one participant candidate excused himself from participation after reviewing the consent forms. This candidate stated he decided he was uncomfortable with his personal information being held/used, even temporarily and anonymously. Participants provided demographic data on the face-sheet, and then proceeded to the 30-question interview survey. I did not take notes beyond the data gathered on the face-sheet. Following the interview, participants were thanked and encouraged to contact me directly by email with any follow-up questions or queries.

Subject Data Inventory

Data inventory began even before data collection. I created Excel sheets to record and track data securely and easily. I held all data on a secure thumb drive. When I began data collection, I

maintained an accurate and complete inventory of all interview data, which included: (1) consent form; (2) face-sheet data; (3) interview transcript; (4) notes; (5) open codes; (6) focused codes; and (7) memos. All written/printed data is held on file and will be destroyed upon completion of this dissertation research. The unique email address created to manage this project (prepsurvey.socialworkresearch@gmail.com) will be deleted upon successful completion of my dissertation defense.

Institutional Review Board

As mentioned above, my research was approved by the Institutional Review Board (IRB) on January 15, 2017 (see Appendix B: Internal Review Board Approval and Mandatory Consent) after some minor revision to my original submission. It was necessary to reword, reorder, and clarify questions to ensure that the topics of inquiry were fully investigated. In the final submission, I requested approval to interview subjects using an interview survey and orientation presented face-to-face, by phone, and/or electronically. On January 15, 2017, after IRB approval, I immediately began collecting data. I spent five consecutive days seeing through the completion and follow-up of all 20 interview surveys, concluding on January 20, 2017. By March 30, 2017, I had coded and analyzed all 20 completed survey interviews (see section “Data Collection” below). Halfway through analyzing the deck, I began to see the emergence of patterns that led toward theory building; these patterns are described in detail in the section “Data Analysis” below.

Data Collection

My data collection was 20 30-question survey interviews, which consisted of five multiple choice questions, 12 open-ended questions, five close-ended questions, and eight fill-in-the-

blank questions to explore male patient experience receiving pre-exposure prophylaxis in a primary care setting, whereas a traditional setting for PrEP education and intervention would be a LGBTQ health center or clinic, or a public health outreach agency. I also developed a survey interview orientation, which provided participants, in writing, a brief educational definition background on PrEP, HIV, common acronyms, and a view of documents included and signed prior to the start of the interview. Before conducting my first survey interview with participant #001, I took the questionnaire myself, rehearsed my delivery and explanation of the nature and scope of the dissertation research I was conducting, and organized my materials, both paper and electronic. I generated standardized email responses for those interested in participating, and for thanking those that participated.

Upon completion of each survey interview I entered all but the qualitative data into my Excel data collection spreadsheet. The qualitative data was later reviewed, analyzed, coded, then grouped by theme outcomes for easy referral. The process of data collection can easily be broken down in the following steps: (1) thoroughly collect data from participants; (2) enter all quantitative data to data collection spreadsheet; (3) review and reading of qualitative data; (4) fracturing data beginning with line-by-line, in-vivo, and preliminary codes; (5) noting emerging categories as I reviewed provisional codes, discovering similarities or differences between interviews, relationships between concepts and theory; (6) further fracturing the data and grouping similar codes together under the observed categories; (7) analyzing the quantitative data and then creating graphs and charts to show results; (8) axial/next step coding and the development of relationships and dimensions of categories; (9) create charts and graphs to show to results; (10) the emergence of theory based upon final coding; and (11) report findings in “Data Analysis” section below.

Memos

Shorthand memos, inquiries, and questions were handwritten on the paper copies of the interview surveys by myself to keep track of observations or things I wanted to remember. Also, assigned participant numbers in lieu of participant names were scribed at the top right corner of the paper copy of each survey interview to identify the responses and pair them with the data collection spreadsheet. If participants wrote their name on a paper survey interview, it was blacked out with marker to protect confidentiality. I also marked the paper copies of the interview surveys with a date/time stamp and made notes for follow-up if requested.

Reflexivity

As a process and as listed above in the section “Memos,” I kept some memos of insights, questions for later exploration, and details of things or phases I could use in the future to be more clear, concise, warm, or focused in my own writing, teaching, and clinical practice in terms of HIV prevention and treatment. I also kept a log of my thoughts while engaged with participants, and questions about content or process to debrief with my chair at a later date. Throughout the process, I was able to see how my clinical practice could and has been strengthened by data collection and analysis. While conducting this dissertation research, I had also been contracted with a team of medical providers in the specialization of HIV prevention and treatment to create Continuing Medical Education (CME) curriculum. It was the process of this data analyzation that strengthened my skills in order to contribute to work at that level.

Perhaps more profoundly, as a black gay man who has multiple personal life experiences related to “HIV scares” or in navigating the testing and prevention resources, I have found that my experiences are similar to those of my patients as well as to the participants of this dissertation research. I often tell my story of navigating through obstacles and barriers when I

was a young professional in a new city. I can remember having moved to Washington, D.C., right after graduation from Simmons College School of Social Work, having earned my Master of Social Work degree. I can remember not long after getting settled into my apartment, but before I was connected to a PCP wanting to take an HIV test, something I did as a standard of care, but also something I would do out of anxiety at times. I can remember looking testing sites up on the internet. I remember traveling to two different clinics on a Saturday morning and one being closed, and the other not open for HIV testing. I drove across town to Planned Parenthood where I walked through a small crowd of anti-abortion protesters to enter the facility. Once inside I was informed that HIV/STI testing was conducted between 2pm–4pm for the first 20 walk-in arrivals, and that I should come back at 1pm to “get on the list.” I returned at 1:30pm and did not make the list and was turned away. I remember feeling frustrated and thought to myself, how many other people have been turned away in the past? How many people who are unknowingly HIV positive have been turned away from a testing site because the facility didn’t have the resources to test, or because they showed up on the “wrong” day or at the “wrong” time? I left feeling defeated, having spent half a day trying to find a place to have an HIV test but never accomplishing it. This was the opposite of my experience living in Boston, where I could easily access a free HIV test at one of many sites across the city at any given time. Further, once I was connected to a PCP in Washington, I was never offered or informed of PrEP. It wasn’t until issues around HIV became a part of my practice that I learned of PrEP. These experiences mirror the data, where Boston has some of the lowest HIV acquisition rates in the country, and Washington has some of the highest. Of course, the reasoning and histories are different and complex, but having access to testing and education are some of the most basic ways we curb HIV acquisition rates and keep communities safe and healthy.

Results

Initially when I took on this dissertation research topic I had one major question: “Is PrEP accessible through primary care providers for patients who report behaviors that place them at high risk for HIV acquisition reaction?” Derived from my own personal experience as someone who might be deemed high risk, and from my practice experience as a therapist working with black gay men and high risk youth, and later in my experience as a behavior medicine clinician, I had a hunch that the access wasn’t “totally” there. If I had more time to spend on this project, I would strengthen this research by including far more men who are both currently taking PrEP and who have not yet accessed PrEP but have a level of interest in it. What I have been able to do is take a cross section of current PrEP users who represent various backgrounds, interact in various environments, and who possess a varying level of education of HIV and HIV prevention, and put together a narrative that speaks of how men communicate (or not communicate) and depend on their primary care doctors to assist them in remaining HIV negative.

Data Analysis

It could be said that data analysis began as early as data was collected. There are moments when participants said the same thing or something similar, had the same sort of reaction to a question, or shared a similar experience. In those moments, perhaps I was already mentally analyzing the data and making mental notes on emerging theory or practice needs. Data analysis may begin well before the recording, review, and coding of data. Formally, I used an inductive approach to analyze the survey interviews, identifying patterns or outliers in the data by means of thematic codes, in order to generate theory. “Inductive analysis means that the patterns, themes, and

categories of analysis come from the data; they emerge out of the data rather than being imposed on them prior to data collection and analysis” (Patton, 1980).

In coding using in-vivo, open codes, I fragmented the data into focused codes and further fragmented and analyzed thematic codes and concepts. I identified patterns that facilitated the emergence of theory. I handwrote and used a variety of colored highlighters on a legal pad, which helped me relate and thoroughly think through the material. This was feasible as I was working with a relatively small interview survey deck. Initially, I coded the data according to the presence of patient-described experiences for each of the 12 open-ended or qualitative questions. I highlighted in a unique color for each of the emerging themes for each question so that each question was written on a legal pad page with all the participant responses listed below, then color coded, then potentially combined (see Figure 2 below).

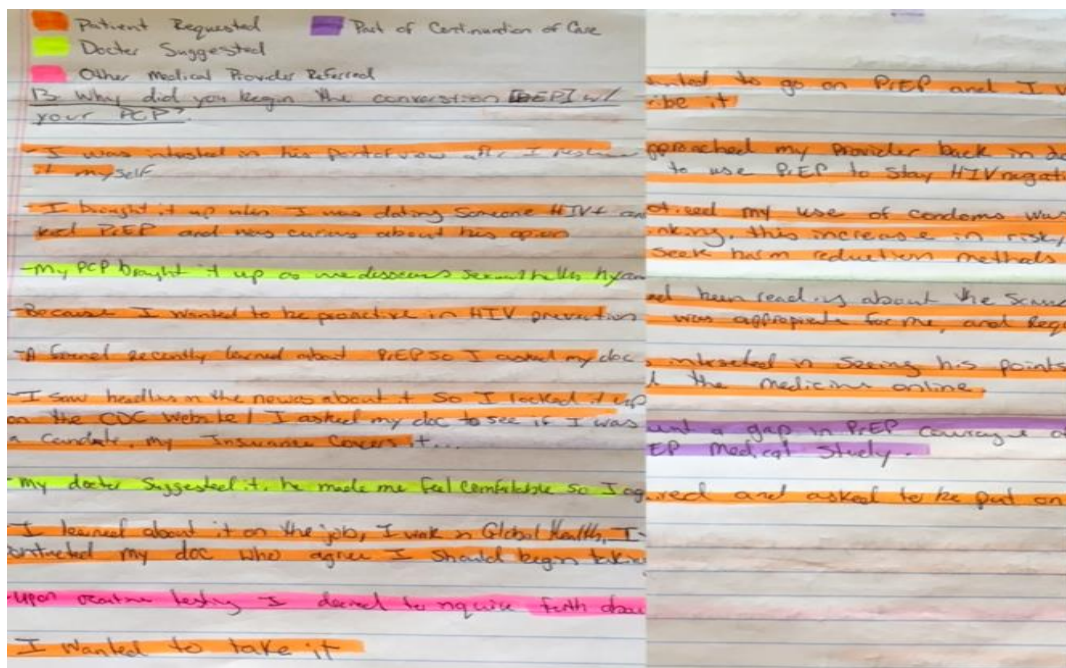


Figure 2: Sample of Qualitative Coding

After continuously fragmenting and coding the data, I was able to reduce each of the 12 qualitative question answers to three or four themes. These themes are essentially my research outcomes and the basis for analytical review, practice recommendations, and are the basis for discussion and recommendation in the following chapter.

Overall data analysis was examined through four lenses: 1) access—patient access to PrEP; 2) engagement—provider engagement in assessment, prescription, and ongoing intervention maintenance; 3) effectiveness—patient adherence to intervention; 4) overall satisfaction—how satisfied a patient was with his interaction with his primary care provider for the purpose of PrEP uptake and continuation.

The survey interview I created examined access with the following questions:

1. Are you (participant) currently connected to a primary care physician?
2. In months and years, how long have you been connected to your current primary care physician?
3. If your PCP was not your introduction to PrEP, has your PCP, without your first asking or initiation, engaged you in dialogue on the subject of PrEP at any time?
4. From the time you received the prescription for treatment, how long in months did it take for you to fill your prescription?
5. If it took more than 90 days to fill your PrEP prescription, please explain why it took more than 90 days to fill your prescription.
6. From the time you began your prescription for PrEP treatment to now, have there been any interruptions in treatment? If so, in your own words explain why.

7. From the time you began PrEP treatment, have you engaged with your PCP in follow up visits? If so, in months, how often?

The survey interview I created examined engagement with the following questions:

1. If your PCP never engaged you in dialogue on the subject of PrEP, why did you begin this conversation with your PCP?
2. In your own words, describe your first experience speaking to your PCP on the subject of PrEP.
3. From the time of your first dialogue with your PCP on the subject of PrEP, in months and years, how long did it take for you to receive a prescription for PrEP treatment?
4. In your own words, describe your experience in any or all of your PCP PrEP follow-up visits.
5. In your own words, describe how you might engage with your PCP to discontinue PrEP treatment for the prevention of HIV.
6. In regards to your overall experience receiving PrEP treatment for the prevention of HIV, how important is it for you to receive this treatment from your PCP? [Multiple Choice]

The survey interview I created examined effectiveness with the following questions:

1. In your own words, describe your satisfaction receiving PrEP through your PCP.
2. In your own words, describe how you might begin to discontinue PrEP treatment when you are ready to do so.
3. In your opinion, how important is it for the public to know of and have access to PrEP for the prevention of HIV?

The survey interview I created examined overall satisfaction with the following questions:

1. Do you feel like your PCP meets your HIV prevention needs, including but not limited to or necessarily including, providing PrEP and PrEP/PEP education, providing access to free condoms, engaging you in HIV prevention dialogue and education, encouraging you to ask questions, and connecting you to additional community related resources as applicable? Why or why not?
2. In your own words, describe your overall experience on PrEP as HIV prevention.
3. In your own words, describe your intended length of time/use of PrEP treatment.
4. If applicable, what would better your experience receiving PrEP treatment through your PCP?
5. In your opinion, how important is it for the public to know of and have access to PrEP for the prevention of HIV? [Multiple Choice]

Access to PrEP

In terms of access for participants of this dissertation research, 14 out of 20 participants stated that they first initiated conversation about or requested access to PrEP. Half of those participants were referred to another provider, allowing weeks or months of time to pass where an HIV acquisition could occur. In their own words, participants recalled, “I felt it was important for me to inform her about the treatment,” “I had initially brought it up when I was dating someone who was HIV positive and had read of PrEP and was curious to hear her opinion,” “I wanted to take it,” and, “He said he never heard of it, and was not comfortable prescribing it, he did not know what to look for in lab results so he referred me to and HIV doc.”

Once connected to a provider who started the intervention protocol, participants acknowledged a variety of other barriers or worries related to access, including ongoing access to health care insurance, difficulty affording sometimes costly co-pays, and lack of knowledge of

low or no cost PrEP resources. In their own words, participants recalled, “I switched primary care doctors because of a gap in insurance and couldn’t afford the prescription without insurance,” “I was off it one week while I was traveling without my PrEP,” and “Sometimes I forget to take it.”

During this dissertation research when participants were asked how they first heard about PrEP, participants overwhelmingly answered, “from a friend, relative, colleague or acquaintance,” followed by “other,” then “primary care provider,” “other specialty or community clinic,” and “educational/academic setting,” respectively. Under “other,” participants wrote in “online news,” “news,” “government website,” “on the job,” “dating app,” and “Craigslis medical research advertisement,” which showed the unique ways in which patients receive information about health care. In the future, I might combine “news” with “media and social media,” as “news” seemed to be a place where participants received health and health care information, including information on HIV prevention and PrEP.

Engagement

In terms of examining engagement as it relates to patient experience, there were seven total questions asked to participants on the survey interview to assess their experience engaging with their primary care physician as it relates to PrEP uptake and maintenance. At the time data was collected, the average length of PrEP use was 19.35 months, or one and a half years.

When asked to describe their first experience engaged in dialogue on the topic of PrEP with their PCP, participants recalled, “The experience was a bit daunting, I had to explain to her what the pill was, what it was used for, and asked her to help me get started,” “My PCP brought it up as we talk about sexual health history as part of my annual checkup,” “I said I want to get on PrEP so I can prevent contracting HIV, the doctor was receptive and easily began the process

to get the prescription,” “I informed my doctor I am HIV negative and want to keep it that way, we then began the process so I could receive PrEP,” and “It was terrifying. I had this doctor for six years but we never talked about sex or sexual health. I was afraid he would disapprove or judge. But he ended up being very cool, very rational. Treated me like an adult who was capable of making his own decisions. No lectures about condomless anal sex, just support in making decisions that were right for me.” These responses could be divided into two categories—patients who recall a positive or somewhat positive experience, and patients who recall a negative or somewhat negative experience.

Another important question asked to assess patient engagement was, “In your own words, describe your experience in any or all of your PCP PrEP follow-up visits.” This question is important because we get a glimpse into the patient experience after the intervention introduction to determine a real sense of the patient perspective on his relationship with his PCP, as well as with his level of PCP trust. Participants recalled, “My PCP from two years ago refused to give me PrEP and insisted that I see an ID doc instead. He later relented since he received so many questions about PrEP from other patients. That doctor was very sex-negative, even advising me to ‘not have sex.’ He was inappropriate in his interactions with me, and has since changed practices. My new PCP felt PrEP was so successful that we didn’t need to test for HIV. I corrected him on that. He is also sex-negative and refused to do an anal swab during my routine STI testing, so I offered to do the swab myself and he acquiesced. I pointed out to him that if I had a prostate concern he would be involved, so refusing an anal STI swab was problematic.” Another participant reported, “I see a specialty clinic every three months for blood test, HIV test, and STI check. They are very supportive and the process is simple,” and “We discuss side

effects, sexual relations, and whether condoms were used, type of sex, missed dosage, a full STI screener.”

Lastly, when asked if it mattered to the participant/patient if they received PrEP through their primary care provider, participants had mixed opinions, although a larger percent of participants stated they preferred to receive PrEP through their primary care provider. In numbers, nine participants answered “extremely important,” three answered “highly important,” four answered “somewhat important,” three answered “not important,” and one answered “I don’t know/undecided” (see Figure three below).

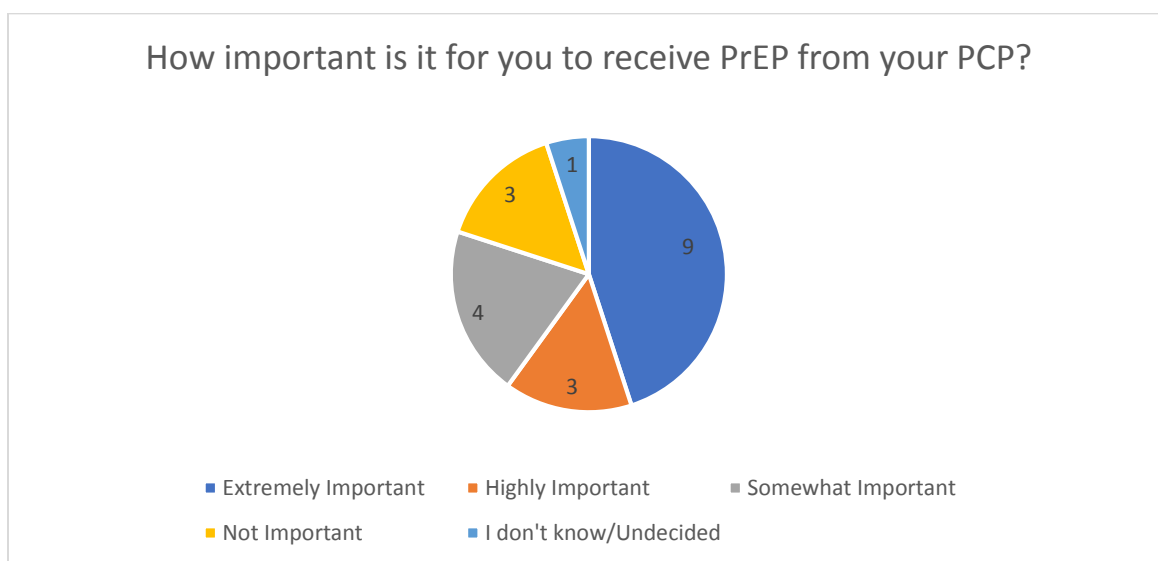


Figure 3

Effectiveness

In terms of effectiveness of intervention, this can be looked at in two categories: 1) Did the patient remain HIV negative while adhering to a PrEP protocol; and 2) Was the patient able to continually access HIV prevention care through his primary care provider with confidence in the provider’s ability to meet his care needs. For the purpose of this dissertation research,

participants were asked three questions on the survey interview that measured effectiveness. Some participant responses during this data collection included, “Getting on PrEP took a lot of effort. First, I had to get to the doctor, and get him to agree, then do the test, then write the script. Then I had to deal with getting prior approval from the insurance. Then I had to deal with a specialty mail-order pharmacy, that my insurance requires I use for Truvada. I also have to deal with keeping on PrEP because the prior authorizations expire and my doctor’s office doesn’t do a good job of keeping up with the insurance company. I fill my scripts early, so I have built up at least two extra months of Truvada, which gets me through the times when insurance/doctor’s office problems delay my refills. I feel like getting and being on PrEP was a lot of work, but well worth it for the peace of mind.” Another participant reported, “I feel like PrEP is an added protection for myself and my partner. My PCP seems to be well informed and uses statistical data to inform me about the medication and HIV prevention.”

Participants of this dissertation research all stated that while on PrEP they have remained HIV negative. Participants unanimously agreed that they felt “safe” and “protected” from HIV while engaged in a PrEP protocol. Participants also found PrEP to be far more reliable than condom use, thus reinforcing their sense of “safety” and “peace of mind.”

In terms of “did the patient remain HIV negative while adhering to a PrEP protocol,” PrEP was effective. In terms of “was the patient able to continually access HIV prevention care through his primary care provider with confidence in the provider’s ability to meet his care needs,” results were not as unanimous. Many participants remained engaged with and confident in their PCP, while others either experienced a lack of confidence, or sought outside medical care for PrEP.

Overall Satisfaction

In terms of overall satisfaction, this dissertation research interview survey used five questions to measure patient overall satisfaction. When asked if their PCP meets their HIV prevention needs, participants responded with, “In general I do, but because I am on the higher end of the information spectrum. I don’t have I think as a high need as others,” “My PCP does not provide free condoms and we haven’t discussed HIV prevention outside of the conversation for PrEP and the follow-up conversations on how the PrEP is working at each six-month visit,” “My PCP does none of the above, however, my specialty clinic does,” “Yes, he is very thorough, answers all my questions, provides helpful statistics, and is always available when needed,” and “Yes, my doctor was quite active in the original Act Up movement. Needless to say he is very engaging.” Again, answers varied. Participants were divided in their responses with half of them stating they felt as if their PCP met their needs, and half stating their PCP didn’t always meet their needs. Of the participants who stated that their PCP met their HIV prevention needs, they also stated that they informed their PCP of or requested PrEP. This suggests that even when PrEP was not offered to a patient, as long as it was received after a request by the patient, the patient felt that their PCP met their HIV prevention needs.

When participants were asked, what would better their experience receiving PrEP through their primary care physician, some responses included, “More time, less visits, remote or otherwise convenient lab serving and counseling,” “I was surprised how easy it was to get it and refill it so I don’t think there is anything to better my experience, but I also think that it is only because I have a doctor who understands its use. If you don’t have a doctor that understands why you would want to be on it, I imagine it would be difficult to get without switching doctors like I did,” “I would prefer that my PCP followed me on PrEP, rather than an ID. I would also

prefer that Kaiser Permanente made self-administered oral and rectal swabs available at the same time and place as he quarterly labs,” “Our PCPs nationwide (and worldwide) have got to increase their knowledge on PrEP, PEP, and other HIV preventive treatments. Spreading the word is key and that is how knowledge is carried in so many instances,” and “It’s not my PCP that bugs me, but my insurance. I seem to pay more than everyone else I know on PrEP. But it’s still affordable.” Participants brought up concerns around cost, provider knowledge, and convenience as major areas that would improve their experience and enhance their ability to engage in HIV prevention through primary care. These areas of patient need are discussed in more detail in the section “Clinical Recommendations” below.

Findings

Participants indicated several significant areas of further research, debate, or exploration during this process. I have compiled the most pertinent items from my notes, recall, and from the survey interviews below:

1. Participants often stated that they preferred to receive all their health care services in the same place, which included HIV testing and prevention interventions. Participants of this dissertation research often stated that it was unwelcomed to be directed to another provider or another facility to access and monitor PrEP use.
2. During this process some participants voiced concern with having to wait for referrals to other providers or to other provider offices when their PCP did not feel comfortable prescribing, refused to prescribe, or did not know about or enough about PrEP. A few of the participants made the connection that while they waited for additional appointments, or for referrals to ID doctors, that they remained at risk of acquiring HIV, and that after

they sought out PrEP that it then became both their care provider's responsibility and liability.

3. Participants on several occasions asked during the process, "How old do you have to be to start taking PrEP?" and "Do kids take PrEP too?" The answer to that is both black and white, and also grey. Gilead Pharmaceuticals, the manufacturer of Truvada, the biomedical HIV prevention protocol also known as PrEP, does not recommend use of Truvada for the purpose of PrEP in children (www.start.truvada.com, 2017). FDA does not allow Truvada to be prescribed to anyone younger than 12 years old, any children receiving Truvada must weigh at least 37 lbs., indicating there are clearly medical reasons for not prescribing to youth. Additionally, there are legal concerns in prescribing to minors despite obvious HIV prevention benefits. On December 19, 2016, I was invited as a panel member at "Adolescent and Pre-Exposure Prophylaxis Opportunities, Cautions, and Critical Issues," a convening of the National HIV/AIDS Initiative, the Foundation for AIDS Research, and the O'Neil Institute for National & Global Health Law, at Georgetown University School of Law, where our roundtable discussion of field experts and practitioners discussed these very concerns. During that session it was clear that there remain concerns about minors' use of PrEP, ability to consent to treatment, safety particularly around long-term use, and the question was asked, "Are minors mature enough to adhere to prevention methods that requires daily maintenance?" These concerns mirror questions asked by participants of this dissertation research and require further community dialogue and interdisciplinary research.
4. On the interview survey provided to participants, one of the questions asked, "How did you first learn of PrEP?" It was a multiple choice question. The possible answers were

A) Primary Physician; B) Other specialty clinic or agency; C) Public advertisement; D) Friend, relative, colleague, or acquaintance; E) Social media, i.e. Facebook, Twitter, or other; F) Educational or academic setting; and G) Other: Please specify. Of the participants that responded “G,” their write-ins included “online news,” “news,” “government website,” “on the job,” “dating app,” and “Craigslist ad for medical research.” Below I have included a pie chart that breaks down the answers.

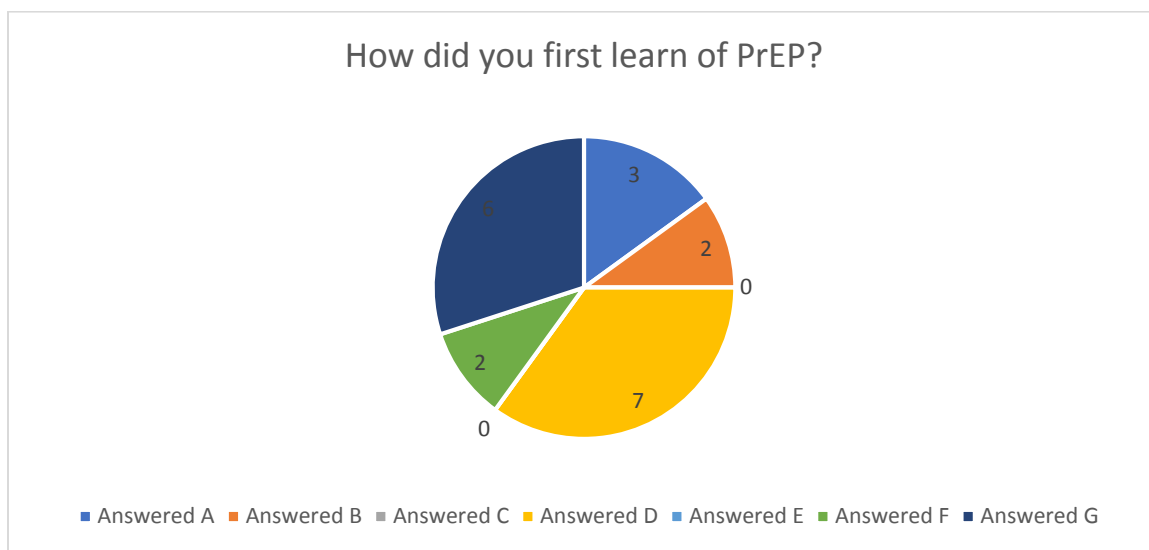


Figure 4

This is important because it speaks to the ways gay men in the U.S. may learn about advances in HIV prevention methods and interventions. It also suggests who might not be accessible through these methods, for example, community members with low or no literacy, community members without internet or smart phone access, or community members with compromised cognition. It also shows that one-third of participants first learned of PrEP through a friend, relative or colleague, suggesting that if you are not part of a familial or social group with knowledge of PrEP you are less likely to learn of the prevention method. Communities want to keep themselves safe, but first they have to

know how. These findings suggest missed opportunities to educate communities about effective HIV prevention methods such as PrEP.

Discussion

Clinical Recommendations

“When new infections among young black gay men increase by nearly 50% in three years, we need to do more to show them that their lives matter.”

— President Barack Obama, 2013 World AIDS Day Remarks

As covered in the section “Data Analysis,” patients most often talked about their provider’s lack of knowledge in the area of HIV prevention, particularly in PrEP as a highly successful HIV prevention method. This was true in providers of all ages, seeing men of all ages, in cases across the country. Participants of this dissertation research, 14 out of 20 participants, stated that they first initiated conversation about or request access to PrEP. Half of those participants were referred to another provider, which allowed weeks or months of time to pass where an HIV acquisition could occur. Participants also stated that their ability to access PrEP was almost solely determined by their ability to hold active health insurance. Participants stated that if they had a lapse in employment, changed jobs, or were unable to afford co-pays (sometimes in the amount of \$50 or more) their access to PrEP would be limited or nonexistent. Essentially, they stated that as long as they possessed money they could keep themselves safe and healthy. This clearly shows how socioeconomic position drives who stays safe and who stays healthy. It shows how in American models of health care, even in a post-Affordable Care Act time, just one life event or change can influence your ability to keep yourself healthy and cared for.

Another theme that is important to mention in this section is that when asked how might a participant discontinue PrEP, the majority of participants (who are all currently taking PrEP) stated they would “just stop,” while some participants stated they would only continue PrEP use if they “were having a lot of sex.” This indicates a need for more thorough guidance, both counseling and education of the importance of remaining adherent to the intervention, even when

sex is less frequent, as well as the importance of engaging with the provider to create a plan for discontinuing use when a patient does decide to end use of the intervention. These particular findings of this dissertation research are areas that require further assessment and attention.

Based on this information, some clinical recommendations might look like:

1. Patients want to talk about their sexual health but often do not know if it is safe and acceptable to do so. Every face-to-face and telephone visit with a patient is an opportunity to keep patients protected from HIV.
2. It is helpful for providers to conceptualize sexuality in terms of three distinct keys. This framework allows providers to assess health behavior over sexual identity or labels in order to ascertain a clear idea of risk and to provide the most appropriate treatment and intervention.
 - a. Culturally: How the dominate society sees and labels your sexuality.
 - b. Self: How one identifies themselves in terms of sexual and romantic attraction, including how an individual labels himself, and in what and how they interact in subculture groups and environments.
 - c. Behavior: With whom and how an individual actually engages in sexual intercourse/sexual behavior.
3. Missed opportunity to establish trust and a low-level therapeutic alliance between providers and black patients persist. Black and Latino/Hispanic men in particular historically and currently have a greater difficulty speaking to providers about same sex sexual behavior due to stigma, histories of medical mistrust, and a will to subscribe to perceived gender norms and roles. Using motivational interviewing-based questions, like, “Whether you are with a male or female partner...” or “If you engage in or experiment

with anal sex with men or women...” or “Is there anything we should cover that we missed today?” could provide a more positive experience for the patient and a more thorough examination of the patient.

4. Based on this dissertation research and the literature reviewed, patient access to PrEP continues to be limited and based on provider knowledge, geographical location, practice environment, health insurance and income status, and patient willingness to disclose risk behavior to their primary care provider. Clinical providers should seek out opportunities to expand their knowledge of new and effective ways of providing HIV prevention and advocate for low or no cost access to the intervention for patients.
5. Another patient concern identified during this dissertation research as well as in my behavioral medicine practice was around protocol adherence. Participants stated during or on their survey interviews, or during wrap up of the survey interview, that they often found it difficult to adhere to the intervention protocol. Guidelines for PrEP protocol for the prevention of HIV instructs patients to take one dose orally, daily, without interruption. Participants of this dissertation research recalled having difficulty remembering to take their medication, and difficulty refilling prescriptions due to hectic work life or family responsibilities. Participants recalled, “I was off my medication for a week while I was traveling,” “I can’t always make it to the pharmacy before they close,” “It’s annoying having to go to the pharmacy every month and my insurance won’t fill a 90-day supply,” “Sometimes I forget to take it or just don’t feel like it,” and “My insurance company is a hassle—only lets me get 30 pills at a time; they just increased the cost by 300%.” In terms of access it is recommended that patients be offered 90-day supplies at the time of refill, that patients be offered mail-order refills, and that patients

be connected to a case manager or nurse through their PCP's office, or wherever they receive PrEP, to assist in navigating through systems and concerns as they arise.

Conclusion

Implications for Further Research

Further research could be expanded to include a larger group of participants representing both urban and rural areas. Further research could be expanded to include participants who would not traditionally be able to afford PrEP but through community care programs have gained access to the intervention; the perspective and voice of the underserved is critical in further research on this topic. Further research might also include looking at how an integrated care team influences or changes a patient's experience receiving HIV prevention care through their primary care provider. These suggestions can only empower our ability as social workers to see that patients are delivered care that is thorough, that keeps them safe and healthy, and empowers them to make health care decisions that meet their health needs and goals.

Future research might include more research on the perspective/experience of primary care providers. This would be important in terms of assessing the providers' perspective in care barriers. Future research might include additional populations including women, particularly African American women, uninsured, and patients resistant to care, both general health care and PrEP as intervention to prevent HIV acquisition.

Implications for Social Work Practice

Implications for social work practice begin of course with meeting the direct needs of our patients. As stated in the section "Clinical Recommendations" above, MSM patients have stated time and time again that, unless they receive care at a specialty clinic, they often feel as though their sexual health and HIV prevention care is overlooked or not attended to at all. As social workers, it is important for us to team with providers in both intervention and education opportunities to meet these health care needs. Further, it is important for us as social workers to

continue to empower our patients and community to advocate for themselves in health care settings and become interactive in their health care. As social work educators, we must teach new social workers to conceptualize sexuality as a combination of cultural influence, self-identity, and behavior in order to avoid labeling and the preconceived ideas associated with labels, as they interfere with intervention and access to intervention.

Limitations of this Study

Limitations to PrEP in general is that it is a prevention intervention most accustomed to middle and upper middle class, insured, educated gay men. Some HIV advocates suggest that is disproportionately more available to Caucasian men of these demographics than black and Latino/Hispanic men. It was this researcher's explicit intention to recruit samples of men that represent various racial and ethnic backgrounds, ages, and socioeconomic backgrounds. However, because access to preventative medicine and PrEP intervention is related to health care access, one limitation of this study may be that uninsured men living at or below the poverty line (the 2016 poverty line is \$11,880 for individuals) and undocumented immigrants might not be included in this dissertation research.

Advertising for this dissertation research was conducted largely on social media. Attempts to advertise through posters and word of mouth were not as successful as social media advertising. While social media advertising yielded dozens of interests in a single day, limitations would include participants with available internet access, participants who are internet and social media savvy, and participants who have Facebook accounts and who are a part of PrEP discussion groups.

The basis of the literature review incorporated my practice frame, behavioral medicine and HIV prevention intervention, education, and therapeutic care, which is not representative of

a global or international understanding of behavioral medicine nor HIV prevention in primary care captured by international practice literature, nor patient adherence to prevention regimens outside HIV prevention. Primary care and preventive medicine, available to populations who obtain health care insurance, and who access it, comes from a Westernized idea of health and wellness, and health care policy; again, not represented of international theory or practice, and thus not included in the literature review. Finally, this dissertation research is generalizable but not conclusive. A larger cohort of male participants would allow for more conclusive outcomes.

Innovations in Future Pre-Exposure Prophylaxis Prevention Intervention

As previously covered, an area of concern by the participants of this study was medication adherence. Participants stated that at times it became difficult to remember, or plan for, or track medication compliance. Participants often stated they, “wished they could take less pills” or “take one a month... like a depo shot².” A long-acting injectable pre-exposure prophylaxis (LAI-PrEP) agent is currently in its third stage of clinical trials. The intervention is designed to provide three months of protection from HIV. It is administered by a medical doctor or licensed nurse in a health care setting. The National Institutes of Health (NIH) in collaboration with ViiV Healthcare, Gilead Sciences, expect full results of the clinical trials by 2012 (NIH, 2017). Innovations such as this could meet the needs of many of this dissertation research’s participants, my patients, and peers alike that have difficulty adhering to a PrEP or PEP regiment, have an aversion to ingesting pills, or who find monthly pharmacy co-pays costly. Additionally, LAI-PrEP could be the answer to the ongoing concerns patients and medical providers have with the effects of long-term use of Truvada on the liver.

Definitions

¹Serodiscordant: Of a couple with one partner HIV positive and the other HIV negative.

²Depo Shot: The depo shot, or Depo-Provera, is an intramuscular injectable form of birth control, administered by a nurse or doctor once every three months.

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Appendix A: Interview Survey Questionnaire & Orientation

Orientation to the Formal Interview (could take 10-15 minutes)

1. Review interview process, criteria, and informed consent, collect signature. File. (Penn consent form, attachment A.).
2. Review questions and concerns of the participant.
3. Review guidelines for audiotape procedure.
4. Explain the shorting of common words or phrases for the purpose of this study.
 - Primary Care Physician = PCP
 - Pre-Exposure Prophylaxis = PrEP
 - Post-Exposure Prophylaxis = PEP
 - Human Immunodeficiency Virus = HIV
- 5a. Provide a standard PrEP definition. “PrEP stands for pre-exposure prophylaxis. The word prophylaxis means to prevent or control the spread of an infection or disease. The goal of PrEP is to prevent HIV infection from taking hold if one is exposed to the virus. This is done by taking a pill that contains two HIV medications every day. These are the same medicines used to stop the virus from growing in people who are already infected.” (www.CDC.gov, 2016)
- 5b. Provide a standard HIV/AIDS definition. “Acquired immunodeficiency syndrome (AIDS) is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus (HIV). By damaging your immune system, HIV interferes with your body's ability to fight the organisms that cause disease. HIV is a sexually transmitted infection.” (www.mayoclinic.org, 2016)
6. Note interview setting and means [For recordings, if applicable. Skip if survey is given electronically.]
7. All participants must be HIV negative AND currently receiving pre-exposure prophylaxis (PrEP) pharmaceutical intervention for the prevention of HIV. If you are not HIV negative and/or receiving PrEP intervention, please discontinue this survey interview.

Face-Sheet Data (could take 10-30 minutes)

1. Participant's first and last name (this will later be coded with a three-digit number and subject's name destroyed).
2. All participants recruited will be male. If your gender is male, please continue.
3. Participant's age in full years (participants must be 18 years of age to qualify).
 _____ Months _____ Years.
4. Participant's self-identified race (circle only one or write in).
 - A. Black/African-American/Afro-Caribbean

- B. White/Caucasian
- C. Latino/Hispanic
- D. Asian/Indian/Pacific Islander
- E. Middle Eastern/Arabic
- F. Self-Identified Race: _____

5. Participant's city/town, state.

6. Are you (participant) currently connected to a primary care physician? YES NO

7. In months and years, how long have you been connected to your current primary care physician?
 _____ Months _____ Years.

8. Since you became connected to your current primary care physician, how many times have you had an in person visit for any reason? _____ times.

9. Is your primary care physician your PrEP prescriber? YES NO

10. How long have you (participant) been engaged in PrEP treatment in months and years.

11. How did you first learn of PrEP:

- a. Primary Care Physician (PCP) [Skip to question 15]
- b. Other specialty or community clinic or agency
- c. Public advertisement i.e. billboard, magazine, flyer
- d. Friend, relative, colleague, or acquaintance
- e. Social Media i.e. Facebook, Twitter, or other
- f. Educational or academic setting
- g. Other: (Please specify) _____

12. If your PCP was not your introduction to PrEP, has your PCP, without your first asking or initiation, engaged you in dialogue on the subject of PrEP at any time? YES NO

13. If your PCP never engaged you in dialogue on the subject of PrEP, why did you begin this conversation with you PCP?

14. In your own words, describe your first experience speaking to your PCP on the subject of PrEP (a few sentences will suffice).

15. From the time of your first dialogue with your PCP on the subject of PrEP, in months and years, how long did it take for you to receive a prescription for PrEP treatment?
 _____ Months _____ Years.

16. From the time you received the prescription for treatment, how long in months did it take for you to fill your prescription?
 _____ Months _____ Years.

[If it took less than 90 days to fill the prescription, skip to question #19]

17. If it took more than 90 days to fill your PrEP prescription, please explain why it took more than 90 days to fill your prescription (a few sentences will suffice).

18. From the time you began your prescription for PrEP treatment to now, have there been any interruptions in treatment? YES NO

18a. If so, in your own words explain why (a few sentences will suffice).

19. From the time you began PrEP treatment, have you engaged with your PCP in follow up visits? If so, in months, how often?

Every _____ Months.

20. In your own words, describe your experience in any or all of your PCP PrEP follow up visits (a few sentences will suffice).

21. Do you feel like your PCP meets your HIV prevention needs, including but not limited to or necessarily including, providing PrEP and PrEP/PEP education, providing access to free condoms, engaging you in HIV prevention dialogue and education, encouraging you to ask questions, and connecting you to additional community related resources as applicable? Why or why not (a few sentences will suffice)?

22. In your own words, describe your overall experience on PrEP as HIV prevention treatment (a few sentences will suffice)

23. In your own words, describe your satisfaction receiving PrEP through your PCP (a few sentences will suffice).

24. In your own words, describe your intended length of time/use of PrEP treatment.

25. In your own words, describe how you might begin to discontinue PrEP treatment when you are ready to do so.

26. In your own words, describe how you might engage with your PCP to discontinue PrEP treatment for the prevention of HIV (a few sentences will suffice).

27. In regards to your overall experience receiving PrEP treatment for the prevention of HIV, how important is it for you to receive this treatment from your PCP?

- a. Extremely important
- b. Highly important
- c. Somewhat important
- d. Not important
- e. I don't know / Undecided

28. If applicable, what would better your experience receiving PrEP treatment through your PCP (a few sentences will suffice)?

29. In your opinion, how important is it for the public to know of and have access to PrEP for the prevention of HIV?

- A. Extremely Important
- B. Very Important
- C. Somewhat Important
- D. Not Important
- E. No Opinion

[End Interview]

Appendix B: Internal Review Board Approval and Mandatory Consent

University of Pennsylvania
 Office of Regulatory Affairs
 3624 Market St., Suite 301 S
 Philadelphia, PA 19104-6006
 Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
 (Federalwide Assurance # 00004028)

05-Jan-2017

Ram A Cnaan
cnaan@sp2.upenn.edu

PRINCIPAL INVESTIGATOR	: Ram A Cnaan
TITLE	: Male Patient Experience Receiving Pre Exposure Prophylaxis through Primary Care
SPONSORING AGENCY	: No Sponsor Number
PROTOCOL #	: 826336
REVIEW BOARD	: IRB #8

Dear Dr. Cnaan:

The above-referenced research proposal was reviewed by the Institutional Review Board (IRB) on 04-Jan-2017. It has been determined that the proposal meets eligibility criteria for IRB review exemption authorized by 45 CFR 46.101, category 2.

This does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for assuring other relevant committee approvals.

Consistent with the federal regulations, ongoing oversight of this proposal is not required. No continuing reviews will be required for this proposal. The proposal can proceed as approved by the IRB. This decision will not affect any funding of your proposal.

Please Note: The IRB must be kept apprised of any and all changes in the research that may have an impact on the IRB review mechanism needed for a specific proposal. You are required to notify the IRB if any changes are proposed in the study that might alter its IRB exempt status or HIPAA compliance status. New procedures that may have an impact on the risk-to-benefit ratio cannot be initiated until Committee approval has been given.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

Please Note: You are responsible for assuring and maintaining other relevant committee approvals.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/IRB/directory>.

Thank you for your cooperation.

Sincerely,

IRB Administrator

University of Pennsylvania
Informed Consent Form

Title of the Research Study: Male Patient Experience Receiving Pre Exposure Prophylaxis through Primary Care

Protocol Number: 826336

Principal Investigator: Ram A. Cnaan, Ph.D., 3701 Locust Walk, Philadelphia, PA 19104, P.215.898.5523, cnaan@upenn.edu

Co-investigator: Nathaniel Currie, LICSW, 2300 N. Calvert St., Baltimore, MD, 21218, prepsurvey.socialworkresearch@gmail.com

Emergency Contact: Ram A. Cnaan, Ph.D., 3701 Locust Walk, Philadelphia, PA 19104, P.215.898.5523, cnaan@upenn.edu

You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

- The aim of this research is to expand knowledge of the experience of male patients receiving PrEP through primary care by creating an opportunity to engage in dialogue, assess and explore needs and benefits, and identify barriers to intervention. The qualitative data and outcomes collected from this research may be used in further mainstream HIV prevention work and PrEP uptake in primary care.
- This study is being conducted as part of a dissertation.

Why was I asked to participate in the study?

You are being asked to join this study because you have volunteered to participate and meet inclusion criteria.

Inclusion: All participants must be 18 years of age at time of the interview and data collection. Participants must be male. Participants must have a negative HIV status AND currently be engaged in consistent (daily) PrEP treatment for the prevention of HIV.

Appendix C: Research Poster

Dissertation Research:

- ✓ Are you male?
- ✓ 18 years of age or older?
- ✓ Currently receiving PrEP through your primary care provider?
- ✓ Want to share your experience?

➤ Email Nathan at prepsurvey.socialworkresearch@gmail.com with your name and contact information to participate in a dissertation research survey titled:

“Male Patient Experience Receiving PrEP through Primary Care”

This is your chance to be heard and contribute to research!

Contact today!



University of Pennsylvania, School of Social Policy & Practice. Study title "Male Patient Experience Receiving PrEP through Primary Care", a qualitative research study using 12-32 electronic survey interviews, for the purpose of expanding knowledge of patient experience, and for direction in future intervention. For more information or to participate in this study please email prepsurvey.socialworkresearch@gmail.com or call Nathan at 610.396.3268. Dissertation Chair: Dr. Sam Crossen

Appendix D: Social Media Call for Participants



Nathaniel Langford Currie

December 21, 2016

Are you currently using PrEP to prevent HIV contraction? Would you be willing to complete a 5-10 minute survey to share your experience? Are you male? Over age 18? Willing to participate in dissertation research? Please comment or inbox me and I will get you started! Thanks!
Email me at: prepsurvey.socialworkresearch@gmail.com



Like

Comment

You, Dewayne Guy, Sheldon Campbell and 19 others

View 39 more comments



Austin Owen Absolutely

Like · Reply · December 22, 2016 at 6:13pm

1 Reply



David Kerr Hi, I am happy to participate. Emailing you now.

Like · Reply · December 22, 2016 at 10:20pm

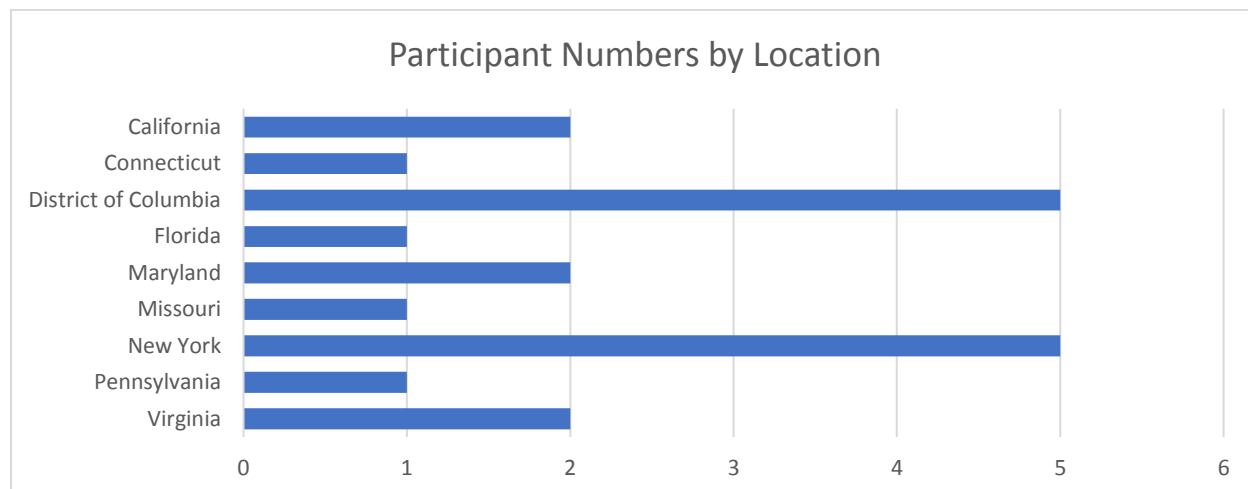


Write a comment...



Appendix E. Subject Demographic Sheet

Subject Demographic Sheet							
Gender	Age	Self Identified Race	Residency	HIV Status	Time on PrEP (mos)	Time w/ PCP (mos)	Recruitment Source
M	36	Black/African American	Maryland	Neg	36	72	Social Media
M	39	White/Caucasian	New York	Neg	3	48	Word of Mouth
M	27	Black/African American	District of Columbia	Neg	15	36	Word of Mouth
M	50	White/Caucasian	New York	Neg	14	3	Social Media
M	34	Black/African American	New York	Neg	18	18	Word of Mouth
M	30	White/Caucasian	District of Columbia	Neg	4	2	Word of Mouth
M	28	Black/African American	District of Columbia	Neg	7	15	Word of Mouth
M	50	Black/African American	Virginia	Neg	28	32	Social Media
M	32	White/Caucasian	New York	Neg	16	77	Social Media
M	26	Black/African American	Virginia	Neg	13	15	Social Media
M	27	Black/African American	California	Neg	3	6	Social Media
M	29	Asian/Pacific Islander	Connecticut	Neg	10	14	Poster
M	56	Hispanic/Latino	Maryland	Neg	37	48	Social Media
M	46	White/Caucasian	New York	Neg	65	1	Social Media
M	36	Black/African American	District of Columbia	Neg	4	4	Social Media
M	47	White/Caucasian	Missouri	Neg	9	192	Social Media
M	54	White/Caucasian	District of Columbia	Neg	24	34	Social Media
M	37	Black/African American	Florida	Neg	16	24	Social Media
M	43	White/Caucasian	California	Neg	24	6	Social Media
M	37	Black/African American	Pennsylvania	Neg	26	14	Social Media



Appendix F. Advertising Tracker

Advertising Tracker			
<u>Posters</u>	<u>Address</u>	<u>Date Posted</u>	<u>Data Collection</u>
Yale University	High Street, New Haven, CT	Dec. 16, 2016	Jan. 5, 2017 - Jan. 13, 2017
Johns Hopkins Univeristy	North Wolfe Street, Baltimore, MD	Dec. 19, 2016	Jan. 5, 2017 - Jan. 13, 2017
Us Helping Us People Into Living, Inc.	Georgia Avenue, Washington, DC	Jan. 7, 2017	Jan. 5, 2017 - Jan. 13, 2017
Whitman-Walker Health Care	14th Street, Washington, DC	Jan. 7, 2017	Jan. 5, 2017 - Jan. 13, 2017
<u>Social Media</u>			
Facebook	Group: PrEP Facts, Rethinking HIV Prevention and Sex	Dec. 21, 2016 & Dec. 30, 2016	Jan. 5, 2017 - Jan. 13, 2017
Facebook	Personal page for Nathaniel Currie	Dec. 21, 2016	Jan. 5, 2017 - Jan. 13, 2017
<u>Other</u>			
Word of Mouth	N/A	Dec. 15, 2016 - Jan. 13, 2017	Jan. 5, 2017 - Jan. 13, 2017

Dear Participant,

I want to thank you for your voluntary participation in this dissertation survey interview. Attached please find a consent form and the interview questionnaire. Below you will find steps for participation.

1. Please read and sign the attached consent form, a consent form must be signed in order to participate in this interview survey. Please scan the signed copy of the consent form and attach it to your reply email if you complete this survey interview by email. An electronic signature will also suffice.
2. Please complete the attached interview questionnaire. Be sure to read each question thoroughly and answer open ended questions in complete thoughts. Length isn't as important as detail. Please attach your completed interview survey to your reply email.
3. Return completed interview surveys to prepsurvey.socialworkresearch@gmail.com
4. Please feel free to contact me directly with any questions or concerns.

Thank you again for your participation,

Nathaniel Currie, LICSW/LCSW-C

Doctor of Social Work Candidate, University of Pennsylvania

Dissertation: 'Male Patient Experience Receiving Pre Exposure Prophylaxis through Primary Care'

Dissertation Chair, Dr. Ram Cnaan

2 Attachments



Appendix H. Pre-Exposure Prophylaxis Intervention Resources

1. Ask your primary care physician if PrEP is the right HIV prevention method for you.
2. If you do not have a primary care physician or to find out more about PrEP call or visit any of the following health care providers:

Atlanta

AID Atlanta

1605 Peachtree Rd. NE, Atlanta, Georgia
Tel. 404-870-7762

Fulton County Department of Health and Wellness

99 Jesse Hill Jr. Dr. SE, Atlanta, Georgia
Tel. 404-613-4708

Baltimore

Baltimore City Health Dept. Druid STD Clinic

1515 W. North Ave., Baltimore, Maryland
Tel. 410-396-0176

Chase Brexton Health Center

1111 North Charles St., Baltimore, Maryland
Tel. 410-837-2050

Boston

Fenway Health

1340 Boylston St., Boston, Massachusetts
Tel. 617-267-0900

The Male Center

571 Columbus Ave., Boston, Massachusetts
Tel. 617- 450-1250

New York

Callen-Lorde Community Health Center

356 West 18th Street, Manhattan, New York
Tel. 212-271-7293

Montefiore- The Oval Center

3230 Bainbridge Ave, 2nd floor, Bronx, New York
Tel. 718-882-5482

Philadelphia**Philadelphia FIGHT**

1233 Locust St., 3rd floor, Philadelphia, Pennsylvania
Tel. 215-985-4448

Mazzoni Center

809 Locust St., Philadelphia, Pennsylvania
Tel. 215-563-0658

Washington**Whitman-Walker Health**

1525 14th St., NW, Washington, District of Columbia
Tel. 202-745-7000

Us Helping Us

3636 Georgia Ave NW, Washington, District of Columbia
Tel. 202-446-1100