MOTIVATIONS TO EITHER ACCEPT OR REJECT PRE-EXPOSURE PROPHYLAXIS: AWARENESS, BELIEFS, AND RISK PERCEPTIONS AMONG AFRICAN AMERICAN WOMEN IN NEW YORK CITY

by

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ABSTRACT

MOTIVATIONS TO EITHER ACCEPT OR REJECT PRE-EXPOSURE PROPHYLAXIS: AWARENESS, BELIEFS, AND RISK PERCEPTIONS AMONG AFRICAN AMERICAN WOMEN IN NEW YORK CITY

Suzanne Robinson Davis

The world has suffered immensely and disproportionately from the ravages of HIV and AIDS. Oral PrEP is a single pill taken once daily that can reduce the risk of sexually transmitted HIV infection by up to 92% (CDC, 2014a).

This study describes African American females' awareness, beliefs, and perception of PrEP and identifies factors that may motivate women to either accept or reject PrEP. This cross-sectional study occurred over a 3-month period from November 2017 to January 2018, following from a previous pilot study. The sample comprised African American women aged 18 and over receiving STD or HIV screening services at a FQHC in Brooklyn, New York. Women were interviewed using the five characteristics of the Diffusion of Innovation theory and also completed a risk assessment for HIV using CDC recommended guidelines for screening heterosexual women for PrEP.

Awareness of PrEP remained extremely low among the 72 African American women interviewed in the study. Using the CDC guidelines, all women reported one or more risk factors for PrEP indication. Awareness about PrEP, negative reactions from partners and shared experiences from female PrEP users were cited as factors that may predict and motivate African

American women to use PrEP. Additionally, skills in pill-taking, cost and insurance, and maintaining privacy while using PrEP were strong enabling factors to support PrEP use. Factors such as initiating couple's PrEP use as an intervention, medical doctors overtly directing PrEP for women, and the role of older women in promoting PrEP use were persuasive factors in reinforcing the utilization of PrEP among African American women in the study.

Creative programming within high burden communities is critically important to penetrate with messages of new innovations and best practices. The results of the current research speak volumes to the continued work needed to educate communities with prevention messages.

DEDICATION

I am forever grateful to the incredible 82 African American and Mixed women who participated in both studies.

“The way to right wrongs is to turn the light of truth upon them.”

Ida B. Wells-Barnett

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And most of all I thank God. For me, science and faith are not competitors. They are complementary in my earnest desire to make people's lives better. I thank God for being the rock I stand on to start, undertake and complete this work.

S. R. D.

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INTRODUCTION

Global HIV/AIDS Epidemic

The world has suffered immensely and disproportionately from the ravages of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS). Globally, 36.7 million people are living with HIV, while each year approximately 2 million people become newly infected with the virus (UNAIDS, 2017a). According to the Joint United Nations Programme on HIV/AIDS (UNAIDS, 2017b), women and girls share equally in the burden of HIV/AIDS. In 2016, 18.6 million women and girls were living with HIV and accounted for nearly 1 million of the 1.8 million new HIV infections globally. While there has been a tremendous decline in AIDS-related deaths, with declines of up to 48% recorded in many parts of the world, approximately 1 million people die from AIDS-related causes each year. Significantly, only 54% of people infected by HIV/AIDS have accessed antiretroviral therapy (UNAIDS, 2017a). At the end of 2016, East and Southern Africa accounted for 43% of new HIV infections and have recorded a 29% decrease in new infections from 2010 to 2016 (UNAIDS, 2017a). In most regions of the world, there have been decreases in new HIV infections in 2016, but Eastern Europe and Central Asia have recorded rises in new infections of 60% between 2010 and 2016 (UNAIDS, 2017a).

HIV/AIDS Epidemic in the United States

In 2010, under the endorsement of President Barack Obama, the White House unveiled the National HIV/AIDS Strategy, *A Vision for Our Future*, the first national strategic document that recognized the impact of HIV/AIDS on the U.S. and its territories. The National HIV/AIDS Strategy (NHAS) for the country sought to provide policy direction, measures, targets, and harness a synergetic collaboration among federal partners to address the HIV epidemic. In 2014, the strategy was revised and expanded to include, among other updates, national actions and the advancement of PrEP as an HIV prevention tool.

In 2016, 973,846 persons in the United States were living with HIV (Centers for Disease Control and Prevention [CDC], 2016a, p. 9). Similar to other parts of the world, the U.S. has recorded uneven declines in new HIV diagnoses from 40,234 to 39,513 in 2014 and 2015, respectively. However, in 2016, a slight increase was recorded of 39,782 (CDC, 2016a). Of the 39,782 HIV diagnoses in the United States in 2016, men who have sex with men (MSM) comprise 67.5% of these new infections. Among MSM new diagnoses in 2016, racial and ethnic disparities are particularly evident. Collectively, African American and Hispanic MSM account for 67% of all new HIV diagnoses, with African American MSM having the heaviest burden of 38%.

Racial and ethnic minorities carry the burden of HIV/AIDS in the U.S. In particular, the African American population continues to be disproportionately affected by AIDS, new HIV diagnoses and AIDS-related deaths. In 2016, African Americans accounted for 44% of new HIV diagnoses while Hispanics accounted for 25.9% of new HIV diagnoses (CDC, 2016a). Similarly, African Americans account for 17.5% of all deaths of people diagnosed with HIV infections, which is the highest rate among all race and ethnicity groups (CDC, 2016a).

In 2016, African American women accounted for approximately 60% of all new HIV diagnoses among women in the U.S. (CDC, 2016a). This is striking since African American women only comprise 12.7% of the population (Catalyst, 2015). African American women in the U.S. experience extreme disparity in new HIV diagnoses. The rate of new HIV diagnoses among African American women in 2015 was 16 times more likely than of White women to receive a HIV diagnosis (CDC, 2017). Amongst women, heterosexual contact is the primary transmission route (86%) through which HIV is acquired, while injecting drugs accounts for 13% of transmissions.

There is an urgent need for more effective HIV prevention strategies to decrease and ultimately end the epidemic in Black women, and in the U.S.. Further, given the racial and ethnic disparities in HIV morbidity and mortality among women, research is desperately needed to inform HIV prevention efforts among this group.

Introduction of Pre-Exposure Prophylaxis (PrEP)

As of April 2018, HIV remains without a cure. A number of biomedical advances have proven useful in mitigating the impact of HIV with the ultimate aim of eliminating AIDS as a threat to public health. One biomedical intervention that has been replicated in different efficacy and effectiveness trials is oral antiretroviral prophylaxis. Oral antiretroviral prophylaxis is “highly effective in preventing HIV among gay men and other men who have sex with men and among sero-discordant couples” (UNAIDS, 2015, p. 7). In 2012, the Food and Drug Administration approved the only medication in the U.S. that can effectively protect against the transmission of HIV among adults.

Pre-exposure Prophylaxis (PrEP) is a single pill taken once daily that can reduce the risk of sexually transmitted HIV infection by up to 92% (CDC, 2014a, p. 9; Grant et al., 2010, p. 2597). The formulation of the medication is the primary drugs of Tenofovir-Emtricitabine (TDF 300 mg co-formulated with FTC 200 mg) (CDC, 2014a). This formulary is within one pill commonly called “Truvada” that is used daily to protect against HIV (CDC, 2014a, p. 9). Taking Truvada to protect against HIV is a preemptive decision based on the perceived increased likelihood of HIV exposure.

Since 2009, the iPrEX (Pre-exposure Prophylaxis Initiative), the Partners and the Bangkok clinical trials have demonstrated both PrEP efficacy and effectiveness in preventing HIV among key populations most affected by HIV/AIDS. In the United States, key populations affected by HIV/AIDS are men who have sex with men (MSM), injecting drug users (IDUs), people with trans experience, and heterosexuals, in particular, heterosexual women. These trials have reinforced the FDA’s decision to approve PrEP as an HIV prevention method.

Among female PrEP trials, evidence has shown the effectiveness of PrEP in preventing HIV in women. Further studies have shown that vaginal microbiota aids in tenofovir (PrEP) uptake and concentration. Secondary analyses of the Center for the AIDS Program of Research in South Africa 004 (CAPRISA) data showed a correlation between tenofovir diphosphate (TFV-dp) in genital tissues and TFV in the plasma to “markers of bacterial vaginosis (Nugent score, increased G vaginalis and Atopobium vaginae)” when applied “intravaginally” (Hillier et al., 2017). Detection of normal or abnormal bacterial vaginosis are not factors that reduces PrEP effectiveness in women. According to data from the Partners PrEP Study of oral PrEP, women who achieved over 80% PrEP adherence levels and had overall efficacy of >70%, PrEP had “comparable

efficacy of HIV prevention among women with normal microbiota (efficacy=77%), intermediate microbiota (73%), and bacterial vaginosis (63%)" (Heffron et al., 2017).

Purpose of the Study

The purpose of this study is to describe Black females' awareness, beliefs, and perception of PrEP, and to identify factors that may motivate Black women to either accept or reject PrEP. Black/African American women will be defined based on self-identification. For the purposes of this current study, the term "Black women" will be used and includes all women of African ancestry. The study is also intended to provide insights into lessons that could be learned by practitioners and stakeholder networks working in the area of HIV prevention to scale-up PrEP use among this population of women.

Specific Aims

1. To describe the awareness, beliefs, motivations and perceptions of PrEP among African American women.
2. To identify factors that may influence Black women's motivations to either accept or reject PrEP.
3. To describe lessons that could be learned by HIV prevention practitioners and stakeholder networks to scale-up PrEP use among this population of women.

Rationale for the Study

In 2014, the U.S. Public Health Service published the first clinical practice guidelines for Preexposure Prophylaxis (PrEP) for the prevention of HIV Infection in the United States (CDC, 2014a). The clinical practice guidelines identify three groups eligible for PrEP as Men Who Have Sex with Men (MSM), Heterosexual Women and Men, and Injecting Drug Users (IDUs). For each group, the guideline defines the meaning for substantial risk of acquiring HIV infection (CDC, 2014a, p. 11). Substantial risk in the MSM group is described as (a) partner with an HIV-positive status, (b) recent bacterial sexually transmitted diseases (STIs), (c) high number of sex partners, (d) history of inconsistent or no condom use, and (e) engagement in commercial sex work. Among Heterosexual Women and Men, substantial risk is described as (a) partner with an HIV-positive status, (b) recent bacterial sexually transmitted diseases (STIs), (c) high number of sex partners, (d) history of inconsistent or no condom use, (e) engagement in commercial sex work, and (f) reside or associate in high HIV-prevalence area. Substantial risk as described for Injecting Drug Users includes injecting partner is HIV-positive and sharing injecting equipment and recent drug treatment (but currently injecting). Although this guideline is overlapping and broadly describes “substantial risk,” they provide practitioners direction for PrEP eligibility.

As mentioned above, PrEP has been shown to be as much as 92% effective at reducing new HIV infections (Grant et al., 2010). The drug combination Tenofovir-Emtricitabine (TDF-FTC) has proven to be a critical tool in the fight to end the HIV/AIDS epidemic. The drug combination formulary, commonly referred to as Pre-Exposure Prophylaxis (PrEP) significantly reduces new HIV infections among groups at higher risk of HIV infection (Baeten et al., 2012; Choopanya et al., 2013; Marcus et al., 2013). Since 2009, gold standard

PrEP clinical trials have investigated the efficacy and effectiveness of PrEP among high-risk groups, such as men who have sex with men (MSM), transgender women, injecting drug users (IDUs), heterosexual women and heterosexual men.

The multi-nation iPrEX trial examined the effectiveness of PrEP among 2,499 transgender women and men who have sex with men from 11 sites and across six countries, Peru, Ecuador, Brazil, Thailand, South Africa, and the United States (Grant et al., 2010). The study results revealed a “92% reduction in the risk of HIV acquisition in participants with detectable levels of TDF/FTC versus those with no drug detected” (p. 2597). Interestingly, risk compensation, to increase unprotected sexual acts resulting from PrEP use, has been flagged as an argument against PrEP. However, the iPrEX trial found no risk compensation. In fact, the trial found reduction in the number of sexual partners among those enrolled in the treatment group, a finding supported by other studies (Marcus et al., 2013; Minnis et al., 2013).

In the literature, almost all studies included adherence as a factor in PrEP trials. Studies show that consistent use of PrEP is positively related to reduced HIV infection. Among people in Bangkok who injected drugs (Choopanya et al., 2013), PrEP reduced new HIV infections by 49% to 74% in those participants who had higher drug concentrations in their blood. Similar findings are evidenced among heterosexual couples. In the Partners Study in Kenya and Uganda, although there were high rates of sero-conversion, the study found that “high adherence is essential to achieve clinical benefits from antiretroviral agents for HIV-1 treatment, and emerging evidence suggests that adherence to pre-exposure prophylaxis is also important for HIV-1 prevention” (Baeten et al., 2012, p. 408).

Further examination is needed regarding PrEP uptake and adherence among high-risk HIV-negative women in the United States as this is relatively unknown (Auerbach, Kinsky, Brown, & Charles, 2015). Although evidence of PrEP effectiveness has been shown in mix-gender (male and female) studies such as the Partners trial, similar successes in female-centered studies have not been found. The two major clinical trials contributing data on PrEP effectiveness in preventing new HIV infections among women have both failed to produce definitive results.

These studies are FEM-PrEP and the VOICE (Vaginal and Oral Interventions to Control the Epidemic) trials. In the FEM-PrEP trial, low adherence was viewed as the primary reason for the failure of the intervention. The study documented 68 sero-conversions, a result attributed to low adherence. Interestingly, of the women who remained HIV-negative, 40% had detectable levels of medication (Van Damme et al., 2012). Although much is known about PrEP and adherence, little is known about how both factors impact women in the United States. Van Damme et al. believed that “a better understanding of indicators of adherence among women at high-risk for HIV infection is needed to ensure the effectiveness of future pre-exposure prophylaxis programs” (p. 422).

Similarly, the VOICE trial experienced less than 30% adherence to medication resulting in 312 sero-conversions among 5029 women enrolled in the three treatment and two control arms of the trial (Marrazzo et al., 2015, p. 513). The study recruited 12,320 women from South Africa, Uganda, and Zimbabwe with 5029 women enrolling in the trial. Although the results were disappointing, the trial gave optimism and direction for future studies: “Our results reaffirm the need for effective and acceptable prevention interventions for women at high-risk for sexual acquisition of HIV-1 and suggest that more accurate measures are critical for the estimation of product use during biomedical HIV-1–prevention

trials" (p. 517). Although these findings have been compelling, other studies have shown that women are adherent to PrEP medication and achieve high rates of effectiveness by using PrEP (Corneli et al., 2015). As part of The Partners Study, 97.7% adherence was found for non-pregnant women in the study. The study used multiple methods of measuring adherence among the women and found high adherence levels among pregnant and non-pregnant HIV-negative women (Matthews et al., 2014).

Although Healthy People 2020 does not address women as a vulnerable group directly, objective HIV-2 clearly includes women: "reduce the number of new HIV infections among adolescents and adults," unequivocally outlining the national and policy-level commitment to reduce new HIV infection among all adults and adolescents who are at risk of HIV acquisition. To achieve this Health People 2020 objective, attention directed toward U.S. women vulnerable to HIV acquisition is an imperative (Celum et al., 2015). There is a dearth of evidence to guide PrEP practice for women, especially Black women in the United States who are at substantial risk of becoming HIV-positive. Although some studies have focused on women, not much is known about U.S. women who use PrEP nor U.S. women's ability to adhere to PrEP medication, which protects them from getting HIV and maintaining their HIV-negative status in a manner that empowers and is "female-controlled" (Auerbach et al., 2015; Flash et al., 2014).

Globally, MSM have received most attention in PrEP related studies as the burden of the HIV/AIDS epidemic resides in this population. Noting that this does not take away from the fact that Black women are consistently at high-risk of contracting HIV and require attention (Auerbach et al., 2015). The proposed study will extend the body of knowledge that exists for women at risk of HIV to improve understanding about factors that may promote or impede initial PrEP use.

Through this study, PrEP providers will further understand that PrEP creates multiple practical uses for women at risk for HIV. The medication serves not only the disease prevention goal of ending HIV transmission but also facilitates a broader societal construct of creating walls of safety and security for women. Flash et al. (2014) reported from their U.S. women PrEP study that "women thought a pill would be easy to conceal and to ingest surreptitiously, thus eliminating the need to discuss concerns about their partner's level of risk" (p. 638). Historically, women have faced barriers in negotiating condom use, communicating relationship concerns, and having open discussion about sexual health. The introduction of PrEP has become, for many women, a silent protector, providing opportunities to protect themselves and reduce their risk of acquiring HIV without involving their partners. The proposed study is intended to describe lessons that could be learned by HIV prevention practitioners and stakeholder networks to scale-up PrEP use among this population of women most vulnerable to HIV.

The National HIV/AIDS Strategy introduced two pieces of information relevant to the importance of PrEP in ending the HIV/AIDS epidemic in the United States. The first was the "2014 U.S. Public Health Service issued clinical practice guidelines for PrEP" (National HIV/AIDS Strategy, p. 1) and the second was the identification of state and local plans to end AIDS (p. 17), particularly the states of New York and Washington and the city and county of San Francisco. In 2014, Governor Andrew Cuomo appointed members to the New York State Task Force to End the HIV Epidemic by 2020. Although at the time little was known about how this would be achieved, in 2015, the Governor presented a plan, the "Blueprint for Ending the Epidemic," which was the result of months of consultation by the Task Force. The Plan presents a 3-point strategy for ending the HIV epidemic in the state by 2020. The strategy comprises "identifying

persons with HIV, linking and retaining persons diagnosed with HIV in health care, and facilitating access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons to keep them HIV-negative (Blueprint on Ending the HIV Epidemic in New York State, p. 4).

The proposed research is quite timely as increasing programmatic focus and funding are being channeled to increase PrEP uptake in New York State and the wider United States. This study is intended to support existing programs, particularly those with state-funded mandates, to scale-up PrEP use among groups identified as at “substantial risk” of HIV infection, of which the population of Black women is of immediate importance.

Chapter II

LITERATURE REVIEW

The aim of this literature review is to present a selective brief description of the current epidemiology of HIV/AIDS globally and in the U.S. A review of pre-exposure prophylaxis (PrEP) prevention strategies and their impact on Black women is outlined. The literature review achieves this aim by presenting, in the first section, a synopsis of the global and intra-national U.S trends, including factors that fuel the HIV epidemic and an introduction to antiviral treatment as prevention. The literature review transitions into the second section by introducing the 2014 Centers for Disease Control and Prevention guidelines for PrEP use indications for women and other high-risk populations. The third section provides a review of PrEP studies and the impact on women in the U.S. and Africa. Although the review focuses on female-focused studies, PrEP uptake in the U.S. represents a broader look at the diffusion of PrEP as an innovation in the U.S. The final section introduces three theoretical frameworks used to underpin the dissertation and ties together the literature review, coding and synthesis and results to each of the theoretical frameworks.

Overview of Descriptive Epidemiology of HIV/AIDS Globally and in the United States

Global Prevalence

The HIV epidemic has disproportionately affected the world's poorest and most disadvantaged regional populations. According to The Joint United Nations Programme on HIV/AIDS (UNAIDS, 2017a), in 2016, Eastern and Southern Africa is considered the epicenter of the impact of HIV/AIDS and accounts for 52.9% of the people living with HIV globally, and over 43% of all new infections. Although Latin American and the Caribbean have an HIV burden of 2.1 million people, because of smaller population size, the region is second only to Eastern and Southern Africa as carrying the heaviest HIV burden. Country-level epidemiological data show that, compared with Western countries, East and Southern parts of Africa continue to be the most affected by HIV, with higher prevalence, higher incidence, higher morbidity, and greater rates of mortality coupled with a lower number of persons on treatment.

Time Trends in the U.S.

Despite progress in the U.S., there remain significant racial and ethnic disparities in HIV infections in the U.S. Racial and ethnic and sexual minorities are disproportionately burdened by HIV infection and remain at substantial increased risk of HIV infection. Within the African American population, the burden of HIV is significantly higher and outpaces all other racial and ethnic populations. African Americans account for 44% of new diagnoses, more than any other racial and ethnic group, according to the CDC (2016a).

The number of new HIV infections in the U.S. has been steadily declining since the mid-1980s. At the height of the HIV epidemic, the CDC (2016b) estimated that new infections peaked at 130,000 cases during 1985. By the

2000s, new HIV diagnoses remained relatively steady at 50,000 new infections per annum until for the first time the number of new diagnoses fell to their lowest ever recorded number of 39,513 in 2015 (CDC, 2016a). Just under 1 million people are living with HIV/AIDS in the U.S., and this will continue to increase as people access treatment, care, and prevention services and are able to live longer.

The Intra-national Comparisons

According to the CDC (2016c), lifetime risk of HIV diagnosis is highest in the District of Columbia, followed by Maryland, Georgia, Florida, Louisiana, New York, Texas, New Jersey, Mississippi, South Carolina, North Carolina, Delaware, and Alabama. Rates of HIV and AIDS diagnoses are higher in the South (CDC, 2016c), and the "Southern states account for approximately 44% of people living with an HIV diagnosis" in the U.S. (CDC, 2016c). The Southern states not only carry a higher intra-national HIV infection burden, but they also account for higher rates of HIV/AIDS-related morbidity and mortality compared to other states. Additionally, according to the CDC, there are also more people living in the Southern states who are not aware of their HIV status (CDC, 2016c). In the four regions in the U.S., 55% of new HIV diagnoses occur in the Southern states among African Americans (see Figure 1), a significantly higher rate for a single racial group compared to any other region in the U.S. The Hispanic/Latino population primarily carries the burden of new HIV diagnoses in the West. Outside of the South, the Midwest region continues to widen the levels of disparity of HIV among racial and ethnic groups. Although African Americans comprise 10.3% of the population in the Midwest (Race and Ethnicity in the Midwest, 2015), they are weighted with 47% of HIV diagnoses. Of the four

regions, the Midwest has the highest HIV diagnosis rate among the White population.

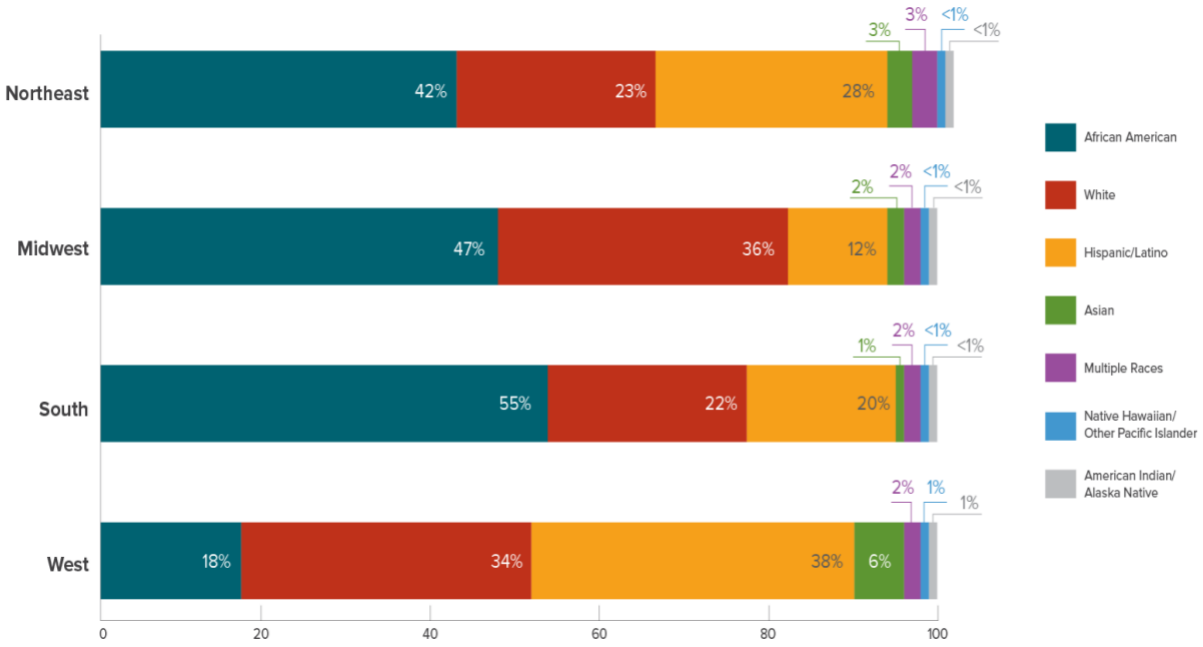

Figure 1. Diagnoses of HIV Infection in the U.S. in 2015 by Race/Ethnicity and Region. Source: Adapted from *HIV in the United States by Geographic Distribution*, Centers for Disease Control and Prevention (2016c).

The CDC (2014b) uses the Office of Management and Budget (OMB) metropolitan statistical areas (MSAs) to define metropolitan and non-metropolitan areas. Rural or non-metropolitan areas are described as areas with fewer than 50,000 people, while urban and large metropolitan areas range from 50,000 to over 500,000 people in a given area. In the U.S., HIV tends to be more prevalent in urban areas compared with rural areas. According to the CDC (2014b), in 2014, non-metropolitan areas accounted for a rate of 6.4% of people diagnosed with HIV compared with urban areas with an inordinately high rate of 20.1% of people with an HIV diagnoses.

The population most affected by HIV does not change throughout the MSAs; however, it is important to note higher rates of HIV incidence among the

Hispanic population in urban areas. Rural-urban differences are seen in the Southern states such as in Florida, where only 3% of people living with HIV reside in rural areas compared to 97% who live in urban areas (Florida Department of Health, 2013). Compared to rural areas, urban areas in the larger cities tend to offer more HIV-related services, including HIV testing, treatment and medication coverage, as well as support services.

Local (New York) Comparisons

In 2016, there were 2,881 new HIV infections in the State of New York (NYSDOH, 2017). New York City accounted for 2,279 of all new HIV infections in 2016 (NYC DOHMH, 2017). Based on the HIV epidemic in New York City, there remain differences of HIV prevalence among the five boroughs. HIV diagnosis is generally distributed across racial and ethnic lines, with African Americans accounting for 43.5% and Hispanics 33.7% (NYC DOHMH, 2017). Brooklyn leads the boroughs of New York City with the highest rate of 25.5%, followed by Bronx (22.8%), Manhattan (20.5%), and Queens (18.2%). Staten Island has a significantly lower rate of HIV diagnosis of 2.7%, an incredibly small rate considering the local HIV epidemic (NYC DOHMH, 2017).

According to the 2016 surveillance report for New York City, racial and ethnic disparities among women with new HIV diagnoses are tremendously disproportionate. Black women had over 14 times higher rates for HIV diagnosis compared to White women and had 2.7 times higher rates than Hispanic/Latina women (NYC DOHMH, 2017, p. 5).

Although the HIV epidemic has slowed its trajectory, it has had a disproportionate effect on African Americans, MSM (men who have sex with men) of color, people of trans experience, young people, and people who had a prior/existing sexually transmitted infection (STI). African Americans comprise the

largest number of persons diagnosed with HIV (44%), outpacing all other racial and ethnic populations in the U.S., according to the CDC (2016a). Additionally, MSM accounted for 67% of all persons diagnosed with HIV in 2016 (CDC, 2016a). This statistic ties closely with the transmission rates and risk factors for acquiring HIV, as unprotected anal sex carries a higher risk of HIV transmission, second only to blood transfusion, which is no longer considered a high-risk factor in the United States (CDC, 2016b).

HIV Risk Factors in the U.S.

Age and current STI diagnoses significantly increase the risk of HIV infection in the U.S. According to the CDC (2016b), people aged 13-24 years accounted for 1-in-5 new HIV diagnoses in 2014. In addition, people within this age group are at even higher risk if they practice anal sex. MSM and bisexual males aged 13-24 years account for 80% of new HIV diagnoses (CDC, 2016b). Furthermore, people engaging in unprotected sexual acts, having multiple partners, or engaging in sexual acts while under the influence of drugs and/or alcohol increase risk of both STI and HIV infection (CDC, 2016b). The transmission of HIV often occurs as a result of breaks or sores in the genital areas, elevating HIV risk for people with STIs.

Social determinants of health can predict and compound the impact of HIV transmission. These include income, education, peer support, accessing health services, and economic status for persons at higher risk of getting HIV. Other studies have found higher rates of unemployment and low income were associated with new HIV diagnosis among Black MSM (Mayer et al., 2014). According to Forsyth and Valdiserri (2015), local studies have found higher rates of AIDS diagnosis among MSM who experience wider income inequalities. They noted, however, that the presence of protective social factors such as peer

support is associated with lower rates of new HIV diagnosis among MSM. Further enabling support services such as attainment of education (skills, qualification, knowledge) and treatment of an HIV-infected partner to reduce HIV transmission have been cited among protective factors from HIV/AIDS (Zhu et al., 2015).

Although the rates of HIV transmission by people who inject drugs have significantly declined, there remains increased risk of HIV transmission during sexual events while persons were under the influence of drugs. Mayer et al. (2014) found that 47% of their participants (MSM, MSM of color, general population) indicated using drugs and/or alcohol during their last anal sex encounter. The study raised a perennial issue in public health around sexual behaviors, namely the reduction in condom use during sexual encounters.

Frequency of sexual acts and condom use impact HIV transmission (Zhu et al., 2015). Condom use has been shown to have high efficacy levels in protecting against HIV transmission. More recent HIV prevention messages are encouraging the concurrent use of condoms and other forms of protection (Goparaju et al., 2015).

Emergence of Antiviral Medication

The year 1996 brought advancement in the treatment of people living with HIV/AIDS. Treatment as prevention (TasP) is one of several effective strategies used to slow/counter-act the HIV epidemic worldwide. In the latest 2016 recommendations of the International Antiviral Society-USA, “all HIV-infected individuals with detectable viremia, regardless of their CD4 cell count, should begin antiretroviral therapy (ART) as soon as possible after diagnosis to prevent disease progression, improve clinical outcomes, and limit transmission” (Günthard et al., 2016, p. 192). The evolution of treatment has become

prominent and vital to sustain HIV gains and reverse the epidemic. However, engaging individuals at greatest risk of getting HIV continues to be a challenge. As evidenced by their determination to end AIDS, many United States public health institutions have expanded the continuum of HIV care to include HIV-negative individuals at substantial risk of getting HIV. The emergence of a drug to protect HIV-negative people from HIV is the newest biomedical HIV intervention available in medical settings. While not a vaccine, antiretroviral pre-exposure prophylaxis (PrEP) is "tailored for individuals who have a recurring risk of being infected with HIV" (Mayer, Krakower, & Boswell, 2016, p. 867). Pre-exposure prophylaxis (PrEP) is the taking of oral "tenofovir daily, with or without emtricitabine," which was shown to be "protective in trials involving heterosexual HIV-discordant African couples, men who have sex with men, transgender women, and injecting drug users" (Mayer et al., 2016, p. 867).

Current (2014) CDC Clinical Practice Guidelines for PrEP

In 2014, the CDC published the *U.S. Public Health Service's Clinical Practice Guideline for Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States* (CDC, 2014a). The guideline summarizes PrEP clinical trial evidence across the three priority risk groups in the U.S. (MSM, injecting drug users [IDU], and heterosexual men and women). Although the guideline equips providers with steps to prescribe PrEP, there is also support for special populations such as women who become pregnant or who breastfeed while using PrEP, adolescent care and people diagnosed with chronic renal failure. Importantly, the guidelines provide risk assessment for the three risk groups.

Recommended Questionnaire Used to Screen Heterosexual Women for PrEP (CDC, 2014a, p. 27)

In the past 6 months:

- *Have you had sex with men, women, or both?*
- *(if opposite sex or both sexes) How many men/women have you had sex with?*
- *How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?*
- *How many of your sex partners were HIV-positive?*
- *(if any positive) With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?*

Guidelines Provided for Additional Risk Factors (CDC, 2014a, p. 27)

- *For all sexually active patients, clinicians may want to consider reports of diagnoses of bacterial STIs (chlamydia, syphilis, gonorrhea) during the past 6 months as evidence of sexual activity that could result in HIV exposure. For heterosexual women and men, sex without a condom (or its correct use) may also be indicated by recent pregnancy of a female patient or sexual partner of a male patient.*
- *Clinicians should also briefly screen all patients for alcohol abuse (especially before sexual activity) and the use of illicit non-injection drugs (e.g., amyl nitrite, stimulants). The use of these substances may affect sexual risk behavior, hepatic or renal health, or medication adherence, any of which may affect decisions about the appropriateness of prescribing PrEP medication. In addition, if substance abuse is reported, the clinician should provide referral for appropriate treatment or harm-reduction services acceptable to the patient.*
- *Lastly, clinicians should consider the epidemiologic context of the sexual practices reported by the patient. The risk of HIV acquisition is determined by both the frequency of specific sexual practices (e.g., unprotected anal intercourse) and the likelihood that a sex partner has HIV infection. The same behaviors when reported as occurring in communities and demographic populations with high HIV prevalence or occurring with partners known to have HIV infection, are more likely to result in exposure to HIV and so will indicate greater need for intensive risk- reduction methods (PrEP, multisession behavioral counseling) than when they occur in a community or population with low HIV prevalence.*

Recommended Indications for PrEP Use by Heterosexually Active Men and Women (CDC, 2014a, p. 29)

- *Adult person*
- *Without acute or established HIV infection*
- *Any sex with opposite sex partners in past 6 months*
- *Not in a monogamous partnership with a recently tested HIV-negative partner*

AND at least one of the following

- *Is a man who has sex with both women and men (behaviorally bisexual)*
- *Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)*
- *Is in an ongoing sexual relationship with an HIV-positive partner.*

U.S. Women Who Have Indications for PrEP

Smith et al. (2015) provided a huge breakthrough in understanding the context and providing researchers with a baseline for the estimated number of U.S. women who have indications for PrEP based on the CDC 2014 PrEP clinical guideline. Smith et al. analyzed national level population-based surveys to estimate the percentages and numbers of persons with indications for PrEP in each of three “transmission-risk populations” (p. 1292). Smith et al. utilized two primary surveys to determine national estimates for the analysis were the National Health and Nutrition Examination Survey (NHANES) and the National Survey on Drug Use and Health (NSDUH). The CDC used three risk categories including: MSM, heterosexually active adults, and persons who inject drugs. To estimate prevalence, the CDC 2014 guideline indications of PrEP eligibility among the risk categories were used to define the size of the target populations. More narrowly, to estimate the number of heterosexually active men and women

at risk of HIV who were between the age 18 to 59 years and therefore in need of PrEP, Smith et al. utilized three years of data from NHANES and also 2013 data from National Survey of Family Growth. The National Survey of Family Growth data included the number of men and women aged 18 to 44 years who “reported sex with two or more opposite sex partners and either of the following: 1) sex with an HIV-infected partner; or 2) sex without a condom in the past 4 weeks and sex with a high-risk partner in the past 12 months” (p. 1292). For women, the study defined high-risk partners as male partners known to also have sex with men (behaviorally bisexual).

According to Smith et al. (2015), 0.4% of heterosexually active adults aged 18–59 years is estimated to have indications for PrEP (624,000 [CI = 404,000–846,000]) (p. 1292). Among heterosexually active women, an estimated 468,000 women have indications for PrEP based on the CDC 2014 clinical practice guideline. Although 468,000 women represent a high absolute number, despite the results, the overall percentage of 0.4 is low.

Female-Controlled PrEP Modalities

A PrEP-informed decision can support women to assert their sexual health rights. In a male dominated society, a woman’s decision to assert her sexual rights can be manifested in many ways. Of most importance, is making a decision that works for the woman, regarding using the most affordable and effective HIV prevention method available.

Although fewer studies focus on women and PrEP, of those studies that actually chronicle PrEP and women stories, the concentration is on adherence and only a negligible number of studies actually report women and their intersections with PrEP uptake. It is therefore relevant to explore these limited

studies to capture the barriers to PrEP adherence, and to discover issues relating to low PrEP uptake and their influence on adherence among women.

Based on a review, despite the paucity of studies, the single most documented concern for women taking PrEP has been adherence difficulties. Studies report (Marrazzo et al., 2015; Van Damme et al., 2012) that taking a daily pill is inherently challenging for women. Longer acting formulations have been proven positive in increasing adherence by preventing common issues such as "missing doses or treatment fatigue to prescribed medication" (Boffito, Jackson, Owen, & Becker, 2014, p. 7). Although several clinical studies in Africa, Europe, and the U.S. have shown promising results in PrEP for women in forms such as injectable, topical (gel), vaginal tablets and vaginal rings, in the U.S. the only approved medication to prevent HIV-negative women from HIV transmission is limited to the oral formulation of the medication. Over the next few years, American women may have longer acting formulation PrEP options from which to choose the best lifestyle method and prevention needs. Importantly, these long acting forms are seeking to provide protection not only against HIV but also other STIs and unwanted pregnancies (Guthrie et al., 2015; McConville, Major, Devlin, & Brimer, 2016).

CAPRISA 004 was a double-blind two arm randomized placebo-control microbicide trial conducted in KwaZulu-Natal, South Africa between May 2007 to March 2010. According to Karim et al. (2010), HIV-negative women between 18 and 40 years were recruited from an urban STD clinic and rural family planning clinics to participate in the study. The study's aim was to assess the effectiveness and safety of 1% tenofovir gel in preventing HIV infection among women. Almost three times as many women were recruited from the rural clinic research site (Karim et al., 2011) with a total of 445 women randomly assigned to the tenofovir gel group and 444 women assigned to the placebo group. To

ensure optimal effectiveness of the tenofovir gel, based on previous studies especially successful outcomes from mother-to-child reduction strategies, women were asked to dose “before and after” sex acts (Karim et al., 2010, p. 3). The dosing strategy, as referred by Karim et al. (2010), was called “BAT24,” which meant women were to insert one dose of gel “within 12- hours *before* sex and a second dose of gel” within “12 hours *after* sex” but “no more than *two* doses of gel in a *24*-hour period” (p. 4). The study calculated gel adherence by three measures: (1) returned used applicator adherence—the number of used applicators returned to the research site monthly by each woman; (2) self-reported adherence—women answered questions relating to the number of sex acts including the last day they had sex to determine the use of the “BAT24” strategy; and (3) applicator-based adherence—the primary measure of adherence. This was calculated by the “dividing the number of reported sex acts per month by half the number of returned used applicators for that month” (Mansoor et al., 2014, p. 815).

A total of 98 women sero-converted during the study, 38 new HIV diagnoses in the tenofovir gel arm and 60 new diagnoses in the placebo gel arm (Karim et al., 2010). Interestingly, self-reported gel adherence was exceptionally high (97.4%), with 95.2% of applicators returned during the study. The reported findings showed that among the 336 women considered high gel adherers, their HIV incidence decreased by 54% in the tenofovir gel arm compared to intermediate gel adherers, who experienced a 38% lower HIV incidence, and 28% lower HIV incidence for low gel adherers (Karim et al., 2010). Although safety was high, participants reported adverse events during the study. Diarrhea was more common among women in the tenofovir gel arm than in the placebo gel arm. There was one death occurring in the study, which was reported as

unrelated to the study. No reports of renal toxicity, an important tenofovir-related safety concern, were found in the study.

A limitation of this study is the sample population used, which limits the generalizability of the study. The study does show the effectiveness of 1% tenofovir gel in reducing HIV infection among at risk women in need of HIV prevention (Karim et al., 2010).

Dapivirine vaginal ring is another female-controlled HIV prevention PrEP option for women. Developed by the International Partnership for Microbicides (IPM), the vaginal ring is a monthly, self-inserted ring with “sustained release of antiretroviral drugs (dapivirine) over time” that protects women against HIV infection (Nel et al., 2016, p. 2134). Across seven sites in South Africa and Uganda, Nel et al. conducted a phase 3 randomized, double-blind placebo-controlled study of 1,957 HIV-negative women aged 18 to 45 years with a 2:1 ratio of treatment to placebo assignment. The aim of the study was to evaluate the “safety and efficacy of extended use of a vaginal ring containing dapivirine for the prevention of HIV infection” (p. 2133). The ring contained 25 mg of dapivirine with the rings (dapivirine and placebo) constructed of “platinum-catalyzed silicone matrix” (p. 2134). With replacement rings provided every 4 weeks or 28 days, 1,307 and 652 women were assigned to the dapivirine and placebo arms, respectively, over 24 months.

According to Nel et al. (2016), one research site discontinued the study, affecting 29.8% of participants, because of observed non-adherence and high rates of non-compliance with the study protocol (p. 2136), resulting in higher sero-conversion. Other factors for discontinuation included relocations, withdrawal of consent, and pregnancy.

The results identified 3.6 and 5.4 sero-conversions per 100 person-years in the dapivirine (excluding the discontinued research site) and the placebo groups,

respectively. According to Nel et al. (2016), in actual numbers, there were 77 women who sero-converted in the dapivirine group and 56 in the placebo group. Dapivirine was effectively shown to lower HIV infection by 31% in the dapivirine group compared to the placebo group. Age was a determining factor in effectiveness of the dapivirine ring. Women over 21 years in the dapivirine group experienced a 37% lower rate of HIV infection, and women younger than 21 years experienced a 15% lower rate (Nel et al., 2016). Factors possibly contributing to higher sero-conversion rates among younger women were more frequent vaginal or anal sex, higher rates of non-adherence and physiological differences in the genital tract or a combination of these factors.

The appropriateness of the pre-specified criteria based on plasma concentrations and residual dapivirine in the used ring was questioned, as it indicates adherence. Suggestions that the pre-specified criteria may have over-estimated adherence because the quick release of dapivirine in the plasma only after 1 hour of ring insertion could have misled the criteria for adherence. Although further work is needed to determine the appropriate level of both plasma and dapivirine needed to provide greater HIV protection against HIV infection, studies have begun examining extended duration of vaginal rings from 28 days to 60 and 90 days (Boyd et al., 2016).

A large-scale study HPTN 083 has started recruiting adults in 2016 through a double-blind safety and efficacy study of injectable cabotegravir for PrEP (HPTN 083, 2017). The study will compare the incidence of HIV infection among people using Cabotegravir and tenofovir/emtricitabine in long-lasting injectable and oral forms taken at 4 weeks and 8 weeks apart. The study design is projected at 4.5 years, extending to four countries: U.S., Brazil, India, and South Africa, recruiting 4,500 MSM and trans-female (TMF) in the target study population with an equal number randomized in each arm of the study

(HPTN 083, 2017, p. 42). Although women are not included in this phase of the trial, the data from the target participants, HIV-negative men, and transgender women who have sex with men are significant to support clinical research in injectable PrEP for women.

Intimate Partner Violence

The use of barrier protection to prevent HIV, STIs, or unwanted pregnancies varies across relationships. For some women, male partners are the sole decision-makers in determining the "course of the sexual relationship and whether or not they used barrier protection" (Choi, Wojcicki, & Valencia-Garcia, 2004, p. 257). Framing PrEP into the wider social context for women is important in reducing their risk for HIV and increasing the benefits afforded to them through this method. As a female-controlled prevention strategy, PrEP provides higher levels of efficacy beyond those of vaginal microbicides and diaphragms and removes the need for partner consent as with female condoms (Braksmajer, Senn, & McMahon, 2016). According to Braksmajer et al., critical advantages of PrEP for women experiencing intimate partner violence (IPV) or male-dominated relationships, are the "potential covert or autonomous use, coital independence, dual protection against sexual and injection HIV risk, and facilitated connections to social services" (p. 276).

Garfinkel, Alexander, McDonald-Mosley, Willie, and Decker (2016) conducted a study at two family planning clinics in Baltimore City and in one of its northern suburbs between January and April of 2014. Women aged 18 and 35 years were recruited during their clinic visit resulting in 75 women participating from the Baltimore City and 71 from northern suburb sites. A 15-minute self-administered survey was administered using Audio Computer Assisted Survey Instrument (ACASI). Major survey categories included "demographics, health

care seeking patterns, sexual and reproductive health behavior, violence experiences and access to and engagement with local support services" (p. 752).

According to the authors, over 50% of the sample was Black (51.4%), with 38.4% White and 10.3% identified as multicultural. A total of 67% of the participants either had some college experience or finished college. Approximately half of the participants had a previous HIV test but not in the last 3 months, while 36.6% indicated being tested within 3 months; but 14.5% indicated that they never had an HIV test. Of the 38.4% with a history of IPV, 25% indicated that they were worried about HIV, which, according to Garfinkel et al. (2016), highlights the need for PrEP within this population of women. In an incongruent manner, however, IPV affected women were less likely to accept PrEP (57.14%) compared to non-IPV participants (62.22%). This was an area of concern for Garfinkel et al., indicating the need to address violence and trauma to improve HIV outcomes for women as a national priority (p. 754).

Women experiencing IPV, as aptly described by Garfinkel et al. (2016), do face trauma, a barrier to protection, including prevention approaches to HIV. In addition, other barriers faced by women IPV-affected survivors that affect PrEP uptake and adherence include partner resistance, difficulties with covert use, cost (particularly outside New York State), and gendered norms regarding sexuality.

U.S.–based Pre-exposure Prophylaxis Studies

Kwakwa et al. (2016) conducted a study in eight Federally Qualified Health Centers in Philadelphia to determine the openness to PrEP in African American adults in Philadelphia. The study recruited 5,606 men and women between May 2012 and December 2014. The PrEP openness survey was administered by rapid testers during the voluntary acceptance of HIV rapid tests. Although 9

African American women tested positive for HIV during the length of the study, none of these women perceived their risk as moderate or high for an HIV infection. Similarly, 26 African American men tested HIV positive, but only 19.2% of these perceived their risk as moderate or high-risk of getting a HIV infection. Kwakwa et al. reported that of the women who tested HIV positive, 44.4% expressed disinterest in PrEP, while 46.2% of men testing HIV positive expressed disinterest in PrEP prior to the results being known.

According to Kwakwa et al. (2016), African American women and men expressing disinterest in PrEP had as their main reasons low risk perception, medication concerns, and preference for other methods (condoms). Unlike men, women found celibacy as more of a reason than men. Where men indicated distrust as a reason for not being open to PrEP, this appeared not to be a concern for women (p. 1447). Participants indicated three primary reasons for openness to PrEP: fear of HIV, importance of a prevention strategy, and high-risk perception.

Smith et al. (2012) conducted one of the first qualitative studies by focus group to “elicit attitudes about, and preferences for, PrEP services from inner-city, African American young adult men and women at risk for HIV transmission” because of both sexual and drug-related behaviors (p. 411). Of the 10 focus groups conducted between June and August of 2009 in Atlanta, Georgia, 8 focus groups comprising 58 people were mixed-gender and two MSM-only focus groups comprising 19 men. The study utilized audio recording, which was transcribed verbatim and uploaded in NVivo analysis software (QSR International Pty Ltd. Version 8, 2008).

Of the five themes identified in the focus groups, barriers to PrEP uptake and maintenance received noted attention. According to Smith et al. (2012), barriers to PrEP uptake included “side effects, medication cost, partial

effectiveness, low perceived personal susceptibility to contracting HIV, burden of taking a daily medication, reaction of peers to taking HIV medication, and for the MSM groups only, fear of risk compensation (decrease use of condoms and other safer sex practices)" (p. 413). The study found the importance of scaling up efforts for continuing education and counseling about PrEP in high-risk, African American young men and women.

Wingood et al. (2013) conducted a nationally representative, random-digit telephone dial household survey of 1,042 African American women and 411 White women aged 20-45 years in the U.S. between October 2006 and May 2007. In an attempt to oversample African Americans, a dual-frame sampling design was used in which the larger frame looked at counties with 10% or greater African American and White population while the smaller frame targeted high density counties where African American women exceeded 7% greater.

According to Wingood et al. (2013), women who were more likely to report potential use of PrEP were of lower socioeconomic status and less educated, with a high school completion or less. Compared with women having at least a college education, less educated women had 2.04 times higher odds of potentially using PrEP. Compared with women with full-time jobs, unemployed women had 1.8 times higher odds of potential use PrEP. African American women were significantly more likely to report potential PrEP use compared to White women, 69.1% and 54.2%, respectively (p. 98). Peer and provider influences were significant factors in PrEP use in African American women. According to Wingood et al., compared with White women, "African American women were 2.2 times as likely to report potential PrEP use" if their friends are perceived to also use PrEP ($P \leq 0.001$) and "1.65 times as likely to report potential PrEP use if it was recommended by a health-care provider" (p. 99). One major limitation of the study was that it was conducted early in the PrEP clinical

trials and before FDA licensure of PrEP. This could have significant impact on the applicability of the findings for African American and White women in a PrEP-FDA-approved era and where significant scale-up and PrEP education has taken place.

While not specifically about PrEP, the study by Flash et al. (2014) has relevance. They recruited 26 Black women aged 20-50 years from the Dimock Community Health Center and 15 affiliated sites located in Boston, Massachusetts to participate in five focus groups. Women responded to flyers posted in the waiting rooms of the health centers and self-identified as Black female. During the 2-hour focus group, participants completed demographic surveys, recording age, race, education, HIV risk perception, focus group experience, zip code. The facilitator utilized a semi-structured discussion guide that focused on “HIV risk perception and perception of the ideal prevention strategy” (p. 636).

In heterosexual women, risky sexual behaviors included “barriers to condom use because of fear of perceived unfaithfulness, financial barriers, personal perception of being low-risk, educational status, desire to conceive, and intimate partner violence” (Flash et al., 2014, p. 635). Using the theory of Gender and Power, categories of “sexual division of labor, structure of cathexis and sexual division of power are examined in relation to HIV-related exposures, risk factors and effective interventions for women” (p. 635). According to Flash et al., although women found condoms to be an effective and low-cost HIV prevention method, women have to negotiate condom use, highlighting the sexual division of power. The women reported the need for a “female-controlled strategy” as an ideal prevention strategy (p. 637). Oral PrEP was found to satisfy the definition of “female-controlled” because of the “perception that it offered greater potential for undisclosed use” and also because PrEP complements “condoms, needle-

exchange behavioral strategies and enhanced testing" (p. 639). To emphasize the point, one participant was quoted as saying:

> I don't think you should trust anyone even if you are married, or something like that. I mean you should, because it's like your partner but, they can step out of the marriage just like a single person. You should use a condom regardless of anything. (p. 637)

Whiteside, Harris, Scanlon, Clarkson, and Duffus (2011) conducted a cross-sectional study in 2009 and 2010 at a South Carolina STD clinic with attendees who had an appointment or walked into the clinic for services. A 20-minute self-administered paper questionnaire was completed by 405 participants, each of whom received a $20 incentive to show gratitude for their participation. Inclusion criteria included being over the age of 16 years, reported sex within the past 6 months, self-reported HIV-negative status, seeking STD services and not previously completing the questionnaire. The questionnaire used a Likert scale to rate questions that determined participants' risk perceptions and knowledge of PrEP. Unlike many other studies assessing risk perception and PrEP awareness, this study included a predominately heterosexual sample (90%). A total of 89% of the participants identified as African American, with 52% of the participants aged 17-24 years and 53% with college education. Interestingly, among participants reporting multiple sex partners (2-4 partners) in the past 3 months, they were 2.35 times as likely to have a "lower level of agreement" with the statement, "I believe I am at risk of getting HIV" compared to participants reporting 1 sexual partner in the past 3 months (p. 367). The study found women to be more receptive than men to using dual protection in the form of condoms and daily-PrEP to reduce HIV infections. An equally important finding was that over 81% of the participants indicated they were not aware of PrEP.

Goparaju et al. (2015) conducted a unique study involving both HIV-negative and HIV-positive women that focused on their “knowledge, attitudes, and potential behaviors (KAB) of biomedical prevention strategies, namely, PrEP and Treatment as Prevention (TasP)” (p. 3). This study was conducted among the Women’s Interagency HIV Study (WIHS) in Washington, DC. At the time of publication, WIHS was the “largest prospective, observational qualitative study of HIV-infected and at-risk HIV- uninfected women in the U.S” (p. 3). The Washington, DC arm of the study conducted eight focus groups segregated equally by sero-status, which were conducted from February to May 2014. A total of 39 women participated, 20 HIV-negative and 19 HIV-positive, aged 31 to 62 years, with the median age being 49 years. African American was the major race involved in the study, representing 80% in the HIV-negative group and 100% in the HIV-positive group. Risk assessment at intake revealed that only 25% of HIV-negative women reported using a condom in the last 6 months and 95%-100% of HIV-positive women reported being adherent to antiretroviral medication in the last 6 months. To allow comparison, both sero-status focus groups addressed the same topics. Topics discussed included, “HIV-negative women’s experiences with HIV; perceptions of their own risk of HIV infection; HIV-negative and HIV-positive women’s awareness of PrEP; acceptability of PrEP; preferred HIV prevention method; concerns about the PrEP package; and potential target groups for PrEP outreach” (p. 4). The focus groups were digitally recorded with verbatim transcription. The study utilized NVivo 10 qualitative analysis software. Using the KAB measures, codes included knowledge, attitude and potential behaviors with inter-coder reliability conducted by two investigators.

Goparaju et al. (2015) found almost polar opposites between sero-status groups concerning PrEP. Although HIV-negative women were excited to learn about PrEP, HIV-positive women were less enthusiastic and gave caution to its

use. All HIV-negative women perceived themselves to be at risk of HIV and all were closely impacted by the HIV epidemic. Combination of PrEP plus condom was viewed as the best prevention approach by HIV-negative women, while "HIV-positive women preferred condoms alone" (p. 4). The researchers found extremely low level of PrEP awareness across both sero-status groups. Although all participants were briefed on PrEP before the focus group sessions, the study noted that of the 39 participants, only 5 had previously heard about PrEP: 4 sero-positive and 1 sero-negative woman. Importantly, the 1 sero-negative woman who previously heard about PrEP, understood PrEP use in the context of gay men protection but did not know it could be used to protect women. This speaks to the extremely slow diffusion of PrEP into the lives of priority populations (since PrEP was approved in the U.S. in 2012). The sero-negative women's awareness of PrEP was in the "context of gay men" and most of the women did not know PrEP "could work for women too" (p. 6). An interesting observation was made by the sero-negative women, who mentioned that PrEP is asking for "too much commitment," particularly for young adults and that it may be "difficult to convince young adults to follow the PrEP regimen" (p. 19).

U.S. Clinicians' Attitude, Knowledge, and Prescribing Practices

Clinicians are important in the narrative of successful PrEP implementation. Understanding providers' knowledge, attitudes, willingness and current PrEP prescribing practices as well as "perceived assessment of potential barriers" are critical aspects of any PrEP conversation (Blumenthal et al., 2015, p. 803).

Blumenthal et al. (2015) conducted a study to compare HIV and non-HIV providers to: (a) quantify PrEP knowledge, (b) determine the current rate of PrEP prescription, (c) evaluate attitudes toward future PrEP provision, and

(d) determine barriers and motivators to PrEP provision (p. 803). A total of 122 HIV providers and 111 non-HIV providers were recruited from three U.S. cities, New York, San Diego, and Los Angeles, while attending the International AIDS Society meeting in New York, AIDS rounds at University of California San Diego (UCSD), Grand Rounds at UCSD and Scripps Mercy Hospital. Individual provider targeting was conducted, during their office hours, for providers who did not attend these settings. Touchscreen tablet technology was used to self-administered a 35-question survey to assess providers' knowledge about PrEP.

Although the majority of respondents were identified as from Southern California (70%), 27% were stretched across New York, New Jersey, and Connecticut. Race and ethnicity of providers who participated in the study included: White (52%), Asian (19%), non-Hispanic (70%) and Black (7%) (Blumenthal et al., 2015, p. 805). The study had roughly an equal spread of HIV and non-HIV providers, 52% and 48%, respectively (p. 806). Providers in the New York tri-state area were more likely to have prescribed PrEP compared to providers in Southern California. While 21% of eligible prescribing providers reported giving a PrEP prescription, 64% indicated their willingness to prescribe PrEP in the future. There was an association found in providers who gave a PrEP prescription and providers who were older, were "private practitioners," completed patient sexual histories, had "higher knowledge scores," and who "felt most comfortable determining PrEP candidacy" (p. 805).

Perceived barriers have been cited as limitation to prescribing PrEP by providers. Blumenthal et al. (2015) found that over 80% of providers wanted more evidence from studies and recommendations from CDC (as this study was prior to CDC 2014 guidelines). One-third of HIV providers perceived risk compensation as a concern more than non-HIV providers but where both groups of providers mutually shared concern it was about cost and insurance coverage

as unknown factors should they consider prescribing PrEP. Blumenthal et al. (2015) noted an almost equal split in where to prescribe PrEP. Although 35% of providers thought HIV clinics were the most fitting of settings to offer PrEP services, 31% thought non-HIV clinics were also adequate settings to prescribe PrEP to community residents. Interestingly, only 10% thought STD clinics were fitting settings to prescribe PrEP, with a higher number of providers (21%) supporting public health departments as appropriate settings.

One of the main limitations to the Blumenthal et al. (2015) study was the sampling method. Convenience sampling not only limited the geographical regions in the study but it also restricted the generalizability of the study. The study drew on people attending an IAS meeting in New York and a AIDS Grand Rounds in California, which may have resulted in there being more non-HIV providers supportive of HIV prevention, whose responses would not necessarily represent non-HIV providers' attitudes and prescribing practices regarding PrEP across the U.S.

Smith et al. (2016) assessed U.S. primary care providers' responses to Porter Novelli's annual web-based DocStyles surveys to "determine the strength of association between clinicians willing to prescribe PrEP to at least one high-risk group" and eight clinician characteristics: "age, sex, race/ethnicity, clinician specialty, clinician work setting, number of clinicians in practice, number of years in practice, having provided anti-retrovirals for post-exposure prophylaxis (PEP) or treatment of HIV infection" (p. 3). The high-risk group was inclusive of the CDC expanded risk categories to include "PWID, MSM, persons with an existing STD, people who change sexual partners frequently, HIV discordant couples, HIV discordant couples attempting to conceive" (p. 3).

Surveys were drawn from two sources over the period of analysis. Although in 2009, 2010, 2012 and 2013, DocStyles surveys were drawn from Epocrates

Allied Health Panel, 2014 and 2016 surveys were taken from SERMO's Global Medical Panel. The process of double opt-in verification was completed for both Panel sources. Interestingly, for the first time in 2012, pharmacists were included in the surveys as providers. Response rates for each of the six survey years ranged from a low of 34% to a high of 84% among clinicians and nurse practitioners across the U.S., resulting in actual numbers surveyed in: 2009 (n = 1,500), 2010 (n = 1,504), 2012 (n = 1,503), 2013 (n = 1,507), 2014 (n = 1,508), and 2015 (n = 1,501) (Smith et al., 2016, p. 1).

From 2009 to 2015, prescribing anti-retroviral medication by providers was reported at 24% and 10% for non-occupational and occupational post-exposure prophylaxis (PEP), respectively (Smith et al., 2016). Although from 2011 to 2013, clinicians reported low exposure to CDC clinical guideline for PrEP use among the risk groups, evidence of incremental increase in awareness of the guideline increased in 2014 (p. 9). The authors reported a significant increase in prescribing PrEP medication over the first three survey years. According to Smith et al., in the combined years of 2009, 2010, and 2012, only 1% of clinicians prescribed PrEP. There was a steady increase reported in prescribing PrEP medication from 4% in 2014 to 7% in 2015. Smith et al. disaggregated the 7% data for 2015 to show who received PrEP prescriptions: 73% prescribed for MSM, 22% for PWID, 22% for "uninfected men," 27% for "uninfected women in HIV discordant couples during conception attempts," 45% for "uninfected women in an HIV discordant couple not planning conception," and 30% for "uninfected men in this situation" (p. 5). Smith et al. found that clinicians were more willing to prescribe PrEP for: "uninfected partner in an HIV discordant couple" (79%), MSM (66%) and PWID (63%), "HIV discordant couples planning conception" (61%), "persons who change sexual partners frequently" (56%), and "persons with a diagnosed STD" (34%) (p. 6).

One of the primary limitations of the study was the timing of assessing clinicians' attitudes during the early phase of PrEP roll out in the U.S. The effectiveness of PrEP reported in clinical trials ranged from 75% in 2009 to ~90% in 2012 to 2015. The study postulates that it "may not be a realistic approximation of primary care clinicians' attitudes in the U.S. in this early phase of introducing PrEP as a clinical HIV prevention method" (Smith et al., 2016, p. 9). Further studies on clinicians' knowledge, attitudes, and prescribing practices of PrEP as the intervention is scaled-up would be important to monitor.

In their review of U.S. based studies on serodiscordant heterosexual couples, McMahon et al. (2014) identified HIV-sero-discordant couples as the most "ideal candidates for PrEP" (p. 464). The authors observe that although traditional clinical settings treating HIV patients are uniquely positioned to provide PrEP services to partners in sero-discordant relationships, providers in other non-traditional settings also present additional opportunities to engage this population.

Additionally, in an opinion-based survey of U.S. and Canadian providers, Karris, Beekmann, Mehta, Anderson, and Polgreen (2014) surveyed 1,175 active members of the Infectious Diseases Society of America's (IDSA) "Emerging Infections Network (EIN), a provider-based network of infectious disease physicians actively involved in clinical practice who belong to IDSA" (p. 705). Between June and July of 2013, a 10-question survey was distributed to elicit current practices and attitudes related to PrEP among expert HIV providers. Encouraging a high response rate, two reminder notices were sent to "non-respondents at 1-week intervals" (p. 464). A total of 48.8% of participants responded to the survey, which was characteristic for the network. Although astoundingly, 74% of providers supported the use of PrEP, only 9% ever prescribed PrEP in their practice. Of the 74% of providers who supported PrEP,

43% would prescribe PrEP, but 34% believed PrEP was not relevant to their practice. Providers identified barriers to providing PrEP in their practice: 77% of providers identified adherence and the risk for future resistance, 57% raised the issue of “cost and reimbursement” (p. 705), while 53% raised issues of toxicity and insufficient evidence to support real-world efficacy of PrEP.

According to Karris et al. (2014), providers described additional barriers to prescribing PrEP. These included risk compensation, noting that limited efficacy evidence creates a “false sense of security”; “concerns about irresponsible sexual activity”; “lack of resources and information”; insufficient knowledge to feel comfortable to prescribe; “lack of effectiveness data in local context”; limited resource allocation; HIV “transmission can be prevented without medications”; “concern about the selling of PrEP from HIV positives to HIV-negatives”; “moral issues”; “medicine should not attempt to reverse bad behaviors artificially”; and finally, the “balance is not right in terms of risks/benefits” (p. 705).

These are two limitations to the study. Firstly, it is a self-selected convenience sample. Although the EIN database was used as the sampling frame, clinicians who register with the Network may not represent the general body of providers in the U.S. and Canada and it raises selection bias as a concern. Secondly, the survey received a relatively low response rate, compounding the external validity concerns (Karris et al., 2014, p. 711).

In a recent study, Calabrese et al. (2016) interviewed 18 medical providers who prescribed PrEP to one of more patients from September 2014 to February 2015. These were conducted either by email or in-person interviews lasting 60 to 90 minutes. The interviews were audio recorded, later transcribed verbatim, and analyzed. Of the 18 providers, 88.8% practiced in the Northeast (14) and the remainder in the South (4). The study aimed to explore “PrEP providers’ firsthand experiences relative to six commonly-cited barriers to prescription—financial

coverage, implementation logistics, eligibility determination, adherence concerns, side effects, and anticipated behavior change (risk compensation)" (p. 1). Each of the six commonly cited barriers was addressed by PrEP prescribing providers and their approaches to mitigate these individual challenges.

Although most providers did not cite financial coverage as a major problem, a majority of the providers indicated the diverting of staff and resources to paperwork and telephone conversations to maintain patient coverage as an issue. Calabrese et al. (2016) quoted a provider who experienced a decline in coverage. This individual stated, "bit of a pain in the neck," although admitting that "it's never been a show stopper" and was "nothing out of proportion with what we see on a regular basis with insurance companies" (p. 6).

Providers demonstrated their flexibility in working with PrEP users through a series of examples in which they adjusted patients' medical visits, the act of pill-taking, and adjusted for pregnancy outcomes to address each individual's needs. Although providers used CDC guidelines, they were just that—guidelines; they therefore either adapted for each patient or implemented as outlined. There was a general sense that staff support was essential in developing PrEP care systems. The function of these care systems was to "educate patients about PrEP, communicate with insurance companies, help patients complete paperwork, schedule and remind patients about appointments, and/or perform risk and adherence counseling, which alleviated provider burden" (Calabrese et al., 2016, p. 7).

Not surprisingly, the CDC guidelines are the backbone of any risk assessment. Notwithstanding this, providers tended to utilize an empowerment model, a "patient-first" principle of assessing risk. One provider phrased it as "harm reduction, so, try to meet them where they're at. So, I really try never to tell people what to do" and another provider phrased it as "do you/could you see

yourself, in the future, being at risk? Is this something that you could incorporate into your life?" (Calabrese et al., 2016, p. 7).

According to Calabrese et al. (2016), perspectives vary on this subject, which we have seen in the literature. Self-referred patients were seen as more adherent than patients who were encouraged to take PrEP. One provider "estimated that 80% took PrEP" and this was "with incredible anal retentive fidelity" (p. 8). Another provider noted that "more than half of my patients who are younger than 25 years old—there's not a single thing in their day that they do at the same time" (p. 8).

Although patients reported minimal to no side effects, during the first 2 to 4 weeks, a small number of patients experienced "nausea, headaches and other symptoms such as rash and fatigue" (Calabrese et al., 2016, p. 8). In extremely rare situations, patients may exhibit change in kidney functions, which can prompt PrEP discontinuation; for the latter, only one provider experienced an issue.

Providers reported "no change in condom use after initiating PrEP" (Calabrese et al., 2016, p. 8). The study found that people who reported no condom before PrEP continued in their behavior while patients reporting frequent condom use before PrEP reported frequent condom use while on PrEP. One provider with the highest number of patients (n = 325) observed, "We're certainly not seeing people who are having a hallelujah risk compensation effect" (p. 8).

Calabrese et al. (2016) highlighted other challenges to PrEP implementation. One concern lies in the inability in "accessing and engaging priority populations" in PrEP care (p. 9). One provider elaborated on this point by stating that "either the community isn't aware enough about it or their primary care providers are still not talking about it enough, are not confident enough, or are not able to answer their questions, so that there's a gate and the gate is

really closed off before people actually get to me" (p. 9). Another concern was the inappropriate labeling of PrEP as a "gay man's prevention tool" (p. 9). Providers were also willing to share patients' perceived barriers, which included "lack of PrEP awareness, medical mistrust, absence of existing ties to the medical system, and structural hurdles, e.g., health centers' daily hours of operation failing to accommodate those with less work flexibility" (p. 9).

This study utilized a convenience sample, which limits the generalizability of the findings. Despite this limitation, Calabrese et al. (2016) successfully achieved a rethinking of barriers experienced earlier at the beginning of PrEP's introduction with more up-to-date accounts, surmounting previous barriers but highlighting the continued work needed to address structural and access to care barriers that exist for populations at risk for HIV.

PrEP Uptake in the United States

Currently in 2018, HIV surveillance does not capture PrEP utilization at national or local levels, nor is there a unified system in which PrEP utilization is captured. Although public health departments are attempting to address this information, localized community studies and database analyses have attempted to fill this gap. In the absence of generalized large-scale PrEP uptake data in the U.S., this literature review draws on limited real-world data, specialized PrEP programs and demonstration projects (Bien, Patel, Blackstock, Uriel, & Felsen, 2017).

Wu et al. (2017) analyzed 2009-2014 data from MarketScan Commercial Claims and Encounters, a large commercial employer-sponsored health insurance database that each year contains 43-53 million Americans' health insurance information. The data capture patient-level data on demographic,

gender, age, residence, health plans, health claims, diagnoses, procedures, and prescriptions (p. 145). Due to the early nature of this analysis, PrEP diagnostic and procedural codes were not available. To address this challenge, Wu et al. created an algorithm for persons prescribed TDF-FTC (tenofovir and emtricitabine). This formulation is used in treating non-PrEP specific medical conditions and treatment, such as HIV infection, hepatitis B, and post-exposure prophylaxis (PEP), conditions that were used as exclusion criteria for the study.

As expected, the results showed incremental PrEP increase over the 5-year period, which would correspond to FDA approval in 2012 and CDC release of guidelines for clinical practice in 2014. Over the 5-year period, Wu et al. (2017) indicated that the number of PrEP users grew from 111 in 2010 to 237 in 2012 and to 2,564 in 2014. In 2014, only 3.7% were female PrEP users, while male PrEP users accounted for 97.5%. The West showed an increase of 43% of PrEP users, and nationally the mean age was 38 years down from 44 years in 2010 (p. 146). The Northeast only accounted for 18.6% of PrEP users behind the South with 24.9% of PrEP users.

Limitations to this study included the use of a commercial insurance database, which restricts the generalization of the findings. The database was limited in its ability to classify risk behaviors of PrEP users, a helpful detail in comparing to CDC risk categories. Additionally, the algorithm used in the study could have been too restrictive and excluded actual PrEP users.

Bush, Ng, Magnuson, Piontkowsky, and Mera-Giler (2015) conducted a study to understand PrEP increase in the U.S. by using a national prescription database to analyze 39% of TVD (Truvada) prescriptions between January 1, 2012 and March 31, 2015. Similar to Wu et al. (2017), Bush et al. (2015) excluded diagnosis codes for other possible Truvada uses because no specific coding is attributed to PrEP. The prescription database provided de-identified

patient-level data on prescriptions, refills, medical claims and patient demographics. Between 2012 and the first quarter of 2015, there were 8,512 unique cases of PrEP use. Bush et al. noted from 2014 to 2015, a 332% increase in PrEP users. During this same period, women accounted for 13.4% of PrEP users, while 86% were male. Since 2014, the 24-34 age group was consistently the main new users of PrEP at 34.6%, while people aged 35-44 years accounted for 26.9% of new PrEP users. Bush et al. found higher PrEP utilization in the Western and Southern regions of the U.S., with rates of 31% and 30%, respectively. The Northeast ranked third in PrEP utilization at 21%, above the Midwest at 17%. A total of 3,920 unique individuals used PrEP in 2014. Although only the first quarter data for 2015 were available, which showed 1,761 individuals started PrEP, the projections model calculated a substantial increase by the end of 2015 with an estimated 7,044 PrEP users.

The study database covered 39% of all Truvada prescriptions for PrEP but was unable track the vast majority of prescriptions in the U.S. The lack of specific International Classification of Disease (ICD) codes for PrEP remains a challenge in analyzing utilization. Errors in the exclusion criteria cannot be discounted and may be a source of under-reporting of PrEP users in the U.S.

Laufer et al. (2015), using Medicaid prescription data, provide further insight into PrEP uptake across the State of New York. The New York State Department of Health/AIDS Institute formulated a strategic framework, through which comprehensive and integrated PrEP services could be provided through the State within primary and HIV care settings as well as settings serving people at risk for HIV and/or STIs. According to Laufer et al., the “State’s Medicaid program approved coverage of Truvada for PrEP through the program’s fee-for-service drug formulary” (p. 1297), supporting the Governor’s Blueprint to End

AIDS Epidemic by reducing “newly diagnosed cases of HIV infection from an estimated 3,000 to 750 by 2020” (p. 1296).

Data were drawn for a 3-year period July 2012 to June 2015, using data submitted from the managed care plans to the NYSDOH Medicaid data warehouse (Laufer et al., 2015). One of the challenges experienced by other studies examining PrEP uptake is distinguishing Truvada prescriptions intended for PrEP from prescriptions intended for PEP and hepatitis B. These nuanced factors were included in the development of an algorithm designed to extract Medicaid recipients filling at least one PrEP prescription.

The results identified New York City as being the leader of PrEP uptake in the state, accounting for 80.7% of PrEP prescriptions filled. The results showed a moderate increase in PrEP prescriptions from the period July 2012 through June 2013 to July 2013 through June 2014 of 17% (Laufer et al., 2015). A dramatic increase of 338.9% in PrEP prescriptions was recorded for the period July 2014 to June 2015, a record of 1,330 recipients compared to the previous period of 303 recipients (p. 1297). The state’s Medicaid program approval of coverage of Truvada for PrEP has been identified as a facilitator to PrEP uptake (Collier et al., 2017). Although Laufer et al. (2015) indicated that the number of females who filled PrEP prescriptions doubled across the study period from 117 to 292, a drastic shift in absolute uptake was seen for males, who increased PrEP prescriptions from 54.8% to 78%. While Black recipients grew in the number accessing a PrEP prescription, 65.7% of all PrEP prescriptions during July 2014 to June 2015 were accessed by White recipients.

One notable limitation not mentioned by other PrEP uptake studies is the limiting use of “PrEP prescriptions” as a measure of PrEP use (Laufer et al., (2015). The filling of a PrEP prescription at least once does not equate to the number of people taking PrEP to prevent HIV. Further, people may fill a

prescription and not take the medication. In addition, the analysis does not speak to adherence to the PrEP regimen as outlined by CDC guidelines.

Sero-discordant Relationships

Bien et al. (2017) present PrEP uptake from a health care system perspective. Using medical charts from the largest health care system in Bronx, New York, Bien et al. sought to describe the “sociodemographic and HIV risk characteristics of individuals who received PrEP prescriptions” with a secondary aim to review PrEP prescription changes from 2011 to 2015 (p. 1310). Using Einstein/ Rockefeller/City University of New York Center for AIDS Research’s HIV clinical cohort database, FTC-TDF prescriptions were pulled for individuals with a negative HIV test between January 1, 2011 and December 31, 2015. Medical records were individually scrubbed, and similarly to Wu et al. (2017) and Bush et al. (2015), FTC-TDF prescriptions for PEP were excluded. Bien et al. (2017) included patient-level demographics, race/ethnicity, age, SOGI (sexual orientation and gender identity) data, clinic sites, and category of clinic site, PrEP prescription dates and importantly, HIV risk groups.

From 177,525 individuals with a negative HIV test during the study period, only 108 from 2064 with a FTC-TDF prescription were actual PrEP users (Bien et al., 2017, p. 1310). The authors found significant uptake in PrEP after 2014, which was denoted by only 10 prescriptions before 2014. A total of 61% of PrEP users reported a HIV-positive partner. At the same time 87% of cisgender women reporting an HIV-positive partner, the prevailing risk factor identified for women. Importantly, Bien et al. elevated the issue of under-representation of women in PrEP literature given the population’s high HIV infection rates in New York and across the country. The study was limited by the data extraction methods, a

common issue noted in most chart review processes. Retrospective chart review results in differentiation in chart completion, and the study's inability to equally assess risk behaviors.

A New York City female-focused study assessed the risk factors associated with PrEP uptake and retention in care. Using retrospective medical chart reviews in a newly opened community-based comprehensive sexual health clinic in the Bronx, Blackstock, Patel, Felsen, Park, and Jain (2017) cross-referenced the medical charts against the PrEP registry to assess the number of women on PrEP at the clinic. The study was conducted from December 2014 to August 2016, during which 554 women accessed services. Of this number, 21 heterosexual women (3.8%) obtained at least one PrEP prescription. Importantly, 38% were Latina, 28.6% were non-Latina Black, and a majority (81.2%) had Medicaid.

In describing the HIV prevention landscape in New York State, Blackstock et al. (2017) provide context to the PrEP assistance framework. According to the authors, the combined efforts of Gilead Sciences' pharmaceutical-sponsored drug assistance program and New York State Department of Health, the State-sponsored PrEP assistance program (PrEP-AP) provides coverage for PrEP clinical visits, lab tests, and medication (Blackstock et al., 2017). Interestingly, of the 21 women, only 3 specifically sought PrEP services, while referrals comprised the sources of PrEP indication of women. The primary risk factor for 85.7% of women was being in a sero-discordant relationship. A total of 83.3% of women reported their HIV-positive partner as being on antiretroviral medications, while 66.7% reported viral suppression status of their partners and 16.7% were trying to conceive (Blackstock et al., 2017).

Using CDC PrEP guidelines, Blackstock et al. (2017) delimit retention as clinic visit schedule of every three months. In addition to Blackstock et al.'s study,

the issue of retention on PrEP in the U.S. has received significant attention. In an MSM study in three U.S. cities conducted by Chan et al. (2016), retention among men on PrEP showed substantial drop-off. At 3 months, 61.1% had their clinic visit, but only 37.5% complete the 6-month visit. One limitation to Blackstock et al.'s (2017) study was the inability to determine PrEP eligibility among women attending the clinic. Secondly, sexual health clinics may have higher at-risk individuals for HIV, a limiting factor for generalizing the results.

Theoretical Framework

Three social sciences theories shaped the design of the current study. The Diffusion of Innovations Theory (Rogers, 2004) influenced the development of the survey instrument and guided the fieldwork. Grounded Theory (Glaser & Strauss, 1967) was instrumental in combing through the transcription pages to produce codes that made sense given the voluminous data. Although the preceding two models were integral in the backbone of the current study, the analysis and presentation of results was possible using the PRECEDE Planning Framework (Green, Kreuter, Deeds, & Partridge, 1980), which was the third and final theoretical model. The PRECEDE Planning Framework provided an explicit and intentional style of presenting the results that were in alignment with the aims of the current study in explaining factors that motivated Black women in New York City to either accept or reject PrEP.

Diffusion of Innovations in Health Promotion

Historically, public health has faced strong challenges in implementing new biomedical interventions. An example is family planning methods. After many years and through the establishment of stand-alone clinics and numerous

campaigns, family planning has been successfully integrated into primary care delivery systems (Rogers, 1983). Within the discipline of public health and health promotion there is recognition that not all innovations will be accepted, nor will they be diffused quickly, and quite possibly, may not be diffused on a wide scale.

The struggle is great but practitioners in the field continue to utilize innovative messages and platforms to ensure that potentially life changing innovations are diffused quickly and equitably. The Director of the CDC's National Center for AIDS and other Sexually Transmitted Diseases, Dr. Jonathan Mermin, stated that "on average, it takes a decade for a scientific breakthrough to be adopted." Speaking directly to pre-exposure prophylaxis (PrEP) as a new drug to prevent HIV, Dr. Mermin further expressed the institution's "hope that [they] can shorten that time frame and increase survival" of people at substantial risk of getting HIV by optimal use of PrEP (McNeil, 2014).

Diffusion of Innovations

Diffusion of Innovations provides a theoretical framework for understanding the process of dissemination of new ideas such as PrEP and the rate of adoption in a social system such as the U.S. The theory identifies a number of factors that influence the diffusion of a new idea or practice. The proposed study draws on Diffusion of Innovations theoretical framework to understand reasons Black women accept (adopt) or reject PrEP.

Although depicted as a paradigm based on five variables that determine rate of adoption, the current study uses only one variable, the perceived attributes of innovation variable described below in Figure 2 (Rogers, 2003).

Rogers's five perceived attributes of innovations. Rogers (2003) defines five attributes of innovation that will be reviewed for the proposed study: relative advantage, compatibility, complexity, trialability, and observability

(Figure 2). Although these characteristics are interrelated, Rogers (1983) notes that they are distinct and contribute differently to the perception of the innovation and rate of adoption.

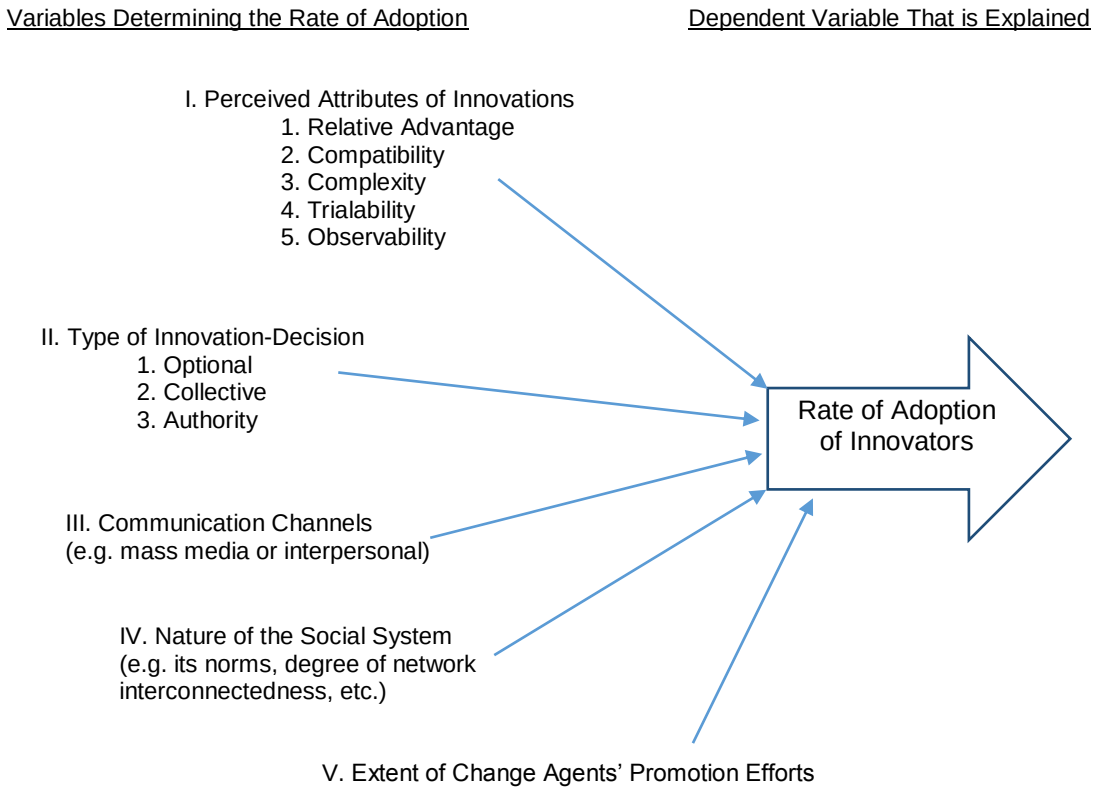

Figure 2. A Paradigm of Variables Determining the Rate of Adoption of Innovation. Source: Adapted from E. M. Rogers (2003). *Diffusion of Innovations* (5th ed., p. 222). New York: Free Press.

Relative advantage is defined as the "degree to which an innovation is perceived as being better than the idea it supersedes" (Rogers, 2003, p. 229). Favorable adoption of an innovation is dependent on the motivation of gain to the individual. Gain can be quantified as having either a monetary value, or, equally or more valuable, an intangible value such as carrying conscience value, or a social status value or a combination of values. Undoubtedly, all four characteristics of innovation play an integral role in the rate of the innovation's

adoption, however, “scholars have found relative advantage to be one of the best predictors of an innovation’s rate of adoption” (p. 217).

Rogers (2003) makes a critical observation about slow rate of adoption among preventive innovations; that preventive innovations are slow to show the immediate benefit of using the innovation, and although addressing the precautions of “unwanted future event” (p. 235) these outcomes are harder to imagine and be valued by the community. Perhaps with significance to the PrEP study, Rogers highlighted two levels of challenges HIV/AIDS and preventive innovations face. First, although adopting the activity, for example “safe sex” may prevent HIV in the future, the person might not get HIV even though they did not practice safe sex. Second, there is difficulty for the individual to perceive the actual occurrence or occurrences when they have prevented the unwanted outcome from happening. According to Rogers, preventing HIV is both “invisible and unobservable,” making the innovation “difficult or impossible to comprehend” (p. 234). The beneficial consequences of PrEP as a preventive innovation may be even harder to diffuse among people at risk of HIV resulting in a slower rate of adoption, as evidenced in the literature by the slower than expected uptake in PrEP across the United States.

The use of incentives to increase rate of adoption has been a strategy used to counter the challenges associated with adoption of preventive innovations. Rogers (2003) illustrates five types of incentives, noting that more research has been done on family planning incentive programs and policies than any other incentive program. Although in the literature no incentive programs were noted among PrEP studies, the New York State PrEP-AP and the Gilead Sciences co-pay programs might be considered system-level variations of incentive programs; drawing on innovations that Rogers (2003) considers are in the best interest of the society, such as fines for not using seat belts.

Compatibility is defined by Rogers (2003) as the “degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential adopters” (p. 240). Therefore, an innovation that is more compatible is also less uncertain and aligns closer to the adopters’ thoughts, ideas, values and beliefs (Rogers, 2003). One striking concept that is introduced by Rogers is leveraging familiarity with new innovations based on decisions and ideas made in the past. Rogers contends that measuring an innovation against the familiarity of past actions (old idea) decreases the uncertainty attributed to the innovation (new idea), thus making the innovation compatible. Although need is an important aspect of compatibility, Rogers cautions change agents against pushing “need” for the innovation among people who initially did consider the innovation, noting that “the felt needs upon which diffusion campaigns are based may be only a reflection of the change agent’s needs, rather than those of his clients” (p. 246). It is therefore important for people to realize their innate “need” for the innovation, as Rogers illustrates that “one dimension of compatibility is the degree to which an innovation is perceived as meeting the needs of the client system,” resulting in a “faster rate of adoption” (p. 246).

Practitioners in the field of HIV prevention, by Rogers's (2003) description, work within the realm of compatibility. Drawing on tools such as motivational interviewing, highlighting discrepancies in goals and behaviors, allows practitioners to introduce new innovations such as PrEP to clients who might be unaware of PrEP as a prevention tool. Importantly, presenting evidence showing where PrEP as an innovation can present benefits, debunking myths and working through potential challenges with clients to formulate a tailored prevention plan that meets their immediate needs, should lead to faster rates of adoption (Rogers, 2003).

Complexity, according to Rogers (2003), is measured on a "complexity-simplicity continuum" (p. 257), where complexity "is the degree to which an innovation is perceived as relatively difficult to understand and use" (p. 257). Research supports a positive correlation between difficult-to-understand innovations and low rate of adoption. Innovation at its core, should be simple to understand for the potential adopters of the innovation, and inversely, the more complex the innovation the lower the rate of adoption. Rogers presents this attribute lower on the totem pole than relative advantage and compatibility as attributes of innovations. The value of presenting non-complex tools for the general population to understand preventive innovation has been supported in the literature (Rogers, 2003).

Although complexity in use and understanding have been evidenced in the literature, a broader meaning of complexity in relation to PrEP might also be considered in reviewing HIV prevention research, which is the issue of access to the innovation. If for example the medication is difficult to obtain because there are fewer providers aware of the preventive method (indicated by previous research) in addition to uncertainty of insurance coverage and high cost layering the maze, then complexity captures much broader socio-economic implications impacting HIV prevention and the demand for PrEP.

Trialability, as defined by Rogers (2003), is the "degree to which an innovation may be experimented with on a limited basis" (p. 258). Although the main element of trialability is divisibility and the ability of the innovation to be tried in installments or on a "limited basis," Rogers concedes that there is not strong evidence to suggest trialability is "positively related to its rate of adoption" (p. 258).

Published studies have found that people who started PrEP in the first month did not necessarily remain on PrEP in the third month (Blackstock et al.,

2017). Such data signify the trial use of PrEP to determine the “best fit” situations and to test whether the prevention method is actually suited for the individual’s lifestyle. Interestingly, studies also show that prescription scripts were written but the medication was never picked up. Rogers and Shoemaker (1971) refer to this as psychological trial. An interesting concept that appears to describe the issue of non-medication pick-up for prescriptions issued to individuals (Blackstock et al., 2017) who initially thought they were ready to adopt PrEP.

Observability is similar to relative advantage and is also a “characteristic of preventive innovations that slows their rate of adoption” (Rogers, 1983, p. 218). According to Rogers (2003), observability is the “degree to which the results of an innovation are visible to others” (p. 258), suggesting that innovations that are not easily observed or “difficult to describe” result in slower rates of adoption.

Perceived attributes of observability have been widely studied in the technology field. The observable innovation of mobile telephones has ballooned into a rapid and arguably insatiable market of adopters. As previously stated, HIV prevention is difficult to observe and perhaps that has resulted in the rapid twinning of HIV prevention messages and the mobile technology. The leveraging of social media and PrEP messages is increasingly becoming normalized with growing number of PrEP studies focusing on social media and social networks.

Grounded Theory

According to the fathers of Grounded Theory, Glaser and Strauss (1967), deriving “theory from data” instinctively resonates with both sociologist and layman (p. 1). These eminent authors advocate that Grounded Theory, which is the iterative and systematic process of discovering theory from data, is important in providing “us with relevant predictions, explanations, interpretations and applications” (p. 1). Glaser and Strauss are quick to differentiate their inductive

qualitative analysis, in which theory is derived from data that are “systematically obtained from social research”, from “theory generated by logical deduction from a priori assumptions” (pp. 2-3).

In this study, utilizing Grounded Theory was an intensive process. Every effort was made by the Researcher to represent clearly the voice of the respondents of the study, which was not to be confused with the Researcher’s own voice, beliefs and perceptions of what the results showed. Grounded Theory helped to reduce bias and accentuate the volume of the 72 Black women interviewed in the study.

Although Grounded Theory provided a more objective method of seeing the data through the perspective of the respondents by creating dozens of useful categories for analysis, the Researcher opted to use the educational diagnosis phase of the PRECEDE planning framework through which to present the results of the analysis. The Researcher realized that moving from an inductive approach back to a deductive and more structured approach has the potential of missing categories that are expected in a structured approach. The Researcher was mindful of this potential limitation and predetermined to indicate in the presentation of results categories that did not fit in the predefined PRECEDE planning framework categories of predisposing factors, enabling and reinforcing factors.

PRECEDE Planning Framework

The predisposing, reinforcing, and enabling causes in educational diagnosis and evaluation, generally known as the PRECEDE planning framework, were useful in presenting the data from the fieldwork associated with this current study on PrEP and Black women. The planning framework provided

a practical way that reflected the aims of the study to describe the motivations, enabling factors and social support relevant to PrEP use among Black women.

One striking utility of the PRECEDE framework is that it “makes it possible to sort the determinants of behavior change that are most responsive to health education into categories convenient for planning” (Green et al., 1980, p. 70). Based on common findings from literature and theories, the authors have identified three categories of factors that act as determinants of behavior change. These three categories will be discussed in the ensuing paragraphs.

PRECEDE is a deductive, intervention-based framework that has been adopted by a number of local, city, state, national and international settings and used in planning rigorous health education programs (Green et al., 1980, p. 11). As noted by Green et al., the applicability of the model addresses a critical gap in health education, which is disjointed planning and, through the framework, presents a comprehensive pathway to planning and evaluation of public health education programs in diverse settings and situations (p. 11).

The PRECEDE framework works from the premise that diagnosis of the health problem must precede the development of an intervention. In a similar way that a medical diagnosis precedes a treatment plan, an educational diagnosis should precede an intervention plan (Green et al., 1980). Importantly, interventions are only created when the factors have been identified and a logic plan developed to address the health problem and achieve the outcome. According to Green et al., an intervention that is developed prior to diagnosing an outcome “will be based on guesswork and runs the risk of being misdirected and ineffective” (p. 12).

Based on the PRECEDE framework, Green et al. (1980) outlined seven phases to the PRECEDE framework. The phases continue the idea of starting with the health concern or problem and working backwards through the

contributing factors to designing the actual health education intervention. The phases are described as Phase 1—social diagnosis: an important step to "consider carefully social outcomes or quality of life concerns before plunging into the intricacies of methodology" (p. 19); Phase 2—epidemiological diagnosis: "identification of the health problems associated with an unsatisfactory quality of life" (p. 35); Phase 3—behavioral diagnosis: "systematic identification of health practices that appear to be causally linked to the health problem or problems identified in the epidemiological diagnosis" (p. 52); Phase 4—educational diagnosis: "the behaviors identified as linked to the health problem or problems of greatest concern in a population are differentiated according to what causes them" (p. 68); Phase 5—selection of educational strategies: "planning of the health education strategy most suitable for community based on the foregoing phases" (p. 86); Phase 6—administrative diagnosis: the "administrative considerations including budget and analysis of the factors that will determine the ease with which the program is introduced into a system" (p. 116); and Phase 7—evaluation and the accountable practitioner: the accountable health educator "cultivates an attitude toward professional practice which ensures that every new population or patient is approached diagnostically and that every program is developed as an experiment" (p. 132).

Our primary interest in the PRECEDE planning framework is understanding Phase 4—educational diagnosis for later application in the results section. The following aspects of Phase 4 will be reviewed: the three categories of factors impacting health behavior—predisposing factors, enabling factors, and reinforcing factors. Additionally, using Green et al. (1980), two additional steps will be used in specifying and selecting factors to discuss in the results section. The first step is identifying and sorting factors, and the second step is setting priorities among the categories for discussion (p. 77).

Predisposing factors, according to Green et al. (1980), “relate to the motivation of an individual or group to act” (p. 70). The authors suggest that predisposing factors can be thought of “as the ‘personal’ preferences that an individual or group brings to an educational experience” (p. 70). Comparable words that reflect “personal” preferences include “knowledge, attitudes, beliefs, values and perceptions,” which are collectively influential and may “either support or inhibit health behavior” (p. 70).

Enabling factors, according to Green et al. (1980), are “the skills and resources necessary to perform a health behavior,” further explaining skills in the individual context as “a person’s ability to perform the tasks that constitute the desirable behavior” (p. 75). Referring to a practical application of individual skills in HIV prevention is the ability to properly open a condom packet and putting on a condom based on the nuanced criteria. According to the authors, “failure to consider the impact of enabling factors on the achievement of behavioral goals can lead to serious practical problems” (p. 75).

Reinforcing factors “are those that determine whether health actions are supported” (Green et al., 1980, p. 76). Of noteworthy mention is the changing source of reinforcement based on the health education program. According to Green et al., the “source of reinforcement will … vary depending on the objectives and type of program,” for example, “in patient education settings, reinforcement may come from nurses, physicians, fellow patients, and again the family” (p. 76). As health educators, it is especially important to understand the group of people who have the most influence. Possible solutions lie in research and in the assessment previously conducted using the PRECEDE framework. Nevertheless, Green et al. shift the burden onto the planners by saying the “program planner must carefully assess reinforcing factors to make sure that

program participants have maximum opportunities for supportive feedback during behavior change process" (p. 76).

Identifying and sorting—formal methods—the importance of accounting for all pieces of data cannot be overstated. In reviewing data, the "list of factors generated for each behavior should be as comprehensive as possible" (Green & Kreuter, 1989, p. 77). In this way, Green et al. (1980) emphasized this principle that the "planner may be able to avoid overlooking a crucial item, a pitfall when his or her attention is diverted by each item as it is listed" (p. 77). The formal method for developing this list representing a "search through the relevant literature can yield information on cultural and social attitudes and descriptions of studies defining specific factors on health-related behaviors" (p. 78). The list might "show both positive and negative factors" relating to the health problem in question (p. 78).

While it is important to categorize factors to their correct classification, the authors acknowledge the cross-cutting relationship between factors. According to Green and Kreuter (1999):

> The three categories (predisposing, enabling or reinforcing) are not mutually exclusive; a factor can appropriately be placed in more than one column. A family may be predisposed to dieting, for example, and reinforce (negatively or positively) that behavior once it has been undertaken. (p. 78)

In setting priorities among categories, according to the authors, "there is no way that all causes in a complex inventory for several behaviors can be tackled simultaneously" and therefore the need to decide on which "factors are to be attached first and in what order are therefore important" (Green et al., 1980, p. 78). One suggestion offered by Green et al. is that "establishing priorities among the three kinds of factors is developmental" (p. 78). The premise is that "people will not adopt a set of behaviors to reduce a health risk if they are not

aware that there is a risk." Therefore, the "belief in the immediacy of the risk and its implications will have to be developed before attention is given to ways to reduce the risk" (pp. 78-80).

Chapter III

METHODS

Study Design

The study utilized a cross-sectional survey design. The research aims focused on improving understanding about the views of Black women who self-report being HIV-negative and were seeking HIV and/or STI screening at a Federally Qualified Health Center in Brooklyn, New York. As a precursor to the main study, a pilot study was conducted with two primary aims. The first was to test the adequacy of the interview instrument and enable the Researcher to practice conducting the interview and obtaining informed consent. The second focused on the logistics of the recruitment to determine effective ways to recruit women to the larger study.

Pilot Study

After obtaining approval from the Teachers College Institutional Review Board, 34 women were contacted for a pilot test. Between August and September 2017, 10 Black women completed the pilot interviews. The recruitment strategy utilized during the pilot was leveraging the calls made by nursing staff to patients. Recruitment of the women involved contacting women, in-person and by telephone, who had recent HIV or STI screens and who were recently contacted by the nursing staff for follow-up appointments. The women

who were contacted were interested in the study and expressed willingness to participate; many, however, faced time constraints, which precluded their participation. Although no incentives were provided during the pilot, 10 women were willing and able to complete the pilot study.

Aim 1: Adequacy of the Interview Instrument

Annexed to the interview was a brief 4-question pilot questionnaire (Appendix A). Through the pilot questions, participants were presented with a clear message that their feedback was critical in reframing, changing, and informing the inclusion of new questions for the larger study. A sample of the responses is presented in the table below. Consequently, as a result of the pilot, the flow of the instrument was rearranged to first address awareness and acceptability of PrEP, with less intensity on risk behaviors, although the latter were also important to the study.

Participants were asked to critically comment on each question. They were asked to identify any questions that were difficult to understand, ambiguous, or uncomfortable to discuss; needless to say, this process was reflective of participants' perspectives. As seen from the table below, tangible suggestions and comments were provided.

Based on the pilot, changes were made to the main questionnaire. Question 2 was revised to now read, "Consider your beliefs about HIV prevention, does PrEP align positively or negatively with those beliefs?" Although question 5 remained relatively unchanged, its placement of the question was changed. The Researcher addressed the concerns by consciously adjusting expression and tone when asking the question. Importantly, this shifted the flow, wording, phrasing, and length (shorter rather than longer compounding questions) of most questions. As an outcome, the updated interview schedule

was based on an informed and iterative process that attempted to capture the constructs of Diffusion of Innovations Theory framed in the context for women as the intended participants.

Table 1. Pilot Study Feedback about Interview Questions

Pilot Questions	Pilot Questionnaire Category	Comment/Suggestion
Based on what you have heard about PrEP (prior to this interview and during this interview), what are your initial thoughts/belief about PrEP as a method to prevent HIV? Based on your initial thoughts/belief, does PrEP aligns with something positive or negative? Can you explain further giving examples of both, if possible?	Question could have been clearer.	Question could have been clearer. Unpack the question, and make the question simpler.
Have you ever used injection drugs in the past 12 months?	Question was uncomfortable to answer.	Question was uncomfortable to answer. Felt to be too personal.
	Additional questions that could be asked.	1. Was expecting more personal questions. 2. How would you perceive taking PrEP would affect your partner? 3. Would your partner be alarmed that you are taking an HIV medication? 4. Do you know if your partner has sex with other partners? 5. Do you think the drug is a good thing? 6. Is the drug relevant to you? 7. Give more information on the reliability of the drug compared to condoms. 8. How would your partner react if you were on PrEP? 9. How would guys feel about women taking PrEP? 10. Would you share/speak to your partner about PrEP?

A striking finding from the pilot study, and a perspective initially left out of the pilot questions, was that of the partner's perspective. The feedback from respondents was overwhelming support to include questions on partner practices, perspectives, and the influence of partners on the perception of women taking PrEP. This is correctly grounded in the diffusion of innovation theory as the relative advantage and impact of PrEP on social relations. Apparently, there is likely an association between women taking PrEP and their partners' practices and perspectives in the use of PrEP. Additional questions on partner and peer reactions to the use of PrEP were included in the revised instrument.

Conducting a face-to-face interview on the topic of HIV and sexual practices is challenging and requires great sensitivity. Although the HIV epidemic is over 30 years old, stigma persists. The recruitment strategy utilized during the pilot was leveraging the calls made by nursing staff to patients. Nursing staff communicated about the study to patients who had a recent STI and/or HIV test, indicating that the Researcher would follow up with additional information, if the patient had no objections. The Researcher utilized a short list of 34 names of patients who received a follow up telephone call by nursing staff. The Researcher spoke to patients broadly about the interview, however, where participants wanted to know more about the type of biomedical medication to be discussed, additional fact-based responses were provided. It was easier to arrange interviews with women who were already in the Health Center or who had an imminent appointment. Nevertheless, approximately half of the participants came to the Health Center only for the interviews. A lesson learned for the larger study was the importance of an incentive. For the main study, a $20 gift card was provided to women completing the interview.

Study Setting

The study setting was a Federally Qualified Health Center (FQHC), which is a private, not-for-profit community health center, located in Brooklyn, New York. It serves as a safety net facility. The Center provides a wide range of high quality healthcare services, including primary care, obstetric and gynecological services, as well as other specialty services such as STI screening and free HIV rapid testing. The Center is well situated to serve a community of over 154,000 residents comprising 64% Black, 20% Hispanic, 11% White, and 2% Asian residents (Community Health Profile, 2015, p. 2). According to the NYC Department of Health's Community Health Profile 2015, one in three residents lives below the federal poverty level, and of the 59 community districts in New York City, this one is cited as the among the 10 poorest neighborhoods in the City (Community Health Profile, 2015, p. 6). Using income and death rates across the City, the New York City Department of Health and Mental Hygiene concluded that 49% of deaths could be averted if the community achieved death rates similar to the five most affluent neighborhoods.

According to information obtained from the Uniform Data Systems from the Health Resources and Services Administration (HRSA), in 2017, the FQHC served over 15,621 people, of which 85.9% were Black/African American (UDS, 2017). Although the data do not provide information on HIV prevalence by gender, the FQHC reports a HIV prevalence rate of 1.7% of the total patient population. The FQHC uninsured rate is approximately 16.1% (UDS, 2017), signifying that approximately 2,515 persons who obtained services at the setting indicated that they did not have insurance at the time of the medical visit. Enveloped in a high poverty, high health burden community, this FQHC providing services to central Brooklyn residents regardless of the ability to pay is an

integral and relevant health provider addressing health disparities within the community. Leveraging such facilities to conduct research captures real-world experiences but also provides practical avenues for reducing the striking health disparities.

Target Population Eligibility

In keeping with CDC recommended guidelines for screening heterosexual women for PrEP (CDC, 2014a), five questions were included (see below). Although these questions are broad and generic in determining “substantial” risk for HIV, they provide a benchmark to help in screening and identifying women for PrEP services.

The recommended questionnaire used to screen heterosexual women for PrEP asks, in the past 6 months:

- *Have you had sex with men, women, or both?*
- *(if opposite sex or both sexes) How many men/women have you had sex with?*
- *How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?*
- *How many of your sex partners were HIV-positive?*
- *(if any positive) With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?*

Additionally, the recommended Indications for PrEP Use by Heterosexually Active Men and Women (CDC, 2014a, p. 29) include:

- *Adult person*
- *Without acute or established HIV infection*
- *Any sex with opposite sex partners in past 6 months*

- *Not in a monogamous partnership with a recently tested HIV-negative partner*

AND at least one of the following:

- *Is a man who has sex with both women and men (behaviorally bisexual)*
- *Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)*
- *Is in an ongoing sexual relationship with an HIV-positive partner.*

For the purposes of the current study, the Researcher used STI and HIV screens as proxy indicators to indicate "substantial risk" for HIV. Both STI and HIV screens were included as determining eligibility for the current study. Eligibility for the current study included women self-identifying as Black/African American aged 18 years and older with a recent self-reported HIV and/or STI test during the data collection period from November 2017 to January 2018. Women who met these criteria were invited to participate in the study.

Inclusion/Exclusion Criteria

The following inclusion criteria were used to determine eligibility, broadly based on the CDC guidelines (CDC, 2014a):

1. At least 18 years old.
2. Self-report HIV status as negative.
3. Willingness to provide informed consent to participate in the study.

   And
4. Self-report having anal or vaginal sex within the past 6 months.

   Or
5. Have had a STI or HIV screen in the past 6 months

   Or
6. Had a STI in the past 6 months.

The exclusion criteria included:

7. Previous participation in the pilot study
8. Inability to speak English
9. HIV-positive diagnosis by self-report.
10. Women of trans experience were not included in the current study.

Delimitations of the Study

The study was delimited to examining factors of initial PrEP use and did not address maintenance of PrEP medication. Focusing on adoption is a meaningful first step in increasing rates of PrEP use by women at “substantial risk” for HIV infection. The sampling strategy is delimited in scope to one locality in Brooklyn and to women attending the participating Health Center.

Another delimitation is that the study focused on limited questions, which were based on the Diffusion of Innovation Theory but also collected information that research has shown can facilitate PrEP uptake. These aspects of the study can also be seen as strengths. Little research has been conducted among women about this topic and using an existing theoretical framework, which has been widely used, may help uncover aspects of the PrEP innovation that are more and less acceptable to the African American women at risk for HIV infection.

Another delimitation is that all of the data were collected and analyzed by a single Researcher. While the results will clearly not be generalizable to a larger reference population, the study is considered a meaningful first step in a longer-term research agenda relevant to PrEP uptake.

Sampling and Recruitment

The sample design utilized one setting in which to recruit Black women for the current study. The setting was within a FQHC in Brooklyn. The use of the electronic medical record was not utilized; as this would have required additional permission from patients. Recruitment was focused on women who were present at the setting or who were contacted, as described in further detail in the recruitment strategies. Purposive sampling was used to recruit Black heterosexual and bisexual women who were at risk of HIV infection. Prior to implementing the recruitment strategy, staff of the FQHC were informed about the study, its purpose, eligibility criteria and the approximate time commitment required for the interviews. The Researcher sought assistance from the staff in recruiting women for this current study. Having approached staff for assistance in promoting the current study, there were clarification questions asked by staff, which were answered. To aid staff in the familiarity of the current study, the Researcher developed a frequently asked question (FAQ) sheet that assisted with answering questions about the study. The FAQ sheet (see Appendix B) guided the information shared with staff at the Health Center and was also provided to staff who were asked to refer clients for interview in the study.

Prior to implementing the study, it was important for the Researcher to discuss study parameters with senior leaders of the agency. The Researcher had support from the President/ CEO to conduct the study (see Appendix C). This permission afforded the Researcher the opportunity to have open discussions with staff, the aim of which was to raise awareness about the study purpose and timelines and to solicit assistance in recruiting participants. These initial steps were found to be most important in creating a shared understanding about the study and gaining initial buy-in before beginning recruitment.

The recruitment strategies initially proposed for the study changed during the on-site recruitment. One of the proposed recruitment strategies that produced no result was leveraging the Health Educators as a referral source for prospective participants who they counseled for having a positive STI. This strategy did not yield participants. Health education sessions were primarily unscheduled and varied based on when the patient had their follow-up visit, most of which were walk-in visits, and the times of the sessions were impromptu and took place when the Researcher was not available.

Another recruitment strategy was posting flyers in clinical areas, medical rooms and on noticeboards (see Appendix D). The benefits from this strategy were unexpected. The Researcher expected that it was the nursing staff that would respond most to the flyers in the clinical areas, but the result was that it was the medical providers who referred patients to the study. The providers indicated that the colorful flyers posted on their computer work-station reminded them of the study. This approach resulted in approximately 10 women completing interviews.

Another strategy that resulted in recruitment was personal invitations by the Researcher. The Researcher followed up with clinic staff to obtain names of patients who had expressed interest in the study. Approximately 55% of the women who received a telephone call or in person invitation from the Researcher scheduled and showed up for the interview. This strategy resulted in the recruitment and successful completion of 21 interviews.

The strategy that surpassed expectations but which, notably, was not a strategy initially proposed was the support of a champion medical provider for the study. After briefing the nursing staff, the Researcher went door-to-door and spoke to every medical provider about the study. As mentioned, a few participants were referred to the study through this strategy. However, one

medical provider invited the Researcher to work alongside the provider on Thursdays and Sundays. During these times, every patient that the provider saw who met the criteria for the study was referred to the Researcher, who assessed the woman's interest and eligibility. This was an unexpected welcomed opportunity. To meet the workflow of the provider, the Researcher worked at the pace of the clinic to interview participants. To maintain pace with the clinic flow, the Researcher completed the interviews in approximately 40 minutes, which spanned the time the patient spent with the provider and completed blood-draw for their laboratory tests. The refusal rate was low, about 10%. Forty-one (41) or 57% of interviews completed were as a result of this strategy.

Almost half of the women who scheduled interviews did not show up for the interviews. Reasons that were later obtained by the Researcher included that they simply forgot, had a competing obligation such as work commitments or that they no longer had the time to meet. To facilitate participation, the Researcher conducted interviews on Saturdays and Sundays as well as during the weekdays. Another lesson learned was that women were more likely to accept the invitation to be interviewed while they were visiting the clinic than they were to schedule a time to come back to the clinic for the interview.

Selected characteristics of the study participants are shown in Table 2. More that 40% indicated that they were single, while almost 1 in 5 were reportedly married and slightly more than 1 in 10 were living with a partner. One-third were under 30 and just over 40% were 50 and older. The mean age of participants was 41 years (SD = 15.430). The majority had completed high school or earned a GED, while approximately 30% had completed at least a 2-year college or higher. Three respondents reported earning more than $3,500 per month, and almost 40% reported earning less than $1,500 per month.

Table 2. Selected Characteristics of Study Participants

	Frequency	Percent
Race/Ethnicity		
Black/African American	63	87.5
Mixed	9	12.5
Current relationship status		
Married	14	19.4
Separated	3	4.2
Divorced	3	4.2
Widowed	4	5.6
Living with partner	8	11.1
Committed relationship	7	9.7
Single	31	43.1
Not sure	2	2.8
Age		
18-29	24	33.3
30-49	19	26.4
50+	29	40.3
Educational Attainment		
Less than high school	8	11.1
High school/GED	44	61.1
2 year college	7	9.7
4 year college	8	11.1
Master's degree and higher	5	6.9
Monthly Income		
Refused to report	1	1.4
Less than $1500	27	37.5
$1501 -$2500	25	34.7
$2501 -$3500	16	22.2
More than $3500	3	4.2

Informed Consent

There was double consent from participants. This was based on whether the participant was referred by a staff member or recruited directly by the Researcher. If staff referred participants to the survey, staff would obtain verbal consent from the participant to either contact the Researcher with the participant's information or to link directly to the Researcher. Additionally, the Researcher also obtained verbal consent from women to confirm their interest in participating in the study. The second step involved explained the study to

prospective participants and each participant completing a signed consent. Signed consent was a criterion for participating in the study (see Appendix E) and all signed forms were kept secured in a locked file. Signed consent was mandated as a condition by the IRB, and all consent forms bore the IRB approval stamp (see Appendix F).

The Researcher arranged to meet eligible participants in private medical rooms in the Health Center, which helped ensure that interviews were conducted in a completely private setting. Trust and safety are realities that the Researcher strongly supported when working with all participants. As cited in Morse and Field (1995), a trusting relationship with the interviewer begins with participants feeling comfortable in their setting.

Measurements

Although the current study drew from three theoretical frameworks, the development of the survey instrument centered on the characteristics of PrEP as an innovation, found in the Diffusion of Innovation Theory. This theoretical framework was used for improving understanding about PrEP as a new biomedical intervention. Particular emphasis was given to open-ended questions that were developed based on five characteristics of an innovation: (1) Relative advantage, (2) Compatibility, (3) Complexity, (4) Trialability, and (5) Observability.

Relative advantage is the extent to which the innovation has advantages over current practice. Compatibility is the extent to which an innovation is compatible with the culture and values of the intended users. Complexity relates to how complicated it is to use an innovation, which in this case would mean taking one pill once daily. Trialability is the degree to which an innovation can be

tried on a limited basis without much consequence. Observability is defined as how easy it is for prospective users to observe others using an innovation or their ability to relate to the use of the innovation based on their social environment.

The interview instrument (see Appendix G) was purposely designed to have as its central focus the awareness, barriers, influences, opinions, and acceptability of PrEP as an innovation among women. Secondly, standardized closed-ended questions were used to describe the demographic, social and risk behaviors of the study sample. The instrument comprises three sections: PrEP awareness and acceptability, demographic information, and individual risk history.

PrEP Awareness and Acceptability

Thirteen open-ended questions comprised the first section of the instrument. Using Rogers's (2003) Diffusion of Innovations Theory, questions in the interview schedule were grouped under Rogers's five attributes of innovation outlined above. PrEP awareness and acceptability questions explored issues of awareness, by the participant, family and friends; the role of social media; awareness of PrEP subway campaigns; and also the participant's previous knowledge about PrEP as a prevention method. Issues of risk perception were explored to understand what risk meant in the context of women and HIV. Questions about partners and peer reactions to PrEP and how those reactions would influence women's decision to use PrEP were asked to determine social factors that inform PrEP use. This section also included items that asked participants to advise providers on key information women need and should know about PrEP. All questions had a range of follow-up and probing questions that anticipated the respondent's positive or negative answers. Overall, these open-ended questions were intended to encourage the participants to share

opinions, feelings, experiences, stories and information about their social world as they considered PrEP as an innovation.

In the second section of the interview, participants were asked to respond to demographic questions. Eleven closed-ended questions with two or more numbered responses were included in this section and covered eligibility, gender, race/ethnicity reason for clinic visit (these three questions were also initially asked when participants' expressed interest to participate), sex partner(s), residence, relationship status, age educational attainment, income, housing situation, and insurance status.

The third section had ten closed-ended questions covering the participant's risk history. Questions with a "yes" or "no" response format focused on condomless sex, multiple partners, knowledge of family and friend HIV diagnosis, injection drug use history, non-injection drug use history, and knowledge of partner's HIV status. Four questions with multiple responses included frequency of condom use, history of STIs, HIV testing history, HIV risk perception.

The interviews were intended to describe lessons that could be learned by HIV prevention practitioners and health care networks to scale-up PrEP use among this population of women who are vulnerable to HIV infection. Prior research by Auerbach et al. (2015) and Whiteside et al. (2011) was utilized in the development of the interview schedule. The Auerbach et al. (2015) study sought to investigate PrEP's acceptability and feasibility among women at risk for HIV in the US and involved conducting 11 focus groups with 144 women across six U.S. cities. Auerbach shared their demographic questionnaire and focus-group questions. Both contributed to the development of the present study's interview schedule. Equally useful was Whiteside et al.'s (2011) work in determining risk perception for HIV infection and attitudes about PrEP among STD clinic attendees. Whiteside shared two questionnaires, which were helpful in

developing the demographic and risk assessment questions. Letters from these colleagues granting permission to adapt their measures are included in Appendix H.

Data Collection

All data were collected by the Researcher on-site at the Health Center during December 2017 and January 2018. As mentioned above, prior to participation, all participants completed a signed consent. After consent, they introduced brief but casual conversations at the beginning of each interview to help participants feel comfortable before asking direct questions. A description of pre-exposure prophylaxis (PrEP) was provided to all participants to introduce the topic and to start the interview. As defined in the Introduction section, the Researcher presented the concept of PrEP as a “single pill taken once daily that can reduce the risk of sexually transmitted HIV infection by up to 92 percent” (CDC, 2014a). Asking of the in-depth questions, and thereafter, the closed-ended questions regarding personal characteristics and risk behaviors, followed the introduction.

All interviews were audio-recorded. The use of an audio recorder was an important tool for capturing detailed verbatim responses by each participant. All audiotapes were transcribed, and narratives kept in a locked cabinet. The transcripts represent the raw data that were used for analysis. The study accommodated and upheld the participants’ right to stop the interview tape at any time either to share experiences off tape or to end the taping of the interview. During the interviews, no participant exercised their right to stop the interview.

Most women did not exhibit reservations in sharing stories or situations on audiotape. Generally, the Researcher found a generous level of willingness to

share experiences regardless of the audiotape. There were quite a few instances where participants issued apologies after realizing the depth of their stories, believing they had strayed from the question. Although the technique of redirecting was used, the Researcher did exercise discretion and generously gave women time and a safe space in which to share stories as this quite fittingly providing unfiltered views in responding to the interview questions.

After the audio interviews were professionally transcribed, random checks were conducted by the Researcher to help ensure completeness and accuracy in the transcription. Accuracy checks were conducted for over 40 interviews during the process of coding. Audiotapes were listened to and compared against the transcriptions before the Researcher coded the transcribed interviews.

Coding, Data Analysis, and Synthesis

Although Rogers's Diffusion of Innovation Theory was used as a guide in conceptualizing the interview questions, the coding and analysis relied on both an inductive and deductive approach. The inductive approach was Grounded Theory, and the deductive approach was the PRECEDE Framework. Grounded Theory was used in an attempt to identify ideas from the women's voices. PRECEDE was used to help ensure that the results would be useful for planning future health education programs.

Three Grounded Theory tools were used: line-by-line coding, focused coding, and memo writing. Line-by-line coding involved writing the description of each line of each transcribed interview. According to Charmaz (1996), line-by-line coding "helps you to refrain from imputing your motives, fears or unresolved personal issues to your respondents and to your collected data" (p. 37). It is intended to reflect as accurately as possible description of the actions, emotions,

and events for each line spoken by the respondents. Another consequence of line-by-line coding that was found by the Researcher was the increased acquisition of knowledge gained from the coding exercise. Unquestionably, “line-by-line coding keeps you close to your data” through which, “you begin to build your analysis, from the ground up without taking off on theoretical flights of fancy” (p. 37). Needless-to-say, line-by-line coding was an intense activity and quite burdensome when coding hundreds of transcribed pages.

After several repetitive codes were emerging from the coding process, the Researcher switched to from line-by-line coding to focus coding, which captured several lines of responses using earlier categories and when necessary creating new categories of codes. Charmaz (1996) describes focused coding as “taking earlier codes that continually reappear in your initial coding and using these codes to sift through large amounts of data” (p. 40).

Memo-writing is recognized as a type of coding, but it is also a bridge to the pre-analysis phase of the study. During the coding process, several observations and questions emerged that were written in memo format for later elaboration in the results and discussion section of the study. The Researcher found that for memo-writing to be effective, a deliberate attempt to question ideas in transcripts as they are being coded was necessary. As articulated by Charmaz (1996), memo-writing is the “intermediate step between coding and the first draft of your completed analysis” (p. 42). It is considered significant in helping to “elaborate processes, assumptions and actions that are subsumed under your code” (p. 43).

After all the transcriptions were coded and all memos were collated, the Precede Planning Framework was selected as a way to synthesize the information. The Framework’s educational diagnosis and evaluation phase has three categories of factors impacting health behavior (which in this case was PrEP use): predisposing, reinforcing, and enabling (described in Chapter II). All

codes were placed in a table format under the respective factors. During this process, the Researcher was mindful to include any coding exception in the synthesis, even if codes did not fit into the three factors impacting behaviors.

Although this study was primarily qualitative, the close-ended responses were entered into SPSS Statistics for Windows (Version 24.0), and descriptive statistics, including means, standard deviations, frequencies, and percentages, were calculated to describe the study sample.

Credibility of the Research

Two areas of credibility are considered important in this current study, trustworthiness and validity. Yin (2016) describes a credible qualitative study as one that "provides assurance that you have properly collected and interpreted the data, so that the findings and conclusions accurately reflect and represent the world that was studied" (p. 85). Conducting the pilot study prior to the larger study built consistency and addressed phrasing of interview questions, ambiguity, sensitivity to cultural and social constructions around sex, and included perspectives from the population that were repeatedly mentioned as influencing and reflective of their reality. This approach aligns with Yin's definition of how to strengthen credibility "choices during the design of your study" (p. 86). The pilot study addressed this issue before beginning the larger study.

Trustworthiness

According to Yin (2016), creating trustworthiness in qualitative research begins with framing the researcher's "attitude throughout your research and during your design work, and not necessarily by employing any specific procedures" (p. 86). The field of HIV prevention is an area of passion for the

Researcher. As a Black woman working in the field for over six years, it was tremendously satisfying to interview women and to tell their stories about PrEP and specifically how they relate to HIV risk. The Researcher also believes that "looking like" the respondents allowed for easier and frank communication on the topics and provided reassurance to respondents of the intended uses of the information.

Validity

Yin (2016) defines a valid study as "one that has properly interpreted its data, so that the conclusions accurately reflect and represent the real world that was studied" (p. 89). Using Maxwell's (2013) validity tests, the following strategies were employed: Intensive long-term involvement and "rich" data. Intensive long-term [field] involvement means "to produce a complete and in-depth understanding of field situations, including the opportunity to make repeated observations and interviews" (p. 126). Although the data collection was not long-term, the Researcher's involvement with this topic was, and the study was field-based, inherently facilitating more insightful and meaningful engagements. "Rich" data means "to cover fully the field observations and interviews with detailed and varied data" but also requiring that for interview studies, such data are generally captured through "verbatim transcripts of the interviews" (p. 126). Utilizing professionally transcribed interview transcripts helped enable the Researcher to obtain "rich" data from the field.

Chapter IV

RESULTS

The current study was aimed at understanding the motivation of Black women to either accept or reject PrEP. The study followed a qualitative approach. Results are presented below in a description of the risk characteristics of the sample and through a series of individual cases and in-depth thematic excerpts from Black women's narratives.

Risk Characteristics of the Study Sample

Using the CDC guidelines (CDC, 2014a), all 72 participants reported one or more of the risk factors for PrEP indication. Risk factors mentioned in the CDC guidelines are an indication for PrEP use, but final determination of PrEP use is based on the clinicians' medical evaluation. Participants visited the clinic for a variety of reasons. Nevertheless, of the 72 Black women in the study, 70 indicated that they received a combination of an HIV or an STD test and a regular check-up. Only two women indicated having only a regular check-up without requesting an HIV or STD test.

Of the two women who indicated no HIV or STD test, one woman indicated no condom use and the other had a HIV test within the past three months. Almost 30% of the women (n = 21) reported never using condoms, while more than 50% reported using condoms every time (n = 30) or almost every time

(n = 9). Almost all of the women (n = 70) had an HIV test in the past year, and over 75% (n = 55) had an HIV test in the past three months. Almost 10% (n = 6) reported having a sexually transmitted disease in the past six months. Collectively, these data show that the sample was considered eligible candidates for PrEP use according to CDC guidelines. During the course of the interviews, almost all of the women indicated that they were currently sexually active.

Individual Case Presentations

In this section, nine women's narratives are presented, which highlight one or more themes that emerged from the interviews. These women allowed insights into their life, risk perceptions for HIV, and their motivations to accept or reject PrEP. All the names used during these presentations are fictitious to preserve privacy. The case presentations are also used to help ensure that Black women's voices are heard as individuals whose stories and perspectives are valued.

Case Presentation 1

Paulette is a Black woman in her mid-60s living in Brooklyn. She reported hearing discussions about PrEP on a television program, possibly on The Dr. Oz Show. She supports safe sex practices and believes people, regardless of their sexual orientation, should use PrEP if they are having unprotected sex. Paulette encourages people not to be too overconfident about any one method but to use both condoms and PrEP together to ensure safe sex. She reports that she always practices safe sex by insisting that her partner put on a "jacket" and will even withhold sex if her partner does not use condoms. Although Paulette

reports no high-risk sexual behaviors, she reports having regular HIV screens, primarily because of a blood transfusion she had a few years ago.

Paulette reported that she would consider taking PrEP if the medication was administered annually through an injection, like the flu shot. These were exciting possibilities to Paulette, who was not aware of the clinical trials being undertaken in the field. Additionally, Paulette voiced serious concerns about PrEP, particularly thinking about possible side-effects of the medication. She firmly believed that her decision to use PrEP would hinge on the impact the medication would have on her body, because her immune system is weaker as she gets older.

Paulette reports being divorced for several years and that she completed high school and earns less than $1,500 per month. Paulette repeatedly mentions her age as a possible determining factor in PrEP use, although she admits that age is less of a consideration because HIV does not discriminate. Paulette is confident that she will definitely not get HIV in her lifetime.

Case Presentation 2

Keisha is a woman in her early 20s who lives in Manhattan but feels comfortable receiving medical services in Brooklyn. The discussion about risk factors was very striking, primarily because even though she reports being sexually active over a few years, she reports that her most recent HIV test was her first time being tested. She reports that she nudged her partners to get tested but has not asked about their results. She hoped that the doctors would provide preventive screens and communicate prevention methods, which would also benefit her. She has moved forward with her beliefs and is encouraging young women with only one risk factor to consider getting an HIV test because they are at risk for HIV, since one risk is enough to get the virus. Keisha supports and

encourages women to make the best decision for them and to investigate PrEP to ensure that the medication has no adverse effects. Keisha reports that her mother plays a role in her decisions. She believes that her mother is a strong influence in her life and would be a person who could introduce PrEP in a positive way.

Keisha has completed an Associate's degree and earns between $1,501 and $2,500 monthly. She reports sex without a condom in the past 6 months and indicates that at her last clinic visit she obtained STD and HIV tests in addition to her regular checkup. More recently, she reports practicing safe sex and over the past 3 months has reported using condoms every time. Additionally, although Keisha reports not injecting drugs, she reports using marijuana in the past 12 months. Keisha is confident that she will definitely not get HIV in her lifetime.

Case Presentation 3

Jennifer lives in Brooklyn, and she believes that the government is holding back on medication to force people to go to the doctor. This is because, for her, the government wants people to spend more money at the doctor. In spite of this, Jennifer believes that people are blinded by sex without being mindful of their health. Her awakening moment was her STD diagnosis. She is, more than ever, vigilant about her need to practice safe sex and to always be protected. She believes that when thinking about risk and protection, women should look beyond their immediate partners to all previous partners. Therefore, Jennifer believes that protection is broader than the commitment to the current partner, but that protection is about the unknown.

Jennifer is a recovering addict who has not used drugs in the past 12 months. She sees herself as getting wiser and would be open to preventive medication to help her live longer and healthier. Jennifer highlights the

importance of hearing from female PrEP users who resemble her. She describes women who look like her as women not living on welfare and not “sitting around” but women who are active, vibrant, and working a fulltime job.

Proudly, Jennifer reports that she loves her doctor and she follows through with her doctor’s advice on her health. She is open about her sex with women and asks for guidance from her doctor. She also reports that her mother helps her to remain healthy, and if her mother knew about PrEP, it could influence her to use the medication.

Jennifer has completed her Associate’s degree and earns between $1,501 and $2,500 monthly. At her last clinic visit, she had STD and HIV tests included in her regular checkup. Jennifer reports having Herpes within the last 6 months but has been treated. Jennifer reports that she is neither in a committed relationship or legally married. She reports knowing the HIV status of the last partner she had sex with and believes she will definitely not get HIV in her lifetime.

Case Presentation 4

Margo is in her early 30s and thinks of herself as being not too young nor too old. Margo reports that people in her age group do not generally share about their experiences and concerns about sexual health. Margo reports that when her friends speak about STDs, it is usually negative and disempowering. She believes there is a lot of ignorance about STDs among her peers and that it alienates people from discussing the topic. Similarly, Margo believes that sharing PrEP use will trigger quite negative comments. Although she firmly believes that women would not become discouraged by the negative comments, keeping PrEP private may be a better option for some women. She believes that women will

find ways around negative comments because for many women, their life is about living for their children.

Although Margo reports safe sex practices, she sees the value in using both PrEP and condoms. She shares her struggles in mentoring her younger sister, who insists on having unprotected sex with her boyfriend. Margo reports that her sister's practices also motivate her to continue to practice safe sex and to lead by example. Margo shares the ravages of HIV/AIDS on her family, as both Margo's maternal grandmother and aunt contracted AIDS in the 1980s and died years ago. She remembers seeing the weight loss and experienced the mourning. Although she reports not knowing anyone currently living with HIV, she is vigilant about using protection.

Margo has her GED and earns between $1,501 and $2,500 monthly. She identifies as bisexual, having both male and female sexual partners, and reports that she is in a committed relationship but does not live together with her partner. Although Margo reports that she uses condoms at every sexual encounter, she also reports having an STD in the past 6 months. She reportedly used marijuana in the past 12 months but reports no injecting drug use. Margo believes that she will probably not get HIV in her lifetime.

Case Presentation 5

Denise is in her early 20s and was excited to hear about PrEP. She believes everybody needs PrEP and that men and women should equally use PrEP. She believes that if PrEP is effective in preventing HIV, it will replace condom use, where people are using condoms to prevent HIV. However, she believes that if condom use is protecting women from pregnancy or STIs, PrEP might not play a significant part in replacing condoms.

Denise reports being scared of getting her last HIV test because she almost never uses a condom, although deep down she believed that she did not have HIV. She is a health worker and has patients who have HIV, which adds to her worrying about HIV. Denise reports that she would like for her medical doctor to discuss PrEP with her and would begin the conversation about PrEP to learn about the side effects, which would help her make a decision about PrEP. Additionally, she reports that her mother is also an important person who she relies on for guidance on important decisions.

Denise reports having an Associate's degree and earns an income ranging from $1,501 to $2,500 monthly. Although Denise shares an apartment, she reports being comfortable with her living situation and considers her housing stable. She reports that in the past 3 months she has received an HIV test and a regular medical check-up but does not believe she has done tests for other STDs. She reports not knowing her current relationship status, and although she knows the HIV status of the last person she had sex with, she reports feeling at high-risk of getting HIV.

Case Presentation 6

Felicia is in her mid-20s and working in the medical field. She tries to protect herself from HIV and encourages her friends to do the same. Felicia reports that, if she believes she is not at risk for HIV, she would not take PrEP. However, she would be open to discussing her risks with her medical provider. If she is at risk for HIV, Felicia reports that she would definitely use PrEP, but would need to be certain of the medication's effectiveness. She believes that women should use both PrEP and condoms to be safer. Safety is very important to Felicia, possibly because of her work in the medical field.

Additionally, Felicia was excited to hear from female PrEP users, their opinions and experiences. She believes the input from female PrEP users would be essential in her decision to use PrEP, particularly if her friends are also using PrEP. They would both have a strong impact on her decision. Although Felicia often thinks about HIV, she does not worry about it but instead increases her vigilance about protecting herself.

Felicia reports completing her Associate's degree and reports earnings of $1,501 to $2,500 monthly. She reports that in the past 12 months, her living situation is one of doubled up—living with friends. She reported not using condoms in the past 6 months but using them in the past 3 months, when she has been practicing safer sex by using a condom every time she had sex. She reports knowing the HIV status of the last partner and believes she will definitely not get HIV in her lifetime.

Case Presentation 7

Tanisha is approaching the end of her teenage years. She has only heard about PrEP on the television show, "How to Get Away with Murder." The show depicted two gay men discussing using PrEP because one of the men was living with HIV. She believes that HIV lives more among the gay population, thus reducing the need for Black women to be concerned.

Tanisha believes that women who use PrEP would be affected by stigma and open to judgment and ridicule from people. She explains judgment as people believing that the woman is having sex with someone who has HIV or that the woman is hiding her HIV status. However, she believes women should be more empowered to protect themselves, not being mindful of the judgment of others.

Tanisha is not enthusiastic about PrEP, although she reports high-risk behavior. Tanisha is worried about HIV and reports having increased her

unprotected and rough sexual encounters with her boyfriend. Her fears about HIV persist, even though she encourages her boyfriend to go to the doctor. Tanisha reports that couple PrEP use would be appealing to her, and reports that she would feel more comfortable using PrEP if her boyfriend was also using it. This sentiment reflects her opinion that women are followers and would be influenced to use PrEP if men started to talk about their PrEP use.

Tanisha indicates that she respects her mother and would look to her for direction about PrEP use. She reports that her mother is very supportive and knows quite a lot about the world, which is the reason that she would be able to convince Tanisha to use PrEP.

Tanisha reports having completed her GED and lives in a stable housing situation. In the past 3 months, she reports receiving STI, HIV, and regular check-ups at the clinic. Although Tanisha reports no STI in the past 6 months nor drug use, she reports having unprotected sex in the past 6 months and only uses condoms sometimes. Although Tanisha asserts that she will definitely not get HIV in her lifetime, she was not aware of her last partner's HIV status.

Case Presentation 8

Melonie just entered her 20s. She believes that, although she would go ahead and take PrEP regardless of her partner's reaction, male partners' reactions to PrEP use would impact some women. In addition, she believes peers' reaction would be more of questioning the reason for PrEP use with the intention of learning more about the method rather than to influence the woman's decision.

Although Melonie indicated that she did not "need" PrEP, her medical provider actually prescribed PrEP for her. In asking Melonie more questions about why she thought the doctor recommended PrEP, she revealed that she

had an STI a few months ago. Having reported that she took PrEP, she saw no need to continue using PrEP and remained on the medication for only one month. After asking her about the importance of speaking to other PrEP users, she indicated she may have continued with PrEP if she knew of other women who were taking the medication. During her time on the medication, she did not inform her partner or her friends about her PrEP use, mainly because she saw it as her private activity.

Melonie refused to indicate her income category, although she did indicate that she completed her GED and reported that she has stable housing. Melonie reported that her reason for her clinic visit was to do an STI and HIV test, possibly due to her reported STD infection. She reports sex without a condom in the past 6 months but indicates using condoms every time in the past 3 months. Although she reports no injecting drug use in the past 12 months, she did indicate that she used marijuana in a similar timeframe. Melonie reports not knowing the HIV status of her last partner but decisively believes she will definitely not get HIV in her lifetime.

Case Presentation 9

Doris is in her early 50s and reports no risk factors for getting HIV. She reports celibacy for the last 3 years and sees no reason for using PrEP, although she recently had an HIV test in the past 3 months. Doris reports that should she take PrEP, it would not stop her from using condoms. The opposite is true; she would ensure that she secures her safety by using both PrEP and condoms to protect her from HIV and STDs.

Doris feels that Black women taking PrEP may feel embarrassed about taking it because of the reactions from other people. She believes that women may feel there would be a perception that they have HIV and, because of that,

believes that women may decide not to take PrEP. Additionally, Doris is concerned about PrEP contraindications with respect to blood pressure medication and side-effects on her health and on her organs.

Doris reports that her clinic visit was for a regular check-up. She completed her GED and reports a monthly income between $1,501 and $2,500. Apart from her recent HIV test, she reports no additional risk factors for getting HIV. Doris reports condom use and practicing safe sex when she does have sex but reiterates her celibacy. Doris also reports knowing people who have died from HIV/AIDS but reports not being aware of anyone currently living with HIV. Doris reports not knowing the HIV status of her last partner but resolutely believes she will definitely not get HIV in her lifetime.

Summary of Case Presentations

These brief case descriptions highlight a number of factors that are relevant to the study aims. Almost all of the women do not perceive themselves to be at risk. If a woman does not believe she is at risk of HIV, it seems unlikely that she will take PrEP. The women with a high-risk perception reported rare condom use, although other women clearly exhibited high-risk behaviors but did not consider themselves to be at high-risk. Some of the other factors that appeared in the narratives above, which are described below, are related to concern about side effects, potential influence of older women and women who are PrEP users, stigma and privacy, and the potential influence of medical doctors.

Classification of Factors

This section presents excerpts from the 72 interviews. Referencing the classification of factors, both positive and negative responses have been

grouped according to their classification of predisposing, enabling, or reinforcing factors. Selected factors have been extracted for subsequent discussion and illustration in the subsequent section. The credibility of this approach was discussed by Green and Kreuter (1999), where priorities are being established within categories. The authors mentioned that “if the factor identified is very widespread or occurs often, it should qualify for priority consideration” (p. 178).

Table 3. Classification of Positive and Negative Predisposing, Enabling, and Reinforcing Factors Reported by Black Women Regarding PrEP Use Based on Data Collected in Brooklyn, New York, November 2017 to January 2018

Predisposing factors

Positive	Negative
protection against HIV is good • people should use protection • HIV is deadly • prevention is critical • dual protection with condoms and PrEP • causal sex should not have a death sentence • PrEP reduce HIV • self-awareness and self-motivation to protect against HIV • discussing PrEP among black women creates opportunities to educate • conduct research (google/internet) to learn about PrEP • age is a factor when promoting PrEP • will ask GYN and primary care doctors (PCP) about PrEP • monitor partner HIV test results • older women need protection • couple safety is important • positive beliefs about PrEP • women are more likely to use PrEP then men • protection is used • not promiscuous • abstinence is an option for being safe • doctors should present facts about PrEP • if risk is perceived, would use PrEP • younger people will take PrEP more than older people • PrEP should be in demand • condoms are used • more positive attitude towards people living with HIV • inform children about PrEP • PrEP is useful for rape victims • men and women will equally use PrEP • condoms provide reassurance	not aware of PrEP • never saw social media sign about PrEP • perception that woman is unfaithful –“stepping out” • not sexually active • do not need PrEP • PrEP does not protect against pregnancies and STIs • many unanswered questions • negative impact on relationships • never tried PrEP • need more information about PrEP • do not use protection • daily PrEP use is not realistic • promiscuous people use PrEP • PrEP is not necessary for committed relationships • men are more promiscuous multiple partners) than women • no advantage to PrEP use • people are too relaxed about sex • limited awareness about risk factors for getting HIV • one risk factor is not as bad as two risk factors • do not worry about HIV • who should use PrEP? • HIV is man-made • do not believe PrEP exists • men do not visit the doctor and less likely to take PrEP • men control the relationship • people do not always use condoms • people are not honest about condom use • more black people are getting STIs • PrEP is for the privileged • people engage in raw sex • not sure if PrEP is the right choice • concern about the effectiveness of PrEP • impact of HIV has been extreme

Table 3 (continued)

Predisposing factors

Positive	Negative
women by nature will protect themselves • injectable PrEP would be more appealing • infidelity is a risk factor • protection is motivated by children, family and friends • sex with causal partner is a risk factor • one risk factor is enough risk for women • understand women's motivation to use PrEP • men and women desire to be protected against HIV • low risk • people desire the pleasure of sex without condoms • do not rely only on doctors • HIV medication is safe • PrEP vaccine would be a good option • male encouragement and sharing their knowledge • PrEP is realistic • PrEP should have been invented years ago • important to be healthy • doctors provide good medication not bad ones • address the different disease affecting women • power rests with women • PrEP gives freedom • PrEP is a new innovation • conversations about PrEP should address safety concerns • motivated to have a long life • encourage children to get tested • important to learn about new prevention methods • doctors do not judge • trust partner • women would follow both men and women in using PrEP • PrEP is the new "freedom pill" • aware of the seriousness of HIV • PrEP is a "magic pill" • promote couple testing • educate women at every doctor visit • would use PrEP • PrEP is an option in dating relationships • men's use of PrEP will reduce women's risk to HIV	gay men and anal sex increase HIV • women are not always open to doctors • who invented PrEP? • women's immune system may protect against HIV • medical staff have limited knowledge about PrEP • partner opinion does not matter • suicidal thoughts • HIV is one of many concerns • comprehensive sexual education is needed • people are scared of HIV • HIV is invisible • people are skeptical about PrEP because no one knows about it • do not agree with risk assessment • should not take pill for HIV • avoid HIV test • feel invincible from HIV • no PrEP information on college campus • surprised at low level of PrEP promotion • HIV is not as pronounced as STIs • fragility of condoms • married and safe HIV • fears – PrEP would reduce sexual urges • was aware PrEP was an acronym • women get talked into not using condoms • sex is usually not planned • reduce stigma • PrEP associated with transgender and LGBTQ people • length of time to build up in system • possibly too early to adopt • mixed reaction to women taking PrEP • being shunned by partner/family/friends because of PrEP use • networks do not know about PrEP • husband has multiple partners • HIV is a touchy subject • no support to take PrEP • fear HIV is in PrEP • negative feedback would discourage PrEP use • people with multiple partners should use PrEP • men would follow other men in taking PrEP • friends can be judgmental • people are not getting tested • poorer people are less aware of PrEP • men do not admit to risk • men transmit HIV more • love reduces the need for condoms • PrEP users will use less condoms • PrEP is a conspiracy

Table 3 (continued)

Enabling factors	
Positive	Negative
interested in PrEP prescription • couples collective use of PrEP • women would use PrEP if they were aware • use of PrEP privately • knowledge of pill-taking • PrEP is similar to vitamins and birth control • advancing medical education • take medication on time at the same time • develop steps for adherence • create routine to use PrEP • use of hand bag as a reminder to take medication • insurance coverage • easy refills-over the counter • injection option is better than pill • confidential nature of pill taking • set reminders • use daily pill boxing •	confused about when to use PrEP • forgetting to take pills • will need tools to communicate to partner about PrEP use • do not like to take medication • concerned about missing a dose and the consequences • not adherent to medication • loss of insurance • use of the pill • length of time on PrEP • did not fill PrEP prescription • cost of PrEP • long wait times for PrEP appointments • PrEP is time sensitive • paranoid about taking medication •
Reinforcing factors	
Positive	Negative
observed HIV testing signs • partner can influence women to use PrEP • positive messages can encourage community to use PrEP • supportive friends • promote PrEP in doctors' offices • would follow doctors' recommendation to try PrEP • value female PrEP users' opinion about PrEP • involve partner in decision to use PrEP • benefits of PrEP outweigh challenges • doctors (GYN/PCP) have influence and are trusted • feel comfortable discussing PrEP with doctor • invite partners to use PrEP • aware of people who are living with HIV • other medical providers such as mental health professionals and dentists should know about PrEP • doctor plays a role is educating partner/family/friends about PrEP use • doctors should promote couple discussions • key influencers of PrEP are older women, doctors and self • friends would be interested in PrEP • health workers can influence PrEP use • doctor mentioned PrEP • use of video, TV, magazine and printed pamphlet to promote PrEP • female PrEP users' experiences would be more valued if they look attractive and who resemble other 'normal' women • doctors should endorse the pill • an accountability partner •	need for advertisements on PrEP • increase the number of people who know about PrEP • partner would react negatively to women using PrEP • medication contraindications • never heard about PrEP from doctors (GYN/PCP) • no discussion with family/friends about PrEP • men cannot influence women to use PrEP • assumption that women have HIV • PrEP side effects • allergic to PrEP • female PrEP users' feedback not important • potential hair loss, weight gain while using PrEP • concern about the prolonged use of PrEP • women should share doctor's concern about their risk factors • people may not report PrEP use • revealing PrEP use is a lose-lose situation • information on clinical trials • embarrassed to take PrEP • life-threatening consequences of PrEP • negative reactions from friends • doctors never mentioned PrEP • adverse side effects • feel isolated • knew no other woman on PrEP • impact on emotions, mood and attitude • PrEP shows positive results with women • partner and family will criticize women for PrEP use • negative result on pregnancy and reproductive health and effects on baby • partner/family will question HIV status • conflicts with partner •

Predisposing Factors

There were similarities and common themes echoes by most Black women interviewed that were captured as predisposing factors, primarily because they relate to their motivation. As only two women have actually used PrEP previously, the majority of the participants were new to PrEP as a prevention method, and therefore their initial reactions to PrEP questions represented a point of view that is not a lived experience. Predisposing factors that may predict and motivate a decision to consider taking PrEP to prevent HIV are outlined below. These factors represent Black women's beliefs and perceptions in moving forward to embrace a health behavior change. This explanation recognizes that, inherently, there is a "cross-cutting relationship between factors", where one factor can "appropriately be placed in more than one column" (Green et al., 1980, p. 78). The predisposing factors include awareness about PrEP, beliefs about PrEP, potential users of PrEP, partner's influence on PrEP use, negative reactions of partners, expected reactions from friends, perceived need for using PrEP, and, importance of shared experience and learning from female PrEP users. In addition, several beliefs that may be barriers to PrEP use are considered, including evidence of PrEP's effectiveness, stigma, limited nature of protection, and the perceived tension between PrEP and condom use.

Lack of Awareness about PrEP

Only a few women indicated some prior knowledge about PrEP. The responses were categorical and included either yes or no responses. The question was "Before today, have you ever heard of PrEP?" Sample responses included the following:

> *Female #16*: I don't know anything, I want to know everything, I want to know where it came from, I want to know when did the study start, I want to know who has it been tested

on, side effects, long term effects, short term, things you have seen, what is the outlook that you have done already… those would be the things I would want to know.

Female #10: This is actually the first time anyone has said it to me.

Female #18: No, this is my first time I ever heard of it.

Women could more easily identify with “HIV get tested campaigns.” These campaigns represent traditional forms of HIV prevention messages that have been disseminated through the City at bus stops and on subway cars. Examples of responses:

Female #57: No. Never heard of that.

Female #5: I saw something but I don’t know unless someone explains to me what it is about.

Dialogue #48

Researcher: Have you seen any ads in the subways from department of Health that speak about get tested, know your status?

Female #1: Yes.

Researcher: Have you seen anything that says pre-exposure prophylaxis or PrEP? possibly at the bottom of ads, it just says PrEP—P, r, E, P?

Female #1: If I did I probably wouldn't remember.

Dialogue #2

Researcher: So, before today, have you ever heard of PrEP—pre-exposure prophylaxis?

Female: No, I haven’t.

Researcher: Have you ever seen any ads on the subway that says protect yourself?

Female: Yes.

Researcher: Can you remember what you saw?

Female: It said better safe than sorry, things like that, use a condom, and protect yourself.

Dialogue #23

Researcher: Before today, have you heard about PrEP?

Female: No.

Researcher: Have you seen any signs, or printed material that has PrEP and say have safe sex, or use a condom?

Female: Well that, yes … I've seen advertising in the subway, on the bus, on buildings about safe sex, even at the bus stop.

Researcher: Mhm, but any with the word PrEP?

Female: Umm, I really didn't take notice if it's from PrEP, I really didn't take notice.

Dialogue #6

Researcher: Have you seen subway signs or printed material that carried the word PREP?

Female: Yes.

Researcher: In what context?

Female: I saw the signs on the subway but I never really looked at it in depth.

Researcher: Could you recall words or anything associated with it?

Female: No, I can't.

Women were surprised and quite interested in learning about PrEP:

Dialogue #14

Researcher: Is there anything you would like to know about PREP as you think about it as an option?

Female: My question is what form does it come in?

Researcher: a pill form.

Female: How often do you have to take it?

Researcher: Once a day?

Female: So, is like birth control? Ok. How new is this?

Researcher: Approved in 2012

Female: So, it's big, so how come I never heard of it? Are there a lot of people using it?

Researcher: Not a lot, but more men than women. That's my reason for interviewing women.

Female: You have got to be kidding me! More men! Wow. I'm shocked because I didn't even know about it. So, they need to put it out there for the women.

Dialogue #18

Researcher: So, before today, have you ever heard of pre-exposure prophylaxis?

Female: No this is my first time I ever heard of it.

Researcher: The short version of the name is P-r-E-P.

Female: PrEP? Yeah.

Researcher: PrEP

Female: Mhm…

Researcher: Have you seen any subway signs or ads?

Female: No, not at all, this my first, that's why I was so interested trying to find out what this is all about.

Among women who knew about PrEP, they obtained the information from various sources and with varying degrees of completeness.

Dialogue #16

Researcher: Have you seen or heard about PREP in the subways or anywhere before today?

Female: I watch a lot of TV. I actually didn't hear that name, but I heard of a drug that prevents someone else from catching HIV if you already have HIV, so I'm not sure if it's the same thing.

Dialogue #42

Researcher: Before today, have you ever heard of pre-exposure prophylaxis or PrEP?

Female: Yes.

Researcher: In what context?

Female: Advertisements on the train.

Researcher: What did you see? Can you remember what you saw?

Female: Basically, it looked like some straight people, lesbians and gay people in the ad it said PrEP. Um, I guess like preventing HIV. I also saw it when I went to my GYN, you know, how they have like the information board go by. That was one of them.

Dialogue #3

Researcher: Before today have you ever heard of PrEP?

Female: Yes, my doctor prescribes it to me. She explained everything to me a few months ago. I never heard of it before that. She mentioned it to me as she thought I was a good candidate as I am sexually active. She said this pill will prevent HIV, I said wow, how come nobody knows about this, and they don't talk about it. I never really heard anybody talk about it so I said I would give it a try.

Dialogue #21

Researcher: Before today, have you ever heard of PrEP?

Female: At the health center.

Researcher: Who told you about it?

Female: A staff member.

Researcher: What did s/he tell you?

Female: He just told me that they have a PrEP … you can take, so you won't get … that's all I heard.

Conducting further research was a constant thread running throughout the conversations. Providing information is the starting point to increase women's independent study, an important factor for women to become more aware.

> *Female #41*: My first thought is before taking it go, get your status checked out. The next thing is you have to be cautious at all times because you never know what can happen and if you're not too sure about it, ask more questions. Look it up, read the side effects, read what it contains. Ask your doctor cause if you're taking medicine for something else, does it cause side effects, will it knock it off.
>
> *Female #6*: She [doctor] would just have to suggest it and I would always read about it myself. I always do that, even to go on Google and follow up and read about things. If she suggested it I know it would be something positive to take.
>
> *Female #7*: Maybe if I talked to the doctor and researched it and know the side effects then yes. But otherwise not just because you tell me to do it right now.
>
> *Female #11*: It would basically come down to the side effects…. I have researched this, and I know if you take this you will be ok. It will not mess with other medications. Any medication, it's always the side effects.…
>
> *Female #13*: You have to educate the partner, and do your research on the medication first and then, if you have one partner, you discus if this is the right thing for you. Because you take these medications and the side effects are deadly.

It was striking to note that of the six women who had prior knowledge about PrEP, three associated its use with LGBT people and people of trans experience.

> *Female #5*: In all the ads that I've seen it's just the LBGTQ group is targeted, so I don't see where women would use it.
>
> *Female #2*: … I don't know any women who are on it. Umm the few people that I have spoken to about it are people who are in the LGBT community. So, I don't know like if straight women use it. I don't even know if straight women really know about it.

Dialogue #57

Female: I don't want to say the wrong advertisement, but maybe it's the one with I think transgender women.

Researcher: So, did it appeal to you in any way to learn more? Or did you say, maybe this is something that I could investigate for myself?

Female: Not necessarily.

Beliefs about PrEP

Black women were asked to assess their beliefs about health and to determine whether PrEP was positively or negatively associated with their beliefs. Using Green and Kreuter's (1999) definition, “belief is a conviction that a phenomenon or object is true or real” (p. 162). The following dialogue provides a rich sense of meaning that is attributed to PrEP. For most women, belief about PrEP use is simple, logical and relates to past experiences:

Dialogue #3

Researcher: When you think about your beliefs about sexual heath and HIV prevention, does PrEP fit positively or negatively with your beliefs?

Female: Definitely positive, the way things are set up now, you even touch someone, or you can have one partner, but you don’t know who they are sleeping with. So, it’s positive.

Dialogue #6

Researcher: OK, so when you think about your beliefs about sexual heath and HIV prevention, does PREP, this medication that you take, does it fit positively or negatively with your beliefs?

Female: I think it fits positively, if this is supposed to prevent. Is this to prevent? Would the person take it before sex?

Researcher: They take it daily before.

Female: Anything that will help a person not get it is a good thing. That's just plain and simple. But I also think people should use protection also.

Dialogue #12

Female: I would say positively, because it's supposed to be against it right?

Researcher: Yes. So, when you say positively can you explain little more?

Female: I had an uncle that passed away from HIV. I just don't want to see anybody go through something like that.

Women also provided their individual beliefs about PrEP as a prevention method:

Female #69: Positive, because it can protect you. But for me, I felt like I would take it to protect myself, just in case, so it will be positive.

Female #18: I think it'll fit in positively with it, with the beliefs, because it's best to be aware of any sexual medication that is out there that can help you prevent from getting something, it'll be a help. You know, what you're up against, cause you could be sexually abused, and that'll be one way for you to take the medicine and you won't have to transmit that disease. So, I think it'll be real helpful.

Female #43: Hearing about it this morning it could be positive because I have two daughters. One is 26 and one 19 and actually they're home with their boyfriends. Their boyfriends spend the night cause they have their own room.... I was just explaining to them you got to be careful, you know if your boyfriend is sleeping over I need to know because I need to know if I my children may be exposing themselves sexually… So, I think it's a positive thing because I would want to know about it so that I can explain to them or even when they come here to get information....

Female #70: I'm aware that some people don't like taking medication at all, but if she was concerned for her being then you have to take it on a daily basis. So, I find a lot of people ain't crazy about it, but my belief is that it should help you and you should take medication if it helps to cure you.

Female #63: I think it is a positive thing because although it is not 100% effective it could possibly prevent you from getting something, I say why not, as long as it doesn't cause any long-term health issues. I think it's good that it's available. I didn't know anything about that. As long as it prevents you from getting it.

For some women, their beliefs were contingent upon conditions, questions and lingering concerns:

Female #67: Positively, if it's something that can prevent the disease from spreading. I guess my only concern would be like the flu vaccine, how they inject you with the strain to prevent it from being so bad. Like I guess that would be the thing I would want to understand more about the drug … to be sure that there's no strain of the virus in the drug at all.

Dialogue #41

Researcher: Based on how you take care of yourself, the beliefs that you hold, like getting regular check-ups, maintaining good reproductive and sexual health.... Does a medication that prevents HIV fit positively with your beliefs or does it fit negatively with your beliefs?

Female: See I'm not too sure, really couldn't say on it because I never had that or never know how to believe about using it. But if you say it prevents you from getting HIV...

Researcher: Right. So, it's for persons who do not have HIV that takes PrEP to prevent them from getting HIV.

Female: Then I think it's pretty good. But is it a hundred percent accurate? What is the percentage of it? Did somebody use it and did it fail? That's, what I want to know.

Dialogue #35

Researcher: When you think about your beliefs about sexual health and how you keep yourself healthy, does a medication that prevents HIV fit positively or negatively in your beliefs?

Female: I mean it could go for me but I'm really not that sexually active so I wouldn't really need….

Researcher: Your doctor prescribed it. So, would PrEP be something you recommend or suggest to friends?

Female: It's like I'm in between

Researcher: Mhmm hmm

Female: Like I would recommend it to certain people but for me I just feel like it's kind of risky with like the side effects or whatever it was because when she told me about it last time and I read the like side effects it was a lot ….

Researcher: Mhmm hmm.

Female: … So I was scared, that's why I just never took it.

There were very few negative associations between PrEP and beliefs. The following responses capture the main examples:

Female #5: If I understand right I don't think it does. I don't know if a pill helps protect you from these things. It's just a cover up to get people to be on the pill and be more sexually active.

Female #62: … It's kinda in between in a sense only because I feel like even though it's very advanced, it's kind of a way for people to not be careful because there was a pill for it now. So, it's like … I don't need to take that caution anymore.

Dialogue #31

Researcher: When you think about how you take care of yourself in terms of keeping healthy, going to see your provider, your OB-GYN, whoever you see … does PrEP, this medication that prevents HIV, does it fit positively or negatively with your beliefs?

Female: I say negative …

Researcher: Mhmm hmm.

Female: … Because I don't believe in medicines.

The skepticism observed primarily originates from a place of uncertainty and being unaware of the medication and the science behind PrEP. Most women

indicated the need for additional research, which will help in making firmer decisions that align PrEP with their beliefs. A few skeptical responses are illustrated below:

Female #48: I don't know. I don't think so. I think it's a gimmick or something like that … what is in the pill that could prevent you from getting AIDS?

Female #40: Well, I don't really know much about it but I guess it will serve its purpose. Not sure.

Potential Users of PrEP

The respondents felt that women would be more likely than men to use PrEP. Unlike responses that favored both genders' use, the justification for women-only use was usually accompanied by a perceived distinction between genders.

Female #1: I think women will use it before the men.… I feel like women are more health conscious than men; if they are sick they will not go to the doctor. They have to be like pretty much near death to go. Women are more health consciences, we worry about things like this, and we study things like that.

Female #3: I talked about it to a few of my male friends. They don't trust it. That was their opinion. It was a few of them. I don't know why. But when I talked to my female friends about it, they said I'm going to talk to my doctor about that. So that's where my opinion comes from.

Female #64: I would think that hopefully I will help them take it equally, but sometimes I think maybe women might take it more than men would. Because they just don't like to do things that they don't feel is okay. But women will think about it and we'd be like, okay, that's something that I would want to do. And then it's like we would have to talk them or push them into doing it. But I think we would take PrEP more first.

Female #72: The woman probably would take PrEP more than the men because the men think they, invincible nothing can

ever happen to them. Do you know that belief that I'm stronger, I could do this, I could do that. That will never happen to me. That could never be me. I would do this and I will do that. Yes. Women are more likely. I don't want that to happen to me. I'm going to try to prevent it as much as possible.

Female #58: We're likely to use it? Because I think men don't go to the doctors often. I think women are more likely to use it.

Female #14: I think more women would than men. Some men don't even want to use a condom. Women are more into health. Men you have to push them.

Female #25: Hmm, I don't wanna say that women are more cautious when it comes to sex as opposed to men, but I feel like we think about the future more than they do, so we will be more inclined to use it compared to them.

Female #19: I think women are more health conscious than men. Men don't go to the doctor, unless something falling off. I'm serious. Women go to the doctor … I guess because we're more family oriented, because we take care of the kids. Even if we may not have kids, I think women will go to the doctor faster than men. When we go to the doctors, maybe two or three times a year, and they only go if something hurts or if somebody say, look, you have to go Men don't often go to the doctor whether they're sick or not. They have to be forced to go.

Partner's Influence on Black Women's PrEP Use

There is recognition among Black women that men have influence over their willingness to use PrEP. Similar influences appear to be associated with the decision about condom use in relationships.

Female #13: Men are the ones who most likely contradict women when it comes to sex, because a lot of them don't like condoms, they don't believe in it, especially West Indian men. They don't like condoms. They say, oh they are not comfortable with that.

Dialogue #15

Researcher: If more men used PrEP would it positively influence women to use PREP you think?

Female: Yes, women are followers, so if men do it they would want to do it too just to show they can do it better.

Researcher: If women were to take PrEP would it affect their partner's reaction?

Female: I don't think it would affect it, but it would cause some concern—like why you taking that? I don't have HIV, so why you taking that?

Researcher: You mentioned that women are followers. Do you think that reaction will impact their use PrEP?

Female: Yes, if my partner wants me to be on it, then I will get on it. I don't want to sound any type of way but that's how most women are. And if he says the opposite she will stop taking those pills.

Dialogue #28

Researcher: If more men used PrEP would it positively influence women to use PREP you think?

Female: I think so, yeah.

Researcher: Why? Why are you thinking so?

Female: Well, because I feel like we don't really have like the strong Black men in our community, so I feel like if more positive Black men you know what I'm saying….

Researcher: Mhmm hmm.

Female: If it be positive Black men that you know, start talking to us and teaching us some knowledge … maybe, you know and kinda get us to talk into it, we might be like okay, like why not, you know … try it out you know. It doesn't hurt to try. Like if it doesn't work out for your body then you just won't do it again, but it doesn't hurt to try.

A few Black women were not as accepting of any reality in which male's PrEP use could be an influence over women. Interestingly, there were different reasons for that conclusion.

Female #57: I don't think because a man uses it that more women are going to use it.… I think some men may try it, you know, but I don't think they actually think, well, why should I try it? It's what I know nothing's going to happen.

Female #55: I think men would be more easily influenced. If the woman is like, I'm taking this, I'm not trying to get HIV or whatever, they'll probably be more on board because they want to have sex.

Dialogue #39

Researcher: If more men use this medication, would it positively influence women to use it?

Female: No, not necessarily. No.

Researcher: Um, why you think, why?

Female: Because men wouldn't tell you. That's just like men they tell you I'm not sleeping with this girl, but normally he is. So just because I tell you, okay, I'm taking it and he tried to get you to take it that don't make sense taking it in a sense.

Dialogue #14

Researcher: If more men used PrEP, would this positively influence women to use it?

Female: I don't think it would, because to me the women would be more likely to use it than the men. I would say no to that.

Researcher: Why? Please explain.

Female: Because women are more into our health than men. So, we don't need a man using it to make us push to do it. I figure we would do it on our own.

Impact of Negative Reactions by Partner

Although there were responses indicating that partners reactions can be encouraging to women's use of PrEP, the sheer majority of responses reflected that Black women feared their partners would have negative reactions to their use PrEP. In Rogers's theory (2003), this can be considered an attribute of the innovation, namely, impact on social relations. Largely, indication of PrEP use was associated with a plethora of disastrous endings, from signs of cheating, questioning of HIV status, having a promiscuous lifestyle, to upheaval in relationships. These reactions appear to have a negative association with Black women deciding to use PrEP. Below are responses and dialogues about this perception of PrEP use:

Dialogue #018

Researcher: So, if women were to take PrEP would it affect their partner's reaction?

Female: I don't think it should, because I'm trying to protect myself and if there's a medication to prevent me from having HIV by all means. I would explain to my partner too, let's all get on board. So then that way there won't be any discrepancies between the two of us; you're on it, I'm on it. Let's just keep it like that, and let's not go outside of our relationship, let's have a consensual relationship … and then you forget to take a pill one day and then boom!

Researcher: What about generally the reaction from men?

Female: If I was taking a HIV pill to prevent having HIV, I think … a lot of men are not gonna be on board because why are you taking a pill if you don't have it? Have you been sleeping with…. It'll be a lot of have you been sleeping with somebody that has it and this is why you're taking the pill and telling…. It'll be a lot of back and forth, it wouldn't be…. Let me see what's the word I'm looking for…. It wouldn't be a good discussion with a man and a woman discussing this situation, but among women we'll feel comfortable talking about it because we're trying to prevent from catching HIV. From a man's point

of view, oh you got it and that's why you're taking a pill. They gonna turn the table around, you know, they gonna turn the table around, that's what I'm trying to say….

Researcher: In that reaction, how would it impact your decision to use PrEP based on their feedback?

Female: Well, me, personally, I would take the pill. Even if I know I don't have and I'm not gonna go out there and explore with anybody to see if they have it, but you never know. Cause that's just like the virus that the kids can get when their 11 years old and they get the shot to prevent it. So, I feel like that's saving me just in case, cause you never know. A man is not gonna come forward with his STD situation. They're not, they gonna slither 'round and slither 'round and "oh you got it from John," John gave it to you, Mary gave it to John, they never gonna be honest about that. A woman would be more honest about taking that pill to protect herself.… I would take it to protect myself, cause you can look like Don Juan and you may have the monster.

Dialogue #5

Researcher: So, if women were to take PrEP would it affect their partner's reaction?

Female: Yes, if it was me I would want to know why are you taking this pill. If this is about sexual health and HIV prevention, it's like why are you using this pill? Who are you sleeping with? I know I don't have anything. We should be on the same page as far as knowing what each other have, what we do on the outside. But why would you be taking this pill? Most of the times people in that lifestyle have higher chances of getting HIV, or AIDS.…

Dialogue #31

Researcher: If women were to take PREP, would it affect their partner's reaction to them?

Female: In this society, yes but I don't think it should.

Researcher: So, when you say yes, what is some of the feedback that the man would give to the woman?

Female: Well, my friend had a urinary tract infection and her boyfriend was like Eww, how you got that?—laughs—So I'm pretty sure the response won't be too far from that.… it shut her down like to the point she didn't even wanna express anything with him with her body. So, I think it's like how they say it. If you say it like, it's dirty, then, yeah, it's over. We're not gonna express anything to you.

Dialogue #10

Researcher: If women were to take PrEP, would it affect their partner's reaction?

Female: Nine times out of ten, yes. They are going to assume, why are you taking that, what's wrong?

Researcher: So, it's on the suspicious end most times. What are other reactions men could have?

Female: They would probably say they will try to get it and sell it. Especially if it does all the things that you say it's supposed to do. The black market is going to get a hold of it.

Researcher: Do you think that the reaction from the men would sway the woman in the decision that she makes to use this medication?

Female: Probably. So, if the man says you go ahead and take it she will, but if he asks why are you taking it? She more than likely will not want to take it.

Researcher: Why do you think that women are more swayed by the men in these decisions as it relates to sexual health?

Female: because of the ding-a-ling.

Women were quite passionate and opinionated about this topic. This was one of the questions that was suggested from the pilot study. Their vivid views on partner reactions were clear.

Partners who have negative reactions will impact Black women's decision to utilize PrEP:

Female #61: Well, I believe the partner might not trust her anymore, you know. He's going to say, well, I know I don't have it and you don't have it, so why are you taking? Are you messing around? So, I think that we will mess-up the trust factor between them.

Female #35: … Why you taking that like I have HIV?

Female #38: Definitely. I do believe that it will affect the partner's reaction because the partners are going to say why are you taking something?… I think definitely men would look at you sideways. I also think the other way around as well that the woman will look at the men funny.

Female # 24: … They'll think she got something, that's why she wanna use it….

Female #57: I think if women would take it, the first thing they're going to see is, so, you're going to go out there and do something that would probably be his thinking … the only reason you're taking it is either you don't trust me or you're going to go out there and do something to protect yourself. So that would be my theory.… Unless I think if the woman took it and she explained it to her mate, you know why they were taking it, I think maybe they would understand better. But sometimes that doesn't work because I may feel like you're taking this, why are you taking this? They may not understand.

Female #12: I think my friends would be interested because they are usually on top of their health. So, I don't think they would look at it as a negative thing. They would be more motivated to try it, too.

There were perspectives from a PrEP user in the study about her thoughts about her partner and how he would react to her using PrEP. She kept her PrEP use private from her partner.

Dialogue #3

Researcher: OK, if your partner knew that you take PrEP, would he have a positive or negative reaction?

Female: A little bit of both. At first maybe negative, but once I explain it to him and become more educated about it he might come around.

Researcher: Why do you think he would react in a negative way at first?

Female: He would probably think I don't trust him. That's the main reason. He might say he doesn't have anything or he is not sleeping around. But it's just more comfortable for me to take it, I feel like I have a peace of mind.

Researcher: So, if he knew and gave you that negative or positive reaction how would it impact your decision to continue to use PrEP?

Female: This is my body. I'm going to use it regardless, as long as I don't have any negative side effects; I'm going to keep taking it. So, no matter what he says, it has nothing to do with him.

Researcher: You're more open-minded. Ok, so if women were to take PrEP, would it affect their partner's reaction?

Female: Maybe. Yes, because they will ask why are you taking that? My partner doesn't know I take it.

Expected Reactions from Friends

Although it does appear that partner influence is much stronger than friends, peers, or girlfriends, women do rely on their friends for encouragement, and to support their decisions about PrEP use and sexual health. Responses reflected mixed reactions and show the void of PrEP education among this community. Dialogue and individual responses are captured below:

Dialogue #28

Researcher: Okay, what about her friends? Suppose she told her friends that she was gonna take this medication, what would some of the feedback from her friends be like?

Female: I think it might be positive. Some of it. And some of it might be negative.

Researcher: Mhmm hmm.

Female: Because the mentality some people have, some of them have childish mentality and some of them are very

mature. I think the good ones would be like I'm glad … if it can prevent yourself from getting it why not? And it could prevent you from giving it to somebody else then why not? But like the negative ones will be like, they just wanna laugh at you and like make jokes.…

Dialogue #30

Researcher: How would their friends react to women using PrEP?

Female: Their friends will react to it well because they know that they will be on the safe side.

Researcher: And would that cause the woman to use, to go ahead and use it?

Female: Uh yes that will cause her to go ahead and use it. Once she has someone to … what's the word umm … not protect her, to umm … not guide her….

Researcher: Encourage?

Female: Encourage, that's the word … to encourage her, and she knows that it's a true friend, then she will.

Researcher: Mhmm hmm.

Female: You have to encourage her, you have to uplift her.

Researcher: Mhmm hmm.

Female: And you have to make her … believe that it's going to work.

Dialogue #35

Researcher: How would her friends react to her if she told them that she was taking this medication and would that impact whether she actually takes it?

Female: At first, if she tells her friends they're gonna to think that she has HIV or something … like something in that order but if she really explains it … I think that they will want to do it too.

Researcher: Mhmm hmm. And would that cause her to take the medication or not take the

medication or be indecisive about taking the medication based on their reaction…

Female: If they have a lot to say about it and if it sounds bad to them then she probably won't take it.

Individual mixed responses about friends' reactions to PrEP use:

Female #22: I feel like her female friends would be onboard for it because we, I guess we…. I don't wanna sound biased, we understand like, that this is for our safety. Like, if nobody else looks out for us, we have to look out for ourselves and we have to look out for each other as well. So, I think they'll be supportive of it, the female peers. I don't know about the male peers but the female peers at least.

Female #25: To be honest, like, I'll be honest, I really keep a lot of stuff to myself but umm, I got a lot of positive female friends so they might say it's a good idea you know. Even though I'm sexually active, I use condoms but it's like, stuff could happen when you use condoms, like the condoms could break and stuff so, its pros and cons to it, it could be a good idea cause you never know what could happen.

Perceived Need of Using PrEP

About half of the initial responses to taking PrEP were no. This is not surprising because the interview did not attempt to discuss individual sexual history as to possibly identifying PrEP as an option. In addition, most of the women were not familiar with PrEP. Among married women, responses ranged from unequivocally no to PrEP to refusing PrEP on the basis of being married and the protection that (is assumed to) be conferred on married women.

Researcher's question: Do you feel that you need to use PrEP?

Female #9: I would say no because I'm married, but who knows.

Female #14: Me personally, I am not active, but if it comes to where I get active, it wouldn't be a problem to use it. Because you really have to be careful now.

Female #1: To be honest, you never really know what somebody is walking around with, so everybody should, I don't know if it's a need, but it is kind of a necessity because you don't know what somebody has, so you have to protect yourself. I would do it. When I researched it I was like PrEP, then I googled it. I was like I would take that as long as it doesn't cause me any risk.

Female #8: No, because I always get tested and if I'm with somebody I make sure they get tested.

Female #72: No, because I kind of I'm kind of scared [medication]. I practice safe sex. That's why I said to myself, I'm practicing safe sex and I know that my partner's not doing nothing. But if my partner is, I'll be the dumbest fool for not taking it….

Female #15: No. I think the best way to avoid STDs is to stay celibate. But I know women have their needs. It protects you but not about everything. So, it should be one pill for everything not one pill for one thing, because I am not just going to be concerned about AIDS and not chlamydia, and gonorrhea.

Female #70: Actually, it'll help a lot of women. I think it'd be beneficial if more women were taking this medication. That's more prevention of HIV … being in prison, I have seen people come in and didn't have HIV, but when they went out they got HIV, because I was doing the testing.

Of note, during the interview, the Researcher realized that the word "need" in the questions was loaded: "Do you think you need PrEP" was perceived in a negative way. Possibly, the language inadvertently suggested inappropriate behavior or represented an 'admission' of sexual risk or took away agency from the women. Although this was rephrased as the interviews continued, a few respondents showed their grit by rephrasing the question along similar lines.

Researcher's question: Do you feel like you would need PrEP?

Female #28*:* I mean I don't feel like I would need it, but I mean, I could use it….

Female #2: Everybody needs PrEP. You never know whom you'll meet. I could tell you I'm clean and I'm not clean. You just don't know. So I think everybody should….

Researcher: Do you see any advantages of PrEP over other methods?

Female: *Yes, sometime people just rush into unprotected sex. I mean not because they mean to, but the urge is there and if you are on PrEP it could reduce the risk of HIV, and the pregnancy, if you are not ready to get pregnant. I would rather have PrEP than not have it.*

This last quote shows that there is confusion about PrEP and pregnancy prevention.

Dialogue #5

Researcher: Do you feel that you need to use PrEP?

Female: No, but to be on the safe side I make sure I am aware and cautious about who I am dealing with or who I want to be sexually active with.

Researcher: So, for you, I am hearing that the need is not to swallow the pill but the need is to be aware that there is such a thing.

Female: Yeah, I don't think it's a need. It's about being on the safe side. Not to say you will go and sleep with so many people, but I will take this pill … you can take this pill and use condoms and stuff still pass through so it's about being safe. Being aware of what you can get is more important than a pill.

Importance of Shared Experience and Learning

The survey sparked great interest about PrEP. Therefore, it was not surprising that there was almost overwhelming support to hear from female PrEP users. Almost every woman indicated that it would be important to ascertain "inside" information from other women who used PrEP.

Researcher: In making a decision about PrEP, how important is it for you to hear from other women who take PrEP?

Female #4: Yes, because I would like to know their feedback, how it affected them. Are there any side effects? Did it really work? All of that I would like to know from that person.

Female #5: It would be very important. I would want to know the side effects. This whole HIV, AIDS stuff is scary. It's a scary topic and people don't care anymore. Nowadays people don't care, you didn't ask for this and they pass it on. But I would ask, did it lower your chances?… The best way of being safe is not doing certain things, to just wait, this is not an STD or STI, this is serious. You have this for life. Use protection and knowing the person you are doing it with.

Female #16: Very important, I want to see what they are going through, what are their battles. What positive or negative outlook they have on it.

Female #45: Sure. Side effects, and also feedback about how they handle, you know, the negativity about it. And that long term goal about taking it and how they're taking care of themselves. So, they just take it and not using protection and stuff like that.

Female #60: The first thing I would ask … why do you feel like you need to take it? … if they want to let me know, I'll know what those risks are, whatever. So, you're taking it for a reason because you have a risk.… if you need to take it to feel safe, for yourself.

Female #8: I would want to know what their daily life is like, how it makes them feel, does it affect their emotions, every little thing I would need to know. So, I would need to speak with other women who are taking it so I can know.

Female #9: … What are the side effects? How does it affect their daily lives? Would there be drowsiness? Things of that nature I would want to hear from other women.

Female #43: It's going to be very important to me. For me, I would like to hear that opinion here, what it did for them or if it they're passing news onto other females in and the other lives in family, how they react. You know, if the man was willing to try.… They don't want to go out and get a test … we take all these tests and there's no

> victim. We feel embarrassed, but we take it because you want to live….
>
> *Female #6:* … I haven't heard people talking about it. I would like to hear other people's opinion who have taken it before. Yes, it's very important to me.

Even when shared experience was not initially considered important, there was an acknowledgement of value.

> *Female #2*: Yes, because I like to read reviews before I purchase a product. It's half and half because at the end of the day it's what I decide. It's what's best for me. What works for me might not work for them.
>
> *Female #1*: … The only thing that matters is what I want to do and how I feel about taking it. But it would be nice to know how women feel based on being protected and how it makes them feel … whether they like it or not. The only thing that matters is if I want to take it.
>
> *Female #7*: … It's not important to me, because it's really about one's health. I would be happy if other women do it to protect themselves, but I can't push it on nobody else.

Beliefs That May be Barriers to PrEP Uptake

A few barriers to the use of PrEP were common among the 72 women interviewed, including the question of whether PrEP really works, assessment of risk, stigma and promiscuous behavior, anticipated effects of PrEP on condom use, and PrEP's limited functionality.

Does PrEP really work? One of the recurring questions was whether PrEP was effective. Women were keenly interested in the pill's ability to deliver protection against HIV. There were questions about PrEP that, as an innovation, requires dissemination of specific information among populations most at risk. Until that happens, it seems that uptake will remain low.

Questions about the drug's effectiveness were mentioned in many different meaningful ways, even when that question was not asked in a specific way.

Researcher's question: Is there anything you would like to know to help you make a choice about PrEP?

Female #9: I would like to know the research, the statistics, how effective is it, what are the risk factors and is it worth taking those risks. If the drug was not effective would I still get HIV?

Female #3: At this moment, no. I have only been on it for a few months so I'm still trying it out. I only have one partner, so there is nothing I'm really concerned about right now, but maybe in the future. The doctor told me if I should be exposed to HIV, that it would fight it. I was really worried about, God forbid, he was sleeping with someone, and I was exposed to it, would this really work? That was my main concern.

Dialogue #11

Female: You said the medication has been out since 2012.

Researcher: FDA approved it in 2012.

Female: And they have been giving it to people? How are the studies? How did it come about? Is it doing what they say it's going to do, or supposed to do? This is 5 years later. Since 2012 till now are the studies 100%, 50/50, 30/70, is it working? If you get 100 people are all 100 on it or what else is there. Has it been doing good on the market since 5 years ago?

Dialogue#15

Researcher: Is there anything you would like to know to help you make a choice about PrEP?

Female: Since PrEP has been out what are the statistics? What has happened since the pill has been out? Did it go up or down?

Researcher: In terms of effectiveness?

Female: Yes. Is it helping Black women? Since it was designed to help us is it really working? If it is such a good pill why is it that it is not being talked about more?

Assessment of risk, stigma, and promiscuous behavior. The assessment of individual sexual risk is a complex issue. Promiscuity (multiple sex partners) is associated sexually transmitted diseases such as HIV. The result is the perpetuation of stigma associated with behaviors such as PrEP use. Discussing HIV prevention in communities of color can improve knowledge of new biomedical innovations and may help debunk stigma associated with efforts to reduce risk.

Black women associate promiscuity with HIV and the consequent need to take PrEP:

> *Female #72*: … If I was promiscuous, I know that I do stuff like that, I'd be like, yeah, I probably would take it [PrEP] because I never know.
>
> *Female #8*: To be honest I don't see myself taking a pill everyday just to prevent something.…I know personally people that are promiscuous and it should not be a problem for them to take it every day. I would question myself, why do I need it, I shouldn't be taking it….
>
> *Female #7*: … But it depends on if you are promiscuous and what kind of sex you are having. If you have a single partner or you are not seeing anybody, then I don't see why it would be necessary.… Protect yourself, use condoms, if you are not using condoms, use birth control, something, a cervical ring, just something.
>
> *Female #24*: Well, it depends, you know how sexually active you are, you know…. If you wanna do it everyday, take the medication.…

An important factor in assessing risk among women is that they also share in the in the conclusion of their risk. Without this acceptance, necessary actions to prevent risk are not likely to follow.

> *Female #4*: If I'm not at risk, I wouldn't take medication for anything.
>
> *Female #5*: Because when other people tell you what's best for you, you don't want to hear it. They might not understand

you. You can give me the good, the bad or the negatives and I decide what I want to do. Some people give prescription on PrEP or any other thing they don't take it, they may agree to it, but they don't take it. It's up to the person at the end of the day if they really want to be on the safe side and be protected. It's really not about what people or the doctor tells you. The doctor can say what he feels is best for me, but it is still up to me to make that decision.

Dialogue #35

Researcher: Before today, have you ever heard of PrEP, Pre-exposure prophylaxis?

Female: Yes.

Researcher: In what context?

Female: My doctor brought it up to me…that was like a couple months ago.

Researcher: Mhmm hmm.

Female: … She was telling me a little bit about it and asked if I was interested and she prescribed it.

Researcher: She actually prescribed it to you, okay. Umm what did she tell you about it? Whatever you remember.

Female: All I remember is it prevents HIV.

Researcher: Mhmm hmm.

Female: …… I mean it could go for me but I'm really not that sexually active so I wouldn't really need it though … I just feel like it's kind of risky with like the side effects or whatever it was because when she told me about it last time and I read the like side effects it was a lot.…

Researcher: Mhmm hmm.

Female: … So I was scared, that's why I just never took it.

This dialogue shows that women have questions about side effects and fear that can result in inaction.

PrEP and Condom Use

There was mixed reactions to condom use and PrEP. Without any doubt, Black women would prefer condoms, primarily because PrEP safety is relatively unknown. Interestingly, responses about condom use tended to be given in an ideal situation, using terms such as "hopefully" or "should" when describing condom use. Generally, beliefs about risk compensation by foregoing the use of condoms for PrEP is low. Among the responses, there was a tone of advocating for the use of both methods, if PrEP use is acceptable.

Researcher's question: If women were to use PrEP would there be a change in their condom usage?

Female #3: I just feel like if you can protect yourself with a condom you still should.

Female #2: Well, if the study goes well and PrEP works and if you are using condoms just to prevent the disease then there should be a change. But if you are using condoms to prevent you from getting pregnant then there should not be a change.

Female #16: It wouldn't change my way, some women yes. You have both sides of the fence that have little loopy girls and guys. I am trying to inform my little sister. She has been with her boyfriend for 3 years and thinks it's okay to have sex unprotected with him. He is 3 years older than her. It's not okay.

Female #11: Not me personally. It wouldn't change my perception of using condoms. Hopefully it's 100% but we don't know that. If I know the condoms and the PrEP would prevent me from getting it, then definitely.

Female #8: Of course, they already don't use condoms as much as they should.… There are more sexually transmitted diseases, so can that [condoms] prevents those also … They should take other steps also because you never know and you can't get rid of it.

Female #9: … You have to look at it from birth control. Are women less likely use condoms because they are on birth control? It would have the same effect.

Female #1: It might, now they just think they are covered, … it could work, and it might not. I don't think they should just stop using it [condoms]. I don't think they should stop, because that just prevents HIV. There are still STD's so I would hope they would still be using condoms. Then there is HPV. There is a lot of different things you can get from sexual intercourse….

Female #7: Maybe, they might get too relaxed. They might think its okay now. They have something to protect them and everything is not 100% proof. I think condoms are still the best thing.

Some women felt that PrEP use might result in lower condom use or increase in risk compensation:

Dialogue #35

Researcher: Do you see any advantage in PrEP over condoms?

Female: Yes.

Researcher: For you, what are those?

Female: Because everybody has to wear condoms …

Researcher: Mhmm hmm.

Female: So, if somebody could just easily take a pill … they would take it because a lot of people don't like the feeling of condoms when they do have sex.

Researcher: Mhmm hmm, so it definitely could fill that gap when….

Female: Yes.

Researcher: Yeah, if women were to use PrEP, do you think that they would change how they use condoms?

Female: I feel like if they use PrEP they would still not use condoms because they feel like they are protected….

Researcher: Mhmm hmm.

Female: … Even though they're not…you know…but I feel like they would feel safe.

Dialogue #4

Female: They could both be used.

Researcher: That's true. Do you see one having more of a weight?

Female: So, you said the PrEP work, so I think it would work better than the condoms, especially if the condom tears.

Researcher: So, if women used PrEP would there be a change in condom usage?

Female: Well for me I would use both. I would still use the condom with the PrEP just to be a little safer.

Researcher: What about other women?

Female: Sometimes the females want to get all wild, so they don't want to use condoms so the PrEP would be an alternative.

Limited Nature of PrEP

Black women want more comprehensive prevention methods. Focusing efforts only on HIV prevention was thought to be too narrow. Among issues that fuel their perception is the gap in STI and pregnancy prevention. Black women labeled PrEP the "freedom pill" and the "magic pill." Examples of Black women reflecting on PrEP and the gap in protection that they may experience as a result:

Female #71: … We got this pill and now this new freedom pill so you know, we could just axed the condom … people do think that way because they have one level of protection so they fit right…. But the pill is not going to stop you from getting syphilis, gonorrhea, …

Female #18: … But I still say you're taking a risk…. The PrEP pill is so you don't catch HIV. It's not saying that you're cured from all the other STDs … I think you should take the PrEP pill and still use the condom, still practice safe sex because, it's other stuff out there … you found one magic pill you still have other things that can happen.

Female #6: But you don't want to have a baby every time you have sex. It's not just HIV, there are other things too.

Female #7: … There is still chlamydia and other STDs so I'm not too sure about that one either.

Dialogue #3

Female: I just feel like if you can protect yourself with a condom you still should.

Researcher: Following up on that point you were making; if women were to use PrEP, would there be a change in their condom usage?

Female: Maybe. It shouldn't though because it doesn't prevent other diseases. They might say I'm not going to get HIV so I shouldn't use a condom anymore, but everybody should still.

Researcher: Is it that they are thinking that they are more worried about HIV than anything else?

Female: Yes, that's what it is. Because when you think of HIV you think about death. That's what it used to be … but they can still get other diseases.

Dialogue #15

Researcher: Do you see any advantages of PrEP over other methods?

Female: No. It's just like any other method. Take the pill, you will be alright, use a condom you will be alright, birth control; it's the same thing as any other method.

Researcher: Interesting. If women were to use PrEP would there be a change in their condom usage you think?

Female: No, I don't think so.

Researcher: Why not?

Female: I think women are still going to use condoms.… if it's not AIDS its pregnancy so they're still not going to do unprotected sex.

Enabling Factors

According to Green et al. (1980), enabling factors are “the skills and resources necessary to perform a health behavior,” and they further note that “a person’s ability to perform the tasks that constitute the desirable behavior” is important to the adoption of the new behavior (p. 75). Categories that emerged as enabling factors are pill taking, privacy and PrEP use, and cost and insurance coverage.

Pill-taking Behaviors

Although there is a list of reasons why women do not take medications, many women also provided strategies and skills that they have acquired to support pill taking behaviors. Shared examples include:

> *Female #9*: They could put notifications on their phone, whatever they use. People use cell phones every day, so they could have an alert on their phone, reminding them to take the medications, they could leave sticky [notes] around the office or home or whatever they find easier as a reminder.
>
> *Female #69*: Yes.… What I would actually do is like have a certain container for every day and put the pills that are needed in each section so I know what to take, what day to take them and keep them on schedule.
>
> *Female #29*: Sticky notes, reminders in my phone. Always have it in my bag…. So that the minute I’m ruffling looking for something “oh shit I didn’t take my medicine!” Put it out right then and there and take it.
>
> *Female #35*: They can keep it in their bag at all times cause that's like one of my biggest problems. Like I’ll forget it at home…. So they can keep it like one in their bag or put it in like a little container where somewhere they know they're gonna see it all the time….
>
> *Female #52*: … I’m gonna take that pill but if I forget it, you can, you can double up make it as a part of our daily regimen. I think she will take it on a daily basis. If you have to take

it at nighttime, I think women would take it at night time.... When you relax and you calm down….

Female #3: It has been difficult because I am not on any medications, so I had to get use to it [PrEP]. I had to get used to taking something every day. The doctor says I have to take it every day. I said every day? I'm one of the people that don't like to take medications. I'm not on any meds, not even birth control, and I have to take it every day. But this prevents HIV so I said okay. But after a while I got used to it…. I set my alarm … when I hear the alarm I know what it means. But I had to build a certain routine. I would take it every day before I had my breakfast, so that's how I got used to it.

Additionally, women often prioritize important health concerns by following through with taking the necessary measures. Black women saw PrEP similar to taking birth control, vitamins and other medications. Examples shared include:

Female #62: I take my vitamins everyday, but even then, sometimes I forget. So, it was like you really have to be on point with it, especially if it's something as important as that.

Female #67: I think most of the women that I know either take prescription medicine or vitamins or supplements or something. I feel like a lot of women are moving toward being more healthy, taking ownership of their health….

Female #8: … I would take it like a daily vitamin. If I have to, I would just take it.

Female #41: So, every day pill. So, it's like a birth control pill basically. Gotta make sure you take it cause, say if you take it and you stop taking it, a whole different side effects your whole body change from taking pills.

Female #46: I'm already taking a pill every day. Birth control pills. So, it's was like, I'm used to taking like, Oh snap my birth control pills. So was like, I know like this won't be a problem. At first, I thought the control pill was going to be a problem, but it's not, it's pretty fine.

Female #42: If I was considering to take it, just like birth control, sure, I would take and set it aside, I have a spot on my dresser for any medication I'm taking. Put it to the side and set my timer on my phone.

Privacy and PrEP Use

During the interviews, Black women's tenacity and a strong sense of agency came up to mitigate perceived stigma, partner and/or relationship concerns and family and friends' interference to their use of PrEP. Black women demonstrated this grit in two ways. The first was by a general consensus that the final decision to use PrEP rests only with the women. They claimed agency over their health rights. Second, Black women found strength within their ability to navigate PrEP use alone and to keep PrEP private. Maintaining privacy over their use of PrEP, as a strategy would allow for better control over their safety and increase their "peace of mind."

Black women shared the importance of discussing PrEP with their partners but took agency over their final decisions:

Female #1: … What other people say shouldn't be important, I guess it's about knowing yourself. If you've been a leader all your life whatever you do, you really wouldn't care about somebody else's opinion. I've never been a follower. I've always had a strong mind. I always did what I wanted to do … what you decide might not be right for somebody else, but it's right for you. If it works for you, what does it matter what anyone else thinks.

Female #5: … They should be understanding and want to be on the safe side with me. If not, then I have to question, are you really for me? What are we doing here? Because this is something serious. So, it needs much thought and conversation.

Female #12: … My partner's opinion doesn't really matter, especially if I am protecting myself. If anything, I would try to convince them they should take it too. Because it is, supposedly, benefitting everybody.

Female #21: … I have my own choice. Yeah, he be important to my life, but I still wanna be safe.

Female #67: … My health is my job … and I would want to really get to the bottom of why this preventative medication would be an issue for my partner.

Female #35: Because it's my body so if I want to be protective of my body…. I don't care what nobody else say.

Female #4: If they say you can't take it, you have to ask them why; what's the reason why you don't want me to take it? You want to protect yourself. They have to have a reason why they don't want you to take it. And if they want you to take it, then that's a good thing.

Female #3: … It would matter but it wouldn't change my opinion or my mind about it. He is understanding. I don't think he would have anything negative to say. I just haven't mentioned it to him. I don't know why, it's just that the conversation has not come up…. He may think she has HIV, that why she is on that medication. A lot of people think that too. So, I try not to scare him.

Examples of responses related to privately navigating PrEP use alone are illustrated below:

Female #3: … It's a mind thing for me … my partner doesn't know I take it.

Female #36: If it's secretive…If they didn't want, I guess their spouse or anybody that they dealing with to find out, I think they'll do it … secretly though.

Female #29: I mean nobody needs to know what you're taking…Put it in a bottle that doesn't have a name on it. Put it in an empty vitamin bottle. "Oh, what is that? Vitamins!" … Umm, it's not anything, nobody needs to know. That's your personal business whether you have it or you don't.

Female #40: I think everybody experiences it differently … people might feel like they might get judged.…But who gonna know you're taking it, unless you tell somebody.

Female #8: ... I mean if they keep it to themselves nobody has to know. You don't have to tell somebody. Why should it be known? I don't see any problems or barriers or anything.

Female #13: I think it would be a good thing for her because that would ease her mind, but you have to because lots of men in today's society are going with men and women. So, I think for any woman that should be a big influence to ease her mind.

Cost and Insurance Coverage

Cost of medication and insurance coverage were huge issues when discussing medication among the population of women interviewed. Concerns about coverage of PrEP by insurance and possible co-pays are issues that can either enable or discourage use of PrEP among Black women.

Examples of concerns relating to cost and insurance coverage:

Female #6: … Cost is probably going to be a big factor because people might not want to pay out of pocket and a lot of people can't afford it. Your insurance being able to pay for it is a big deal.

Female #1: … Because sometimes these aren't covered by Medicaid or whatever you have. You might have to pay for it out of pocket. I guess you have to ask the doctor if it's covered or not.

Female #23: Cost, side effects, long term use, will it affect anyone who is thinking about having a baby.... That's it, that's all I can think of.

Female #43: … What kind of price? What kind of money would I have to have to put it all together? … can you get it free? … if insurance will cover? I want to hear those kinds of questions.

Female #57: What would the cost be?

Reinforcing Factors

According to Green et al. (1980), reinforcing factors "are those that determine whether health actions are supported" (p. 76). Awareness of PrEP among the sample of women was extremely low. Therefore, with the exception of two women who previously used PrEP, women's insights in determining reinforcing factors are more perceived rather than actual lived experiences. Five common themes that emerged as reinforcing factors: couple use in normalizing PrEP; doctors' role in advancing PrEP among Black women; pointers for health

care providers; older Black women as resources of behavior change; and the fear of extreme side-effects.

Couple Use in Normalizing PrEP

One of the most striking results of the survey was the interest and seemingly logical thinking about encouraging PrEP use as couple activity. One of the immediate benefits couples' use provides, aside from reinforcing the behaviors among intimate partners, is alleviating possible negative reactions from partners. Black women are quite concerned about the impact of PrEP use on their relationships and believe that, similar to couple HIV testing, PrEP use can be normalized in a similar way among couples.

Black women perspectives on couple PrEP use:

Female #6: … If we can do this together and be safe I think that's a plus … just to be safe, let's both take this…. Anything that is going to help people not get HIV is a good thing.

Female #10: I would find out if they have a partner and invite them so they could get schooled together … because everyone is not completely honest.

Female #61: … we would definitely have to discuss it … [if] one of us decided for whatever reason to cheat on the other, at least we will protect it from that.

Female #66: Because when you're in a relationship or you have that person sharing that type of intimacy … I think you know, you should go with too because nowadays somebody is going to backslide and go out, you know. So, if you could prevent anything, that's the best way.

Female #5: But for the women I think it's more serious because she is expected to maintain her health. There is a certain expectation … but its okay if they take it together.

Female #24: … You [health provider/doctor] should let them know so they can take it together, instead of passing it over.

Doctors' Role in Advancing PrEP among Black Women

Overwhelmingly, Black women expressed respect and trust for their medical providers. Of the 72 women, 69 indicated that they most frequently visit either their gynecologists or their primary care providers. Intriguingly, the results reveal little to no reluctance to speaking with medical doctors about HIV prevention such as PrEP. However, at the time of the study only three women recalled conversations with their medical providers about PrEP. Additionally, women rely their high levels of comfort with their doctors and, with the exception of six women, the majority of women indicated that they would consider using PrEP if their doctor recommended its use.

Importance of doctors in promoting and scaling up PrEP among Black women:

Female #18: Of course, look I know there's this magic pill around here named PrEP, how do I take it? How many times? … I would be intrigued to know how can I get this medication.

Female #49: Because she knows how I'm feeling. She knows what is good for me. What am I supposed to take?

Female #2: First, if my doctor recommended … it's for my safety.

Female #6: She would just have to suggest it and I would always read about it myself.… If she suggested it, I know it would be something positive to take.

Female #17: Show me that this product works, they have to show me results… that's it!

Female #43: But if the doctor says you have to try it, … I would try it.

Female #67: … It's good to have a personal opinion, but you know, I would want to incorporate some type of professional opinion in there too.

Female #71: … We've had conversations as far as my sexual partner and my sexual preference and stuff like that. … as I said to you, at the moment I am not as popular as it used to

be in that department.… If my doctor was to give me instructions, hey, that's a good thing.

Female #48: … She's a doctor so she's not going to sit here and tell me false information to make me take a medication that's really not going to work.

Female #9: I depend on my physician for medical updates, so she would come to me and say there is a new drug on the market and I believe it would be very beneficial for you and your partner. Then I would definitely consider it.

Female #13: I think most of the time when you are sexually active your doctor would ask you if you are using protection. I would think that my doctor would be the person to advise me the most because she may have more experience in dealing with the virus and know more about it than I do. Then sometimes too it depends on the information the patient gives to the doctor. This is what you should do if you have multiple partners.

Female #71: I think this is something that you should probably try or like here's some information about it.… I would like for you to read over it, talk to me about what you think or whatever and let me know … we can't stop them from having sex. We can't stop them from making poor decisions. But if you have more tools such as this available to them, perhaps it'll stop some of the inferno you know, of what's going on in this inner city.

Female #42: If he recommended it and I fell into one of those categories. Yes.

Female #6: …I trust her opinion, she is a good doctor, I've been with her a long time.... So, I value her opinion and I trust her.

Female #40: I don't know what the big deal is. I wanna take something to prevent myself from getting HIV. Can you help me with that? What's the big thing about asking your doctor that?

Female #4: If I think that I am at risk, then I would ask her to [prescribe PrEP].

Female #7: I don't have a problem with that [asking about PrEP], because that's what they are here for. I haven't seen my gynecologist in a while but I would ask her because she

> recommended the HPV shot. So, she would recommend it if she feels that I need it. She would say something about it.

Pointers for Health Care Providers in Promoting PrEP among Black Women

There are vast possibilities for increasing awareness and promoting PrEP as an option among Black women. A few suggestions for beginning that process, which will help to reinforce HIV prevention are captured below. To summarize, Black women believe that the environment in which PrEP is presented as a prevention option should be comfortable. They encourage providers to speak openly about HIV without any attempts to scare them. In addition, it is important to talk about risk and to do risk assessment, and they believe that doctors should educate women at every visit.

Lessons for preparing PrEP related health education discussions and materials:

> *Female #4*: So, the doctor needs to say how effective it is, how you can prevent yourself from HIV, even more than just the regular condoms, other pills or whatever you take and just basically educating them about PrEP. A lot of people don't really know about it so they need to educate people, so they can talk to somebody else about it.

> *Female #13*: Well, I would say give every patient the option. Educate them about it and give them a choice so they can think about it. Introduce it to them so they will know.

> *Female #8*: There are a lot of women out there that are being promiscuous, so they need to speak to all women, … and there are a lot of drug addicts…. I think every doctor and every nurse should sit down with every patient they have and talk to them about it. Personally, I think it's a good drug.

> *Female #41*: HIV scares everybody. Let's get that out the way. Tell them that this is not a scare. This is something that you think that is the next best thing to a condom. Just like birth control pills.

Female #6: I would tell them, just have some information like handouts in your office so as you see your patients—GYN I'm talking about, or regular doctor, just have information that people can read, so after your office visit say, "check this out and see how you feel about it." I think they need more paper hand-outs. That would help a lot.

Female #5: Just let them know that they could still catch something even with the pill. I think they should be realistic, speak facts, no matter how young they may be, don't trick people to thinking this is the only option.

Female #2: … She [doctor] would have to talk to me about it, like a mother daughter conversation, make it flow, don't make it seem like an authoritative thing. Just talk to me about the importance and what it does.

Female #3: I want everybody to know that this is here.… A lot of people don't know. My doctor said she spreads the word….

Dialogue #3

Researcher: What advice would you give a doctor/nurse/health educator to help them communicate effectively to women about PrEP?

Female: just to educate them at every visit

Researcher: What type of education?

Female: About what it is, what it does and they should recommend it to especially young females, I would suggest that. My doctor, she did her job and I know she is spreading the word to other young women too, which is good. But I don't know if other doctors do that. My GYN doctor didn't.…

In the following excerpts, Black women provide the "how to" for practically reinforcing the information. Interventions suggested represent local and community level strategies that Black women perceive would be effective in reinforcing messages for PrEP use among their population.

Female #3: She [doctor] gave me a pamphlet.… I was waiting for her to come back in the room, and she asked if I was

interested in it. She explained everything about it, including the side effects….

Female #70: … Go into the hood to the poorer neighborhoods to be more aware of this type of the option. Go to the streets and give out the information. You go out to the street with signs …. Educate, educate, give flyers out.

Female #1: … It would be nice if they had flyers on the walls when you come in. I see a lot of flyers on the walls for different things like the HPV shot. A poster will always help. They might see it and say well what is that is for. Advertisement is good…. If you put up flyers that's the best way. I feel like it's always a conversation starter, oh what's that.

Female #43: Well get educated. Just like what I'm learning here. Get your hands on the flyers….

Female #9: I think they should have the education in their office, whether it be a pamphlet, a short video, especially youthful women or if they don't have the time to sit down for an elaborate explanation, they can read on the train or they can call the doctor's office back and say I am interested.

Female #34: The side effects … am I gonna be a crazy person after I take it?

Female #15: Social media, and talking to young people, because they are all about sex. We don't really watch TV we are mostly on our phones.

Female #3: Yes, on the radio, billboards, bus-stop places; maybe I missed it, maybe I haven't seen it.

Older Black Women as Resources of Behavior Change

One of the more surprising results was that Black women looked to older women for direction and advice about HIV prevention. The idea is that whether or not their mothers or respected older women are actually using PrEP, their advice is valued.

Examples of older women in scaling up PrEP use among Black women:

Female #34: … it would be my doctors and more than likely my mother.

Female #63: Women, older women … they just need to be like more of a, I take this pill every day and I'm safe and everything is okay and they'll give me no complications.

Female #42: I will say people my own age group and maybe women a little bit older. I would say like around twenties, forties, because I would figure they were, they're still like a little bit more sexually active … that age group, that would appeal to me.

Female #36: If my mother was to tell me, "You know, I'm taking PrEP. You should do it," I would do it.

Female #62: … this may sound generic, but my mom … she would have to … be really reassuring in order for me to be like, all right, cool.… She would just have to say how it is really beneficial going into detail about it, but as if she was taking herself and she's trying to like to put me on it.

Fear of Extreme Side Effects

The most frequently asked questions about PrEP were about side effects. Caution was exercised by Black women about medication and it was important that before PrEP could be considered an option, to understand the effects of the medication. One young lady who received a PrEP prescription but who did not fill the prescription indicated:

Female #28: I just feel like it's kind of risky with like the side effects or whatever it was because when she told me about it last time and I read like the side effects it was a lot …so I was scared, that's why I just never took it.

To increase knowledge and to actively reinforce the option of PrEP-taking behaviors among Black women, discussing side effects is very important. Black women are concerned about the effects on the emotion, their moods, their mental agility, their weight, their health, their reproductive, health including their ability to get pregnant and pregnancy outcomes, among other factors.

Female #48: … I don't take birth control pill because it makes me gain weight. That's the reason why I choose not to take it. If I didn't gain weight, I'd probably kept taking the pills. So, you have to put all the side effects to the pill out there.

Female #8: No, the side effects, pregnancy; those are the major stuff.

Female #4: What are the side effects? … that's basically what I want to know.

Female #59: My thing is the side effects, because sometimes even though the medication might be good for one thing, side effects off of a medication … lady for the side effects. I'll just stay with what I got. You know.

Female #72: Yes, the medicine does sound like a good idea.… But I'm a scaredy cat. I do not like the side effects. Tell me the side effects … deaf, bleeding out the nose. Not Pancreatic. Your pancreas may blow up.… I don't like the side effects. The most medicines, the side effects scare me more than the disease do. Sometimes she'd rather be sick. muscle loss … heart murmurs, all that. No, no, no.

Female #43: I would want to know the side effects … when I hear about a medication and the side effects, sometimes even worse than the sickness you have, so I decided effects would make me go crazy. I wouldn't take the medication. I will want to know exactly what it would do to my brain?

Female #43: I want to get pregnant. She would think about what would happen if I take this.… But I know for sure if they're going to get married and they want to have babies in the future that would bother them, you know.

Female #5: I have taken a lot of pills prescribed to me; for sleeping, anxiety or mood, and it harmed me, it didn't do me any good and the longer I was on this pill the more things started happening to me…. Our people always get tricked up to thinking this is to help us and people are the cause for a lot of things in our community. Have you given them an option? What is this really doing to my inside, my organs, since I have to take it every day and not like once a year.

Dialogue #2

Researcher: The last open-ended question, is there anything you would like to know about PrEP to help you make a decision?

Female: Side effects.

Researcher: OK, what about side effects?

Female: What are the side effects of PrEP? That's what I would want to know. It's not just about PrEP. It's me and every medication. How it makes my face look.

Researcher: Do you mean like acne?

Female: I mean any medication I look at the side effects before I decide if it's worth me trying.

Chapter V

DISCUSSION

This study sought to describe the awareness, beliefs, perceptions, and motivations to either accept or reject PrEP among African American women and to describe lessons that could be learned by HIV prevention practitioners and stakeholder networks as they design and implement interventions to scale up PrEP use among Black omen. The conclusions outlined below focus on awareness of PrEP; willingness to accept or reject PrEP; impact of partners' reaction to PrEP use; barriers to PrEP use; adherence concerns; privacy in PrEP use; and the doctors' role in advancing PrEP use among Black women.

Awareness of PrEP

Using Smith et al.'s (2015) calculation based on the CDC guidelines, over 468,000 U.S. women have PrEP indication. One benefit the CDC guidelines provide to high burden communities is that the screening of heterosexual women should be a priority in health care settings. Referencing the 2017 NYC annual surveillance report, the results of this study revealed that Black women are experiencing disconcertingly low rates of awareness of PrEP. Of the 72 Black women who participated in the current study, only 6 had prior knowledge about PrEP before the study.

As such, time was made available in the interview to provide information about PrEP. In spite of the pronouncements about PrEP in New York City, three of the women with knowledge about PrEP believed PrEP was not for Black women, but instead believed PrEP was for gay people or people of trans experience. These findings are consistent with those of Whiteside et al. (2011), who reported that in their cross-sectional study of 405 clinic attendees, over 81% indicated they were not aware of PrEP. Although Whiteside et al.'s findings were six years earlier, the rate of awareness among Black women remains appallingly low. Additionally, Goparaju et al. (2015), in the Women's Interagency HIV Study (WIHS) in Washington, DC, also found low PrEP awareness. In the WIHS study, 39 women participated in eight focus groups separated by sero-status. The groups comprised 20 sero-negative women and 19 sero-positive women, with African American women representing 80% and 100%, respectively, of the racial composition of the groups. In the WIHS study, sero-negative women were excited and interested to learn more about PrEP, a finding consistent with the current study.

Calabrese et al. (2016) interviewed 18 medical PrEP providers in the Northeast and South regions of the U.S. by either email or in-person interviews and theorized that one challenge experienced in PrEP implementation was "accessing and engaging priority populations" in PrEP care (p. 9). Optimizing traditional settings to increase awareness of HIV prevention tools is a viable and readily available option in inner-city communities. In the current study, although only one community-based clinic was sampled, all 72 participants were at varying risk levels for HIV. Scaling up early prevention outreach efforts at clinics such as this should be prioritized as part of a wider set of strategies to increase awareness and interest among women. Clinics routinely provide care to high-risk

populations, such as Black women, and are therefore a reasonable setting for reaching and engaging priority populations in PrEP care.

Accepting/Rejecting PrEP

Many women refused the use of PrEP primarily for two reasons. First, they knew nothing about PrEP; it was the first time the medication was being introduced to them. Understandably, this lowers the chances that PrEP would be accepted during these initial discussions. Second, Black women in the current study did not believe they were at high-risk of getting HIV. Whether it was being married, not being sexually active currently, using condoms during sexual acts, or favoring PrEP for "other" women, in many cases, the respondents did not believe they would use the medication. This finding is supported by studies that show that low perceived risk of HIV equates to low PrEP uptake (Kwakwa et al., 2016; Whiteside et al., 2011). One of the findings emerging from this study was that Black women associated PrEP with being promiscuous, and the women in the study did not perceive themselves as being promiscuous because, for example, they only have one partner or they do not sleep around. Black women wanted to distance themselves from being perceived as “in need” of this medication.

Among Black women in the current study who were more willing to consider PrEP use, factors contributing to their decision were their fears about HIV, encouragement by older women, advice from their medical providers, knowledge of partners using PrEP, and if they perceived themselves at risk of getting HIV. After gathering more information about PrEP, Black women expressed their willingness to consider using PrEP. Black women indicated that they would learn more about PrEP by reviewing additional information and conducting their own

research into the medication's effectiveness and side effects, and by asking their medical doctors about PrEP and whether it was the right option for them. In a similar FQHC setting, Kwakwa et al. (2016) found that willingness to use PrEP was triggered by fear of HIV, importance of a prevention strategy, and high-risk perception.

Impact of Partners' Reaction to PrEP

The current study revealed a recognition that men reportedly have strong influence over Black women's willingness to use PrEP. Black women showed high agreement that men's use of PrEP would also result in women using PrEP. Men using PrEP was favored by women, as this was associated with reduced risk for women to get HIV.

At the same time, if Black women were to initiate PrEP use, they anticipated that their partners would respond in an unfavorable way. Black women feared that their use of PrEP would result in underlying relationship concerns levied by their partners. Women were concerned about accusations of "stepping-out" of the relationship, which is considered cheating. Further concerns were that partners would look at them "side-ways" if they mentioned using PrEP. Overall, there was concern that PrEP use would create trust issues resulting in disastrous consequences for relationships. This finding was consistent with that reported by Flash et al. (2014) in relation to condom use. Flash et al. recruited 26 Black women aged 20 to 50 years old in Boston, Massachusetts, and conducted five focus groups. Flash et al. found that barriers to condom use included "fear of perceived unfaithfulness, financial barriers, personal perception of being at low risk, educational status, desire to conceive and intimate partner violence" (p. 635). The barriers identified for both PrEP and condom use might represent

broader behavioral barriers that exist regardless of the HIV prevention methods being discussed. Therefore, the broader intervention of HIV prevention, sexual health rights, women's rights, and behavior change should be more integrated and complementary in program execution and less fragmented in implementation.

Although Black women in the current study were not asked about intimate partner violence (IPV), as mentioned in Flash et al. (2014), IPV is a barrier to safe sex. The Garfinkel et al. (2016) study in Baltimore City and in Baltimore's northern suburbs recruited 75 women aged 18 to 35 years from two family planning clinics. Although only 50% of the sample was Black, women who experienced forms of IPV were less likely to accept PrEP compared to women reporting no IPV. One strong recommendation from Garfinkel et al. was the appeal to raise IPV as a national priority by addressing violence and trauma as part of wider interventions to reduce HIV among women, which the Researcher from the current study strongly supports.

Barriers to PrEP

In decisive ways, Black women articulated their perceptions of barriers to PrEP use. Among barriers identified were questions about effectiveness of PrEP, low risk perception, stigma and promiscuous behavior, limited use of PrEP, and the effect PrEP will have on condom use. Black women raised concerns about the medication actually fulfilling its purpose of preventing HIV. Black women were interested in the statistics that showed the effectiveness of the medication and the results from studies since the FDA approval in 2012. Another reason for the concern is the idea that good innovations tend to be known. Women were

conflicted about trusting PrEP because it was neither known nor was PrEP "talked about."

One of the striking findings about assessment of risk is the importance of Black women owning their risk assessments. Women who were told by their doctors that they are at risk would either go along with the assessment for a short period of time or dismiss the assessment altogether as not being representative of how they define themselves and their behaviors. It seems clear that if women do not consider themselves to be at risk, they will not be motivated to obtain a PrEP prescription, or ultimately fill the prescription, and will be far less likely to take the medication once it is prescribed.

Blackstock et al. (2017) found that of the 554 women who accessed services and had PrEP indication in Bronx, New York, only 21 heterosexual women (3.8%) obtained at least one PrEP prescription. Of the 21 women, only 28.6% were non-Latina Black women. A study by Kwakwa et al. (2016) found that Black women appear to have a low risk perception of getting HIV. In that study, among the nine women testing positive for HIV, only one indicated a moderate to high-risk perception of getting HIV. The other women perceived themselves as at low risk of getting HIV and also expressed that before their new HIV diagnosis, they had low interest in PrEP.

In the current study, although the results show that there were perceptions that PrEP use might result in lower condom use, thereby increasing risk compensation by using PrEP, the perceptions were mixed and varied by situations. The idea of PrEP being a "freedom pill" and "magic pill" does flash scenes of a "free for all" sexual revolution. However, fewer Black women thought that would be the norm, with more women advocating the use of dual protection, and for like messages to be reflected on flyers and social media campaigns. The use of dual messaging was considered as the best way to increase protection

and reduce HIV. Another reason for concurrent condom use was primarily because of the limited nature of PrEP. Black women were deliberate in the use of dual protection because PrEP is limited in protecting them from pregnancies and STIs. Repeated feedback from women highlighted the need for comprehensive protection, which is not obtained from PrEP. This finding was consistent with results reported by Whiteside et al. (2011), which indicated that women were supportive of dual protection, using both condoms and daily-PrEP to reduce HIV infections.

Although the literature is limited in female-focused PrEP studies, Smith et al.'s (2012) findings also present areas of similarities. Findings of mixed-gender focus groups found barriers to PrEP uptake, including “side-effects, medication cost, partial effectiveness, low perceived personal susceptibility to contracting HIV, burden of taking a daily medication, [and] reaction of peers to taking HIV medication” (p. 413). One clarifying point regarding peers’ reaction as a factor for PrEP use is that, in this current study, although reaction of peers was a factor, it was less of a factor compared to reaction from a partner, which elicited stronger and more visceral reactions.

Adherence Concerns

Another important finding from the current study, which is controversial in the literature, is adherence. Adherence to PrEP is essential for preventing HIV (Baeten et al., 2012). In their review of literature, McMahon et al. (2014) found adherence as a significant concern among medical providers. Other authors found that 77% of providers were concerned about adherence to medication and the possible risk for future resistance to antiviral medication (Karris et al., 2014). Karris et al.'s study surveyed 1,175 active members of the Infectious Diseases

Society of America's (IDSA), which is a provider network of infectious disease clinicians. Given the evidence for PrEP in 2013, Karris et al. also presented additional clinicians' concerns, which included concerns about toxicity and insufficient evidence to support real-world efficacy of PrEP.

In the current study, Black women reported a similar concern, primarily, that consistent pill taking is challenging. Examples were provided about forgetting to take either prescription or over-the-counter medications. However, there was consensus in the belief that Black women have developed skills in pill taking, and although there are excusable misses of daily doses, they can be adherent to taking pills. Strategies included using phone alarms, sticky notes as reminders, creating set times for taking medication, and the use of the handbag in pill reminders. Additionally, birth control and vitamin use were also widely cited to show where Black women have exercised deliberate practice in managing their health and reproductive goals. These perspectives were supported in the Partners Study, where Matthews et al. (2014) found 97.7% adherence among non-pregnant women in the study.

In spite of participants' strategies for promoting medication adherence, prior studies have found adherence to be a major challenge. According to the FEM-PrEP and VOICE studies, the findings showed that low adherence by women was viewed as the primary reason for the failure of the intervention. According to Marrazzo et al. (2015), the VOICE trial experienced less than 30% adherence to medication, which resulted in 312 sero-conversions among 5029 women enrolled in the three treatment arms and two control arms of the trial (p. 513). In an additional study, Boffito et al. (2014) found women to have difficulty in adhering to the daily pill regime, resulting in "missing doses or treatment fatigue to prescribed medication" (p. 7).

Privacy in PrEP Use

Black women exercised agency in making final decisions about PrEP use and the best way to navigate PrEP. In the current study, it was important for some women to navigate PrEP use alone, as privacy was felt necessary for keeping them safe. Stigma toward HIV is a reality that is closely aligned to PrEP use. Black women indicated that, although their partners would most likely discourage PrEP use, their family and peers would also provide negative and unhelpful remarks about using PrEP. To navigate these realities, Black women believed that using PrEP privately would not only increase their safety, but also boost their "peace of mind" when protecting themselves from HIV. Flash et al. (2014), in their U.S. women PrEP study, found that "women thought a pill would be easy to conceal and to ingest surreptitiously, thus eliminating the need to discuss concerns about their partner's level of risk" (p. 638). Therefore, emphasizing the benefits and value of PrEP as a female-controlled modality becomes absolutely critical in PrEP education and navigation that involves Black women.

Black women also advocated for clinical PrEP research to evolve beyond the use of oral medication toward injections or vaccines, or other long-acting methods of protection that allow for "6-month" dosing. In the broad body of research, these perspectives are considered to be female-controlled modalities, therefore indicating a preference for added privacy as a priority consideration.

Doctors' Role in Advancing PrEP among Black Women

Another finding in the current study was that medical providers had a significant influence over their willingness to use PrEP. Black women expressed respect and trust for their medical providers, who primarily comprised

gynecologists and primary care providers. Although, medical providers did not impact Black women's awareness about PrEP, women expressed comfort and willingness to openly discuss PrEP with their providers. To facilitate PrEP awareness to Black women, providers are expected to be educated and equipped with PrEP tools. Initiatives to increase providers' awareness about PrEP and to encourage PrEP prescribing practices are significant in scaling up PrEP among Black women at risk of HIV. Undoubtedly, further work in engaging providers to openly discuss PrEP among Black women is strategically beneficial in ending the epidemic. Although there are gaps in practice, Smith et al. (2016) report evidence that, in 2014, clinicians were increasingly more aware of the CDC guideline for prescribing PrEP. Further, Calabrese et al. (2016) noted, "Either the community isn't aware enough about it or their primary care providers are still not talking about it enough, are not confident enough, or are not able to answer their questions, so that there's a gate and the gate is really closed off before people actually get to me" (p. 9).

As expected with gaps in female-focused PrEP research, additional factors that impact women's decision on using PrEP were not readily identified in the literature review. These include couple use in normalizing PrEP, leveraging older women as resources for behavior change, sharing experiences among PrEP users, and managing perception of extreme side effects. These will be reviewed in later sections.

Limitations of the Study

The conclusions outlined above must be considered in light of the study limitations, which are outlined below. The limitations include sample deficiencies, lack of triangulation, cross-sectional design, and researcher's potential bias.

These limitations point to the need for more robust future studies. They also provide context in which the results from this current study can be understood in its implications for practice and future studies.

One limitation was the study sample, which was purposive and selected from a particular reference population who were willing to participate in the study. The current study used two CDC guidelines for female PrEP indication to recruit Black women who received care at a health center in Brooklyn, New York. The current study sample was not random in participant selection and utilized one site for recruitment. Another problem with the study sample was that since they had limited awareness about PrEP, they may not have been in a good position to reflect on the interview questions. The current study clearly represents exploratory work that requires further research to verify the findings.

Another limitation is lack of triangulation. The ability to "apply the principle of triangulation throughout your study, continually watching for opportunities to triangulate your steps," further strengthens the credibility of a study (Yin, 2016, p. 87). According to Yin, triangulation involves the principle of "seeking at least three ways of verifying or corroborating a procedure, piece of data, or finding" (p. 87). Drawing from Patton's (2002) work, Yin (2016) cites four ways in which data can be triangulated:

1. data sources (data triangulation)
2. investigators who have worked on the same study team (investigator triangulation)
3. perspectives about the same dataset (theory triangulation)
4. methods (methodological triangulation) (p. 87).

In the current study, only one source of data was used, namely, self-reports from the participants; only one researcher conducted all of the interviews, and interviews were the only method of data collection.

Another limitation of the current study was the cross-sectional design. The study was implemented over a 3-month period from November 2017 to January 2018. Participants were interviewed only once, and there was no overlap of participants in the pilot study and those in the larger study. According to Carlson and Morrison (2009), cross-sectional studies are often “described as taking a 'snapshot' of a group of individuals” (p. 77). The authors highlight one advantage of cross-sectional design as its ability to understand the prevalence of various conditions, treatments, services, or other outcomes and the factors associated with such outcomes (p. 78). Although the current study is helpful in identifying factors that may impact Black women’s motivation to either accept or reject PrEP, a limitation in conducting this type of study is that no causal associations between factors identified for either accepting or rejecting PrEP can be made.

To a great extent, the veracity of this study relied on the Researcher herself. It is, therefore, important to reflect on how her background, prior experiences, and orientations may have influenced the results. Recognizing that the Researcher was not only involved in the collection of the data but was also personified in the questions asked, the responses given, the respondents’ openness, the completeness of the interview, the ethical concerns, and later activities that included the transcription, coding, analysis, and presentation of results, it is therefore pertinent to understand the Researcher, her story, and possible impact to the study. Roberts (2002) furthers this statement by eloquently stating that to “place the researcher fully within the research is to recognize that we all have stories and it seems a fundamental part of social interaction to ‘tell our tales’” (p. 13). The Researcher is a Black woman in her 30s who contends with various social roles, including sex, gender, wife, motherhood, religious beliefs, daughter, employee at the Health Center, and student. She must grapple with what it means to thrive and excel in all these roles while maintaining a

full-time job. Presently, the Researcher leads an HIV prevention team at the Health Center in Brooklyn, promoting and implementing HIV prevention strategies, while also navigating newly diagnosed and people living with HIV into medical care.

Psychologically, it was utterly rewarding interviewing Black women in Brooklyn in my workplace. The fieldwork was comfortable and safe, as these women were considered my sisters, mothers, friends, and community. Yet I was also uncomfortable and insecure because of the topic. I knew what HIV means in the community and knew that the stigma was real. However, I believed, although the realities may be different, that women in New York City are all at risk of HIV. This was a reassuring factor in pushing the boundaries of the study. Of course, it also helped that I conducted a pilot study, which was useful in finding rhythm in asking the questions, working on my expression (which women are quick to point out), and learning from women's reactions about possible offenses caused by questions or how they were asked.

Interviewing 72 Black women who had different attitudes, beliefs, ages, perspectives, and cultures was tremendously humbling. There were many times when in my mind I may not have agreed with the perspectives being shared, but those were the times I was deliberate in my expressions; seen through a gentle "smile" or a "nod of support" to urge the respondents to continue. I was always trying to be mindful of reactions, while creating an enabling space where women felt safe sharing their experiences. Women shared stories of resilience, successes, and strength but also shared stories of abuses, family conflicts, and fear. There were times I wanted to give advice but restrained myself. Yet there were decided moments when women asked specifically for advice. At those times, I shared my experiences, with the hope it could be helpful. Needless to say, women were quite forthcoming with their advice, particularly when they

learned the study was related to the Researcher's graduate degree. In keeping with her culture, advice was taken with appreciation, and, where appropriate, hugs and well wishes were exchanged.

By way of professional experience, the Researcher started her work in the field of HIV prevention in 2009 when she lived and worked in South Africa. Currently, she manages federal-, state-, and city-funded HIV prevention and access to health programs in Brooklyn, New York.

Implications for Practice

The findings from the current study have pronounced implications for practice. The areas that are reviewed include understanding the disconnect between perception of PrEP uptake and practice; increase education of providers; and a new PrEP navigation model for Black women. These are implications that should be interwoven into health education and health promotion programs for Black women.

Disconnect Between Perception of PrEP Uptake and Practice

In the U.S., Bush et al. (2015) reviewed PrEP prescriptions through a national database over a 3-year period from 2012 to the first quarter of 2015. The authors found over 8,500 PrEP prescriptions. Bush et al. found a 332% increase in PrEP users from 2014 to 2015. During this same period, women accounted for 13.4% of PrEP users, while 86% were male. As expected, the results showed incremental PrEP increase over the 3-year period, which would correspond to FDA approval in 2012 and CDC's release of guidelines for clinical practice in 20014. Similar trends have been found in other studies (Bien et al., 2017; Blackstock et al., 2017; Laufer et al., 2015). Although Black women in the current

study believed that more women would use PrEP, based on an assumption that they are more connected to the health care system than men, the findings of other studies (Bien et al., 2017; Blackstock et al., 2017; Bush et al., 2015; Laufer et al., 2015) clearly reject that perspective. Based on new HIV diagnoses reported in the literature, compared with Black women, the rate in New York City among MSM is three times greater. This is consistent with use of PrEP primarily among MSM. Nevertheless, there are noticeable disparities in PrEP prescriptions and PrEP uptake among Black women.

As health educators, the question of access to PrEP becomes very important. Understanding where PrEP information is being shared is an important element in piecing together PrEP uptake and HIV prevention messages. Identifying what sources Black women use to learn about PrEP with an aim of replicating such education in settings where Black women obtain health care services may be helpful in increasing awareness and interest about PrEP among this priority population.

Increase Education with Providers

The findings of the current study show that medical providers did not educate Black women about PrEP. Of the 72 Black women interviewed, 6 had knowledge about PrEP, and only 3 received information from their medical provider. This finding is congruent with the body of literature that exists. According to Karris et al. (2014), although 74% of providers supported the use of PrEP, only 9% ever prescribed PrEP in their practice. Of the 74% of providers who supported PrEP, 43% would prescribe PrEP, but 34% believed PrEP was not relevant to their practice (p. 464). The clinical support for PrEP as a biomedical prevention in ending the epidemic has to drastically increase. As health educators in the field, working alongside clinicians to increase buy-in and

support for the entire tool kit of HIV prevention methods is a persistent need that should be included in work plans and health education interventions. Identifying the kinds of educational approaches that are most acceptable to various groups of women and most feasible to implement in various health care and other settings remains a current need. Creative partnerships with health care systems should be focus areas for health educators to ensure that vulnerable communities are accessing tools to prevent new HIV infections.

New PrEP Navigation Model for Black Women

Navigation and linkage to care are critical to the New York's Blueprint for Ending the Epidemic by 2020. Among priorities for the plan is the component of "facilitating access to pre-exposure prophylaxis (PrEP) for high-risk persons to keep them HIV-negative" (Blueprint on Ending the HIV Epidemic in New York State, p. 4). Increasingly, as Black women are engaged in PrEP conversations, the goal of linking women to PrEP care is critically important. However, a shift in navigation for women must be consciously made for linkage to PrEP services to be successful. The findings of the study speak clearly to the importance of a gender-specific PrEP navigation approach for Black women.

The findings from the current study create a ground-up perspective in understanding key components that should be involved in PrEP navigation for Black women. The components are risk assessment and shared understanding of the identified risk; the use of female-specific PrEP materials, including flyers, posters, and videos; connection to female PrEP users; initial thoughts about disclosure or non-disclosure; linkage to medical providers for PrEP prescription; and post-prescription follow-up.

Risk assessment and shared understanding of the identified risk are important first steps for women who are aware of PrEP. From the current study, it

was revealed that one reason for not taking PrEP prescription is that women do not share the concern about risk as the provider or PrEP navigator. As practice becomes responsive to the research, approaches for assessing and, where appropriate, changing Black women's risk perception of HIV infection need to change. Health educators are challenged to reframe PrEP risk assessment questions to help Black women explore individual reasons for being at risk of HIV. In settings of HIV testing or HIV prevention workshops, including reflective questions helps to elicit personal reasons for feelings of risk.

After risk assessment is completed and there is acknowledgement of shared risk perceptions, introducing female-specific PrEP materials would be a practical next component. Materials are needed to answer questions such as: What is PrEP? What are the benefits? Is it recommended for use with condoms? What are the possible side effects? How effective is PrEP? How much will it cost, and will my insurance cover the cost? From the current study, in-depth communication about side effects and possible interactions with other medications, including birth control, is critical at this stage, although realizing that additional information will be shared by the medical provider.

Black women who are interested and have PrEP indications may benefit from connecting with female PrEP users. Based on current literature, this component does not exist. The findings in the current study are clear on this point. All Black women either associate strong importance to this component or recognize its importance. Two options are utilizing Black female PrEP users as navigators, which helps in first-hand peer-to-peer exchanges about the benefits of PrEP and utilizing a PrEP navigator.

Weekly or bi-weekly PrEP groups discussing and share testimonials about their PrEP journeys are available options. Ideally, this component would be important before medical providers prescribe PrEP; however, individual journeys

are different, and timing to begin PrEP is also a factor. This component can also follow post-prescription for strongly motivated Black women and would become more of a support intervention, encouraging PrEP maintenance.

Once there is a decision that PrEP is an option, it is important to have conversations about Black women's initial thoughts about disclosure or non-disclosure of their PrEP use. This component can be a stand-alone conversation but, ideally, will form part of either risk assessment discussion or discussion after the connection to Black female PrEP users, realizing that time is a factor and another opportunity may not be present before the medical appointment. Black women should have a clear strategy of how they intend to take the medication. This may translate into keeping PrEP private, changing the pill bottle and creating a routine for taking the pill. In addition, as mentioned by women in the current study, developing "know-how" response to questions about the pills is important and prepares the woman for real-world settings. Moreover, if PrEP use will be revealed to a partner and or friends and family, understanding how to navigate those conversations, flagging key points to use, is also important for reinforcing safety and "peace of mind" for Black women. This component has not been mentioned in the literature but may be an important component in PrEP initiation and maintenance.

Currently, the most mentioned component in PrEP navigation is the linkage to medical providers for PrEP prescription. Arguably, the outcome of all PrEP navigation is for medical providers to prescribe PrEP. However, the simplicity of this act is overshadowed by the complexity that not everyone who receives a prescription actually fills it, and further, they may fill the prescription but never take the pill (Laufer et al., 2015). The importance of the preceding components works together to increase the impact the medical interventions will have in facilitating anticipated behavior change. Additionally, the medical provider is

expected to address lingering concerns, but should reassure Black women of the effectiveness of PrEP in protecting against HIV, citing clinical studies occurring in real-world settings, even their own experiences. Another important element in the conversations with Black women is managing the perception of extreme side-effects. Working with Black women to review their current medications, whether prescribed or non-prescribed, to assess potential contraindications cannot be overstated. Finally, the PrEP navigator follows up with the Black women to note the date of PrEP start, but also to address any lingering concerns.

Implications for Future Research

Further research is needed to advance HIV prevention interventions and strategies to end AIDS in vulnerable communities. Three gaps are identified, leveraging older women as resources for behavior change; couple use in normalizing PrEP; and understanding the future of PrEP prescription for Black women.

Leveraging Older Women as Resources for Behavior Change

Undoubtedly, gaps exist in the literature for Black women and PrEP use. Based on the findings of the current exploratory study, further research is needed to understand the extent and role of older women in communities of color to expand messages about PrEP and, quite possibly, other public health problems affecting Black women. This insight indicates another, more indirect, strategy for educating this target population. Further research would be useful in understanding the practical and possible impact that can be effected by leveraging older women in communities, who may be easier to reach in order to connect with hard-to-reach populations. Inherently, measuring the outcomes may

require innovation to ensure that the education is actually reaching the intended priority group would be an area of concern. Presenting models, not only for reaching hard-to-reach populations through older Black women as an intervention model, but also exploring ways of measuring outcomes of these interventions, are tools that would most definitely help end AIDS in our communities.

Couple Use in Normalizing PrEP

Another viable strategy for PrEP uptake among Black women is normalizing PrEP use among couples. This was a surprising finding from the current study, as Black women identified the importance of reinforcing positive behaviors of PrEP if implemented as a couple's activity. The results of the current study indicate that women are generally interested, as a first option, to discuss PrEP with their partners and to involve them in their decision-making process. Although Black women were quick to indicate their agency in making these decisions, there was a general agreement that positive input from partners would be helpful as they make their decisions.

Additionally, findings from the current study suggest that couple PrEP use also helps to alleviate possible negative reactions from partners and avoid potential negative strain on relationships. The concept is similar to couple HIV testing, which has slowly been accepted as part of the HIV testing landscape and is empowering couples across the world (Matovu et al., 2015; Rendina et al., 2014; Wagenaar et al., 2012). Couple PrEP initiation and use are an unknown area in the literature, and further research in understanding approaches, benefits, and means of engagement will help grow this area of HIV prevention.

Future of PrEP Prescription for Black Women

Although the CDC-recommended guidelines for PrEP indication are not limited to sero-discordant relations, most PrEP prescriptions among women have been provided because of discordant relationship status. However, of the less than 4% of PrEP prescriptions generated for women, sero-discordant relationship is the dominant risk factor (Smith et al. (2015). In their study, McMahon et al. (2014) believed that HIV-sero-discordant couples are the most "ideal candidates for PrEP" (p. 464). In the U.S., Smith et al. (2016) found that PrEP prescriptions were highest among sero-discordant couples, where one partner has HIV and the other partner is free of HIV. Additionally, in New York City, Blackstock et al. (2017) found that of the 21 women who received a PrEP prescription, 85.7% had as their primary risk factor being in a sero-discordant relationship.

Collaboratively, agreeing that sero-discordant relationship is one of the "low hanging fruit" that validates risk assessment indicates that further research is needed to provide direction to practicing clinicians and health educators in strategies for conducting effective risk assessments. Vulnerable Black women require greater attention and should be factored in when prescribing practices for PrEP beyond discordant relationships. This will become even more critical amidst the movement of U=U. The "Undetectable=Untransmissable (U=U) slogan was launched by the Prevention Access Campaign" (Editorial, 2017, p. e475). The campaign promotes the finding that people living with HIV who remain virally suppressed cannot sexually transmit HIV to other people. This is now accepted in the HIV/AIDS community. According to *The Lancet*'s Editorial (2017) in early 2016, the "campaign has been rapidly gathering momentum, having been endorsed by more than 400 organizations from 60 different countries since its launch," with the U.S. Centers for Disease Control and Prevention (CDC) joining the "movement by endorsing the science in a letter released on National Gay

Men's HIV/AIDS Awareness Day" in October 2017 (p. e475). As practitioners, framing the U=U discourse for Black women is strikingly urgent. How is the U=U discourse resonating with Black women in sero-discordant relationships? Do they still need PrEP? Is U=U discourse unintended consequence that may jeopardize the need for PrEP among Black women? Whatever the outcome, as practitioners and clinicians in HIV prevention, there are huge signals to move past low-hanging fruit to reach to those behaviors further up the tree of HIV risk in order to end AIDS.

Final Comments

First, as a final comment in this current study, although there is a dearth of female-focused PrEP studies to compare with findings of this current study, the barriers faced by Black women are unique. In addition, more women were diagnosed with HIV in New York City; quite noticeably, 68% of new diagnoses occurred among women aged 30-59 years with Black heterosexual women accounting for 38.3% of those new HIV diagnoses (NYC DOHMH, 2017). This is also framed within the reality that HIV stigma remains quite pronounced among Black Women. HIV prevention activities will continue to experience strong resistance, making health educators' and public health professionals' work even more difficult. Creative programming within high burden communities is even more critically important to penetrate with messages of new innovations and best practices. Smith et al. (2012) shared similar comments by highlighting the importance to scale up PrEP education and counseling efforts among African American men and women. The results of the current research speak volumes to the continued work needed to educate communities with prevention messages.

Second, the current study was conducted in a traditional setting in which HIV prevention messages should be routine and integrated in primary care. However, there is a ravine that exists between implementation and State recommendations. Quite possibly, this discrepancy may be due in part to low levels of provider awareness of PrEP as an HIV prevention method that is also suitable for women. This study indicates the need for collaboration and partnership between health departments and traditional and non-traditional settings to push targeted and newer innovations and practice models about HIV prevention to high-risk populations. The forging of these partnerships and iterative dialogues can stem the tide and drastically reduce new HIV infections among Black women in New York.

Third, the last comment seeks to be an encouragement for researchers. One lesson that has become quite obvious to this researcher is the need to be transparent and inclusive with the community about the research being attempted in the community. Historically, within Black communities, there exists a level of mistrust of research. Going beyond the description of research flyers to discuss the importance and driving force behind the research is not only an opportunity to build advocacy for the research, but it also breaks down skepticism and mistrust toward the research. After explaining the relevance of the research to potential participants, this Researcher found that Black women were also able to share the value of the research and increase their interest. Whether the research is quantitative or qualitative, generating support for the research, particularly within high burden communities, is one strategy to increase uptake of the research and boost participants' involvement. The experience from the current study was that communities were welcoming of research when they believed the research objective was to help the community. As researchers, it is our responsibility to demonstrate to communities that our work is to empower

people, support improved policies, reflect light on persistent health challenges, build shared consensus, and contribute to improved health outcomes.

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Appendix A

Pilot Questionnaire

1. When you think about the questions I asked, were there questions that:

a) were difficult to understand? Can you remember the question?

b) could have been clearer?

c) made you feel uncomfortable?

Final thought:

2. Is there a question would you like to suggest?

Appendix B

Frequently Asked Questions (FAQ)

For Women in the PrEP Study Briefing for Nursing and Health Educator Staff

The following questions and answers help to provide a consistent and clear message about the study to the nursing and health educator staff of the Health Center. Through this tool, staff will be clear about the study's purpose and ultimately increase the number of women referred to the study. Participants will get one consistent and clear message about the study to help them in their decision to participate in the study.

Q. What is the Purpose of the study?

A. The purpose of this study is to describe Black females' awareness, beliefs and perception of PrEP, and to identify factors that may influence Black women's willingness to consider PrEP as an HIV prevention strategy.

Q. Importance of the study?

A.

- This study is intended to support existing programs, to scale-up PrEP use among groups identified as at "substantial risk" of HIV infection, of which the population of Black women is of immediate importance.
- The results of the study elevate and will contribute to better understanding of the concerns women have as they navigate their awareness and perception, and intentions regarding PrEP to remain HIV negative.

- The study will provide tangible directions to HIV prevention practitioners that they can use to scale-up PrEP use among Black women.

Q. Who is supports the study?

A. The study is supported by Teachers College, Columbia University. Specific oversight is provided by dissertation advisors in the faculty of Health and Behavior Studies and Sociomedical Sciences at Teachers College and Mailman School of Public Health at Columbia University.

Q. Who will have access to the Data?

A. Data that is collected is restricted to the Researcher and the Researcher's advisors.

Q. What is required of participants?

A. Agree to participate in the study and sign the informed consent form.

Q. Who is eligible for the study?

A. Individuals who:

1. Are at least 18 years old.
2. Self-report having anal or vaginal sex within the past 6 months.
3. Have had a STI or HIV screen in the past 6 months or had a STI in the past 6 months.
4. Self-report HIV status as negative.
5. Are willing to provide informed consent to participate.

Q. What are the incentives?

A. As a small token of appreciation, each participant will receive one Visa Gift card in the amount of $20. No cash will be available.

Appendix C

Site Permission

MEMO

To [redacted] CEO/President

From: Suzanne Robinson Davis

Date: June 26, 2017

Subject: Approval to Collect Data

RECEIVED 6/30/17

As part of my doctoral program at Teachers College Columbia University, I will be conducting research on the awareness and uptake of PrEP amongst black women in Brooklyn.

The purpose of this study is to examine how Black females' awareness and perception of PrEP in New York City impact their beliefs about their use of PrEP, and to describe factors that influence Black women's rejection of PrEP among women considered most vulnerable to HIV. The study will also provide insights into lessons that could be learned by practitioners and networks working in the area of HIV prevention to scale-up PrEP use among this population of women. Ultimately, I want Black women in our community to experience better health and to take advantages of available and creative health programs and resources.

I am seeking your approval to utilize relevant information from the health center's electronic medical records to contact patients and/or to invite patients who visit the health center to be participants in the study. Data is expected to be collected from July 2017 to December 2017.

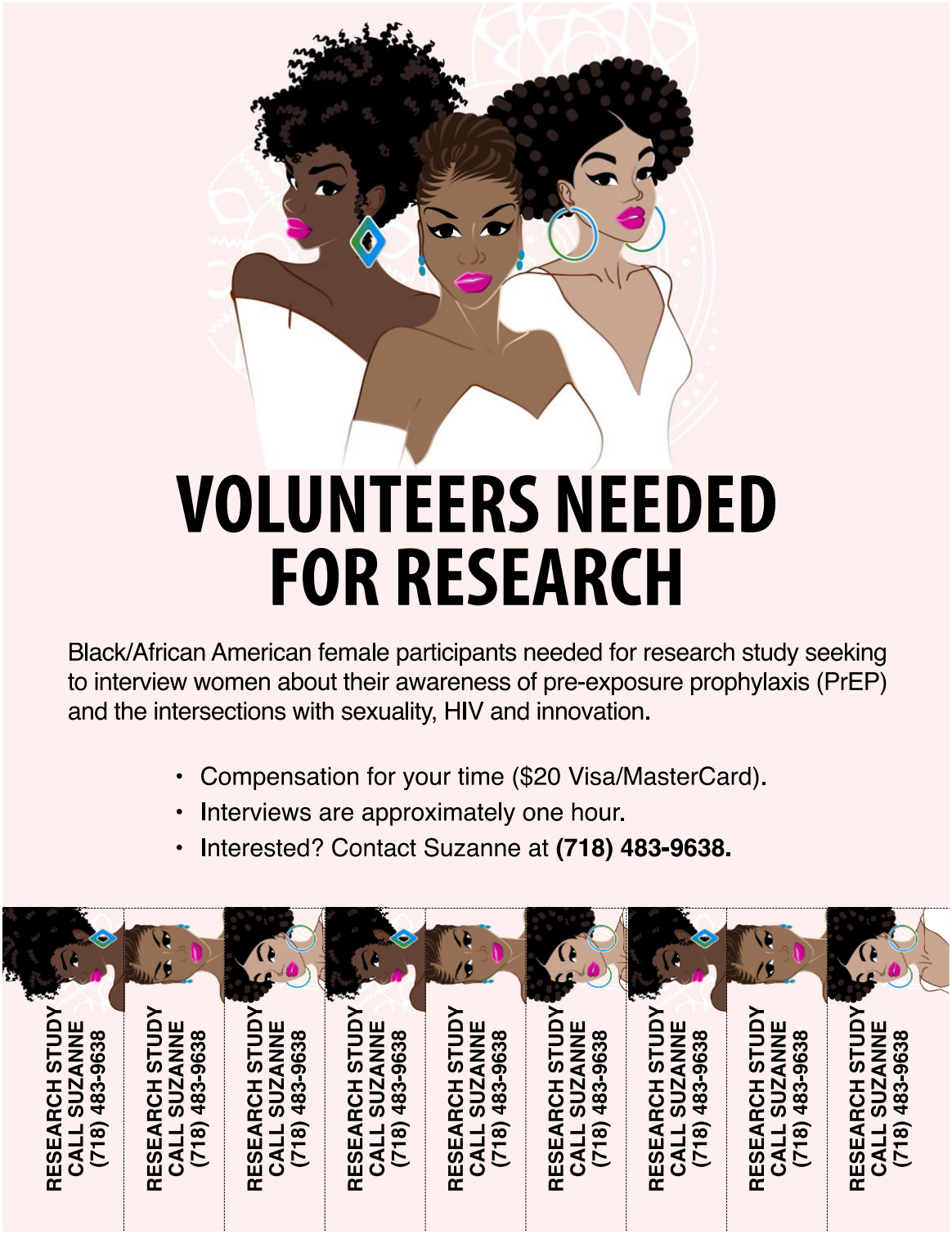
This investigation will form the backbone of my dissertation, through which I hope to demonstrate the need for greater attention to this important population in the fight to end AIDS by 2020.

I thank you for your continued support and look forward to a favorable response.

Yours sincerely.

Appendix D

Study Flyer



Appendix E

Informed Consent

Teachers College, Columbia University
525 West 120th Street
New York NY 10027
212 678 3000

Informed Consent

Protocol Title: **awareness, beliefs and risk perceptions and decisions to use preexposure prophylaxis among African American women in New York City.**

Principal Investigator: Suzanne Robinson Davis, Teachers College
646-525-1359, sr3275@tc.columbia.edu

INTRODUCTION

You are being invited to participate in this research study called "**Black female's awareness and perceptions about PrEP in New York City**." You may qualify to take part in this research study because you are over 18 years old and HIV-negative women or women who are unaware of their HIV status. If you are HIV-positive or currently taking PrEP you cannot be part of this study. Approximately 100 people will participate in this study and it will take 60 minutes of your time to complete.

WHY IS THIS STUDY BEING DONE?

Only few studies have looked at women perceptions about PrEP but none in Brooklyn focusing on Black women. The study will provide insights into lessons that could be learned by practitioners and networks working in the area of HIV prevention to scale-up PrEP use among Black women.

WHAT WILL I BE ASKED TO DO IF I AGREE TO TAKE PART IN THIS STUDY?

If you decide to participate, you will be interviewed by the Principal Investigator. During the interview, you will be asked to discuss your perceptions about PrEP, and questions about condom use and sexual practices**.** This interview will be audio-recorded. After the audio-recording is transcribed the audio-recording will be deleted. The interview will take approximately sixty minutes. Your identity will be kept confidential.

WHAT POSSIBLE RISKS OR DISCOMFORTS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Participants may experience minimal risk such as feelings of judgment, embarrassment, stigma, and general hesitation in discussing sexual practices but not greater than you would ordinarily encounter in daily life while taking routine physical or psychological examinations or tests related to HIV infection. An attempt to reduce such feelings will be made by reassurance from the interviewer that the discussion is confidential. **Also, you do not have to answer any questions you don't want to talk about. You can stop participating in the study at any time without penalty.** The Principal Investigator is taking precautions to keep your information confidential and prevent anyone from discovering or guessing your identity by keeping all information on a password protected computer and locked in a file drawer.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

There is no direct benefit to you for participating in this study. Participation may benefit the field of public health education to better understand the best way to engage women of color about HIV prevention. Additionally, if you are interested in PrEP, a referral can be made with a provider at the health center, which could be seen as a benefit.

WILL I BE PAID FOR BEING IN THIS STUDY?

Appendix F

Institutional Review Board (IRB) Approval

TEACHERS COLLEGE
COLUMBIA UNIVERSITY

Teachers College IRB *Expedited Approval Notification*

To: Suzanne Robinson Davis
From: Curt Naser, TC IRB Administrator
Subject: IRB Approval: 17-435 Protocol
Date: 08/22/2017

Please be informed that as of the date of this letter, the Institutional Review Board for the Protection of Human Subjects at Teachers College, Columbia University has given full approval to your study, entitled "*Black female's awareness, perception and willingness to take pre-exposure prophylaxis (PrEP) to keep them HIV-negative in New York City*," under **Expedited Review** (Category **(7) Research on individual or group characteristics or behavior**).

The approval is effective until **08/21/2018.**

The IRB Committee must be contacted if there are any changes to the protocol during this period**. Please note:** If you are planning to continue your study, a Continuing Review report must be submitted to either close the protocol or request permission to continue for another year. Please submit your report by **07/24/2018** so that the IRB has time to review and approve your report if you wish to continue your study**.** The IRB number assigned to your protocol is **17-435.** Feel free to contact the IRB Office (212-678-4105 or IRB@tc**.**edu) if you have any questions.

A waiver of documentation of informed consent (waiver of collecting signed consent forms) is granted as the signed consents would be the only record linking the subjects' data to their identity**.**

You can retrieve a PDF copy of this approval letter from the Mentor site**.**

Best wishes for your research work.

Sincerely,
Curt Naser, Ph.D**.**
TC IRB Administrator
curtn@axiomeducation.com

Appendix G

Interview Instrument

Interview Schedule for PrEP Acceptability Study

Opening Questions:

How is it going? Have you done interviews before? How did you feel about it? Well, together we will work to create a safe space while exploring your thoughts and feelings about this topic.

Section 1: PrEP Awareness & Acceptability

Observability/ Awareness

1. Before today, have you ever heard of PrEP? Have you seen subway ads, printed materials, or any campaign on social media/Facebook about PrEP?

2. Have you heard friends talk about PrEP? Do you have friends who have used PrEP? What have you heard and what are some of the experiences friends/people have shared?

Compatibility

3. Consider your beliefs about sexual health and HIV prevention, does PrEP fit in positively or negatively with those beliefs? Can you explain further giving examples?

4. Do you think that men and women are equally likely to use PrEP, or is one group more likely to use it? If more men use PrEP, would this positively influence women to use PrEP? Why/why not? If women were to take PrEP, would it affect their partner's reaction? How would it impact your decision to use PrEP? What about their peers' reaction? How would it impact your decision to use PrEP? Explain.

Relative Advantage

5. Do feel like you need PrEP? Do you see any advantages of PrEP over other methods? If women were to use PrEP, would there be a change in their condom usage? Give reasons. In your experience, what are reasons for not using condoms? Do you think PrEP could fill those gaps? If yes, how would you imagine that to be? If no, explain.

Awareness/Observability

6. Can you describe three risk factors for getting HIV? Would you consider a woman at risk if she just had one risk factor? If yes, which? If no, how about two risk factors?

7. Can you identify two barriers you think women would face in taking a daily HIV medication that can prevention HIV? How could they overcome those barriers? Examples.

Trialability/ Observability

8. Have you ever tried PrEP? If yes, how did you like it? If no, would you consider taking PrEP if your doctor recommended it? Is PrEP something you could incorporate into your life? Why/why not. In making a decision about taking PrEP, how important is it for you to hear from other women who take PrEP? Explain. Would your partner's opinion matter to you? Please explain.
9. Who would you say could most influence you to take PrEP and why? What would they need to say or show you to convince you to use PrEP?

Trialability/ Compatibility

10. Do you know of anyone who has HIV? Do you worry about getting HIV? Why/why not? Would taking PrEP every day be a realistic option for you? Why/why not? What is another option for keeping you safe and free of HIV?

Complexity

11. What advice would you give to a doctor or nurse to help them communicate effectively to women about PrEP? What three key points should women know when they consider PrEP?

Compatibility

12. What type of medical provider/specialist do you see most often? Has s/he ever mentioned PrEP? Would you feel comfortable asking your provider to prescribe PrEP? Why/why not?

Observability

13. Is there anything you would like to know to help you make a choice about using PrEP? Probe financial coverage, costs, side effects and efficiency.

Section 2: Patient Demographics

1. What is your gender:

1. Female ___

2. Who do you have sex with?

    1. Male (Men) ___
    2. Female (Women) ___
    3. Both___
    4. Transmen___
    5. Transwomen___

3. What is your race/ethnicity? **(circle the selected answer).**

    1. Black or African-American
    2. Mixed race: _____

4. Please provide the name of the city and state where you live:
   Borough: _____ Zip code: ___

5. Reasons for last clinic visit: STD test___ HIV test___ regular check-up ___

6. What most accurately describes your current **relationship / marital** status? **(circle the selected answer).**

1. Legally Married
2. Separated
3. Divorced
4. Widowed
5. Not Married
6. In a domestic partnership (living with a committed partner)
7. In a committed relationship (not married and not living together)
8. Neither in a committed relationship or legally married (i.e. Dating)
9. Don't Know
10. Other:_____

7. What is your year of birth: (yyyy) _____

8. What is the highest level of education you have completed? **(circle the selected answer).**

    1. Less than high school
    2. High school/GED (Some college)
    3. 2-year college degree (Associates)
    4. 4-year college degree (BA, BS)
    5. Master's degree or over

9. What is your **monthly** income from all sources? **(circle the selected answer).**

    1. Less than $1,500
    2. $1,501-$2,500
    3. $2,501-$3,500
    4. More than $3,500

10. What is your current housing situation?

    1. Stable___
    2. Unstable___
    3. Homeless ___

11. Do you have health insurance? Yes___ No___

Section 3: Individual Risk Questions

1. Have you had condomless anal or vaginal sex in the past 6 months? Yes___ No ___

2. When you think about the past 3 months, have you had more than one partner? Yes___ No___

3. When you think about your sexual encounters in the past 3 months, how often did you use a condom: **(circle the selected answer).**

    1. Never
    2. Almost never
    3. Occasionally/sometimes
    4. Almost every time
    5. Every time

4. Have you ever had a Sexually Transmitted Disease (STD) in the past 6 months? Yes___ No___.

If Yes, which ones **(circle all that applies)**:

1. Chlamydia
2. Gonorrhea
3. NGU
4. Syphilis
5. Herpes
6. HPV (warts)
7. Trichomonas
8. Unknown

5. Have you ever used injection drugs in the past 12 months? Yes___ No___

6. Have you ever used **non**-injection drugs in the past 12 months (crack or marijuana or crystal meth, etc.)? Yes___ No___

7. Do you have knowledge about a family or friend who has been diagnosed with HIV? Yes___ No___

8. When last did you have a HIV test? **(Circle the selected answer).**

    a) 0-3 months ago
    b) 4-6 months ago
    c) 7 months-1 year ago
    d) Over 1 year ago
    e) Never tested before

9. Thinking about the last person you had sex with, do you know their HIV status? (such as if they were HIV-positive or negative?) Yes No

10. Rate your perceive risk of getting HIV.

    a) Definitely
    b) Very probably
    c) Probably
    d) Probably not
    e) Definite

END

Appendix H

Emails from Researchers

Robinson-Davis, Suzanne <sr3275@tc.columbia.edu>

Request for Instruments **Auerbach, Judith**

<Judith.Auerbach@ucsf.edu> Wed, Dec 21, 2016 at 3:02 PM

To: "Robinson-Davis, Suzanne" <sr3275@tc.columbia.edu>

Dear Suzanne,

Thanks for your message, and for your interest in addressing PrEP use among Black women in New York. This is a very important topic, and I'm pleased to know you are pursuing it in your doctoral research.

For our study, we used focus groups, not interviews, as our method. I have attached the focus group guide here. I've also attached a questionnaire we used to collect basic demographic information about the focus group participants. Feel free to use or adapt either or both of these. Acknowledgement of their source is much appreciated.

Also, in case this is helpful, here's the link to the updated version of the fact sheet we used at the beginning of our focus groups: http://www.thewellproject.org/hiv-information/prep-women. Much has happened in the area of women and PrEP since we did our research, so this fact sheet and associated videos are an excellent up-to-date resource for you.

I hope all of this is helpful.

Best regards, Judy

From: Robinson-Davis, Suzanne [sr3275@tc.columbia.edu] **Sent:** Tuesday, December 20, 2016 5:53 PM **To:** Auerbach, Judith **Subject:** Request for Instruments

[Quoted text hidden]

2 attachments AU PrEP Focus Group Questions.pdf

PrEP preFG questionnaire.pdf

Request for Survey Instrument(s) **Yohance Whiteside** <yowhiteside@gmail.com> Mon, May 15, 2017 at 8:53 PM

To: "Robinson-Davis, Suzanne" <sr3275@tc.columbia.edu> Hello Suzanne,

I've attached two surveys that we conducted. One was the HIV PrEP survey for STD clinic attendees and the other was a PrEP survey for seronegative partners of HIV positive individuals. Good luck.

Best,

[Quoted text hidden] -- Yohance Omar Whiteside, MSPH, PhD