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Addressing Barriers Affecting Primary Care Providers Willingness to Prescribe Pre-Exposure Prophylaxis Care as a Prevention Strategy Among Black/African American Men at Higher Risk for HIV: A Quality Improvement Project

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Addressing Barriers Affecting Primary Care Providers Willingness to Prescribe Pre-Exposure
Prophylaxis Care as a Prevention Strategy Among Black/African American Men at Higher Risk
for HIV: A Quality Improvement Project

A Scholarly Project Presented to the Faculty of the
Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements
For the Degree of Doctor of Nursing Practice

By

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Abstract

Introduction: Approved since 2012 by the Food and Drug Administration, pre-exposure prophylaxis (PrEP) for HIV prevention has significantly evolved. Taken daily, PrEP reduces an individual's risk of contracting new HIV infections (Eakle et al., 2018). Despite the proven effectiveness of PrEP in reducing new HIV infection among high-risk HIV-negative individuals, the percentage of Black/African American who filled prescriptions for PrEP in 2016 was only 11.2%, compared to 68.7% among Whites (Centers for Disease Control and Prevention, 2018). The purpose of this scholarly project was to develop a quality improvement project by creating an educational module based on CDC's PrEP implementation guidelines to improve barriers affecting primary care providers' willingness to prescribe PrEP care as a prevention strategy among Black and African American men at higher risk for HIV.

Methodology: IRB approval was obtained from Florida International University. Participants included two MDs (n=2) and thirteen APRNs (n=13). A Qualtrics link was electronically provided to all participants to complete the online survey, pre-test, and post-test during a 4-week period.

Results: 15 participants completed the study. The mean of the pre-test survey was 12.58 with a standard deviation (*SD*) of 5.36 while the post-test survey had a mean of 17.00 with a *SD* of 5.95. PCPs' knowledge increased by 25.65%, attitude by 12.63%, and behavior by 4.93%. A paired-samples *t* Test was performed, the two-tailed P value was 0.0004. By conventional criteria, the difference was extremely statistically significant.

Conclusion: Educational intervention was effective in improving PCPs' knowledge, attitude, and behavior towards PrEP. Ongoing work focused on educating primary care clinicians on the implementation of PrEP and other HIV prevention strategies will be crucial in reducing and

eradicating the HIV epidemic, more importantly in high-risk vulnerable population such as Black/ African heterosexual men and BMSM.

Keywords: *Primary care providers, Black/African American, pre-exposure prophylaxis, HIV, men who have sex with men, knowledge, attitude, behavior, barriers.*

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Chapter I: Introduction

Problem Statement

Human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) remains a major cause of morbidity and mortality around the world despite major efforts by healthcare organizations (McCance et al., 2019). Although the number of new cases and HIV-related deaths have been stabilized through the implementation of aggressive antiretroviral therapy and countless public health campaigns, the number of cases and deaths continues to increase rapidly worldwide (McCance et al., 2019). The most notable form of secondary or acquired immunodeficiency by an infectious agent is acquired immunodeficiency syndrome (AIDS), a viral disease caused by human immunodeficiency virus (McCance et al., 2019). HIV is a blood-borne pathogen present in body fluids such as blood, semen, vaginal fluid, and breast milk, which is typically transmitted through the following routes: blood or blood products, heterosexual and homosexual activities, intravenous drug abuse, and maternal child transmission before and during birth (McCance et al., 2019). HIV infection targets and depletes a portion of the immune system, the Th cells, increasing an individual's susceptibility to contract life-threatening infections and malignancies (McCance et al., 2019).

Funding for HIV care, assistance in cash and housing, research, prevention, and the Minority HIV/AIDS Initiative (MAI) constitute the domestic HIV budget (Kaiser Family Foundation, 2019). Health care services and treatment represent the largest component of the federal HIV budget. \$21.4 billion were spent in 2019, accounting for 62% of the total HIV budget and 77% of the domestic share (Kaiser Family Foundation, 2019). A 5% increase compared to the fiscal year 2018 due to increased mandatory spending for Medicaid and Medicare (Kaiser Family Foundation, 2019). Cash and housing assistance in the U.S. accounted

for \$3.1 billion, 9 % of the overall budget. Ironically, only \$900.8 million (3%) of the HIV budget went towards domestic HIV prevention (Kaiser Family Foundation, 2019). Based on the numbers, domestic HIV prevention had the smallest budget. \$2.6 million were dedicated for research. The Minority HIV/AIDS Initiative (MAI), created to address the disproportionate impact of HIV and AIDS on racial and ethnic minorities in the U.S., received \$54 million (Kaiser Family Foundation, 2019).

In the United States, based on the Centers for Disease Control and Prevention HIV surveillance report of 2018, HIV/AIDS is predominantly associated with a history of male-to-male sexual contact: about 67% of the newly diagnose cases were attributed to men who have sex with men (MSM), 34% to high-risk heterosexual contact, and 7% to intravenous drug abuse (Centers for Disease Control and Prevention, 2020). Compared to other racial and ethnic groups, Blacks or individual of African American descent have higher rates of some sexually transmitted infections (STIs), particularly HIV (Centers for Disease Control and Prevention, 2018). Black/African American men accounted for 75% of the overall number of HIV cases among the Black/African American population of the United States, with the majority of cases (82%) attributed to male-to-male sexual contact (Centers for Disease Control and Prevention, 2020).

According to the Centers for Disease Control and Prevention, pre-exposure prophylaxis (PrEP) serves as a mean to allow individuals who are HIV negative but are at very high risk of contracting HIV such as Black/African American men to reduce or prevent HIV infection by adhering to a daily regimen of antiretroviral medication (Centers for Disease Control and Prevention, 2020). The pill, currently marketed as Truvada, contains a combination of tenofovir and emtricitabine. Individuals who have a high risk of contracting HIV due to exposure through sex or injection drug use may benefit from these medications, which work by preventing the

virus from establishing a permanent infection (Centers for Disease Control and Prevention, 2020). PrEP is highly effective in preventing HIV when administered daily. Studies have shown that PrEP has the potential to reduce an individual's risk of acquiring HIV from sex by about 99% when taken daily. As for individuals injecting drugs (PWID), daily dose of PrEP reduces their risk of getting HIV by at least 74% (Centers for Disease Control and Prevention, 2020). Adherence is the key to PrEP maximum efficacy. Oral PrEP is currently included as a component of the recommended standard of prevention instituted by the World Health Organization for individuals with substantially high risks (Eakle et al., 2018).

Despite the proven effectiveness of PrEP in reducing new HIV infection among high-risk HIV-negative individuals, the percentage of Black/African American who filled prescriptions for PrEP in 2016 was only 11.2%, compared to 68.7% among Whites (Centers for Disease Control and Prevention, 2018). According to Mayer et al, (2020) many factors have contributed to the low uptake of PrEP among Black/African American; the authors noted that many individuals at high risk of HIV acquisition such as Black men who have sex with men (BMSM) and heterosexual Black men had no awareness or knowledge of PrEP, impacting their ability to even ask their providers for the medication (Mayer et al., 2020). A lack of PrEP awareness and knowledge was also identified among certain healthcare professionals (Mayer et al., 2020). Compounded with individuals and providers' barriers, HIV-related stigma continues to discourage some individuals at high risk of HIV acquisition to seek the treatment (Mayer et al., 2020). Additionally, many individuals at risk of HIV acquisition have experienced bias at the hand of healthcare clinicians, worsening distrust of the medical establishment (Mayer et al., 2020). Many individuals at risk also experience socioeconomic disparities and even though

several financial assistance programs for PrEP exist, the lack of support can make it difficult to access them (Mayer et al., 2020).

Significance to Nursing

In overcoming the vast array of barriers associated with PrEP uptake, it is of utmost importance to provide improved education and training to providers and patients at high risk of HIV transmission such as Black/African American heterosexual men and BMSM. The delivery of brief educational sessions to patients at risk during clinical visit could be proven an effective approach in raising awareness and PrEP uptake among these individuals (Raifman et al., 2018). Similarly, the provision of online resources could have the same impact (Mayer et al., 2020). Primary care providers who are willing to prescribe PrEP and wish to learn more about its implementation must use public resources provided by organizations such as the Centers for Disease Control and Prevention. Providing education and training to the public and primary care providers in particular, may address many of the barriers to PrEP identified in the literatures, but deep-rooted barriers such as bias and racism will require remarkable changes within the U.S. healthcare system (Mayer et al., 2010).

Chapter II: Summary of the Literatures

A literature review was conducted utilizing databases and sources such as FIU Libraries, CINHALL, Google Scholars, PubMed, Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), Corporation for Enterprise and Development (CFED), National Center for Biotechnology Information (NCBI), and MEDLINE to obtain relevant journal articles and reports. The Key words utilized in the literature review include Black, African American, HIV/AIDS, pre-exposure prophylaxis (PrEP), Truvada, stigma, cultural beliefs, disparities, discrimination, racial, ethnic group, bias, barriers, perception, access, healthcare, men who have sex with men, heterosexual, and risks. The search was limited to full-text research articles in English, published between 2015 and 2021, include health care providers implementing PrEP as an HIV prevention strategy, and barriers affecting heterosexual Black/African American and Black/African American who have sex with men (BMSM) access to PrEP. The search generated 24 articles (n= 24) 10 were excluded after careful screening of title, abstract, and methodology; resulting in the review of 14 full-text articles. The purpose of this literature review is to systematically investigate the barriers affecting the prescription and uptake of Pre-exposure prophylaxis (PrEP) among Black/African American men as it relates to the lack or absence of awareness and willingness of some primary care providers to provide information related to PrEP and potentially prescribe PrEP. This literature review will also address the cultural influences and socioeconomic disparities hindering the prevention of HIV among Black/African American men with high-risk behaviors, using PrEP as the primary prevention method. Finally, proposed interventions suggested by previously conducted studies to address the barriers impacting PrEP uptake among minority groups will be explored.

HIV Among Black/African American Men

HIV Statistics Among Black/African American

According to the Centers for Disease Control and Prevention populations and surveillance fact sheets published in 2018, HIV diagnoses are only tracked among seven racial and ethnic groups: American Indian or Alaska Native, Asian, Hispanic, or Latino, Native Hawaiian, or other Pacific Islander, White, Black, or African American, and individuals of multiple races (Centers for Disease Control and Prevention, 2018). Compared to other racial and ethnic groups, male of Black or African American descent have higher rates of some sexually transmitted infections (STIs) (Centers for Disease Control and Prevention, 2018). According to a report published by the Centers for Disease Control and Prevention published in 2018 and based on the most recent data available in January 2021, Black or African American individuals accounted for 42% of the 37,968 cases of new HIV diagnoses in the United States and dependent territories (Centers for Disease Control and Prevention, 2018). Majority of the new cases within the Black or African American group were men (Centers for Disease Control and Prevention, 2018). Male-to-male sexual contact within this ethnic group accounted for 79% (9,444), heterosexual contact 15% (1,739), injection drug use 4% (436), male-to-male sexual contact and injection drug use 2% (268) and others counting for less than 1% (18) (Centers for Disease Control and Prevention, 2018).

At the end of the year 2018, it was estimated that 482,900 Black/African Americans adults and adolescents were infected with HIV, among them 67,800 (14.0%) whose infection was undiagnosed (Center for Disease control and Prevention, 2020). An estimated 41% of Blacks/African Americans with diagnosed or undiagnosed HIV infection were living in the United States, 68% of whom were male. Their HIV prevalence rate (1,434.3) was seven times

the rate of Whites individuals (198.7) (Center for Disease control and Prevention, 2020). The highest prevalence rate remains among Blacks/African Americans (1,434.3), followed by persons of multiple races accounting for (1,125.5), Hispanics/Latinos accounting for (593.0), (198.7) among Whites, (196.0) among American Indians/Alaska Native, and (109.2) among Asians. Among Individuals living with HIV, Blacks/African Americans represented the second largest percentage of individuals with undiagnosed HIV infection, (14%) (Center for Disease control and Prevention, 2020). Male with HIV infection. In 2018, HIV incidence among Blacks/African American remained stable compared to 2014. Black/African American represented 42% of all HIV infection in the United States, the race with the highest rate (Center for Disease control and Prevention, 2020). 61% were attributed to male having sex with male (MSM) and heterosexual contact accounted for 33% (Center for Disease control and Prevention, 2020). According to the HIV surveillance report Published in 2018, the new HIV infection rate for Black/African American was nine times the rates for Whites (Center for Disease control and Prevention, 2020).

HIV Prevention Among Black/African American Heterosexual Men

Men identified as Black/African American living in the United States are at greater risk of contracting HIV infections compared to men of other racial and ethnic groups, of being diagnosed late in the course of infection, and of complications and mortality associated with HIV (Wilson et al., 2019). Although most of the HIV infections among Black/African American men are attributed to same-sex sexual relationship (MSM), an acceptable burden of HIV acquisition among Black heterosexual men exists (Wilson et al., 2019). Compared to White heterosexual men, their diagnosis rates are significantly higher, and they are more likely to be diagnosed with HIV simultaneously with AIDS-related complications (Wilson et al., 2019). Factors impacting

the risk of HIV among heterosexual Black men include the following: residing in areas characterized by poor socioeconomic status, greater income inequality, and neighborhood disparities (Buot et al., 2014; Bowleg et al., 2014); higher rates of incarceration creating lower male-to-female ratios within these geographic areas and compounds risk of transmission; limited access or use of prevention, screening, and treatment of HIV and the STIs, which can contribute to lower skills, motivation, and self-efficacy for condom use (Crosby et al., 2014; Sheeran et al., 2016). Interpersonally and individually, the risk of a Black heterosexual men to contract HIV are driven by the effect of the previously mentioned social determinants on depression, alcohol, and substance abuse, which in turn share a strong association with condom use (Wilson et al., 2019), as well as the influence of sex roles and conceptualizations of normative gender-specific behaviors on partner concurrency, condom use, and stigma related to HIV (Wilson et al., 2019). Analyzing these factors, one can immediately see the need to eradicate these social determinants and, at the very least, making sure that HIV prevention strategies are implemented in high HIV-risk areas and accessible to Black heterosexual men (Wilson et al., 2019).

To respond to the need to implement interventions designed to reduce HIV rates among Black heterosexual men, Wilson et al. (2019), developed the Barbershop Talk with Brothers (BTWB) program. This program was designed to provide single-session to a small group using peer-led interventions to men through barbershop partnerships. BTWB is located within communities of high risk for heterosexual HIV infection (Wilson et al., 2019). Resulted from a community-academic collaboration, BTWB focus on leveraging the strong bonds and recurrent interactions that exist between the barbers and black heterosexual men at high of HIV transmission (Wilson et al., 2019). Within the community, barbershops are considered trusted venue for Black men, and serve as regular points of contact where HIV prevention education can

be provided to Black men with limited access (Wilson et al., 2019). By implanting the intervention in the existing barbershop community structure, the BTWB program successfully reached an underserved priority population (Wilson et al., 2019). The implemented interventions were greatly effective, with statistically significant increases in the number of men who reported at follow up the use of condom during sexual encounters (Wilson et al., 2019). Based on the findings, the authors were able to suggest that single-session intervention has the potential to be effective when implemented in settings such as barbershops, where health services are not generally provided (Wilson et al., 2019).

HIV Prevention Among Black/African American Men Who Have Sex with Men (BMSM)

Research exploring HIV prevention in BMSM has implemented some innovative and effective approaches, such as the examination of syndemics. As related to HIV infection, the CDC describes how syndemics happen when there is a synergistic interaction between multiple epidemics, which can create an excess burden of HIV infection within a specific racial or ethnic group (CDC, 2010). By adopting a syndemic approach when addressing HIV prevention, researchers have observed how combined biological, social, and cultural factors have contributed to greater seroprevalence among sexual minority groups (Singer et al., 2006; Singer & Clair, 2003). Certain condition such as drug abuse, depression, and violence victimization have been explored to better understand their impact on the HIV burden among Black/African American men (Dacus & Sandfort, 2020). Therefore, HIV prevention research commonly encourage the exploration of syndemic phenomena in BMSM population to understand the drivers of the HIV epidemic (Dacus & Sandfort, 2020).

Based on the study conducted by Dacus and Sanford in 2020 exploring HIV prevention among BMSM in New York City, HIV risk was perceived and understood differently among the

participants (Dacus & Sandfort, 2020). Due to their intersecting identities as Black men and MSM, they demonstrated an increased awareness of risk. The BMSM awareness during this study led to the development of a reasoning process that informed their risk reduction strategies for preventing HIV infection (Dacus & Sandfort, 2020). Due to the proficient level of knowledge demonstrated by the participants about high HIV rate in the BMSM community of New York City, they show a strong preference to know their partners' serostatus from the beginning also referred to as "knowing from the jump" (Dacus & Sandfort, 2020). Being more likely to attract, pursue, and prefer other Black male partner, the participants normalized the possibility of meeting Black men with an HIV-positive status (Dacus & Sandfort, 2020). The participants in this study were open and crossing the "sero-devide", pursuing potential partners with an HIV-positive serostatus was not considered excluded (Dacus & Sandfort, 2020). Therefore, the implementation of serosorting was not considered as a prevention strategy (Dacus & Sandfort, 2020). On the contrary, they expressed a sense of relief knowing from the very beginning that their sexual partners were HIV-positive, and knew the necessary measures required to protect themselves. This behavior is why "The Talk" was implemented, allowing them and their partners to initiate in conversations addressing HIV testing and serostatus (Dacus & Sandfort, 2020). Information gathered during "The Talk" helped in making informed decision and evaluate HIV risk. Limitations of "The Talk" were also recognized by the participants; partners may lie about their serostatus or simply unaware. To address any ambiguity regarding HIV status, the participants commonly engage in HIV testing with new partners prior to engaging in sexual relations with them (Dacus & Sandfort, 2020). Another preventive method used by BMSM is the topping theory. They topped in order to decrease their HIV risk based on their increased perception of how they were at risk. It is crucial to consider the participants' topping theory was

not always effective; “insertive” partners have acquired HIV (Dacus & Sandfort, 2020). “Checking the goods” is another risk reduction strategy that was mentioned and recommended, which involves the visual inspection of partners’ genital and anus for signs of possible sexually transmitted infections (Dacus & Sandfort, 2020). The way BMSM who remain HIV-negative perceive their HIV risk will immensely contribute to public health efforts to end the HIV epidemic. With a better understanding of their perception of risk, researchers and future studies can focus on findings ways to reinforce the strengths and resilience in BMSM as they stay seronegative (Dacus & Sandfort, 2020).

Black/African American Men Barriers to PrEP

Traditional Masculinity

In the United States, the HIV prevalence among Black/African American men who have sex with men (BMSM) is four times higher than White MSM, accounting respectively for 32% and 8% (Eaton et al., 2018; Centers for Disease Control and Prevention, 2020). One mathematical model based on the continuation of the current epidemiological trends suggested that as many as 60% of BMSM may be acquiring HIV by the age of 40 (Driver et al., 2020). Despite the slow increase in PrEP awareness, BMSM access and use of PrEP remain relatively few (Driver et al., 2020). Traditional masculine ideology according to qualitative research has been identified as a consistent barrier associated with HIV prevention behaviors among BMSM, as well as PrEP use (Driver et al., 2020). Based on the ideology of traditional masculinity, the engagement in health-promoting behaviors may indicate femininity, while practicing risk behaviors that may jeopardize one’s health are considered ideal expression of masculinity (Courtenay, 2000). Avoiding femininity as a Black/African American man, has shown by previous studies, is directly associated with a lack of engagement in various health-promoting

behaviors (Campbell et al., 2012; Hawkins et al., 2017). The Avoidance of being perceived as feminine among BMSM may interfere with their interest in adopting HIV PrEP as a prevention method. Since anti-femininity is a crucial component of traditional masculinity and the privileges associated with being heterosexual, some BMSM may repress or internalize their femininity in order to be perceived as heterosexuals by others disregarding their sexual preference (Driver et al., 2020). According to Garcia et al. (2016), MSM with a strong heterosexual self-presentation are less likely to test for HIV, creating a barrier to PrEP initiation. Furthermore, the anticipation that the use of PrEP may inadvertently expose their sexual preference for men may prevent BMSM who do not openly identify as a sexual minority to develop an interest in PrEP (Quinn et al., 2017). Previously conducted research shows that one's effort to hide a concealable stigmatized identity, including sexual preference, can greatly impact health-related decisions creating an opportunity for risk-taking behaviors and poor health outcomes (Quinn et al., 2017). The poor uptake of PrEP among BMSM, as suggested by previous studies, is associated with the perception that PrEP use indicates that an individual is gay (Garcia et al., 2016; Ojikutu et al., 2018). Men who belong to racial and sexual minorities such as Black/African American heterosexuals and Black men who have sex with men (BMSM), are more reluctant to practice and engage in preventive behaviors compared to racial majority men or those men who do not practice same-sex sexual behaviors (Vandello et al., 2018).

PrEP Stigma and Conspiracy Beliefs

Individuals using PrEP as a prevention strategy have been labeled "Truvada Whores" by popular press reports, a derogatory term that creates an association between the use of PrEP and promiscuity (Calabrese & Underhill, 2015; Duran, 2012). These disparaging remarks have created substantial discussions on social medias (Crary, 2014), yet the impact of these

sociocultural barriers have on individuals interested in PrEP have only been explored by a few empirical research (Eaton et al., 2017). There exists a lack of understanding of the impact these potential barriers have on PrEP interest, more focus research is needed to explore this novel area (Eaton et al., 2017). According to information generated by informal reports and empirical research regarding the acceptance of PrEP by communities, stigma associated to PrEP represents an important sociocultural barrier to PrEP interest (Calabrese & Underhill, 2015). Stigma is defined as a social construction where social devaluation occurs through a process of labeling, stereotyping, separation, status loss, and discrimination (Eaton et al., 2017). This method is used as a tool to maintain social power structure by lowering individuals with devalued characteristics and elevating those who do not. As related to PrEP, the rise of negative stereotyping—a key component of stigma—toward PrEP users require further attention and understanding (Earnshaw & Chaudoir, 2009). The negative labeling of certain groups, PrEP users in this case, is known to dissuade one's interest to join such group (Eaton et al., 2017).

Similarly, conspiracy related beliefs surrounding biomedical interventions used to prevent HIV are likely to impact PrEP implementation, but this novel barrier has yet to be researched. Conspiracy beliefs are generally thought to insinuate that organizations or people in power implement furtive events in the intent to manipulate others in a self-serving way (Eaton et al., 2017). Conspiracy beliefs regarding HIV treatment among racial, ethnic, and sexual minorities stemmed from the historical legacy of mistreatment endured in medical establishments by these individuals (Eaton et al., 2017). For example, the prevalence of conspiracy beliefs surrounding the use of biomedical HIV prevention strategy such as antiretroviral is well-documented and are strongly associated with poor HIV-related health outcomes, specially, among HIV positive individuals belonging to a racial, ethnic, and sexual

minority group (Bogart & Thorburn, 2005). Considering the existence of these beliefs in HIV prevention and treatment strategies, one could probably conclude that they would impact PrEP interest as well (Eaton et al., 2017).

Based on the study conducted by Eaton et al. (2017), 70% (N= 186) of the participants strongly believed that PrEP use would cause individuals to engage in more risky sexual behaviors; however, these beliefs were not related to interest in using PrEP. 45 % (N= 120) of the participants believe that the careful selection of their partner was a better way to prevent HIV instead of using PrEP, which created of greater likelihood for selected population to not develop any interest in PrEP (Eaton et al., 2017). Sixty of them, a percentage of twenty-three, strongly believed that PrEP is for promiscuous individuals, which was related to a lack of interest in prescribing PrEP for all groups (Eaton et al., 2017). Overall, it observed that PrEP-stigma strongly influenced the number of sexual partners, but not sexual behaviors (Eaton et al., 2017). Among the participants, those sharing the belief that the CDC cannot be trusted in their PrEP-related messaging developed lower interest in adopting PrEP as a prevention method (Eaton et al., 2017). The phrase "Truvada Whore" have been heard by 19% (N=50) of the selected sample, however, the phrase did not have any impact on their interest in using PrEP (Eaton et al., 2017). No significant differences were found across the selected sample regarding responses to the PrEP stigma beliefs items. However, Black men and transgender women who have sex with men (BMTW) (56.5%) were more likely to report distrust in the CDC regarding the provision of accurate information on PrEP compared to White men and transgender women who have sex with men WMTW (43.5%) (Eaton et al., 2017).

Awareness and Knowledge of PrEP

Some studies have reported that knowledge of PrEP among racial, ethnic, and sexual minorities such as Black men who have sex with men and heterosexual Black men is low. According to a study conducted in Atlanta, Georgia among BMSM, close to 75% of the participants had no knowledge of PrEP, with no signs of improvement noted twenty months after the approval of FTC/TD by the FDA (Eaton et al., 2015). Studies have shown that African American participants demonstrated lower estimated HIV knowledge scores compared to White and Latino participants (Janulis et al., 2018). This finding is in accordance with limited prior research suggesting that among both the general population and MSM samples, African American participants generally scored lower on questions pertaining to HIV knowledge (Janulis et al., 2018). Based on a study conducted by Garnett et al, (2018). among a sample of 1673 Black men, 24% of those identified as gay and those who reported more than one sexual partner were more likely to be aware of PrEP (Garnett et al., 2018). Participants identified as gay were more likely to be exposed and interact with multiple sources of PrEP information, such as social networks, gay friendly venues, literature, and media addressing gay issues (Garnett et al., 2018). Participants who reported multiple partners and potentially aware of their risk of HIV acquisition may have sought PrEP-related information (Garnett et al., 2018). The possibility exists that those with multiple sexual partners may have been presented with more occasions and exposures to information regarding PrEP either through their sexual partners or by expanding their social network (Garnett et al., 2018). Importantly, other behaviors such as condomless anal sex, transactional sex, HIV-seropositive partners, associated with increased risk of HIV infection had no associations with PrEP awareness (Garnett et al., 2018). As indicated by these findings, only a small portion of this population at substantial risk of HIV acquisition had an awareness of PrEP, which stresses the need to implement more intensified outreach and educational programs

beyond traditional gay venues to reach the racial and sexual minorities that may benefit from PrEP (Garnett et al., 2018).

Medical Mistrust

Black or African American men have the shortest life expectancy at birth of all other men and women in the United States despite the growth in current initiatives to eradicate racial and ethnic health inequities (National Center for Health Statistics, 2015; Gilbert et al., 2016). The shortened life-expectancy among this marginalized group is an obvious consequence of the interconnection between biological, economic, and sociostructural factors (Gilbert et al., 2016; Hammond et al., 2016). Such factors encompass a high morbidity and mortality rate from illnesses amenable to early intervention and treatment, decreased access to opportunities to climb the social ladder, and well-recorded instances of experienced structural racism (National Center for Health Statistics, 2015; Gilbert et al., 2016; CDC, 2013). These factors also coincide with data affirming the more limited delivery of timely preventive health screening and medical treatment among Black/ African American men (Gilbert et al., 2016; Cheatham et al., 2008). Unsurprisingly, they have higher rate of HIV infection than no-Hispanic White men (CDC, 2020). In general, men tend to be less likely than women to seek preventive health services, such as routine check-ups (Williams, 2003; Vaidya et al., 2012), and HIV screenings. However, the utilization patterns are even more predominant among Black/African American men who delay health services due to a diversity of unique, psychosocial reasons (Powell et al., 2019). Previously conducted studies addressing African American men's broad health services use have attributed delay and underutilization to fatalism, socioeconomic barriers, limited health knowledge and awareness, masculinity beliefs, medical mistrust, and perceived racism (Cheatham et al., 2008; Hammond et al., 2010). Available reports have identified a significantly

high rate of mistrust of healthcare organizations and professionals among the Black/African American community, which share a strong link with negative health-related outcomes such as unsatisfactory care, treatment noncompliance, and underutilization of health services (Hammond et al., 2010a; Eaton et al., 2015; Birkhäuser et al., 2017). In a study that has been widely cited by others, Hammonds and colleagues identified links between higher medical mistrust and decreased likelihood of routine health examination engagement among Black/African American men (Hammond et al., 2010a). In parallel, the high rate of medical mistrust among Black/African American men has been related to factors such as delays in routine clinical visit, blood pressure screenings, cholesterol screenings (Hammond et al., 2010b), and HIV screenings. Medical mistrusts appear to play a crucial role in Black or African American men's ability to make health-related decisions to participate more invasive screenings or treatments such as prostate cancer and HIV/AIDS (Quinn et al., 2018; Talcott et al., 2007). Based on Powell et al. (2019), a strong association exists between medical mistrust and delays in the least invasive type of preventive health screening. The findings suggest that invasive screenings among Black/African American men involving the collection of blood in the case of HIV, may be accompanied by increased concerns about receiving different treatments from healthcare system and providers simply on the basis of their race (Powell et al., 2019). Similar to the study conducted by Klassen and colleagues, their findings infer the accumulation of negative lived experiences strongly dices the perception and preventive health choices among Black/African American men (Powell et al., 2019; Klassen et al., 2002). In other words, there is a probability that the accumulation of frequent emergency room experiences has induced an expectation of prejudiced treatment affecting Black/African American men's trust in medical organizations (Powell et al., 2019). The authors suggested that medical mistrust did not mediate the relation between ER experiences and

preventive screening delays (Powell et al., 2019). It is feasible that an interaction exists between medical mistrust and other demographic factors, which impact screening delays in more complex manners. Despite the shared similarities between their mediation results and previously conducted research, they authors contended that the preventive health screening delays noted in their study should be viewed as potential carry-over effects of “interactional social histories” experienced by Black/African American men (Powell et al., 2019).

Medical mistrust has been identified among Black/African American individuals as a barrier that has been impacting their engagement in routine health care, which in turn affects their PrEP uptake (Eaton et al., 2015). Particularly, mistrust in biomedical treatment of HIV is especially detrimental to providers' abilities to engage the racial, ethnic, and sexual minorities at high risk of HIV acquisition (Eaton et al., 2015). An individual's health outcomes such as antiretroviral adherence and good mental health are directly linked to their trust in healthcare providers (Eaton et al., 2015). However, the role of medical mistrust among Blacks have only been investigated by a few studies, and limited data exist on BMSM regarding this matter (Eaton et al., 2015). Two focus assessments have been generally recommended by the literature when addressing medical mistrust: first, an assessment focusing on the system, that is, general trust in medical establishment; and second, an assessment focusing on the individual, that is, trust in clinicians' abilities to provide adequate care. These concepts, system and individual, are believed to affect the likelihood of a patient to seek and stay in care (Eaton et al., 2015).

The study conducted by the authors provides some insights on psychological factors associated with routine engagement in care among BMSM (Eaton et al., 2015). Experience stigma from healthcare providers is related to a longer elapsed time since last examination for both HIV-negative and HIV-positive BMSM (Eaton et al., 2015). Furthermore, the mediation

model proposed that the perception of a greater level of global medical mistrust among BMSM that are HIV-negative guides this relationship (Eaton et al., 2015). For seronegative BMSM, the time since last clinician visit shared a strong association with global medical mistrust, but personal trust in healthcare providers did not (Eaton et al., 2015). To properly investigate engagement in routine care, it is important to properly establish the distinction between global medical mistrust and personal trust in provider (Eaton et al., 2015). The authors were unable to identify the exact reasons why there wasn't an association between personal trust in healthcare provider and engaging in routine care appointment. It is impossible that having encountered a clinician who one trusts nullifies the influence of previous negative encounters with healthcare clinician in general (Eaton et al., 2015). Comparably, global mistrust and personal trust in provider did not predict time elapsed since last examination for HIV-positive BMSM (Eaton et al., 2015). Regarding the overall rates of stigma, medical mistrust, and personal trust in providers, varying rates and similarities across HIV status were observed by the authors (Eaton et al., 2015). They expected a greater number of HIV-positive BMSM to report experienced medical mistrusts due to the stigma associated with their health condition, contrarily, medical stigma and medical mistrust were less like to occur with HIV care specialists compared to primary care provider (Eaton et al., 2015).

Pre-Exposure Prophylaxis (PrEP)

What is Pre-Exposure Prophylaxis (PrEP)?

According to the Centers for Disease Control and Prevention (2020), pre-exposure prophylaxis (PrEP) serves as a mean to allow individuals who are HIV negative but are at very high risk of contracting HIV to reduce or prevent HIV infection by adhering to a daily regimen of antiretroviral medication (Centers for Disease Control and Prevention, 2020). The pill,

currently marketed as Truvada, contains a combination of tenofovir and emtricitabine. Individuals who have a high risk of contracting HIV due to exposure through sex or injection drug use may benefit from these medications, which work by preventing the virus from establishing a permanent infection (Centers for Disease Control and Prevention, 2020). PrEP is highly effective in preventing HIV when administered daily. Studies have shown that PrEP has the potential to reduce an individual risk of acquiring HIV from sex by about 99% when taken daily. As for individual injecting drugs (PWID), daily dose of PrEP reduces their risk of getting HIV by at least 74% (Centers for Disease Control and Prevention, 2020). Adherence is the key to PrEP maximum efficacy. Oral PrEP is currently included as a component of the recommended standard of prevention instituted by the World Health Organization for individuals with substantially high risks (Eakle et al., 2018).

Since its early conceptualization of protection tested in animal models with strong evidence of prevention using antiretrovirals for occupational and non-occupational post-exposure prophylaxis and authorization for use by the Food and Drug Administration in 2012, pre-exposure prophylaxis (PrEP) for HIV prevention has significantly evolved (Eakle et al., 2018). Pre-exposure prophylaxis is taken daily as a preventive strategy to reduce an individual's risk of contracting new HIV infections (Eakle et al., 2018). Conducted clinical trials have demonstrated clear efficacy of oral PrEP. Collected evidence from 18 studies also demonstrated that that PrEP has a significant impact in reducing the risk of HIV acquisition (Fonner et al., 2016). Different levels of efficacy have been documented based on differences in medication regimen compliance within and across the selected populations, with men who have sex with men (MSM) showing the higher levels of efficacy compared to studies including only women (Fonner et al., 2016). Adherence plays a central role and must be considered by primary care providers for program

planning, budget, and PrEP effectiveness (Eakle et al., 2018). PrEP is not a standalone intervention; it is rather integrated into existing prevention programs and systems in place to prevent HIV transmission. To be successful, PrEP users must consider combination prevention and programming as a whole (Eakle et al., 2018). Based on mathematical modeling, it is suggested that PrEP could play an integral role in the HIV prevention game, potentially enhancing conventional prevention efforts depending on the ability of assistance programs to prioritize those at high risk and manage costs of treatment (Stover et al., 2016). A desperate need for improved HIV transmission prevention exists, it is of utmost importance that primary care providers understand and implement strategically focus PrEP interventions to achieve optimal outcomes and reinvigorate the need for prevention programs (Eakle et al., 2018).

Current State of PrEP in the U.S.

For thirty years the recommendation to use condoms by public health officials was considered the primary tool to directly reduce and prevent the transmission of HIV infections (Siegler et al., 2020). In 2012, with the approval of antiretroviral medication for HIV pre-exposure prophylaxis (PrEP) by the U.S. Food and Drug Administration, a new biomedical prevention era started (Siegler et al., 2020). PrEP uptake has been substantially progressing in the United States, with an estimated of 172,479 individuals who have been prescribed PrEP in the year 2017. However, a substantial need for improvement exists (Siegler et al., 2020). According to the Center of Disease Prevention and Control, it is estimated that 1.2 million individuals living in the U.S. have a strong indication for PrEP care (Siegler et al., 2020). In order to maximize PrEP impact on HIV transmission and improve their contribution to health equity, primary care providers must ensure that groups facing the highest risk of HIV transmission figure among those prescribed PrEP (Siegler et al., 2020). Based on a survey

conducted by Finlayson and colleagues in 2019, Black MSM across 20 cities in the United States accounted for 26% of all PrEP prescriptions compared to 42% among White MSM (Finlayson et al., 2019). Such similar disparity was also observed in individuals with low income.

Additionally, those faced with higher copayments or with less insurance coverage were found to be less likely to continue PrEP care after initiation of treatment (Siegler et al., 2020).

In an effort to increase PrEP uptake statewide and locally, several states have adopted state PrEP Drug Assistance Programs (PrEP-DAPs) for patients. These programs assist patients in at least one of the following two areas: finance assistance toward medication costs or financing of ancillary costs such as clinical visits and the expenses of laboratory tests (Siegler et al., 2020). Many PrEP-DAPs also provide individuals with assistance finding local provider, by answering questions regarding PrEP, or by offering other wrap-around services to address other patients concerns and needs (Siegler et al., 2020). Enhancing PrEP uptake and targeting interventions and health policy appropriately requires primary care providers to track progress made in increasing national PrEP use, as well as a continuous monitoring of existing and emerging disparities directly and indirectly affecting PrEP use (Siegler et al., 2020). PrEP-DAPs have recently been recognized as a potential mean to help in the promotion of PrEP uptake, unfortunately no recent evidence have been presented to support the impact of PrEP-DAPs (Siegler et al., 2020). Studies related to Drug Assistance Programs for HIV treatment have shown positive impact when states contribute supplemental funds to allow the expansion of the services provided and the identification of key components of the most successful programs such as less-restrictive eligibility criteria (Siegler et al., 2020). Finding the optimal combination of PrEP-DAPs services for individual unable to afford PrEP care may be an important factor of PrEP scale-up (Siegler et al., 2020). In a data set encompassing most PrEP users who currently

residing in the United States, Siegler and colleagues determined that state-level policies supportive of PrEP access were associated with a higher PrEP use (Siegler et al., 2020). The adoption of Medicaid expansion or only PrEP-DAPs demonstrated a 25% increase in prevalence, but a combination of both Medicaid expansion and PrEP-DAPs adoption yielded to a 99% higher PrEP prevalence (Siegler et al., 2020). Implementing both policies nearly doubled the number of PrEP user per studied population. This relation was observed in a descriptive and multilevel analyses, and for outcomes of PrEP use per population and PrEP use per new HIV infections (Siegler et al., 2020).

States and Local Policies Associated with HIV-PrEP

The federal government implemented a comprehensive framework to facilitate and improve access to pre-exposure prophylaxis. It serves as a blueprint for federal activities to increase awareness and scale up PrEP as a HIV transmission prevention strategy to decrease the occurrence of new infection in the U.S. (HIV National Strategic Plan, 2016). The HIV PrEP framework constitute a model that highlights current support provided by federal agencies and programs, as well as additional activities needed to improve the awareness, use, monitoring of PrEP, and reduction of new HIV infections among individual at high risk (HIV National Strategic Plan, 2016). Considering the strength of the scientific evidence associated with PrEP efficacy in the prevention of HIV transmission, the National HIV/AIDS Strategy recognized the importance of PrEP (HIV National Strategic Plan, 2016). The National HIV/AIDS Strategy encourages the development of policies allowing full access to comprehensive PrEP service for those meeting the requirements, as well as support to promote medication adherence among PrEP users (HIV National Strategic Plan, 2016).

Primary Care Providers Barriers to PrEP

Awareness and Knowledge of PrEP

Healthcare providers' knowledge and awareness of PrEP are crucial to successfully implement treatment and directly increase uptake rates of prescriptions (Mayer, Agwu, & Malebranche, 2020). After conducting a study at different local health departments in North Carolina, it was found that the rate of prescriptions or referrals for PrEP were negatively affected by the lack of PrEP knowledge and awareness among the staff (Mayer et al., 2020). Contrarily, a study conducted among healthcare workers of the state of New Jersey in 2018, which included prescribers, administrators, nurses, and social workers generated a 91% demonstration of high level of PrEP knowledge and awareness. Other studies have also identified healthcare professionals with inadequate knowledge and awareness of PrEP. For example, among 271 U.S. nurse practitioners only 40% reported receiving prior PrEP training and education, while 58.3% of 12 healthcare providers residing in Florida admitted having read the CDC's PrEP clinical practice guidelines, and only 58.3 % could properly identify PrEP prescribing recommendations (Mayer et al., 2020).

A clear difference in knowledge and awareness exists among healthcare professionals. Among 735 licensed medical professionals surveyed in 2016 in the state of Washington only 65% had prior knowledge of PrEP; compared to older healthcare professionals and those with other training background, younger healthcare professionals and those with a medical degree were like to be aware of PrEP (Mayer et al., 2020). Healthcare professionals' specialty also create a disparity in awareness; all infectious disease specialists surveyed had knowledge about PrEP clinical practice guidelines, compared to 75% of board-certified family medicine and internal medicine providers and 50% of pediatric and obstetrics/gynecology providers (Mayer et

al., 2020). Similarly, a study found that 71% of 53 family physicians had no limitation of knowledge regarding PrEP clinical practice guidelines (Mayer et al., 2020).

Time Constraints

Several logistical concerns have been reported by providers when prescribing Pre-exposure prophylaxis, notably time constraints, which has the potential to create challenges for primary care providers to complete an appropriate and complete HIV risk assessment (Silapaswan et al., 2016). The brief nature of the time allocated for a health and wellness visit makes it difficult for primary care providers to gather enough information to accurately assess an individual's risk behaviors and provide medication adherence counseling (Silapaswan et al., 2016). A thorough risk behavior assessment is a critical component in the identification of appropriate PrEP candidates, and time is affecting it (Silapaswan et al., 2016).

Potential Adverse Clinical and Behavioral Consequences

Other issues affecting providers willingness to prescribe PrEP can be associated with their belief of potential unintended clinical consequences such as drug toxicity, antiretroviral drug resistance, and behavioral disinhibition and sexually transmitted infections (Silapaswan et al., 2016). As related to drug toxicity associated with the use of TDF-FTC, only a minority of PrEP users have reported symptoms. The reported symptoms, commonly referred to as "startup syndromes", include headache, nausea, and diarrhea, which are often resolved within the first few days or weeks following PrEP initiation (Silapaswan et al., 2016). Studies have not observed a strong association between TDF and decreased renal function or modest, reversible bone mineral density (Silapaswan et al., 2016). Despite having such a favorable safety profile, certain providers remain concerned about PrEP-associated toxicities. Even with the need for long-term follow-up data, studies addressing the efficacy and safety of TDF with or without FTC for PrEP

did not demonstrate sufficient differences in rates of clinically significant renal events between treatment and control groups (Silapaswan et al., 2016). After the discontinuation of Truvada, abnormally elevated creatinine levels generally return to baseline. Only 1% decrease in bone mineral density was observed among a small group of individuals using TDF with and without FTC, which is expected to occur during the first few months following initiation of treatment (Silapaswan et al., 2016). There was no incidence of progressive loss of bone mineral density, levels generally return to normal several months after PrEP discontinuation. Current guidelines recommend provider to schedule follow-up appointment in the first few weeks of treatment initiation to assess patients for side effects and perform renal function testing every three to six months, especially those susceptible to renal injury (Silapaswan et al., 2016). Patient with a history of osteoporosis predisposing them to bone fractures, are required to seek appropriate consultation and management prior to start PrEP care (Silapaswan et al., 2016). Additionally, PrEP formulations with safer side effects profiles, such as tenofovir atafenamide fumarate, are presently undergoing evaluation for the treatment of HIV (Silapaswan et al., 2016).

The development of antiretroviral drug resistance, according to data resulting from PrEP clinical trials, was rare among the individuals who acquired HIV during PrEP treatment (Silapaswan et al., 2016). During the initial efficacy trials a minority of patients developed drug resistance after the acquisition of HIV, and transmitted drug resistance was rare. Only a few cases of resistance potentially happen among individual who started PrEP with undiagnosed acute HIV infection (Silapaswan et al., 2016). Additional studies are needed to properly assess the association of PrEP and antiretroviral drug resistance due the fact that data and modeling studies were limited, and only suggested that PrEP may have the potential to minimally contribute to drug resistance at the population level (Silapaswan et al., 2016). Since there is a

potential for antiretroviral resistance to occur among patients who experienced seroconversion while taking PrEP, providers should perform baseline and routine HIV testing every three months, or sooner if there is a suspicion for acute HIV infection to avoid selection for resistant HIV (Silapaswan et al., 2016). The same baseline evaluation is also recommended for patients who have discontinued their PrEP treatment and decided to restart (Silapaswan et al., 2016).

Influenced by personal bias, some providers tend to believe that informing their patients about PrEP or initiating PrEP to reduce their risk of contracting HIV could lead to the development of behavioral disinhibition and sexually transmitted infections (Silapaswan et al., 2016). Behavioral disinhibition also referred to as “risk compensation” can be seen in some PrEP users. It may be an unintended consequence of PrEP, which could increase their risk of STIs transmission. During PrEP efficacy trials there were no observation of unintended increase in sexual risk behaviors. The early studies conducted implemented intensive risk reduction counseling, however, the possibility exists that some participants did not accurately report their sexual risk behaviors to avoid social desirability bias (Silapaswan et al., 2016). Based on a recent observational study conducted in a primary care setting, it was noted that some MSM receiving PrEP reported having more sexual partners and less frequent condom use. Despite the observation of behavioral changes, the lack of a control group makes it difficult to strongly associate PrEP use with behavioral disinhibition and sexually transmitted infections. Those behavioral risk factors observed among PrEP users appears to have been present prior to the initiation of treatment, they did not use condoms prior to use PrEP, and continue the same behavior thereafter (Silapaswan et al., 2016). One can conclude that this pattern or behaviors is suggestive of “risk maintenance” and not “risk compensation”. However, primary care providers must prescribe PrEP in combination with other prevention methods since PrEP does not prevent

the acquisition of other sexually transmitted infections. Considering the high rates of bacterial STIs incidence recently observed in PrEP groups, regular STI screening for prevention and timely treatment of STIs must be adopted by providers (Silapaswan et al., 2016).

Racial and Ethnic Biases

Inferred racial and ethnic bias by healthcare providers practicing in the United States have been thoroughly documented and have been found to impact clinical decisions-making (Mayer et al., 2020). Fifteen studies addressing implicit bias by healthcare professionals were identified by one systematic review; fourteen of the selected studies found low-to-moderate levels of racial and ethnic bias affecting healthcare professionals' treatment decisions (Hall et al., 2015). There was a significant relation between implicit bias and treatment decisions, patient-provider relationships and interactions, adherence, critically, patient outcomes (Mayer et al., 2020). According to a second systematic review, 31 out of 37 qualified studies reported racial and ethnic bias among U.S. healthcare professionals, and fourteen studies exploring the relation between bias and outcomes, six found high implications between bias and treatment disparities (Mayer et al., 2020). Additionally, the 2011 Report of the National Transgender Discrimination Survey found that 20% of 6540 transgenders and gender non-conforming individuals across the United States reported being refused care, and approximately 33.3% endured some form of harassment in a healthcare setting (Grant et al., 2011).

Systemic biases exist even beyond the individual provider level; significant racial disparity was exhibited by an algorithm frequently used in the U.S. healthcare system (Mayer et al., 2020). For individuals labeled by the algorithm as having the same risk level compared to White individuals with similar conditions Black individuals had an increased sign of uncontrolled medical condition (Mayer et al., 2020). This bias emerged because the algorithm

predicted patient outcomes based on cost, rather than illness, which was a reflection of the spending inequalities existed among Black and White patients' communities (Mayer et al., 2020). Such misrepresentation, therefore, creates a significant level of mistrust between the U.S. healthcare system and certain racial and ethnic groups (Mayer et al., 2020).

Underutilized Local Resources

Another barrier to the implementation of PrEP can be associated with the providers inability to properly identify and utilize local social service organizations, since the expenses associated with the treatment of PrEP can be a daunting task for certain individuals (Silapaswan et al., 2016). The average monthly wholesale price of Truvada for PrEP is approximately \$1425 (Silapaswan et al., 2016). While most privately own insurance companies and state Medicaid programs provide coverage for PrEP, out-of-pocket expenses greatly vary among individual insurance plans (Silapaswan et al., 2016). The manufacturer of Truvada, Gilead Sciences, has created a program called "Truvada for PrEP Medication Assistance Program" to provide financial support to uninsured individuals that may benefit from PrEP (Silapaswan et al., 2016). Ideally, it is the responsibility of the providers or case manager to review the copayments requirement with patients before the initiation of PrEP and may suggest patient to seek the assistance of programs based on their financial needs (Silapaswan et al., 2016). Determining cost-sharing requirement based on individual health plan may pose a logistical challenge for provider prescribing PrEP (Silapaswan et al., 2016).

Interventions to Reduce PrEP Barriers

Improved Providers and Individuals Education and Training

In overcoming the vast array of barriers associated with PrEP uptake, it is of utmost importance to provide improved education and training to providers and patients at high risk of

HIV transmission such as Black/African American heterosexual men and BMSM. The delivery of brief educational sessions to patients at risk during clinical visit could be proven an effective approach in raising awareness and PrEP uptake among these individuals (Raifman et al., 2018). Similarly, the provision of online resources developed by organization such as the New York City Department of Health and Mental Hygiene, and the National Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Education Center at the Fenway Institute could have the same impact (The National LGBT Health Education Center, 2019; New York City Department of Health and Hygiene). The PrEP4Love campaign in Chicago have reached millions of individuals, thus the implementation of social marketing campaign could have a significant impact on PrEP uptake (Dhelin et al., 2019). However, despite the well-recorded need to increase the awareness of PrEP, a recent systematic review noted the lack of ongoing study addressing this barrier (Sophus & Mitchell, 2019). With the provision of education, it is possible to instill trust in the healthcare system and its providers among people at risk. For example, improved access to educational materials addressing the credibility of HIV prevention in minority racial, ethnic, and sexual groups may negate the impact of PrEP related conspiracy beliefs (Olansky et al., 2019). Peer-led interventions implemented through social media could also yield to significant population-level influence on PrEP uptake among at risk population by tackling issues such as knowledge and awareness, attitude, stigma, and access to treatment (Patel et al., 2018); identical interventions could successfully reach transgender women and MSM. Counseling session detailing the benefits of PrEP and providing reassuring information on the risk and monitoring of side effects, may also improve adherence to PrEP (Wade et al., 2014).

It is significant that educational training and intervention target the primary care providers, including intervention to optimize PrEP knowledge and reduce concerns related to

PrEP safety (Newman et al., 2019). Reluctance to prescribe PrEP to eligible candidates among some primary care providers has been linked to concerns surrounding risk compensation among individuals at risk, where an increase in risk-taking behaviors followed by a decrease HIV risk perception can be observed (Blackstock et al., 2017). Concerns related to occurrence of risk compensation does not justify withholding PrEP from individuals at risk of HIV acquisition, even if it is the case (Marcus et al., 2019). In accordance with this notion, PrEP should be viewed as an opportunity to improve STIs control, which may increase the detection of STIs due to frequent testing, with the chance of early diagnosis and treatment, to potentially counteract or surpass the negative effects associated with risk compensation (Quaife et al., 2019). However, support addressing risk-behaviors should be provided to all patients prescribed PrEP (CDC, 2017). In the case of PrEP related antiretroviral resistance, few supporting evidence is available and the number of known cases is extremely low, which generally occurred in undiagnosed HIV-positive individuals or during sporadic unsupervised use (Gibas et al., 2019; CDC, 2017; Volk et al., 2017), thus emphasizing the importance of testing for HIV before the initiation of PrEP care and regularly thereafter, per clinical guidelines (CDC, 2017). Education designed for primary care providers have proven to be effective: after the implementation of an educational intervention training to increase primary care providers' awareness and knowledge of PrEP, there was an increase from 66% to 92% among providers who believed in the safety of PrEP and the percentage of those who believed in its effectiveness increased from 78% to 94%. Only one-third of the participating providers were willing to prescribe PrEP in the next six months before the training, which increased to two-thirds post training (Newman et al., 2019). Primary care providers who are willing to prescribe PrEP and wish to learn more about its implementation can use public resources such as the CDC/ US Public Health Service (USPHS) clinical guidelines,

the World Health Organization implementation tool for PrEP, as well as the US Preventive Service Task Force recommendations for comprehensive information on the implementation of PrEP (CDC, 2017)

Cultural Humility

Educational training may also incorporate strategies to improve PCPs' cultural humility to overcome the detrimental impact of stereotypes, implicit bias, and anticipated risk compensation on willingness to prescribe PrEP (Calabrese et al., 2015). Nonetheless, to successfully eliminate bias embedded in the healthcare system, changes need to happen at the societal level (Mayer et al., 2020). In order to reach that ultimate goal, the healthcare community workforce must have an adequate reflection of the community it serves. Programs that increase the number of racial, ethnic, and sexual minority healthcare providers are needed (Mayer et al., 2020).

Individual Barriers

Barriers to access identified at the individual level, such as the inability to locate PrEP prescribers, should be addressed by maintaining an improved communication with individuals at risk of HIV acquisition (Greene et al., 2019; Liu et al., 2019). However, to improve access to PrEP, the implementation of innovative approaches to delivery is of utmost importance (Mayer et al., 2020). It is important that these approaches extend PrEP outreach by involving a different range of providers, including those practicing in a non-traditional setting such as pharmacies, substance use clinics, mental health clinics, emergency rooms, HIV testing centers, correctional institutions, and community-based organizations (Underhill et al., 2014). One example is the incorporation of HIV screening in emergency rooms, which has shown a high level of success (Kelen & Rothman, 2009). This initiative compounded with the apparent willingness of high-risk

patients frequenting the ER to accept PrEP from ER providers strongly suggest that ERs could serve as a setting where quick connection with PrEP providers can be facilitated (Underhill et al., 2014). As for non-emergency settings such as pharmacies, their role is important in supporting the implementation of PrEP in the community (Mayer et al., 2018). For example, the One-Step PrEP program, a pharmacist-managed approach allowing PrEP access after one patient encounter, has been logistically and financially practicable, yielding to a vastly positive response from individuals willing to adopt PrEP as a preventive strategy (Kelley-Ross Pharmacy Group, 2019; Tung et al., 2017).

The integration of technology can make PrEP accessible to more individuals at risk of contracting HIV; PrEP uptake may be supported using application capable of optimizing the delivery process. TelePrEP is an app-based delivery model, which connects individuals to a PrEP provider using a cellular device or computer (Louisiana HealthHub, 2019; Iowa TelePrEP, 2019). Similar strategy such as PrEP@Home, has been designed to address the patient and provider burden to encourage PrEP adherence by decreasing monitoring and replacing quarterly PrEP follow-up visits with home visits. This strategy, in a pilot study, was widely accepted by the participants and was in demand for future use (Siegler et al., 2019). Individuals with limited access to transportation and affected by HIV-related stigma may find this approach extremely valuable (Siegler et al., 2019). In February 2018, a pharmacy-based TelePrEP model was implemented in a large county hospital in Atlanta, 93% of the forty-four participants who initiated PrEP remained on PrEP in 2019 (Mayer et al., 2020).

Cost and insurance coverage may be one of the surmountable barriers affecting PrEP uptake. Clear evidence exists and has identified cost as a perceived barrier to PrEP uptake for those willing to start PrEP, yet the actual scale of this issue may be limited (Mayer et al., 2020).

Based on a recent independent study analyzing nationally representative data, including collaborators from the CDC, has shown that less than 1% of the individuals with indications for PrEP needed financial assistance for the cost associated with PrEP medication and clinical care (Smith et al., 2017). For an additional 7%, financial assistance was only required for the clinical care associated to PrEP, not the PrEP medication. Thus, only a small number of individuals did not have financial coverage for expenses associated clinician visit, laboratory tests, and an even a smaller number were not financially covered for both the medication and clinical expenses of PrEP (Smith et al., 2017). To address the unmet need for financial assistance in PrEP care among this small proportion of patients, the US Department of Health and Human Services created the “Ready, Set, PrEP” program, which provides PrEP medication free of charge to qualifying recipients. This initiative is part of the US government’s bigger plan “End the Epidemic”, which aims to reduce new HIV infections in the United States by 75% in five years and by 90% by 2030 (US Department of Health and Human Services, 2019; Khalili & Landovitz, 2019).

Chapter III: Purpose, PICO Clinical Question, and Objectives

Purpose

Education and training addressing the barriers impacting the uptake pre-exposure prophylaxis among Black/African American men who have sex with men (BMSM) and heterosexual Black/African American men have the potential to increase the awareness and willingness of primary care providers to prescribe the treatment and potentially reduce this population's risk of HIV acquisition. The goal of this quality improvement project is to review the literature and use the findings to guide the development of an educational training module for primary care provider serving the high-risk population. The educational training module will explore solutions to overcome identified barriers to PrEP and emphasize the importance of PrEP in preventing HIV among the selected population.

The purpose of this quality improvement project is to improve PCPs' awareness and willingness to help in reducing and preventing new HIV infection among Black/ African American men by providing pre-exposure prophylaxis (PrEP); primary care providers (PCPs) must eradicate both providers and patients' barriers. Continuous Care Center's primary care providers can help reduce the incidence of HIV infections among Black/African American men and improve their health outcome by successfully integrate PrEP into HIV screening and prevention services (Mayer et al., 2020). Despite the benefit and effectiveness of PrEP in the prevention of HIV infection, its optimal impact as a preventive intervention among Blacks/African American has yet to realized (Mayer et al., 2020). The literature reviews have successfully helped identify a complex and varied range of barriers to PrEP uptake that exist at the structural, social, individual, healthcare system, and provider levels (Mayer et al., 2020). These barriers include: a lack of awareness of PrEP among primary care providers and eligible

patients, fear of side effects, discrimination, fear of perceived and experienced stigma, provider implicit bias, distrust of the healthcare system, and lack of access to medical care and financial assistance (Mayer et al., 2020). When asked about PrEP, clear differences exist in awareness and knowledge among primary care providers (Wood et al., 2018). Primary care providers can be educated on effective approaches to eradicate the diverse barriers affecting PrEP uptake, they understand the importance of helping the US government achieve its goal of stopping the HIV epidemic in the United States by 2030 (Khalili & Landovitz, 2019).

PICO Clinical Question

The following is the PICO question: Will the implementation of educational interventions addressing the barriers impacting primary care providers' knowledge, comfort, awareness, and attitude towards PrEP increase their willingness to prescribe PrEP care as prevention strategy among Black/African American males at higher risk for HIV (Black/African American men who have sex with men (BMSM) and heterosexual Black/African American men)?

Objectives

The quality improvement project objectives are as follow:

1. Develop an educational training module by June 2021 using online resources such as the Centers for Disease Control and Prevention pre-exposure prophylaxis (PrEP) clinical guidelines to educate primary care providers at Continuous Care Center about PrEP and technique to overcome barriers affecting PrEP uptake among Black/African American MSM and high-risk heterosexual Black/African American men to help them reduce their risk of contracting HIV infection.

2. Administer an online survey consisting of 15 questions using Qualtrics to will evaluate the primary care providers' awareness, knowledge, comfort, attitude, and familiarity with pre-exposure prophylaxis care and current guidelines.
3. Conduct a pre-test and post-test to assess the primary care providers' knowledge and awareness of PrEP, as well as culturally sensitive issues associated with Black/African American men's sexual health beliefs and practices, using Qualtrics, which will allow the DNP student to create custom interactive quizzes that can be sent directly to the primary care providers participating in the quality improvement project via e-mail.
4. Educate at least 75% of the primary care providers at Continuous Care Center by August 2021 by delivering a voice-over PowerPoint educational training module electronically, online resources developed by the Center for Disease Control and Prevention for PrEP clinical implementation, training to increase PrEP knowledge, and culturally appropriate educational interventions tailored for Blacks/African American men.

Chapter IV: Definition of Terms

The following are important definitions of terms in this quality improvement project:

HIV, HIV-related stigma, implicit bias, racism, medical mistrust, and pre-exposure Prophylaxis.

1. **HIV (human immunodeficiency virus)** is defined as a virus capable of attacking the body's immune system. If not treated, it can lead to **AIDS (acquired immunodeficiency syndrome)**. Flu-like symptoms such as fever, chills, rash, night sweats, muscle aches, sore throat, swollen lymph nodes, and mouth ulcers will occur in some individuals as early as 2 weeks following infection, these symptoms may last for a few days to several weeks. No effective cure is currently available, but with appropriate antiretroviral therapy HIV-positive individuals can live long and healthy lives (CDC, 2020).
2. **HIV-related stigma** refers to irrational or negative attitudes, behaviors, and judgments towards individuals living with or at risk of HIV, which may dissuade them from knowing their status, seeking treatment, or remaining in care (Division of HIV/AIDS Prevention, 2020).
3. **Implicit bias**, also known as implicit social cognition, refers to the attitudes or stereotypes affecting one's understanding, actions, and decision in an unconscious manner. Including both favorable and unfavorable assessments, these biases are involuntary and take place without one's knowledge and intentional control (Heath, 2020).
4. **Racism** is defined as the belief that humans may be divided into separate and exclusive biological entities called "races"; that there is a causal link between inherited physical traits and traits of personality, intellect, morality, and other cultural and behavioral features; and that some races are innately superior to others (Smedly, 2020). The term is also applied to political, economic, or legal institutions and systems that engage in or

perpetuate discrimination on the basis of race or otherwise reinforce racial inequalities in wealth and income, education, health care, civil rights, and other areas (Smedly, 2020).

5. **Medical mistrust** is defined as absence of trust that health care professionals and organizations properly care for patients' interests, are honest, practice confidentiality, and possess the capability to produce the best possible results (Hostetter & Klein, 2021).
6. **Pre-exposure Prophylaxis (PrEP)** is an HIV prevention method that allow individuals who are HIV negative but are at very high risk of contracting HIV to reduce or prevent HIV infection by adhering to a daily regimen of antiretroviral medication. The pill, currently marketed as Truvada, contains a combination of tenofovir and emtricitabine (Centers for Disease Control and Prevention, 2020).

Chapter V: Conceptual Underpinning and Theoretical Framework of the Project

The Diffusion of Innovation Theory (DOI)

Considered one of the oldest social science theories, the Diffusion of Innovation Theory (DOI) was developed in 1962 by Rogers E. M. (LaMorte, 2018; Rogers, 1982). This theory originated in communication as a mean to explain how, over time, and idea or product gains momentum and spread through a specific population or social system (LaMorte, 2018; Rogers, 1982). The outcome of this diffusion is that individuals, as part of the social system, take on new idea, behavior, or product (LaMorte, 2018; Rogers, 1982). Adoption is defined as an individual's ability to do something different from what they had previously. The key to adoption depends on the individual's perception of the idea, behavior, or product as new or innovative, which makes diffusion possible (LaMorte, 2018; Rogers, 1982). Historically, the Diffusion of Innovation Theory was first discussed by French sociologist Gabriel Tarde in 1903 who created the S-shaped diffusion curve, followed by Ryan and Gross who introduced the adopter categories that were later implemented in the current theory publicized by Everett Rogers (Toews, 2003). The Diffusion of Innovation Theory is continually viewed as a valuable change model for guiding technological innovation where the innovation itself is refined and presented in ways that meet the needs across all levels of adopters (Kaminski, 2011). During the adoption process, the importance of communication and peer networking is heavily emphasized (Kaminski, 2011).

In simpler terms, the diffusion of innovation refers to the process that happens as individuals adopt a new idea, product, practice, philosophy etc. Rogers documented this process, emphasizing that in most cases, fewer individuals are initially receptive to the new idea and adopt its use (Kaminski, 2011). As the early innovators share their use of the product or idea, more and more individuals become receptive to it which leads to the development of a critical

mass. Over time, the innovative idea or product becomes diffused among the population until it reaches a saturation point (Kaminski, 2011).

Five categories of adopters of an innovation have been distinguished by Rogers: innovators, early adopters, early majority, late majority, and laggards. Often, a sixth group can be added: non-adopters (Kaminski, 2011). Innovators are individuals who expressed curiosity and excitement when it comes to new ideas. They are willing to take risk and are not hesitant to seize opportunities to become pioneers. This population demonstrates a certain level of comfort with uncertainties and does not require much persuasion to adopt an innovation or idea (LaMorte, 2018; Rogers, 1982). Early adopters are generally respected individuals occupying leadership positions. Typically, they are the first to identify the need for changes and embrace change opportunities. Their decision to either adopt or reject an innovation heavily relies on the credibility and success of the innovators. Being considered as “opinion leaders”, the decisions made by the early adopters creates a “tipping point”; their decision can either help an innovation to move forward or terminate it (LaMorte, 2018; Rogers, 1982). Early majority includes individuals who are not necessarily in leadership positions promoting changes, but they are receptive to new ideas. Nonetheless, they generally require proof that an innovation works before widespread adoption. To persuade this population, implementation strategy of a new innovation must include success stories based on evidence of its effectiveness (LaMorte, 2018; Rogers, 1982). Late majority refers to individuals who are skeptical of the new innovation and changes. They will only consider adopting an innovation after it has been successfully implemented by the majority. Therefore, it is of utmost importance to implement convincing strategies such as the inclusion of information detailing the success of the innovation among early adopters when trying to appeal to this population (LaMorte, 2018; Rogers, 1982). The fifth category, laggards,

encompasses the hardest individuals to influence as they are very conservative and rooted in traditions. They share a strong skepticism of new innovation, idea, product, and practices. Strategies such as the inclusion of convincing statistics, a sense of urgency, and pressure from individuals in the other adopter groups are necessary to persuade the laggards (LaMorte, 2018; Rogers, 1982).

Pre-exposure prophylaxis is still considered a new and innovative tool at the disposal of primary care providers to utilize as an HIV prevention strategy (Krakower et al., 2015). However, many of the current barriers and concerns expressed by both providers and individuals are not uncommon in the dissemination of an innovation. In conducting this quality improvement project, the adoption of PrEP, the innovation, will be promoted through a series of educational training sessions addressing the barriers affecting primary care providers' willingness to prescribe the treatment. The Diffusion of Innovation Theory is a very important theory, with the potential to facilitate primary care providers at Continuous Care Center to adopt changes that will facilitate the uptake of PrEP among Black/African American MSM and high-risk heterosexual Black/African American men. This theory also has the potential to benefit the targets of change, since respect and consideration for all involved participants is intertwined with robust strategies for integrating innovative change.

Chapter VI: Methodology

Study Design

The DNP project implementation plan has been communicated effectively to all participants (n=15). Communication regarding the quality improvement project with the staff of the selected organization started since January 2021 upon meeting them. In collaboration with the DNP mentor, all potential participants have been made aware of the nature and purpose of this quality improvement project and how it may help improve primary care providers knowledge while implementing current PrEP clinical guidelines based on evidence-based practices, and at the same time potentially help high-HIV risk individuals such as Black/African American men reduce their HIV acquisition risks. Additionally, the participants' contact information have been provided by the office manager after receiving clearance from the administrative team to facilitate communication with DNP student and other involved investigators regarding any concerns or questions the participating subjects may have.

Primary care providers at Continuous Care Center were contacted via email, with prior authorization from the administrative team and medical director, Dr. Michael P. Choi. The quality improvement project aims to educate at least 75% of the healthcare providers at Continuous Care Center using voice-over PowerPoint educational module. A survey, pre-test and post-test assessment evaluating their knowledge of individuals and providers' barriers affecting the uptake of PrEP among Black/African American MSM and high-risk heterosexual Black/African American men at high risk of HIV acquisition were administered. One expectation was to get all the primary care providers to actively participate in the proposed quality improvement project. Participation was voluntary and data collected from the survey, pre-test and post-test will remain confidential. Voluntary participation indicated consent.

Setting

The quality improvement project occurred at Continuous Care Center, a primary care clinic serving the underserved population in Oakland Park, FL. The clinic is committed to providing quality health care to individuals from all walks of life regardless of their race and ethnicity, religion, sexual orientation, and socioeconomic status. The organization strive to provide care to every patient while promoting respect, dignity, and integrity (Continuous Care Center, 2021). As for vision, Continuous Care Center and its leaders want to meet the medical needs of their community by providing a comprehensive panel of medical services that facilitate the prevention and treatment of common diseases such as diabetes mellitus, hypertension, hyperlipidemia, chronic obstructive pulmonary disorder etc. (Continuous Care Center, 2021). The practice has now expanded its services to four different locations; Daytona Beach, Tampa, Orlando, and Las Vegas (Continuous Care Center, 2021). Dr. Michael P. Choi, a board-certified general surgeon who brings his extensive expertise in Lap-Band and gastric sleeve weight-loss surgery to Strax Rejuvenation in Lauderhill, Florida, serves as their Medical Director, and Clinical Instructor of Surgery for Nova Southeastern Medical School. He's a member of the American Osteopathic Association and the American College of Osteopathic Surgeons (Strax Rejuvenation, 2021).

Sample

The quality improvement project targeted all primary care providers at Continuous Care Center. The practice in Oakland Park is composed of 2 medical doctors, including one infectious disease specialist (n=2), and thirteen advanced practice registered nurses (n=13).

Intervention

Approximately 15 primary care providers at Continuous Care Center received an online voice-over PowerPoint educational training module using materials incorporating online resources from the CDC and other healthcare organizations about PrEP, to address barriers to PrEP and increase their knowledge and willingness to prescribe the treatment to Black/African American MSM and high-risk heterosexual Black/African American men at high risk of HIV acquisition. A Qualtrics link was also be provided to all participants to electronically access the survey, pre-test, and post-test, which included questions to evaluate the increase in knowledge from the educational training. The Pre and post-test were developed using Qualtrics and made available online 24 hours a day, 7 days a week for approximately 4 weeks. The pre and post-test were made available to all participant from July 1st, 2021, to July 31st, 2021.

Instruments

The survey, and pre-test assessments were administered prior to the provision of the educational training. After receiving the educational training and Post-test, the results served as the instrument to measure improvement in knowledge about strategies to eradicate patients and providers' barriers affecting PCPs' willingness to prescribe PrEP to Black/African American MSM and high-risk heterosexual Black/African American men at high risk of HIV acquisition. The survey consisted of 15 questions, the survey will evaluate primary care providers awareness, knowledge, attitude, comfort, and familiarity with PrEP care current clinical guidelines. The survey is expected to take between 10-15 minutes to complete and will be available for 2 weeks. After the completion of the survey, a pre-test consisting of 20 questions will follow. The pre and post-test questions remained the same, and scoring ranged from 0% to 100%.

Data Collection Procedure

All required documentation tools were in place for the implementation of this quality improvement. The survey and pre-test questionnaire were readily available 24 hours and 7 days a week for 2 weeks in Qualtrics. The post-test, which was made available upon completion of the initial evaluation during a 2-week period, was created and distributed using Qualtrics to the providers who agreed to participate in the quality improvement project.

The DNP student maintained continuous communication with all participating subjects electronically using personal emails and other communication software of choice during the implementation phase. Using Qualtrics as the main software to create and distribute the survey, pre-test, and post-test, the DNP student and other investigators monitored the progress of all the participants as needed; including their acceptance to participate in the QI project, the date and time the participants completed the required tasks, and any other activities. Weekly emails were also sent by Qualtrics to the DNP student and other involved investigators regarding the progress of any current and active survey.

Due to the current impact of the COVID-19 pandemic on large social gathering and face-to-face contact, communication with the participants during the implementation phase remained strictly virtual as stressed by the IRB before approving this project. Communication via email and other available software such as Zoom were used to provide pertinent details regarding the implementation process and answer any questions or concerns the participants had.

Data Management and Analysis

The records were kept protected and confidential, except from the principal investigator and author of the quality improvement project. Data from Qualtrics were kept private and only accessible with a username and password shared between the author and principal investigator. Information or report that may help identify the participants were not included in future

publication. Data pertaining to the research study were kept private and secured, and only the author and the investigators will be able to access them, However, authorized Florida International University or other agents may request access to inspect collected data.

All data were stored in Qualtrics as the participants completed their required tasks (survey, pre-test, and post-test). Qualtrics also allowed users to generate reports and analyze data from any surveys that was built and distributed using the software engine in various formats (Words, Excel, PPT, PDF, etc...). As for troubleshooting during the various stages of the QI project, the DNP student contact information was provided to all participants and could be reached any time a concerns or question emerged. As for issues that emerged during the use of Qualtrics while completing the required tasks, the software offered a support page with quick answers to common issues that may be encountered. If their support page did not have the needed answers or solutions, their support team was eager to help and was available 24/7 through the "Submit a Request" link on their website page.

Protection of Human Subjects

Regarding protection of human subjects, all investigators involved in the quality improvement project completed a Collaborative Institutional Training Initiative Program (CITI) training. This project was approved by the Florida International University's Institutional Review Board. This quality improvement project was very unlikely to involve any risks that may negatively impact the psychological, physical, social, and economic well-being of the participants; the possibility of confidentiality breach and legal risk to occur was also very unlikely. The primary benefit from participating in this quality improvement project was the possibility to learn interventions to address barriers affect PrEP uptake in the primary care settings while promoting PrEP as an HIV prevention strategy among Black/African American

MSM and high-risk heterosexual Black/African American men at high risk of HIV acquisition.

The only other known option was to decline participate in the study. Participant voluntarily participated in the quality improvement project, and they had the right to refuse or withdraw from the quality project at any point of its implementation. The investigator held the right to remove participants without their consent at any time. All healthcare providers participating in the quality improvement project received the researcher and IRB contact information in the consent form.

Chapter VII: Results

The primary care providers' willingness to prescribe pre-exposure prophylaxis at the selected clinic was initially assessed using a survey. The DNP student found a low percentage of PrEP prescriptions and utilization, among primary care providers who have seen potentially eligible Black/African American men. Only 36.36% of the participating primary care provider stated that they had prescribed HIV-PrEP to at least one patient in the past 12 months. Among 80 charts pertaining to Black/African American men reviewed between January and June 2021, 70% (n=56) were found to be eligible PrEP candidates based their sexual history, but only 8.93% (n=5) were currently prescribed PrEP (Figure 1).

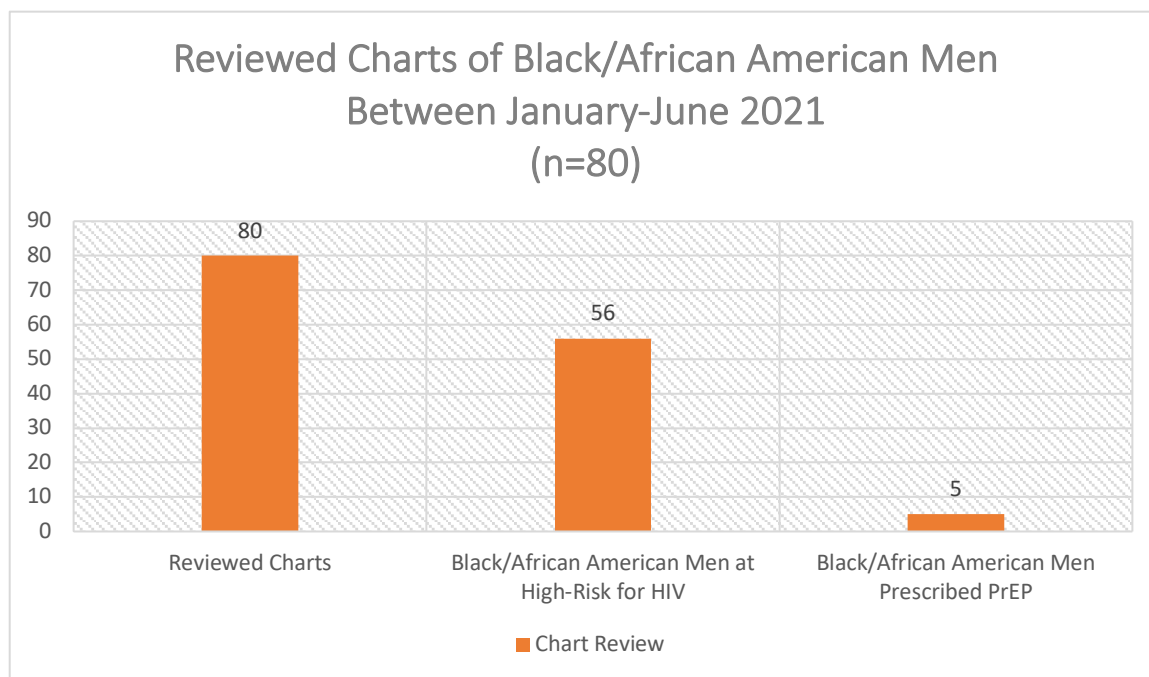


Figure 1. Review of charts (n=80) pertaining to Black/African American men at CCC during January and June 2021.

A thorough organizational assessment helped identify the following barriers affecting the implementation of PrEP in the clinic: lack of knowledge related to PrEP prescription and implementation guidelines among the providers, improper maintenance and follow up among eligible patients with significant risk for HIV acquisition, and time constraint.

The initial survey and pre-test revealed poor knowledge of pre-exposure prophylaxis clinical guidelines among the participating primary care providers as well as perceived discomfort related to offering and prescribing PrEP among them. Initially, only 18.18% of clinicians stated that they were extremely familiar with the CDC PrEP guidelines. Their inability to adequately discuss PrEP and answer their patients' questions regarding the treatment was a direct reflection of their lack of knowledge, which in turn affects their willingness to prescribe PrEP. Among all the participating primary care providers, only 54.55% correctly identified eligible candidate for PrEP when presented with certain clinical scenarios.

To address the current gaps in PrEP clinical guidelines knowledge among the providers, an educational training module was developed by the quality improvement project investigators. All clinicians received an hour-long interactive PowerPoint educational module addressing the implementation of PrEP clinical guidelines. After completing the educational training module and post-test, the DNP student met with the providers to assess changes in knowledge and attitude. The providers were able to properly discuss patients' questions and concerns regarding PrEP. There was an increase in knowledge from 64.46% to 91.11% (24.65% increase) (Figure 2).

Time constraint was a major barrier to PrEP uptake at CCC. Upon initial assessment 81.82% of the participants stated that they do not have enough time during clinical visit to thoroughly assess their patients' sexual risks factors and provide HIV-PrEP counseling. This

issue remains well after the implementation of the QI project as there were no changes made at the organizational level to address the problem. The allocated time for new clinical visits and follow-up visits had not changed. Only a slight increase was noted after the implementation of the QI project, with only 25% of primary care providers at CCC stating that they have enough time during clinical visits to address patients' sexual risks and provide prevention counseling and PrEP monitoring.

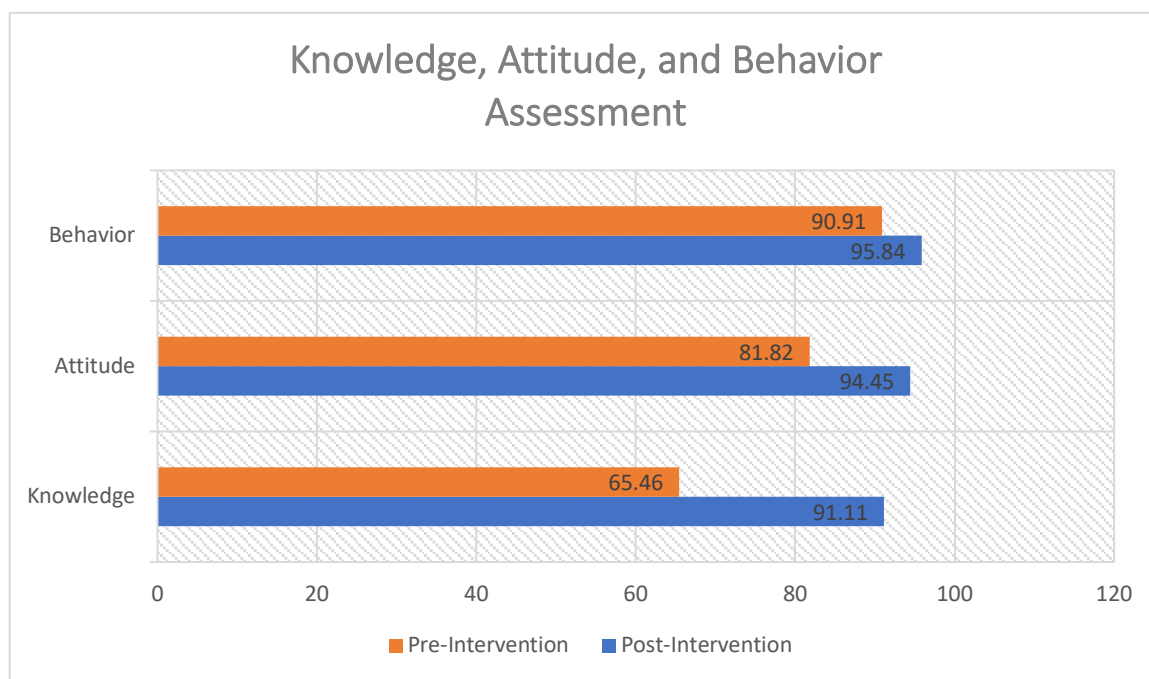


Figure 2. Primary care providers' knowledge, attitude, and behavior assessment comparison before and after educational intervention.

After the completion of the pre-test and post-test, a paired-samples *t* Test was performed by the quality improvement project's investigators. The two-tailed *P* value equals 0.0004, by conventional criteria, the difference is considered to be extremely statistically significant. As for confidence interval, the mean of the pre-test minus the post-test equals -21.6285, a 95%

confidence interval of this difference. From -32.8368 to -10.4202. The following are the intermediate values used during the calculations: $t=3$, $df=38$, and standard error of difference=5.537 (Figure 4).

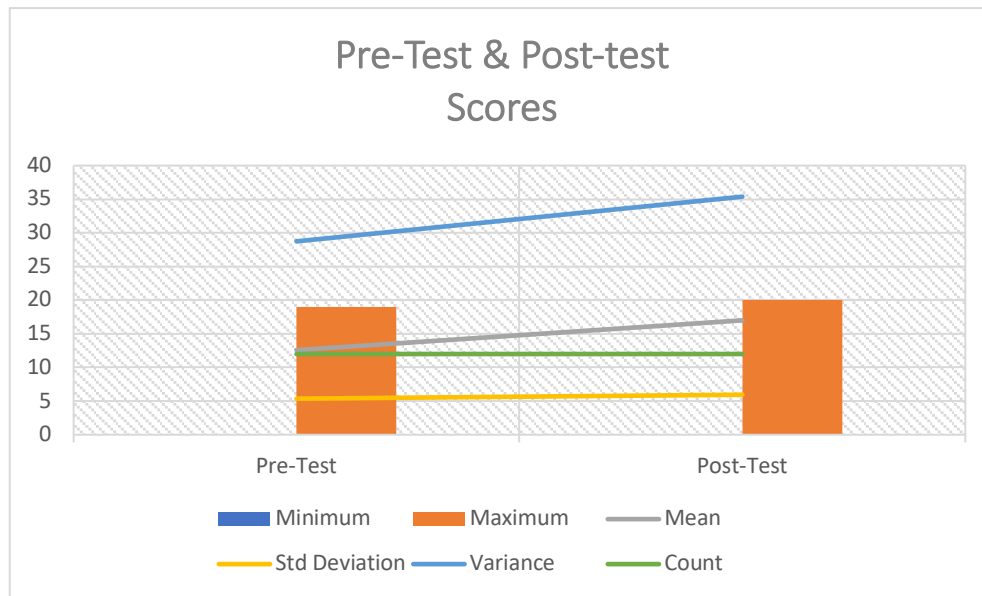


Figure 3. Pre-test and post-test scores comparison.

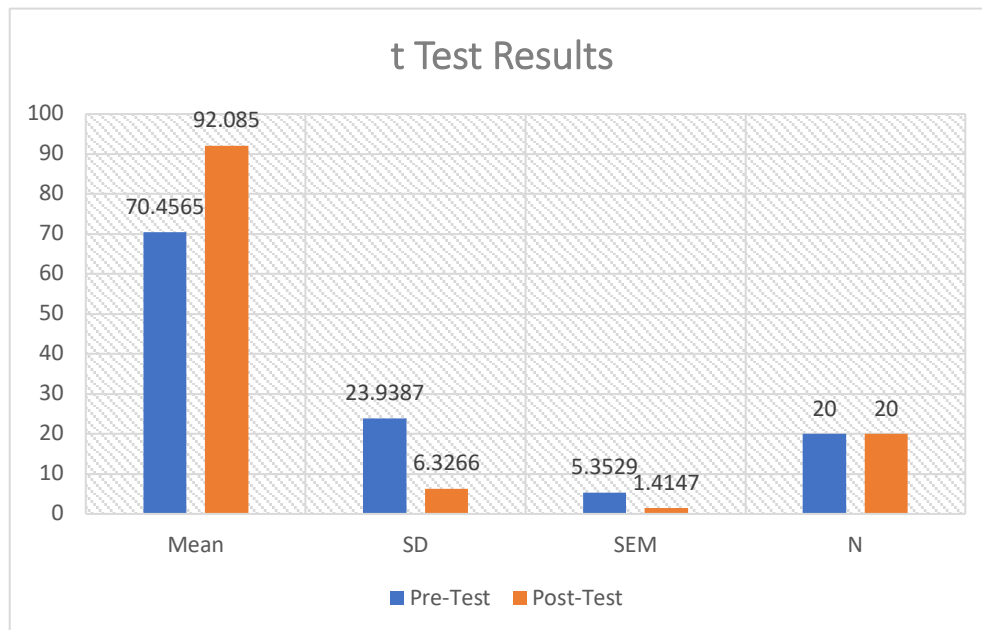


Figure 4. Paired *t* Test results.

Chapter VIII: Discussion

Approved by the Food and Drugs Administration since 2012, pre-exposure prophylaxis remains underutilized among high-risk population such as Black/African American men despite being an important HIV prevention tool. This quality improvement project allowed us to identify barriers such as lack of knowledge and time constraint impacting primary care providers willingness to implement and prescribe PrEP in a primary care clinic serving a large population of Black/African American men at high-risk for HIV acquisition. Majority of individuals are willing to develop a strong and trusting relationship with their primary care providers, which may facilitate the discussion of sexual health, high-risk sexual behaviors, and HIV prevention through PrEP. Failure by a primary care provider to demonstrate sensitivity, inclusivity, support, and risk assessment skills due to their lack of knowledge may contribute to a decrease in HIV prevention opportunities.

This project demonstrated that the provision of minimal training and available resources, primary care providers' willingness to prescribe PrEP may increase. The clinical and non-clinical staffs significantly supported this quality improvement project and the proposed interventions to increase primary care providers' willingness to increase PrEP uptake. Such support can potentially guarantee a far-reaching effect and continuous success of PrEP implementation and adoption among providers practicing in a primary care setting.

Chapter IX: Limitations

The first limitation of this quality improvement project is the size of the selected sample. The small sample size (n=12) interferes with the validity and generalizability of the project results. The timeframe allowed for the survey, pretest, posttest, as well as the length of the educational training module may have contributed to the small size sample. The small size may also reflect the primary care providers interest in the subject of HIV prevention through PrEP.

Time constraint was identified as the second limitation impacting this quality improvement project. The primary care providers at the selected clinic experienced time stress, especially during new patients' clinical visit. The time required was higher than the time allocated for the different consultations. Majority of the primary care provider expressed concerns regarding the length of the study, particularly the pretest, posttest, and educational online module. The providers also mentioned their inability to always complete their clinical notes during their shift. They often must continue to work at home, leaving them less time to review the provided material by the DNP student. As shown by the results of the survey 18.18% of all participating primary care provider stated that they had enough time during clinical visit to provide HIV prevention and PrEP counseling.

The third and final limitation can be associated to the COVID-19 pandemic. This quality improvement project was conducted during the COVID-19 pandemic which resulted in the inability to have large gathering and face-to face contact with the participants. Due to the pandemic, the IRB prohibited the any face-to-face interaction between the investigators and participants, resulting in the adoption of virtual interaction using available software to conduct recruitment, interactions, data collection, and interviews. COVID-19 drastically limited the

sample size because of the decreased interaction between the researcher, participants, organizations, and stakeholders.

Chapter X: Implication for Advanced Practice Nursing

Educating primary care provider to facilitate the implementation and adoption of the HIV pre-exposure prophylaxis guidelines provided by the CDC has positively impacted their knowledge, attitude, and behavior. The participating providers have reported an increase in the frequency in which they informed, educate, and offer the treatment to patients at high-risk for HIV acquisition. Although some patients have declined the offer to initiate PrEP treatment despite being at a high-risk of contracting HIV, the primary care providers have successfully increased their awareness regarding other alternative to prevent new HIV infections.

By participation in this quality improvement project, the providers at the selected organization improved their ability to properly and comfortably identify individuals at risk for HIV acquisition. Standard of care was also implemented when offering and prescribing PrEP to individuals at risks. Understanding and adopting the PrEP guidelines provided by the CDC the providers have acquired valuable information and knowledge, which allowed the safe adoption and implementation of the standard of care for HIV PrEP in a primary care setting.

Providing a comprehensive educational module has evidently demonstrated a positive impact on primary care providers' knowledge, attitude, behavior, familiarity, as well as the uptake of pre-exposure prophylaxis care as stressed by the literature. When provided with the knowledge and necessary skills, providers' willingness to adopt and prescribe PrEP is more likely to increase. However, more initiative and work are required to reach more primary care providers. With more primary care providers adopting the current CDC PrEP clinical guidelines, further implementation of this quality improvement project can potentially improve patients' experience and outcomes within the primary care setting.

Despite being approved since 2012 by the FDA, PrEP care is still considered a new prevention treatment. As elaborated by Rogers' diffusion of innovation theory, longevity and patience are needed when attempting to influence a group of individuals to adopt new products, ideas, and behaviors. Time is required for complete adoption to be considered a realistic possibility; initially small changes should be expected. Consequently, during the planning phase the DNP student understood this quality improvement project would be one of many smaller initiatives that would contribute to a wide-spread implementation and adoption of PrEP clinical guidelines by primary care providers to reduce HIV infection among Black/ African American men at higher risk, high risk heterosexual black men as well as Black men who have sex with men included.

To eradicate barriers affecting primary care providers willingness to prescribe pre-exposure prophylaxis care as a prevention strategy among Black/African American men at higher risk for HIV acquisition and help increase PrEP uptake, primary care provider must be comprehensively educated. Similar study must be implemented and replicated to reinforce its reliability, validity, and generalizability.

For the findings of this quality project to gain momentum and explore primary care providers' knowledge, attitude, and behavior about PrEP and HIV prevention, further research is required. Researchers' focus should also remain on the proper identification of perceptions, beliefs, and barriers impacting the identification of primary care providers as PrEP prescribers, which may provider more understanding on their reluctance to adopt the current PrEP guidelines.

Chapter XI: Conclusion

This quality improvement project addressed existing barriers affecting primary care providers' willingness to prescribe HIV-PrEP as a prevention strategy among Black/ African American men at high-risk for HIV acquisition. The model for implementing PrEP within the primary care setting stressed the importance of the provider's role in improving their knowledge of PrEP clinical guidelines to increase their comfort level, reduce missed HIV-prevention opportunities, and create an inclusive, supportive, and nonjudgmental environments for their patients.

As a result of the implementation of this quality improvement project, the primary care providers were able to increase their awareness and knowledge of PrEP as another strategy to prevent HIV infection among their high-risk patients. Additionally, education addressing the standard of care for initiating PrEP was provided. At the end of the quality improvement project, not only were the providers able to properly identify individuals at high-risk for HIV acquisition, but they were also comfortable discussing and offering PrEP to patients at risk while following standard of care. Ongoing focus on educating primary care clinicians to implement PrEP and other HIV prevention strategies will be crucial in reducing and eradicating the HIV epidemic, more importantly in high-risk vulnerable population such as Black/ African heterosexual men and Black men who have sex with men.

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Chapter XIII: Appendices**Appendix A: IRB Approval Letter**

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To: Dr. Eric Fendl
CC: Roodolphe Desvarieux
From: Maria Melendez-Vargas, MIBA, IRB Coordinator 
Date: June 4, 2021
Protocol Title: "Addressing Barriers Affecting Primary Care Providers Willingness to Prescribe Pre-Exposure Prophylaxis Care as a Prevention Strategy Among Black/African American Men at Higher Risk for HIV: A Quality Improvement Project."

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #: IRB-21-0211 **IRB Exemption Date:** 06/04/21
TOPAZ Reference #: 110501

As a requirement of IRB Exemption you are required to:

- 1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
- 2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
- 3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at <http://research.fiu.edu/irb>.

MMV/em

Appendix B: Letter of Support

Date: 05/14/2021
Eric A. Fenkl, PhD, RN, CNE
Clinical Professor
Nicole Wertheim College of Nursing & Health Sciences
Florida International University

Dear Dr., Fenkl:


Thank you for inviting Continuous Care Center to participate in the DNP Project of Roodolphe Desvarieux. I understand that this student will be conducting this project as part of the requirements for the Doctor of Nursing Practice program at FIU. After reviewing the proposal of the project titled "*Addressing Barriers Affecting Primary Care Providers (PCPs) Willingness to Prescribe Pre-Exposure Prophylaxis (PrEP) Care as a Prevention Strategy Among Black/African American Men at Higher Risk for HIV: A Quality Improvement Project*". I have warranted him permission to conduct the project in this company.

Education of clinicians has been shown to be one of the most effective strategies to improve the screening and diagnosis of various conditions and illnesses. This proposed quality improvement project seeks to investigate and synthesize the latest evidence on educational interventions for clinicians to improve barriers affecting PCPs' willingness to prescribe PrEP. There is clearly a need for a quality improvement that will consolidate all the available information on strategies to effectively address barriers affecting PCPs' willingness to prescribe pre-exposure prophylaxis (PrEP) care as a prevention strategy among Black/African American men at higher risk for HIV. Prior to the implementation of this QI project, the Florida International University Institutional Review Board will evaluate and approve the procedures to conduct this project.

We are understanding that the project will be developed in our setting and will occur for about 5 months. We are also aware of our department participation in supporting the student to complete this project, including warrant the student access to our Primary Care Offices, give electronic consent, deliver the pre-test questionnaire using Qualtrix, provide the educational intervention electronically and two weeks after providing the posttest to the recruited participants. We will provide a peaceful and virtual environment to safeguard our participant privacy during the conduction of the educational teaching module. The educational intervention will be an online PowerPoint and will last 60 to 90 minutes. Any data collected by Roodolphe Desvarieux will be kept confidential.

We expect that Roodolphe Desvarieux will not interfere with the normal office performance, behaving in a professional manner and following the office standards of care. As the Office Manager of Continuous Care Center, I support the participation of our primary care department in this project and look forward to work with you.

Sincerely,


Tonya Singh; Office Manager
Continuous Care Center

Appendix C: Recruitment Letter**RECRUITMENT LETTER****Recruitment Email for addressing barriers affecting primary care providers willingness to prescribe pre-exposure prophylaxis care as a prevention strategy among Black/African American men at higher risk for HIV: A quality improvement project.**

Dear Participants,

My name is Roodolphe Desvarieux, and I am a student from the Graduate Nursing Department at Florida International University. I am writing to invite you to participate in my quality improvement project. The goal of this project is to address barriers affecting primary care providers (PCPs) willingness to prescribe pre-exposure prophylaxis (PrEP) care as a prevention strategy among Black/African American men at higher risk for HIV and improve their knowledge of PrEP clinical practice guidelines. You are eligible to take part in this project because you are a primary care provider at Continuous Care Center, and you provide or may provide care to Black/African American men at higher risk for HIV. I am contacting you with the permission of your Office Manager and Administrative Team at Continuous Care Center. If you decide to participate in this project, you will be asked to complete and sign an electronic consent form for participation. You will complete a pre-test questionnaire, which is expected to take approximately 15-20 minutes. Then, you will then be asked to view an approximately 90-minute-long educational voice-over PowerPoint module online. After completion of the online educational module, you will be asked to complete the post-test questionnaire, which is expected to take approximately 15-20 minutes. *No compensation will be provided.*

Remember, this is completely voluntary. You can choose to be in the study or not. If you'd like to participate, please click on the link provided (link for Qualtrics questionnaire). If you have any questions about the study, please email or contact me at rdesv00@fiu.edu or (786)344-2473.

Thank you very much.

Sincerely,

Roodolphe Desvarieux, APRN, FNP-BC.

Appendix D: Pretest and Posttest**PRETEST-POSTTEST****Addressing Barriers Affecting Primary Care Providers (PCPs) Willingness to Prescribe Pre-Exposure Prophylaxis (PrEP) Care as a Prevention Strategy Among Black/African American Men at Higher Risk for HIV.****Introduction:**

This questionnaire is an essential part of a quality improvement project aiming to address barriers affecting primary care providers (PCPs) willingness to prescribe pre-exposure prophylaxis (PrEP) care as a prevention strategy among Black/African American men at higher risk for HIV and improve their knowledge of PrEP clinical practice guidelines.

Please, answer to the best of your knowledge. Your response will help in understanding gaps in knowledge and room from improvement. The questions are structured to evaluate your awareness, knowledge, attitude, comfort, and familiarity of current pre-exposures prophylaxis clinical practice guidelines, as well as barriers affecting primary care providers' willingness to prescribe pre-exposure prophylaxis care as a prevention strategy among Black/African American men at higher risk for HIV.

- *Please do not write your name or other personal information of this questionnaire*
- *Your answers are anonymous and will be kept confidential*
- *Your participation is voluntary and will not have any bearing on your position*

Demographic:

Gender: Female____ Male____ Other____ Wish not to disclose____

Age: 20-30 yrs.____ 30-40 yrs.____ 40-50 yrs.____ >50 yrs.____

How long have you been a primary care provider? _____

Race/Ethnicity: White____ Black____ Hispanic____ Haitian____ Asian____ Other____

PrEP Knowledge, Attitude, Comfort, and Familiarity Survey

1. How comfortable are you discussing sexual risks behavior with patients, BMSM included?
 - a) Very comfortable
 - b) Comfortable
 - c) Neither comfortable nor comfortable
 - d) Uncomfortable
 - e) Very uncomfortable
2. Is your patient population at risk for HIV infection?
 - a) Yes
 - b) No
3. How often do you ask patient about the types of sexual activities in the past 12 months?
 - a) Every time
 - b) Almost every time
 - c) Occasionally/Sometimes
 - d) Almost never
 - e) Never
4. How many HIV-positive patients have you treated in the past 12 months?

- a) None
 - b) 1-5
 - c) 6+
5. Have you ever been asked information about PrEP by a patient?
- a) Yes
 - b) No
6. Have you ever prescribed antiretroviral for HIV prevention?
- a) Yes
 - b) No
7. How many times have you prescribed HIV-PrEP in the past 12 months?
- a) Never
 - b) 1-5
 - c) 6-10
 - d) >10
8. If unable to prescribe PrEP, how often to you refer your patients?
- a) Always
 - b) Sometimes
 - c) Never
9. Are you familiar with the CDC PrEP clinical guidelines?
- a) Very familiar
 - b) Familiar
 - c) Unfamiliar
10. Support of the provision of HIV-PrEP to at-risk patient?

- a) No
- b) Unsure
- c) Yes

11. Preferred learning method for HIV-PrEP

- a) Peer-reviewed journals
- b) Website
- c) CME/CE
- d) Brochure
- e) I don't need more information about HIV-PrEP

12. Are you concerned about HIV PrEP effectiveness?

- a) Yes
- b) Unsure
- c) No

13. Do you believe HIV-PrEP will increase riskier sexual behaviors among patients?

- a) Yes
- b) Unsure
- c) No

14. Do you have enough time during clinical visit to provide prevention counseling and PrEP monitoring?

- a) Yes
- b) No

15. How often do you encourage regular HIV testing among patients at high-risk for HIV acquisition?

- a) Always
- b) Sometimes
- c) Never

Pre-Test and Post-Test

1. What is pre-exposure prophylaxis (PrEP)?
 - a) PrEP is the use of ARVs by people who are HIV negative to prevent the acquisition of HIV before exposure to the virus.
 - b) PrEP is the use of ARVs by people who are HIV positive to prevent the acquisition of HIV before exposure to the virus.
 - c) PrEP is the use of ARVs by people who are HIV negative to prevent the acquisition of HIV after exposure to the virus.
2. When should PrEP be started?
 - a) PrEP should be started after exposure.
 - b) PrEP should be started before potential exposure.
3. PrEP provides additional HIV prevention intervention and should be used concurrently with condoms.
 - a) True
 - b) False
4. PrEP is a replacement or substitution for existing prevention interventions.
 - a) True
 - b) False
5. Vulnerable populations targeted for PrEP include:
 - a) Black men who have sex with men (BMSM)

- b) Sex workers (SW)
 - c) People who inject drugs (PWID)
 - d) All the above
6. PrEP efficacy depends on adherence.
- a) True
 - b) False
7. All the following are side effects associated with PrEP except:
- a) Nausea, Vomiting, abdominal pain
 - b) Bleeding
 - c) Creatinine elevation
 - d) Loss of bone mineral density
8. "Start-up syndrome" are transient and usually resolves by month 3.
- a) True
 - b) False
9. Does PrEP protect against other STIs?
- a) Yes
 - b) No
10. To initiate PrEP care, a patient must:
- a) Be HIV seronegative
 - b) Be at high-risk for HIV acquisition
 - c) Have a eGFR > 60 ml/min
 - d) Be willing to take PrEP as prescribed
 - e) All the above

11. HIV testing is required before prescribing PrEP.
 - a) True
 - b) False
12. When offering PrEP, a PCP must be sensitive, inclusive, supportive, and nonjudgmental.
 - a) True
 - b) False
13. Screening questions should address patients' behavior rather than their sexual identity.
 - a) True
 - b) False
14. A PCP should recommend PrEP if a client:
 - a) Had sex with more than one partner
 - b) Had sex with a person who has HIV
 - c) Had sex with people whose HIV status you do not know
 - d) All the above
15. Patients must be coerced into using PrEP.
 - a) True
 - b) False
16. Providers must inform and counsel potential PrEP users and perform an individualized risk assessment.
 - a) True
 - b) False
17. Initial PrEP visit should not include testing for hepatitis B virus (HBV).
 - a) True

b) False

18. Patients using PrEP should visit their healthcare providers:

a) A month after initiating PrEP

b) Every 3 months thereafter

c) All the above

19. Patients' HIV risk should be reviewed during every visit.

a) True

b) False

20. PrEP can't be used with drugs and alcohol.

a) True

b) False