INTEGRATION OF PREEXPOSURE PROPHYLAXIS PROTOCOL IN MEN WHO HAVE SEX WITH MEN

by

Cynthia Denise Dalton

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Approved by:

_____
Dr. Judith Cornelius

_____
Dr. Tonya Anderson

_____
Dr. Candice McNeil

_____
Dr. Susan Johnson

ABSTRACT

CYNTHIA DENIES DALTON. Integration of preexposure prophylaxis protocol in men who have sex with men. (Under the direction of DR. JUDY CORNELIUS).

In the United States, men who have sex with men (MSM) remains the highest group infected with HIV. Truvada (PrEP) in combination with safer sex practices has shown efficacy in preventing HIV infection. Yet a PrEP protocol had not been initiated with MSM in an outpatient infectious disease clinic in North Carolina. The purpose of this study was to examine the effect of initiating a pilot PrEP protocol (brief educational intervention and 2 follow-up visits) on medication knowledge and adherence and sexually transmitted infection (STI) outcomes. The design of this study was case series. The sample consisted of 8 MSM who completed demographic and pre/post-test surveys, documented recall of pill usage, and provided blood and urine samples. The participants were primarily African American MSM, employed, and attended college. On the first visit, 63% of the participants demonstrated PrEP knowledge accuracy, on the post-test 100% demonstrated accuracy, and 38% reported no missed doses. None of the participants became infected with an STI compared to baseline and 63% reported consistent condom use. Despite the small sample size, there were trends in that data that the integration of a PrEP protocol with an educational intervention was associated with improvement in PrEP knowledge and medication adherence.

Additionally, there were no new STI outcomes, from January 7 until March 7, 2019. We expected this project would demonstrate the importance of a PrEP protocol in the setting of an infectious disease clinic at Wake Forest Baptist Health. The findings

suggest that knowledge of PrEP is considered essential to ensure effective PrEP implementation.

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Chapter One

1.1 Introduction/Background

Human Immunodeficiency Virus (HIV) is an incurable infection and if left untreated it can become acquired immunodeficiency syndrome (AIDS). In 2017, more than 36.9 million people were living with HIV and in one year 1.8 million new cases occurred globally (World Health Organization, [WHO], 2017). More than 1.1 million people in the United States [U.S.] are living with HIV, and 1 in 8 do not know that they are infected. In the past year, 39,782 people in the United States were newly diagnosed with HIV. Men who have sex with men (MSM) remain the highest infected group.

Although MSM represent only 4% of the U.S., population, this subpopulation has the highest rate of new HIV infections and in 2016 accounted for 86% of new infections (Montano et al, 2018), with rates continuing to increase annually. Traditional HIV prevention strategies have centered on public health campaigns, HIV testing and counseling, safe sex practices including condom use, and needle exchange programs (Usher, 2015). In a WebEx entitled "A Pill for Prevention: Understanding HIV Pre-Exposure Prophylaxis Dr. Christopher Hurt (2018) explained that these traditional methods aren't enough to curb the current epidemic. Hypothetically if someone is unable to prevent HIV transmission and becomes infected, treatment with antiretroviral (ARV) medication is utilized and has proven effective in managing the infection and postponing the onset of AIDS. These strategies for prevention and treatment for HIV have traditionally been viewed as separate and distinct, but now, there is clear convergence

toward overarching strategic use of ARV medications to both treat and prevent HIV infection (Baggaley et al., 2015).

In 2014, the CDC published pre-exposure prophylaxis (PrEP) guidelines for HIV prevention with Truvada in the U.S. These guidelines recommend that PrEP be considered for people who are HIV negative and are at high risk of HIV infection. This includes those, in an ongoing relationship with an HIV positive partner, not in a mutually monogamous relationship with a partner who recently tests HIV negative, being an MSM who has had anal sex without condoms, or an MSM who has been diagnosed with an STI in the past six months.

Truvada has been shown to be safe and effective in reducing the risk of sexual HIV acquisition (CDC, 2017). In multiple studies, a significant amount of peer-reviewed, placebo-controlled, randomized trials (RCTs) demonstrate the effectiveness of PrEP in preventing at-risk patients from acquiring HIV (Arkell, 2017; Highleyman, 2018). Evidence from the WHO (2012) and CDC (2014) suggest a substantial impact in protection rates against HIV when using PrEP.

1.2 Problem Statement

MSM living in the southern U.S. have been identified as being disproportionately affected by HIV and AIDS diagnosis and accounted for 50% of new rates of HIV infection (CDC, 2018). Southern states targeted for prevention efforts include Alabama,

Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Texas (CDC, 2018). MSM living in these states are disproportionally affected by HIV and share specific characteristics, such as overall poor health, high poverty rates, high levels of STDs and high rates of being uninsured. The setting for this project is in one of these southern states (CDC, 2016) and approximately 20 new HIV cases occur each month in the Infectious Disease Specialty Clinic (IDSC) at Wake Forest Baptist Health in North Carolina.

1.3 Purpose of the Evidence-Based Project

New approaches to HIV prevention are urgently needed to reduce the increasing number of HIV infections identified annually with MSM in the U.S. Despite high levels of efficacy, the implementation of PrEP as a strategy to prevent new HIV infections has been slow. Studies demonstrate that PrEP works as long as it is taken, making adherence one of the challenges. Given that effective PrEP use requires ongoing self-administration of pills by individuals at high risk of HIV acquisition, it is a strategy that's best understood not as merely biomedical, but as bio behavioral or biopsychosocial, meaning that social, psychological, cultural, and structural factors all contribute to the success or failure of the intervention.

The willingness of people to adhere to PrEP depends greatly upon social understandings, whether it is seen as effective, as a healthy option, and a socially acceptable strategy for preventing HIV. Stigma, which can be defined as unfavorable can

negatively influence the implementation of PrEP. Because it is associated with high-risk sexual activity, PrEP risks multiple stigmas that can differ according to specific cultures. This includes the stigma of being HIV (which may also relate to other stigmas, such as homosexuality, sex work, and/or drug use) and the stigma of PrEP being an alternative to condoms (as condom use is associated with responsible sexual activity). PrEP-related stigmas have emerged as a significant social harm that can develop from PrEP research participation, reported by trial participants from a range of different trial sites, different trial populations, and spanning different continents (Haire, 2015).

If social advertising would redress PrEP and PrEP related stigmas through health promotion campaigns aimed at clinicians and HIV-affected communities, then there will be a significant number of people on PrEP. Hence, this can help people remain HIV negative. The purposes of this DNP project were to assess PrEP knowledge in qualifying HIV negative MSM involved in a serodiscordant relationship, examine PrEP medication adherence, assess PrEP knowledge retention after an educational session, and examine rates of STIs (sexually transmitted infections) which may occur while taking PrEP.

1.4 Significance

HIV affects millions of people worldwide. However, specific sub-groups of affected people have been recognized as having a higher risk of contracting the virus. These groups include MSM, transgender women who have sex with men, and HIV serodiscordant couples. In 2017, Yi reported that only 29.7% of MSM were aware of

PrEP treatment, and none had reported using PrEP. If individuals contract HIV they will be forced to live with an incurable virus for the rest of their lives. Once diagnosed, a daily antiretroviral medication is required in order to prevent HIV from becoming acquired immunodeficiency syndrome (AIDS). AIDS is defined by the development of multiple severe clinical manifestations including cancers and infection, resulting in a poor prognosis and high mortality rate (WHO, 2015). Additionally, Schnackman et al. (2015) estimated the lifetime cost of from preventing HIV infection was $379,668 per person. This supports the significance of implementing a PrEP protocol with MSM.

In groundbreaking research called the Initiativa Profilaxis Pre-Exposición (iPrEX) trial, published results examined the safety and efficacy of once-daily oral emtricitabine and tenofovir disoproxil, also called Truvada, as an effective HIV prevention strategy (Grant et al., 2010). The iPrEx trial was the first human study, which showed a significant reduction of HIV infection rates among study participants. Subsequent studies have been conducted that analyzed the effectiveness of Truvada among different populations, effective adherence and implementation strategies and medication associated costs.

On July 16, 2012, the United States Food and Drug Administration (FDA) approved Truvada known as PrEP, a one pill regimen in combination with condom use and other safer sex practices to reduce the risk of sexually acquired HIV infection. Given that pre-exposure prophylaxis (PrEP) is a highly effective form of HIV prevention, it is

no surprise that a number of countries (e.g., USA, Belgium, France, Norway, and Thailand) have made PrEP available for HIV high-risk populations, such as MSM (Jonas & Yaemin, 2018). The current endeavor is to increase PrEP uptake, which is still at suboptimal use among certain populations levels in the U.S. and Thailand. In many other countries, medical service providers, community-based organizations (CBOs), activists, and lesbian, gay, bisexual, and transgender (LGBT) associations are lobbying governments to make PrEP available. Independent of formal availability and insurance coverage, LGBT associations, and medical service providers are focusing on MSM to increase PrEP uptake since levels are still comparatively low.

The success of PrEP will be dependent on behavioral variables such as knowledge of PrEP, willingness to take PrEP, acceptability, readiness, and adherence. Few studies to date have explored behavioral and demographic constructs of PrEP use, medication adherence, and few have focused on predictors of MSM's intentions (i.e., likelihood) to use PrEP. Additionally, understanding the demographic and behavioral predictors of intentions to use PrEP may prove useful to identify trial participants for future efficacy studies or programs for its use (Mimiaga, 2016).

If HIV infections can be prevented with PrEP treatment, (reported as 92% effective if taken regularly) the number of new HIV infections per year will decline, preventing the spread of the HIV in the U.S. (White House Office, 2015). With this DNP scholarly project, the student integrated a PrEP protocol into clinical practice with Truvada, an antiretroviral that offers a promised decrease in the transmission of HIV

among MSM along with a combination of condom use and other safer sex practices to reduce the risk of sexually acquired HIV infection.

1.5 Clinical Question

In MSM serodiscordant couples with one HIV-negative partner who is educated and treated with pre-exposure prophylaxis (PrEP), what are medication adherence, knowledge retention, and STI outcomes in 2 months when compared to baseline?

1.6 Definition of Terms

Definitions of terms, as operationalized within this project appear in the subsection of words that were consistently used throughout this project. These words are:

Medication adherence: For this study medication adherence was defined as the degree in which a patient correctly followed medical advice with medication treatment. Medication adherence was measured by the number of doses taken divided by the number of doses scheduled. This was measured with a pill log that was given to participant at the first visit and was measured weekly. Participants brought their pill log to each clinic visit. The pharmacy was contacted to ensure that each participant was picking up prescriptions.

Knowledge retention: Knowledge retention involves capturing knowledge. For this study knowledge retention involved retaining PrEP information so it could be used, shared and applied later. Knowledge retention was measured with a pre and posttest that

consisted 9 questions. If the participant scored an 8 on the pretest and an 8 on the post, then we can say knowledge was retained.

Sexually transmitted infection (STI): For this study an STI was defined as an infection you can get by having sex. Some STIs (such as gonorrhea and chlamydia) infect your sexual and reproductive organs. Others (such as HIV, hepatitis B, and syphilis) cause general body infections. STIs use to be called venereal diseases (VDs). STIs are spread predominantly by sexual contact, including vaginal, anal, and oral sex. Some STIs can also be spread through non-sexual means via blood or blood products. Many STIs—including chlamydia, gonorrhea, primarily hepatitis B, HIV, and syphilis—can also be transmitted from mother to child during pregnancy and childbirth (CDC, 2017). To measure STI outcomes, Gonorrhea, chlamydia and syphilis screening and testing were performed at all three visits.

1.7 Objective

The objective for this DNP scholarly project was to identify at least twenty HIV negative MSM who were eligible for the PrEP protocol and enroll seven to ten of them in this pilot study. Once enrolled the outcome variables of PrEP knowledge, medication adherence and STIs were examined, measured, and analyzed.

CHAPTER 2: LITERATURE REVIEW AND THEORECTICAL FRAMEWORK

2.1 Literature Review

A literature review was completed to review findings related to PrEP knowledge, medication adherence and STI infection rates while taking PrEP. The database Cumulative Index to Nursing and Allied Health Literature (CINAHL) was used. The time period for the search ranged from January, 2013, to January, 2019. The following keywords were entered in the database: "pre-exposure prophylaxis" or PrEP, knowledge, willingness, retention, "men who have sex with men" or MSM, knowledge, medication adherence, and sexually transmitted disease/infections. Titles, abstracts, citation information, were identified through a search strategy. Full-text articles were obtained for all selected abstracts and the reviewer independently assessed all full-text articles for eligibility to determine final study selections. The initial database search yielded 577 citations. Articles were excluded if the study was conducted outside of the United States and was not original research. The titles and abstracts were refined with key terms: MSM, PrEP knowledge, medication adherence, and STIs, which yielded 21 articles with 16 excluded. Medication adherence, PrEP, and MSM yielded 25 articles with 19 excluded. MSM, PrEP, and STI yielded 36 research articles with 33 excluded. A total of 14 articles were included in this review.

2.2 MSM and PrEP Knowledge

The HIV epidemic represents a global health crisis and reducing new HIV infection is a priority public health concern. Nelson et al. (2019) conducted a study to

explore factors that position nurse practitioners (NPs) to lead implementation of HIV pre-exposure with MSM. The American Association of Colleges of Nursing's advanced nursing practice competencies were included as a source of data for identifying and cross-referencing NP assets that align with HIV PrEP care continuum outcomes. There were four main evidenced-based arguments that could be used to advance policy-level and practice-level changes that harness the assets of NPs in accelerating the scale up of HIV PrEP. The global health goal for HIV prevention cannot be achieved without broader adoption of PrEP as a prevention practice. NPs are the best hope for closing the gap with PrEP access in populations vulnerable to HIV infection.

In a web-based survey study, Kahal, Sullivan and Stephenson (2018), examined respondent characteristics associated with PrEP functional knowledge. A sample of 573 MSM participated in a web-based survey which included four questions on: (1) the efficacy of consistent PrEP use, (2) inconsistent PrEP use and its effectiveness, (3) PrEP and condom use, and (4) effectiveness at reducing STIs. Although awareness and knowledge increased, little is known about the functional knowledge of PrEP and its impact on willingness to use PrEP. Based on the findings, PrEP knowledge was high regarding adherence, condom use, and STIs. Low PrEP knowledge scores were associated with minority race/ethnicity, lower education, and not having an HIV test in the past year.

Despite the effectiveness of oral PrEP for HIV prevention, knowledge retention of this new prevention strategy has not been studied longitudinally. Parker et al. (2015)

conducted a study to examine MSM's awareness and willingness to use PrEP daily in two cities—Washington DC and Miami, Florida. Demographic and behavioral correlates of being "very likely" to use PrEP were assessed. PrEP awareness and knowledge increased, but the likelihood

of using PrEP remained low. Being likely to use PrEP decreased over time in Washington D.C. but increased in Miami. In Washington, D.C. race was associated with the increased odds of being very likely to use PrEP. In Miami, a higher population of White versus Hispanics MSM reported being very likely to use PrEP. Based on the findings, geographic differences in awareness and knowledge, use, and willingness to use PrEP indicated that innovative strategies are needed to educate MSM about this effective prevention strategy. One limitation of this study was that the findings were based on self-reported data, which may have been affected by recall or bias.

To understand PrEP patients' experiences in real-world settings, Parker et al (2015) conducted in-depth qualitative interviews with MSM being treated at an infectious disease outpatient center in Rhode Island. Interviews were structured to allow flexible responses and introduction of additional topics by both interviewer and participant. The interviews were conducted until data saturation was reached. Each interview was digitally recorded. A grounded theory approach was used to interpret the interview findings. Parker et al. (2015) found that the patients generally reported positive experiences with PrEP and experienced few adverse clinical outcomes. One limitation of the study was that

the sample was limited to participants enrolled in PrEP care. Another limitation was thatdata could not be captured for patients lost to PrEP follow-up. The study was one of the first to examine the experiences of patients taking PrEP in an outpatient treatment setting.

Gersh (2014) conducted a study on seronegative MSM's attitudes and barriers towards PrEP. A 19-item Likert-scale survey was used to assess knowledge of PrEP, attitudes towards the cost, side effects, alternative prevention methods, and the impact of taking PrEP on sexual risk behaviors. PrEP was found to be uncommon among men at high risk for sexual acquisition and the cost of ARV drugs was a significant barrier to future PrEP use. If PrEP is to have a significant impact on transmission of HIV-1, expanded efforts to decrease cost and to increase community awareness of PrEP safety and efficacy is needed.

2:3 MSM and PrEP Medication Adherence

Medication adherence may be assessed via biomarkers, which are expensive and invasive, or via self-report using audio computer assisted self-interviewing (ACASI), which may result in over-reporting of adherence. Baker et al., (2018) conducted a study with 167 MSM to assess the potential of a new method of self-report, the Interactive Questionnaire System (iQS), in estimating accurate PrEP adherence rates. PrEP adherence was measured via dried blood spots (DBS). Both ACASI and iQS data revealed that over 40% of individuals self-reported adequate PrEP adherence but DBS-estimated drug levels indicated inadequate adherence. Young MSM had greater odds of

over reporting when compared to older MSM. Being African American was associated with 3.22 times odds of over reporting when compared to being non-African American.

Fuchs et al. (2018) performed a mixed method study to evaluate a mobile health intervention (iText) that utilized weekly bidirectional text or e-mail support messages to encourage PrEP adherence among participants in a multi-site study. A convenience sample of 56

MSM PrEP users from San Francisco and Chicago participated in a 12-week pilot study. The iText intervention was found to be feasible and acceptable, particularly among younger participants (under age of 30) and participants of color.

In another study, Mayer et al. (2017) examined medication adherence at 3 and 6 months with two PrEP medications (Wisepill and tenofovir) in a study with 50 HIV-negative MSM. Participants in the study were randomized to a cognitive behavioral intervention or a time and session-matched comparison counseling intervention. The cognitive behavioral intervention entailed four nurse-delivered sessions augmented with two booster sessions based on Life-Steps, an ART treatment adherence intervention. The comparison condition received basic PrEP information and supportive counseling. Wisepill adherence was high in both groups yet not statistically different among the groups. Plasma tenofovir levels were significantly higher in the intervention group at 6 months using mean substitution analysis (i.e., computing missing variables) ($p = 0.037$), however, in the complete analyses (i.e., using only those completing all 14study visits), there were no statistically significant differences between the randomized

conditions. Medication adherence was high across the cognitive-behavioral group with some evidence suggesting effectiveness with the Life-Steps intervention.

In one study Liu et al., (2014) examined self-reported medication-adherence experiences (facilitators and barriers) among a geographically diverse online sample of 1480 HIV-uninfected MSM. Facilitators of medication adherence included an established medication routine, keeping the medication visible, and using a pill-box. Barriers included forgetting to take the medication, changes in routine, and being busy or away from home. Older men and those not reporting any adherence barriers were more likely to report excellent adherence. Additionally, men willing to use PrEP were more likely to report perfect 30-day adherence. Based on these findings, the authors recommended that younger MSM receive additional counseling strategies to build pill-taking strategies into their PrEP routine.

Housek et al. (2017), examined PrEP adherence with 277 young HIV-negative MSM who reported HIV transmission risk behaviors in the previous 6 months. Participants who received daily Truvada were examined using dried blood spots to quantify therapeutic levels at baseline, and monthly for 3 months and then quarterly until week 48. Diagnosis of STIs at baseline remained high across all visits. A noticeable drop off with Truvada medication adherence occurred at week 24. Results indicated that four HIV-negative MSM seroconverted. Condomless sex was reported by greater than 80% of participants and condomless anal sex with last partner was associated with higher Truvada levels. PrEP acceptability was high and most participants achieved therapeutic

protective drug levels during monthly visits. As clinic visit frequency decreased so did adherence rates.

One study used mobile technology to promote retention and adherence to PrEP. Liu et al. (2018) conducted a randomized controlled trial to evaluate the impact of a bidirectional text messaging intervention on study retention and PrEP adherence with 121 MSM. The authors found that participants who received PrEP bidirectional text messages were more likely to attend study visits and had therapeutic PrEP blood levels (at 4, 12, 24, and 36 weeks) when compared to those who did not. The PrEP bidirectional text messaging intervention was found to be acceptable and increased study-visit retention with young MSM.

2.4 MSM Taking PrEP and STI's

Several studies have addressed STI rates in MSM who take PrEP. Montano et al (2018) conducted a study with 183 MSM who initiated pre-exposure prophylaxis (PrEP) at an STI clinic in Seattle, Washington to examine changes in sexual risk behaviors and STI prevalence. Findings showed that reporting never using condoms in the prior 30 days increased at 12 months when compared to PrEP initiation. The percentage of PrEP patients diagnosed with an STI was higher when compared to prior PrEP use. MSM taking PrEP reported decreased condom use resulting in higher STI prevalence.

In a community-based clinic serving MSM in San Francisco, California, Hojilia et al. (2018) characterized key steps of a pre-exposure prophylaxis (PrEP) cascade to identify correlates of uptake and retention in care. In total, 344 patients were evaluated

for PrEP uptake and retention. Three-fourths (78%) of those who sought PrEP services initiated PrEP. The overall cumulative incidence of discontinuing PrEP at 13 months was 38%. Men with a sexually transmitted infection (STI) were 44% less likely to be retained. Individuals diagnosed with a rectal STI or syphilis at baseline was significantly less likely to be retained in PrEP clinic services. Because STI diagnoses like syphilis increase the risk of HIV seroconversion, comprehensive interventions such as PrEP adherence counseling, motivational enhancement, and navigation support services may help optimize PrEP retention in these individuals. The authors concluded that it was difficult to determine if the comprehensive retention efforts for men with STIs was optimized by the benefits of using PrEP.

The valuable role of antiretroviral therapy in preventing HIV transmission in serodiscordant couples has been clearly demonstrated when the infected partner is receiving treatment. Sagaon-Teyssier et al. (2016) conducted a double-blind randomized trial with 400 high-risk MSM to evaluate sexual activity based on HIV pre-exposure prophylaxis. Based on findings, there was an 86% relative reduction in HIV incidence among participants with tenofovir disoproxil fumarate-emtricitabine vs. placebo. Overall, respectively, 70.3% and 69.3% of participants reported, condomless anal and condomless receptive anal intercourse during their most recent sexual encounter without significant change during follow-up. On average 83.3% of participants protected themselves by PrEP intake or condom use or both during the trial, with no increase in at-risk sexual practices observed. As a result, none of these indicators showed significant trends after follow-up care, although the researchers found a tendency toward decrease ($p = .19$) in

the median number of sexual partners strengthening the absence of behavioral disinhibition. The authors recommended that on-demand PrEP with a comprehensive HIV prevention package could improve prevention in MSM.

2.5 Theoretical Framework-

Lippitt's change theory consists of seven phases that focuses more on the role and responsibility of the change agent than on the evolution of the change itself (Hill, 2004). The key to change is having the right person be the voice of change and the support for reform, empowering the process. In this project the DNP student was identified as the right person to be the voice for reform, hence empowering the process. In Stage 1, the DNP student identified that HIV is a crisis in the infectious disease clinic in Wake Forest, North Carolina. In Stage 2, the DNP student, assessed participation motivation and capacity for change (preventing transmission of HIV). In Stage 3, The DNP student assessed resources and her personal motivation to make this change (commitment to change, power, and stamina). In Stage 4 the DNP student identified progressive stages of change (reduced HIV diagnoses among MSM). In the next stage, Stage 5, the DNP student ensured that her role and responsibility as a change agent was clearly identified and understood by others. The following stage, Stage 6, required that the DNP student support change through communication, feedback and coordination (educational session, handout, surveys, pre/post surveys, communication with DNP committee and subject matter expert). In the final stage, Stage7, the DNP student will gradually remove herself from the relationship, as the change becomes a part of the organizational culture (the clinic will continue with the PrEP protocol).

Lippitt's change theory was excellent in helping the DNP student, nursing leadership and management make the necessary changes needed for the integration of a PrEP protocol. This change theory assisted in the process of developing a protocol for notifying stakeholders as well as patients about the change and education that was to be provided in the infectious disease clinic.

CHAPTER 3: PROJECT DESIGN

3:1 Methodology

For this pilot study project, a case series design was used to determine the impact of the integration of a PrEP protocol with HIV negative MSM. A case series is a group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment (NIH, 2019). The PrEP protocol was designed to be implemented to help reduce the transmission of HIV. The target population was HIV-negative MSM in an ongoing relationship with an HIV-positive partner, not in a mutually monogamous relationship with a partner who recently tested negative, MSM who had anal sex without condoms, or an MSM diagnosed with an STI in the past six months. After obtaining Institutional Review Board (IRB) approval, participants were recruited and consented to participate in the pilot study (Appendix A).

3.2 Setting

The setting of the project was at an Infectious Disease Specialty Clinic (IDSC) at Wake Forest Baptist Hospital (WFBH). The clinic provides interprofessional services to more than 2000 patients with the diagnosis of HIV. The majority of this patient population is MSM.

3.3 Patient Inclusion Criteria

The inclusion criteria for this study were MSM age 18 and older, who were HIV-negative and in a relationship with HIV positive partner, able and willing to consent. A single attending physician and scheduler screened all referrals to the IDSC; all referrals for PrEP were directed to the DNP student. Additionally, other providers were encouraged to ask their HIV negative partners if they were interested in an appointment to discuss PrEP.

3.4 Patient Exclusion Criteria

Those under the age of 18, unable to give consent, HIV positive or infected with hepatitis B or C were excluded from participating in the study. Although research indicates that people with hepatitis B virus (HBV) can safely take Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP), "flares" or other health problems occur when it is used or discontinued (www.poz.com, 2015). In addition, there is a risk of hepatitis B rebound if Truvada is stopped.

3.5 Sample Size

The convenience sample of twenty-six HIV negative MSM was screened by a scheduler at the IDSC. The scheduler screened 26 participants, 18 participants were eligible, 10 were scheduled and 2 were no shows. The sample size consisted of eight HIV negative MSM participants who were deemed appropriate to detect significant changes in integrating a PrEP protocol.

3.6 Tools/Measures

The Evaluation of Candidacy for HIV Pre-Exposure Prophylaxis (PrEP) (Appendix D) was utilized to guide the design and development of the PrEP Protocol. In addition, the screening tool provided a framework for which to develop the protocol in an organized and comprehensive manner.

All participants completed a 24- item survey, items 1, 2, and questions 13 through 24 adapted from Gersh et al. (2014), Attitudes and Barriers towards Pre-Exposure Prophylaxis (PrEP) among High-Risk HIV-Seronegative MSM, questions 3 through 8, and question 10, were adapted from PrEPfacts.orgsurvey and questions 9, 11, and 12 adapted from the CDC website. The 24-items assessed baseline demographics, exposure risks, and attitudes towards PrEP. Next, a face-to face educational session accompanied by a PrEP 101 handout was provided followed by the 9-item pre-test (Appendix F). A post-test (Appendix G) consisting of the 9-item survey was performed at visit three. We encouraged the participants to be open and honest with their responses. Participants were assured that the information would remain confidential and anonymity would be ensured.

3.7 Outcome Measures

Outcome measures consisted of the number of participants on PrEP, the number who stayed on PrEP, the number of participants who stopped taking PrEP, the number who became HIV positive while taking PrEP, medication adherence, PrEP knowledge and STI outcomes.

3.8 Intervention and Data Collection

On the first visit, participants were scheduled to meet with the DNP student. The DNP student discussed the PrEP protocol (Appendix B) and provided all participants with information about the project including the purpose, DNP student investigator contact information, and explanation of record-keeping and data collection procedures. If they agreed, a consent form (Appendix C) was signed by participant at the first visit, after signing the consent form participants completed the 24-item survey tool (Appendix E) and a 9-item pre-test, followed by a face to face educational session with a PrEP 101 handout, which was reviewed at each follow-up visit (Appendix F). Labs such as HIV testing, completed complete metabolic panel (CMP), STI swabs (oral and anal), and RPR blood specimen were collected at the first visit and each follow-up visit. A medication pill log was given at the first visit and at the two follow-up visits. On the final visit the 9-item post/test survey measuring PrEP knowledge was administered (see Table 3.1).

At, each visit the DNP student reviewed the PrEP 101 handbook and laboratory results with each participant. Strategies to maintain adherence, as well as, identifying negative consequences of unprotected sexual encounters were emphasized with condoms given at each visit. A medication pill log (Appendix H) was given to patient at the first visit to be checked daily. The pharmacy was contacted to monitor prescription refills after the second and third visit.

At the first visit the 24-item PrEP attitudes and willingness survey was given to the participants. At the second visit (4 weeks later) and at the final visit (2 months from baseline) a 9-item PrEP knowledge survey was administered to assess retention.

Medication adherence was tracked at the second visit (4 weeks later) and at the third visit (2 months from baseline) with a pill log that was given to participants at the first visit. Additional data included calling the participant's pharmacy to make sure that emtricitabine/tenofovir (Truvada) was picked up or mailed to participants (Table 3). Participants were given a $25 gift card at first visit and a $25 gift card at the third visit. No monetary compensation was provided for the second visit.

PrEP laboratory tests including HIV antigen antibody testing, comprehensive metabolic panel (CMP), hepatitis panel, syphilis, and gonorrhea and chlamydia testing at anatomical sites of exposure were reviewed if available, if PrEP laboratory test results were not available, then these lab tests were collected at the clinic IDSC. See Table 3.3.

Table 3:1- PrEP Protocol Table of Events

Study Procedures	Enrollment	Visit 1 (4 weeks)	Visit 2 (3 months)
Review PrEP criteria/screening tool (24-item survey) and obtain informed consent	X		
Assess readiness to take PrEP and administer the 9 item- PeEP knowledge Pre-test (Survey)	X		
Conduct face to face educational session and administer PrEP 101 handout	X	X	X
Obtain specimens for HIV testing, complete metabolic panel (CMP), hepatitis panel, and STI testing), and syphilis	X	X	X
Medication Adherence: Pill log Contact pharmacy for prescription refill information		X	X
Knowledge of PrEP/knowledge retention: post-test		X	X
Participant gift card compensation	X		X

This pilot study assessed PrEP knowledge and retention in qualifying HIV negative MSM in serodiscordant relationships, evaluated medication adherence, and STI transmission while taking PrEP. Data from this study identified the number of participants enrolled and the number of participants who completed the three visits while on the protocol.

3.9 Project Analysis

With this pilot study, the DNP student was committed to reducing the transmission of HIV in MSM. By providing education and PrEP to MSM at high risk for acquiring HIV, the DNP student was able to empower this population to make changes

with their health risks by bringing awareness to this protocol. All data was collected and managed with Excel spreadsheets. As the result of the small sample size, all study outcomes were analyzed using descriptive statistics.

CHAPTER 4: PROJECT RESULTS

4:1 Introduction

The critical integration of a PrEP protocol into an infectious disease clinic at Wake Forest Baptist Hospital (WFBH) underscored the importance of this project with a high-risk population of HIV negative MSM. There were several challenges with the implementation of a PrEP protocol. The concerns identified with PrEP usage included high costs, safety screening, toxicity arising from continuous use, adverse drug reactions, poor medication adherence, possible abuse, the fear of decreased condom use, and retention in care. Retention in care (RIC) was a critical step in ensuring efficacy of PrEP. Getting the message to this high-risk population is one of the biggest challenges remaining today.

4.2 Clinical Question

In order to address the problems surrounding challenges that men who have sex with men face in receiving PrEP for preventive measures in this high-risk population, the DNP student investigated the clinical question – With MSM in a serodiscordant relationship, what is the effect of a, face-to-face educational intervention on PrEP knowledge, medication adherence, and STI outcomes after two follow-up visits when compared to baseline? The overall objective of the pilot study was to examine the effect of the integration of a PrEP protocol with MSM in an effort to reduce rates of HIV infection in North Carolina.

4:3 Sample

During January 7 to March 7, 2019, a total of eight study participants shown in table 4.1, consented to participate in the study.

Table 4:1 Participants Baseline Characteristics (*N*=8)

	Case demographics							
#	Age	Race	Gender	Employed	Education	PrEP Pretest Knowledge Visit 1	Condom Use	Partners Last 3 months
1	22	AA	M	Yes	S	8/9 (88.9%)	80%	6 - 7
2	25	AA	M	Yes	S	9/9 (100%)	50%	4
3	25	White	M	Yes	C	9/9 (100%)	30%	10 - 12
4	27	AA	M	Yes	G	8/9 (88.9%)	100%	2
5	32	AA	M	Yes	H	9/9 (100%)	100%	1
6	32	AA	M	Yes	C	8/9 (88.9%)	80%	4
7	34	AA	M	Yes	G	9/9 (100%)	90%	1
8	41	AA	M	No	H	8/9 (88.9%)	0%	1

1) G=Graduate school, C=college graduate, S=some college, H-high School graduate
2) Questions answered correctly/total questions

The sample was primarily African American MSM (*n* = 7), 29.7 years of age, employed (*n* = 7), and attended college (*n* 6). Most of the participants did not have any significant past medical health problems; one participant had unilateral agenesis of the kidney, which did not interfere with PrEP administration.

4.4 Pre-Screening Sexual Risk Behaviors, Attitudes and Barriers Towards PrEP Survey

Once the consent form was signed all eight participants completed a 24-item adapted survey, which assessed high risk sexual behaviors, attitudes, and barriers, towards PrEP. The first set of questions pertained to sexual behaviors associated with HIV/STI risk. In regard to HIV/STI exposure, 50% of the participants (n = 4) had greater than four partners, 50% (n = 4) were involved in receptive anal sex, and only 25% (n = 2) used condoms 100% of the time. The second set of questions asked the participants about their attitudes toward PrEP. The majority 87.5%, (n= 7) of the participants had heard of PrEP, 100% knew that PrEP could not be prescribed to an HIV positive individual and that Truvada was use as a PrEP medication that should be taken daily. Over only 12.5% *(n*= 1) of the participants thought that PrEP was 100% effective in reducing HIV, and over half (87.5%) knew that you should continue to use condoms while taking PrEP.

The next set of questions pertained to PrEP adherence. The majority (87.5%) were willing to take PrEP if it was free. Only 37.5% (n = 3) were willing to take PrEP regardless of the cost and of only 50% (n = 4) were willing to take PrEP regardless of the side effects (that could affect the kidneys, liver, and bones, and cause diarrhea, nausea, dizziness, headaches, and cause a rash).

4:5 PrEP Knowledge:

On the first visit only 63% (n =5) of the participants demonstrated PrEP knowledge accuracy by scoring 100% on the 9- item pre-test. The following questions were answered correctly on the pre-test.

1) PrEP is 100% effective in reducing HIV risk- 87.5% (n = 7)

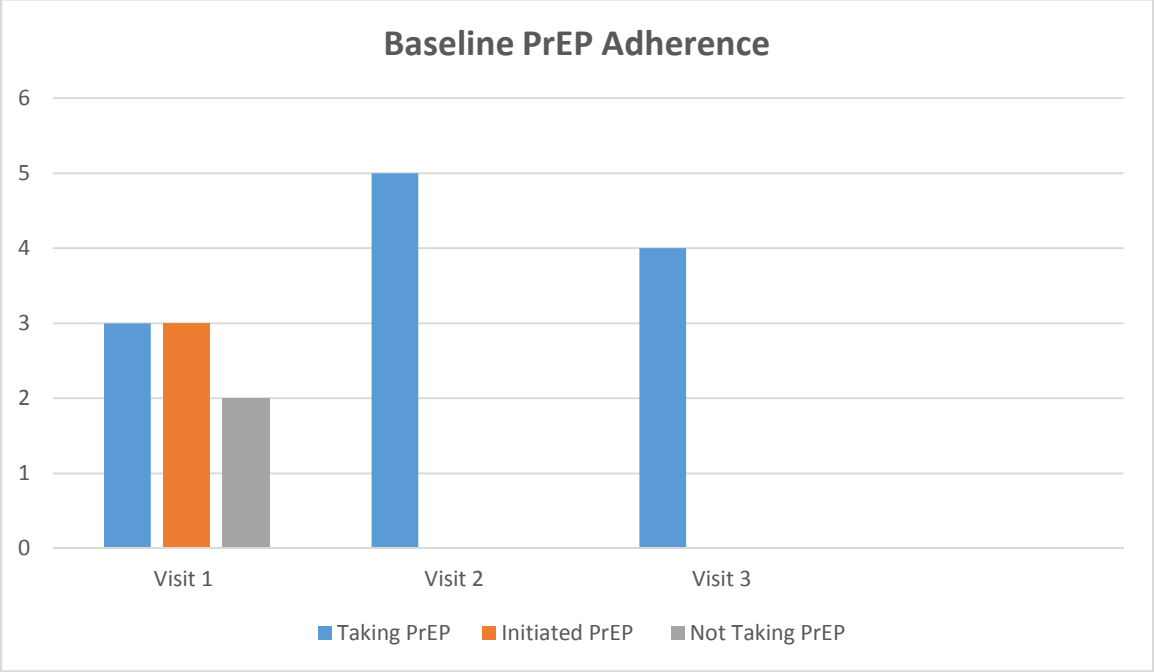
2) If you take PrEP should you stop using condoms when having sex? – 87.5% (n = 7)
3) Is there a vaccine for PrEP to help your body fight off the HIV for several years? - 87.5% (n = 7)
4) How often should you take PrEP? 87.5% (n = 7)

The four participants who completed the PrEP posttest (2 months later) demonstrated 100% accuracy on the PrEP knowledge post-test.

4.6 Baseline Medication Adherence

At the time of enrollment (first visit), those taking PrEP (n = 3), those participants PrEP was initiated for (n = 3), and those who were not taking PrEP n = 2, were examined for medication adherence, at the second visit five participants were taking PrEP and at the third visit four continued taking PrEP (see Table 4.2).

Table 4:2 (N = 8) Baseline PrEP Adherence



All participants were given pill bottles and a medication pill log (n = 8*)* and were asked to bring the pill logs to the second and third visits. Reasons that the participants missed PrEP doses at the first visit included:

1) they ran out of medication (PrEP);

2) they needed an appointment in order to get refills on Truvada;

3) they couldn't get PrEP due to cost; and

4) the Gilead Advancing Assess application had expired.

Participants were given reminder tips for PrEP adherence such as; setting mobile alerts, setting clock alarms, keeping pill bottles visible, developing calendar alerts, and tying PrEP doses to daily activities.

Visit two addressed medication adherence and reasons for missing doses of PrEP. Only five participants returned and only two (40%) brought the pill logs. The DNP student called the pharmacy to verify whether or not prescriptions had been refilled and picked up. Only three of the five participants (60%) were taking PrEP without missing any doses. Reasons that the participants missed PrEP doses at the second visit included:

1) I forgot

2) was working late and fell asleep

3) As long as I take at least 4 pills a week I am alright

Visit three also addressed medication adherence. Only one participant (25%) brought their pill logs for review and recorded missing 5 of the 30 doses. The DNP student called the pharmacy to verify if the prescription had been refilled and picked up. By calling the pharmacy, this confirmed that the participant did pick up the medication or that the participant got the medication mailed to their home. Reasons given for not adhering to PrEP included:

1) forgetting to take PrEP because they fell asleep;

2) working late and could not get home to take the medication; and

3) missing doses of the PrEP because the side effects caused discomfort.

4:7 STI Outcomes:

Baseline treatment for STI outcomes began at visit one. At baseline, two were treated for an STI, one was treated for syphilis and one participant was treated empirically for trichomonas,

(as treatment was required since the participant's partner reported being positive for trichomonas) (see Table 4:3). All (n =8) tested negative for gonorrhea and chlamydia via urine, throat and rectal swabs and syphilis (RPR testing). One of the participants refused a rectal swab since he denied being involved in anal sex (this was the same participant who that was treated empirically for trichomonas). At the second (n=5) and third visits (n=4) all remaining participants tested negative for syphilis (RPR testing), gonorrhea and chlamydia (throat, rectal swabs, and urine specimens). All participants tested HIV negative at visits one, two, and three.

Table 4:3 (*N* = 8) STI Outcomes: Visit One- Baseline

Cases	**Gonorrhea/ Chlamydia** Throat/Rectal swabs Urine	**Syphilis**	**Trichomonas**	**HIV test**	
1	Negative	Negative	(not tested)	Negative	
2	Negative	Negative	(not tested)	Negative	
3	Negative	Negative	(not tested)	Negative	
4	Negative	Negative	(not tested)	Negative	
5	Negative	Negative	(not tested)	Negative	
6	Negative	Negative	(not tested)	Negative	
7	Negative	Positive (RPR titer 1:64)	(not tested)	Negative	
8	Negative (throat and urine, anus not swabbed)	Negative	Treated empirically (partner reported being positive for Trichomonas)	Negative	

RPR- Rapid Plasma Reagin- Blood Test for Syphilis

4.8 High-Risk Sexual Behaviors

At the first visit only 25% (n =2) reported consistent condom use with sex and 63% (n =5) reported having multiple partners. At the second visit 20% (n = 1*)* reported 100% condom use, and 80% (n = 4) reported having multiple partners. At the third visit equally 50% (n = 2) reported condoms use, and 50% (n = 2) reported having multiple partners.

4.9 Participants Who Dropped Out

Those who withdrew from the study were identified as participants that missed the second and/or third visits. The reasons participants gave for not returning to follow-up clinic visits were: 1) I had to work, 2) my schedule was busy, 3) my family member was sick, 4) I forgot about my appointment, and 5) I was out of town. When the scheduler tried to contact them for return visits, some participants did not answer phone calls (n = 2) or had disconnected or inaccurate numbers (n=2).

4.10 Discussion

The primary outcomes of the study were met. The first outcome was to increase participant's knowledge of PrEP, this outcome was met with the remaining study participants. The second outcome, medication adherence was improved. The third outcome, none of the participants tested positive for an STI at visit two or three, when compared to baseline data.

Secondary outcomes included rates of consistent condom use. At visit one only 25% (n =2) reported 100% condom use with sex and (n = 6) reported less than 100% condom use. Some of the participants felt since they were on PrEP they did not have to

use condoms and those who had multiple partners also reported, the majority of their partners were HIV negative. The potential impact of PrEP on sexual risk behaviors was reinforced by counseling the participants on the efficacy of PrEP for HIV prevention, the critical role of adherence to daily PrEP use and consistent condom use along with other protective barriers (dental dams) for high-risk sexual behaviors.

Half of the participants (50%, n = 4) completed the three visits that were recommended for this DNP scholarly project and PrEP was initiated on 38% (n = 3*).* As a result, it is evident that following a brief educational intervention, PrEP knowledge was retained and increased, medication adherence improved and there were no incidences of STIs reported at visits two and three. Eight participants were given pills logs at the first visit and of the 4 that completed the 3 visits only 25% (n = 1*)* returned with completed pill logs at the second and third visits.

This study showed that following a brief educational intervention there was a significant increase in PrEP knowledge with the remaining four participants scoring 100% on the posttest survey. Medication adherence increased when compared to baseline because at enrollment only 38% (n = 3) were taking PrEP, and at the end of the study (third visit) 75% (3/4) reported 100% adherence with PrEP. The risk of acquiring an STI was significantly lower when compared to baseline STI outcomes.

The results of this pilot study illuminate some of the many challenges faced by the DNP student such as high dropout rates, low PrEP uptake, and no staff support with retention and recruitment. Another challenge occurred when participants were provided with more than one prescription refill at the first visit. This empowered the participants to

not return to the second follow-up visit since they had another refill, consequently, the participant may have felt that there was no reason to keep the second visit.

Although, PrEP has demonstrated to be safe and efficacious in clinical trials and emtricitabine/tenofovir was approved by the U.S. FDA for use, PrEP uptake was low. This finding is consistent with the literature, that low PrEP uptake is associated with the high cost, and fears of medication side effects (Liu et al. 2014; Housek, et al. 2017). Data from clinical trials suggest factors influencing PrEP use and adherence such as bidirectional text messages or email support (Lie et al, 2014; Fuches et al., 2018) and supportive counseling (Mayer et al., 2017) are warranted. Some facilitators of PrEP medication adherence were associated with the age of the participant (younger versus older). In this study the sample was too small to examine trends with medication adherence based on the age of the participant.

With the results of this study, I feel that it is still feasible to incorporate a PrEP protocol into clinic settings. This study was a beginning step and it is significant that healthcare professionals continue to work to reduce the rates of HIV infection. If I can continue to link HIV negative MSM to care, screen them for PrEP, initiate PrEP usage, and monitor PrEP usage, no matter if it's one patient a week or one patient a month, it will be well justified. Despite all the difficulties I faced during this project, saving one person from this incurable disease *is the* main goal that I want to accomplish! The key steps for PrEP implementation should include increasing PrEP knowledge, expanding PrEP access, combating PrEP stigma, and developing innovation strategies to promote

PrEP uptake and adherence while reinforcing the reduction strategies in preventing HIV acquisition (Liu et al., 2014).

This DNP scholarly project has been dear to my heart; it has allowed me to be the first Advance Practice Provider (APP) to pilot a PrEP protocol at WFBH. I am honored to be a part of this process. Since the completion of this this DNP scholarly project I have been allowed to initiate as well as monitor PrEP as an APP. This is very significant accomplishment; ordinarily it is the IDSC attending physicians who initiate and monitor PrEP. On a personal level, this DNP scholarly project has improved my awareness of the challenges of PrEP treatment.

CHAPTER 5: IMPLICATIONS

The purpose of the study was to examine the effect of initiating a pilot PrEP protocol with a brief educational intervention and two follow up visits, on medication knowledge and adherence, and STI outcomes after two follow up visit when compared to baseline. Though results of data suggest there was improvement in PrEP knowledge, medication adherence, and no new STIs post an educational intervention, the findings cannot be generalized beyond the small sample size. For successful implementation of PrEP, it is important to understand that an individual's PrEP knowledge and motivation to stay healthy are important to consider when measuring the success of any project.

Studies have shown that with the implementation of PrEP there were perceived potential decreases in condom use, high incidences of STI's, and increased financial burdens associated with medication costs (Bil et al. 2018). In recent years, the high cost of the medication has placed a financial burden on patients. In the past seven years the price of Truvada has increased by about 45 percent. Now, the drug, which rakes in billions of dollars in annual global revenue for its manufacturer, Gilead Sciences, carries a list price of close to $2,000 for a 30-day supply (Luthra & Gorman, 2018). Public health officials are expanding efforts to get PrEP into the treatment of those most at risk.

5:1 Implication of Challenges and Limitations

One of the challenges of this pilot study was the lengthy institutional review board process. The review process was longer than anticipated since additional patient protections had to be considered. The other challenge was that the timing of study initiation was at the end of an academic semester with pending holidays. Limitations of the study were that this was a pilot study with a small sample; hence we can only provide trends with the data. The study was also limited to HIV negative MSM in a serodiscordant relationship, therefore the results may be different if the participants were in heterosexual serodiscordant relationships.

5:2 Summary

Despite the small sample size, there were trends in that data that the integration of a PrEP protocol with an educational intervention was associated with improvement in PrEP knowledge and medication adherence. Out of the four participants that completed all three visits, only one reported missed doses of PrEP. Additionally, there were no new STI outcomes, from January 7 until March 7, 2019. We expected this project would demonstrate the importance of a PrEP protocol in the setting of an infectious disease clinic at Wake Forest Baptist Health. The findings suggest that knowledge of PrEP is considered essential to ensure effective PrEP implementation. The development of a PrEP protocol and educational intervention about PrEP is warranted, as it enables informed choices among potential users and thus improve the chances of successful

implementation of PrEP interventions. Participants in this study were willing to use PrEP. Guidelines from the CDC (2017) suggest that daily PrEP use reduces the risk of getting HIV by sexual contact by 92%. The effective use of PrEP can reduce the fiscal impact of HIV.

Initiating PrEP, monitoring STI outcomes, and encouraging HIV testing should be treatment guidelines of all sexually active or drug using individuals. Despite the high cost of treatment, Gilead Sciences has agreed to donate free pre-exposure prophylaxis, or PrEP, for HIV prevention for up to 200,000 individuals each year for up to 11 years (Stuplin, 2019). The agreement between the Department of Health and Human Services and Gilead will last through Dec. 31, 2025, and possibly through Dec. 31, 2030.This agreement will guarantee that uninsured individuals who are at risk for HIV may reduce medication at no cost. Individuals interested in receiving no-cost PrEP should go to a Federally Qualified Health Center with their basic information, including their name, date of birth and the last four digits of their Social Security numbers. Truvada, which costs approximately $20,000 per patient per year, will be continuously donated until Gilead's second-generation HIV preventive medication, Descovy (FTC/tenofovir alafenamide), becomes available (Stuplin, 2019).

For the past two decades, research has been ongoing to identify new biomedical strategies to prevent HIV infection. We now have a pill that will prevent HIV transmission, a medical breakthrough only envisioned about just a decade ago. It's

inexcusable that so few individuals know that it exists. This pilot study demonstrated that MSM can increase PrEP knowledge, adhere to PrEP medication and reduce the number of STIs while taking PrEP. Continuous education and the integration of PrEP may reduce the reduce the risk of HIV acquisition in MSM and other high-risk individuals. Understanding PrEP knowledge and having the willingness to use PrEP is a significant step in eradicating HIV infection in the US and in the world.

5:3 Recommendations

There are three recommendations for initiating PrEP in this infectious disease clinic setting. First, additional staff is needed to assist with the retention process. This could be addressed with the hiring of additional staff such as, patient navigators. Patient navigators have been successful in recruiting and retaining patients in cancer care and in eliminating health disparities (Natale-Pereira, Enard, Nevarez & Jones, 2011). The use of patient navigators can increase equity and equal access to care for high risk individuals. Second, future studies should include heterosexual serodiscordant couples, which are virtually absent in the literature and the use of technology for medication reminders. Third, comprehensive STD screening and high impact HIV prevention efforts should be operationalized in sexual health clinics and infectious disease clinics.

In summary, the findings from this pilot PrEP study identified challenges and limitations with the process of initiating PrEP with a sample of HIV negative MSM in a serodiscordant relationship. Recommendations for improvement of care within one infections disease clinic in North Carolina are provided. The success of any project can be measured by dedicated staff and individuals motivated to stay healthy.

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APPENDIX A
IRB Approval letter

MEMORANUM

To: Cynthia Dalton
Int Med-Infectious Disease

From: Sally Bulla, Chair, IRB # 1
Institutional Review Board

Date: 11/8/2018

Subject: Human Protocol: IRB00052082
Integration of a PrEP Protocol

Study Documents:
Protocol Version: Clean Version Integration of PrEP Protocol Dalton Revisions 11-6-18.docx; Informed Consent Version: Clean Version Consent Form for Integration of PrEP IRB_Cynthia Dalton Revisions 11-6-18.docx; Other Documents: BYOP Pre-Post test questions.docx, PrEP survey REVISED.docx, Screening Tool BYOP PrEP Protocol.docx

The Institutional Review Board (IRB) has approved the above-named protocol and study documents, after review at a convened meeting on 11/5/2018. A submission requesting renewal together with a summary progress report must be submitted to the Board at least one month prior to 11/4/2019.

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA autorization will be sought. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

This application indicates that advertising materials will be used for research purposes. Please consult with Creative Communications to ensure the appropriate visual identity is put forth.

Federal regulations and Board policy require that you promptly report to the Board for review/approval:

· Proposed changes in the research activity (e.g., protocol amendments; consent form revision; advertisements). Changes may not be initiated without IRB review and approval, unless necessary to eliminate an immediate hazard to subjects.

· Serious adverse events and unanticipated problems involving risks must be reported to the Board, institutional officials, FDA, sponsor and other regulatory agencies as required by the protocol, local policy and state or federal regulation.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.

APPENDIX B
PrEP Protocol

Integration of Pre-Exposure Prophylaxis (PrEP) Protocol

Principal Investigator
Principal Investigator
Cynthia Dalton, FNP .
Section on Infectious Diseases
Wake Forest University School of Medicine
Medical Center Blvd.
Winston-Salem, NC 27157
Tel: 336-716-2700 Fax: 336- 716-3825 Page: 336-806-9791
cdalton@wakehealth.edu

Faculty mentor/other investigator,
Candice J. McNeil MD MPH
Section on Infectious Diseases
Wake Forest University School of Medicine
Medical Center Blvd.
Winston-Salem, NC 27157
Tel: 336-716-2700 Fax: 336- 716-4556
cmcneil@wakehealth.edu

Sponsor or funding source: None

Background, Rationale and Context

Men who have sex with men (MSM) are disproportionally affected by Human Immunodeficiency Virus (HIV) and other sexually transmitted infections (STIs). MSM account for two-thirds of new HIV infections in the United States (U.S.) and are the only risk group in whom infection rates are rising (Liu et al., 2016). Being diagnosed as having an STI is among the most consistent and longstanding risk factors associated with HIV acquisition. As HIV prevalence climbs globally, including more than 50,000 new infections per year in the United States (U.S.), we need more effective HIV preventions strategies; the use of antiretroviral (ARV) for preexposure prophylaxis (PrEP) among high-risk persons without HIV is emerging as one such strategy (www.cdc.org) The advent of (PrEP) has created a new impetus for identifying the populations of MSM at greatest risk of HIV infections.

On July 16, 2012, the United States Food and Drug Administration (FDA) approved emtricitabine (FTC) 200 mg and tenofovir disproxil fumarate (TDF) 300 mg as Truvada in combination with condom use and other safer sex practices to reduce the risk of sexually acquired HIV infection. The CDC has provided guidelines that reflect input from providers, HIV patients, partners, and affected communities for the use of PrEP. These guidelines recommend that PrEP be considered for people who are HIV negative and are at high risk of HIV infection. This includes those, in an ongoing relationship with an HIV positive partner, not in a mutually monogamous relationship with a partner who recently tests HIV negative, being an MSM who has had anal sex without condoms, or an MSM who has been diagnosed with an STI in the past six months.

Truvada has been shown to be safe and effective in reducing the risk of sexual HIV acquisition (CDC, 2017). In multiple studies, a significant amount of peer-reviewed, placebo-controlled, randomized trials (RCTs) demonstrate the effectiveness of PrEP in preventing at-risk patients from acquiring HIV. Evidence from the World Health Organization (WHO) (2012) and CDC (2014) suggest a strong impact in protection rates against HIV when using PrEP. A literature review was completed to study the methodology of PrEP trial and success rates, which summarized the evidence supporting PrEP. The literature was retrieved from searching the following keywords on CINAHL database: *PreP, pre-exposure prophylaxis, HIV prevention.*

Objectives

The intent of this study is to monitor and evaluate the effectiveness of PrEP in HIV negative men who have sex with men in an outpatient setting at Wake Forest Infectious Diseases clinic. The objectives are to define PrEP, know the current CDC recommendations for PrEP, identify candidates for PrEP, linkage to care, and resources for providing PrEP to our participants.

This study will assess knowledge of PrEP in qualifying HIV serodiscordant men who have sex with men (MSM) couples, assess adherence, assess knowledge retention, and sexually transmitted infection (STI) transmission during PrEP in the setting of Ryan White HIV clinic.

Specific Aim 1:

- Review the CDC guidelines for eligibility for PrEP
- Documented negative HIV test results
- No signs or symptoms of acute HIV infection
- Normal renal function
- No use of contraindicated medication
- Documented Hepatitis B Virus (HBV) infection status and vaccination status

This data will allow the study to determine the number of participant enrolled in the study, number of participants who completed the three month visits. Will assess attrition rates, for example, number of participants who fell out of care within the three months and the reason they fell out of care.

After participates have participated in initial new patient consultation and have kept the twofollow up visits, will gather data and conduct data analysis and findings to determine how many participates was on PrEP, how many participates stopped PrEP, how many became HIV positive when taking PrEP, how many STI's, posttest to assess knowledge retention on PrEP.

Methods and Measures

Design

The descriptive study will consist of approximately ten to twenty HIV negative MSM who consent to enrollment and PrEP initiatio
Demographic Data

- Age
- Gender
- Race/Ethnicity
- Zip code
- Employment status
- Relationship status
- Medical condition
- Sexual practices
- Substance abuse

Analysis of this data descriptive characteristics of those consenting to be in the study will be calculated with median, mean, and standard deviation, and percentages. Comparison between those who agree to enroll in the study and those who do not agree will be compared. Knowledge retention will be measured by comparing the absolute number of questions correct on the original test as compared to the follow-up test.

New approaches to HIV prevention are urgently needed to reduce the increasing number of HIV infections identified annually in the United States, especially among men who report having sex with men. The intent of this study is the continued improvement in the HIV infection yearly by reducing the rate of HIV in men who have sex with men with Truvada known as PrEP. We expect this project will demonstrate the importance of PrEP in this high risk population.

Setting

Wake Forest Baptist Medical Center
Infectious Diseases Specialty Clinic (IDSC) Outpatient Clinic

Subjects selection criteria

Inclusion Criteria

- Age 18 and older

- HIV negative MSM who are in a relationship with a HIV positive partner(s) at Wake Forest Baptist Health (WFBH).
- Referrals from the in-patient providers from WFBH and surrounding health departments, who identify MSM's at high risk for contracting HIV infection will be recruited.
- Able and willing to independently consent

Exclusion Criteria

- Those under the age of 18, those who are unable to give consent, those who are HIV positive, those who are hepatitis B or Hepatitis C positive

Sample Size

Up to 20 participants

Research Interventions and Interactions

- Review PrEP criteria/screening tool
- Assess readiness to take PrEP: Pre test
- Linkage to care: PrEP visit adherence based on WakeOne appointment attendance
- Monitor Treatment: Review available HIV testing, complete metabolic panel (CMP), STI testing at all visits
- Medication Adherence: Pill log
- Knowledge of PrEP/knowledge retention: Post test

Table of Events

Study Procedures	Enrollment	Visit 1 (4 weeks)	Visit 2 (3 months)
Review PrEP criteria/screening tool	X		
Assess readiness to take PrEP: Pre-test (Survey)	X		
Linkage to care: PrEP visit adherence based on WakeOne appointment attendance	X	X	X
Monitor Treatment: Review available HIV testing, complete metabolic panel (CMP), STI testing at all visits	X	X	X
Medication Adherence: Pill log		X	X
Knowledge of PrEP/knowledge retention: post-test		X	X

Outcome Measure(s)

- Number of participants on PrEP
- Number who stayed on PrEP throughout the study
- How many participants stopped taking PrEP
- How many participants became HIV positive while taking PrEP
- How many STI's during this study
- Knowledge retention to assess how well the participant retained the education given to them while on PrEP

Analytical Plan

Results will be analyzed initially using descriptive statistics.

Human Subjects Protection

Subject Recruitment Methods

Referral to our IDSC is screened by a single attending physician and scheduler. All referrals for PrEP will be directed to the principal investigator. Other clinic providers will be encouraged to ask any of their patients with HIV negative partners if they would be interested in an appointment with their partners to discuss PrEP. This will be referred to as 'bring your own partner' (BYOB method). Will also make announcement at the post-research conference.

Informed Consent

Written informed consent **will be** obtained. The risk of harm or discomfort that may occur as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. The rights and welfare of study will be protected through the use of measures to maintain the confidentiality of study information. Study results will be presented or published in lieu of providing individual subjects additional information regarding the study.

Confidentiality and Privacy

Any Protected Health Information collected from you in this study that is maintained in the
research records will be kept for at least six years after the study is finished. At that time any
research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center, you will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

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APPENDIX C

Consent Form

Wake Forest School of Medicine

Department/Section of Internal Medicine/Section of Infectious

Integration of Preexposure Prophylaxis (PrEP) Protocol
Informed Consent Form to Participate in Research
Cynthia Dalton, MSN, FNP, MSN –BC Principal Investigator

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study provider or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

You are being asked to take part in this study because you are a male over 18 and you are HIV negative. We are trying to determine if the use of Pre-Exposure Prophylaxis (PrEP) will reduce the transmission of HIV by assessing and monitoring those who are on PrEP. . With this study we will monitor participants who have been taking Truvada for at least one month. On July 16, 2012, the United States Food and Drug Administration (FDA) approved emtricitabine (FTC) 200 mg and tenofovir disproxil fumarate (TDF) 300 mg as Truvada a one pill regimen in combination with condom use and other safer sex practices to reduce the risk of sexually acquired HIV infection. The CDC has provided guidelines that reflect input from providers, HIV patients, partners, and affected communities for the use of PrEP. These guidelines recommend that PrEP be considered for people who are HIV negative and are at high risk of HIV infection. This includes those, in an ongoing relationship with an HIV positive partner, not in a mutually monogamous relationship with a partner who recently tests HIV negative, being an MSM who has had anal sex without condoms, or an MSM who has been diagnosed with an STI in the past six months.

How Many People Will Take Part in the Study?

Twenty people at this research site will take part in this study. In order to identify the **(20)** subjects needed, we may need to screen as many as **(30)** because some people will not qualify to be included in the study.

What Is Involved in the Study?

At your first visit you will complete a survey on a tablet device with basic information about (i.e. age, race/ethnicity, zip code, employment status, relationship status, medical condition). Part of this survey will also ask you about the status of your relationship, detailed questions on your sexual practices, and habits including substance use. We know that some of these questions may be very personal in nature. We would encourage you to be open and honest in your responses. Please be assured that your information will remain confidential and will not become a part of your medical record. You will then complete a survey on your knowledge of PrEP. At follow up visits you will be given post testing and education on PrEP with one on one counseling. The post test will be the same as the pretest to assess knowledge retention. We will also monitor your visit attendance and PrEP labs performed by your provider.

If you consent to take part in this study:

- Identification and Demographic Information
- Review criteria for PrEP
- PrEP Knowledge Pre test
- PrEP Knowledge Post test

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 3 – 4 months

- There will be a total of 3 visit.

- This study will take place in an outpatient setting, referrals will be made the study provider. Participants who are taking Truvada (Emtricitabine /tenofovir disproxil fumarate) in combination with condom use and other safe sex practices, to reduce the risk of sexually acquired HIV infection will be monitored.

At your first visit/enrollment (40-60 minutes):

- You will be asked to sign a written consent agreeing to participant in the study before moving forward
- The criteria for PrEP will be reviewed
- Pre-test will be given to assess knowledge of PrEP
- Reponses will be reviewed and you will be educated about PrEP and safe sex practices
- Will review labs
- Visit 2 will be scheduled

At your second visit/ 4 weeks (40-60 minutes):

- Will assess adherence in taking PrEP by self-reporting, picked up prescription from the pharmacy, and reviewing medication log sheet
- Labs will be reviewed
- Condoms will be given to you
- Refresher test to assess knowledge retention
- Visit 3 will be scheduled

At your third visit (40-60 minutes):

- Will assess adherence in taking PrEP by self-reporting, picked up prescription from pharmacy, and reviewing medication log sheet
- Labs will be reviewed
- Safe sex education will be reinforced
- Condoms will be given
- Post-test given to assess knowledge retention
- Review plans for PrEP continuance and provider follow up

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

____YES you many contact me for future research studies
____NO I do not want to be contacted regarding future research studies

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examination or test. You should discuss the risk of being in this study with the study staff.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

You may or may not receive any direct benefit from taking part in this research study; however, we hope the information from this study will benefit other people in the future.

What Other Choices Are There?

This is not a treatment study. Participation in this study will not impact the medical care that you receive. Your alternative is to not participate in this study.

What About My Health Information?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The Information we will collect for the research study includes:

The date of your last physical exam

General classes of medical problems you had in the past

Sexually Transmitted Infection history

Hepatitis B and Hepatitis C history

HIV-uninfected by 4th generation antigen/antibody combination testing
No clinical signs or symptoms of acute HIV infection within past 30 days
Comprehensive Metabolic Panel (CMP) to obtain estimated creatinine clearance

If this research study involves the diagnosis or treatment of a medical condition, then Protected
Health Information collected from you during this study will be placed in your medical record,
and may be used to help treat you, arrange payment for your care, or assist with Medical Center
operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information")
may be given to others during and after the study. This is for reasons such as to carry out the
study, to determine the results of the study, to make sure the study is being done correctly, to
provide required reports and to get approval for new products

Some of the people, agencies and businesses that may receive and use your health information
are the research sponsor; representatives of the sponsor assisting with the research; investigators

at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any

research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center, you will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Cynthia D. Dalton that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Cynthia Denise Dalton
Wake Forest Baptist Hospital
Medical Center Blvd.
Winston-Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

What Are the Costs?

Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card as compensation for taking part in this study at the first visit and the third visit for a total $50. Should you withdraw from the study early, you will be paid for all completed study visits.

WHO IS SPONSORING THIS STUDY?

This study is not being sponsored by an organization or company.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop

your participation in the study at any time. This could be because you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Cynthia Dalton at (336716 2700).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

You will be given a copy of this signed consent form.

Signatures

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm
Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____
Time:_____ am pm

APPENDIX D

SCREENING TOOL

New Patient Visit
Evaluation of Candidacy for HIV Pre-Exposure Prophylaxis (PrEP)

Referred by:

Assessment/Plan

Patient's name: *** was evaluated in the ***ID Clinic today for possible initiation of pre-exposure prophylaxis (PrEP) for the prevention of HIV infection. Based on the history, physical exam, and assessment documented below, I believe he {is/is not:23060} an appropriate candidate for PrEP with emtricitabine/tenofovir.

__has been sexually active with {Blank single::"women","both men and women","men"} in the past 6 months
__He is not in a monogamous sexual relationship with a recently tested, HIV-uninfected partner
__He has had condomless "insertive anal","receptive anal"} sex in the past 6 months
__He has had an STI diagnosed or reported in the past 6 months
__He is in an ongoing sexual relationship with an HIV-infected partner(s)
__He injects drugs and shares needles or "works" (paraphernalia)
__He is employed as a commercial sex worker

At today's visit, I provided:
__Counseling on the efficacy of PrEP for HIV prevention
__Counseling on the **critical role of** adherence to **daily use** to provide maximal protection, along with strategies to maintain adherence
__Medication facts about emtricitabine/tenofovir, including common side effects and the potential for reversible nephrotoxicity and bone mineral density loss
__Counseling on proper condom use and other risk-appropriate HIV and STI prevention strategies
__Written instructions on how to apply for pharmaceutical company-sponsored assistance and/or access programs
__Written instructions on how to apply for financial and pharmacy assistance programs
__Printed copy of "Truvada® for Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program" application form, with provider information filled in by the social worker and patient navigator
__A Gilead copayment assistance card, with instructions for use
__Condoms given on the day of the visit

__Information about PrEP use during conception and pregnancy was not discussed

To safely initiate emtricitabine/tenofovir as PrEP, he must still meet the following laboratory-based criteria:
1. □ HIV-uninfected by 4th generation antigen/antibody combination testing
2. □ No clinical signs or symptoms of acute HIV infection within past 30 days
3. □ Estimated creatinine clearance >= 60 mL/min (by Cockcroft-Gault)
4. □ Negative hepatitis B surface antigen (HBsAg)

Plan

1. We obtained the following labs today as part of baseline assessment: {Blank multiple:19196::"HIV Ag/Ab combination test (4th generation)","HIV RNA","serum creatinine","urinalysis","hepatic function tests","RPR","GC/CT NAATs from exposed anatomical sites","Trichomonas NAAT","pregnancy testing","HAV IgG","HBsAb","HBsAg","HCV antibody","HCV RNA"}.

2. I will contact the patient with the results of these studies and to discuss arrangements for any STI treatment(s) that might be needed (as appropriate).

3. If labs come back and he meets all criteria, then a prescription for emtricitabine/tenofovir (Truvada) 200/300 mg, one pill once daily, #30, zero refills, will be sent to {Blank single:19197::"the patient","the patient's pharmacy"}.

4. Return to clinic in 4 weeks.

I spent {Blank single:19197::"15 minutes","20 minutes","25 minutes", 40 minutes "more than 50%"} of today's visit counseling the patient.

APPENDIX E

SURVEY

INSTRUCTIONS

We are conducting a study on Pre-Exposure Prophylaxis (PrEP) in men who have sex with men. In this survey, we are assessing the knowledge, attitudes, behaviors, and adherence to PrEP. Your participation in this survey is completely voluntary and will not affect the care that you will receive. The questions in this survey include your sexual and STI (sexually transmitted infection) history. This information will remain confidential and is not a part of your medical record. However, to accurately evaluate your responses, we ask that you please answer this survey in its entirety and as honestly as you feel comfortable.
Please answer all questions and upon completion click the "submit" button located at the bottom of the survey. Please let our staff know if you have any questions.
Thank you for your time and participation.

DEMOGRAPHICS/EXPOSURES

What year were you born? _____

Gender at birth: _____

Gender at completion of survey: _____
What is your race/ethnicity?
____ White/non-Hispanic
____ White/Hispanic
____ Black/African American
____ American Indian
____ Other

What is your level of education?

____ Less than a high school diploma
____ High school diploma or GED
___ More than high school
___ College graduate
___ Graduate studies or higher

EXPOSURES

Please answer the following questions about your sexual partners within the past 6 months:

Total number of partners:
Total number of encounters as receptive ("bottom") partner during anal intercourse:
Total number of encounters as insertive ("top") partner during anal intercourse:
Percentage (%) of times you and your partner used a condom

KNOWLEDGE AND ATTITUDES TOWARDS PrEP

The following questionnaire will ask you about your feelings on the medications known as
PrEP

1. Before today, have you ever heard about PrEP?

   ___Yes
   ___No

2. Have you ever taken PrEP medication to prevent HIV infection after a high risk sexual exposure - before?
   ___Yes
   ___No

3. What medications are used in PrEP?
   ___ Atripla (efavirenz/Tenofovir/FTC
   ___ Complera (rilivirine/Tenofovir/FTC)
   ___ Truvada (Tenofovir/FTC) or Viread (Tenofovir)
   ___ Combivir (AZT/3TC)
   ___ Maraviroc (Selzentry)

4. Is there a vaccine for PrEP to help your body fight off the HIV infections for several years?
   ___ Yes
   ___ No

5. True or False: PrEP can be prescribed to HIV positive people.

___ True
___ False

6. How often should PrEP be taken (as recommended by CDC)?
___ Every day
___ only before sex
___ Weekly
___ Before and after sex
___ Once a month

7. True or False: PrEP is 100% effective in reducing HIV risk
___ True
___ False

8. What else should be used with PrEP to prevent HIV transmission? (check all that apply)
___ HIV testing
___ Lube
___ Juice
___ Candles for a romantic night
___ Condoms
___ Regular provider's appointments

9. If you take PrEP should you stop using condoms when having sex?
___ Yes
___ No

10. If you are HIV negative, how likely are you to take PrEP in the future?
___ unlikely
___ Somewhat likely
___ Likely
___ Very likely

11. If you decided to take PrEP how long will you need to take PrEP (check all that apply).
___ Once every week
___ Daily
___ If your risk of getting HIV becomes low because of changes in your life
___ If you have side effects from Truvada that are interfering with your life
___ If you become HIV positive

12. The CDC guidelines states that PrEP may be appropriate for HIV-negative adult men who have sex with men who are at "substantial, ongoing high risk for acquiring HIV," or HIV-negative heterosexuals with very high risk (e.g., a partner

who is HIV positive), or people who inject drugs. Do you fit into any of these categories?

___ Yes
___ No
___ Unsure
___ Decline to state

13. How likely would you be to take PrEP if it was provided to you free of charge?

___Definitely
___Very Likely
___Somewhat Likely
___Not Very Likely
___Definitely Not

14. How likely would you be to take PrEP if it cost you money out-of-pocket each month
(estimate $500/month)?

___Definitely
___Very Likely
___Somewhat Likely
___Not Very Likely
___Definitely Not

15. How likely would you be to take PrEP if it had side effects affecting your kidneys liver, and bones, and including diarrhea, nausea, dizziness, headaches, and rash?

___Definitely
___Very Likely
___Somewhat Likely
___Not Very Likely
___Definitely Not

16. How likely would you be to take PrEP if it had to be taken every day, missing as few
pills as possible?

___Definitely
___Very Likely
___Somewhat Likely
___Not Very Likely
___Definitely Not

APPENDIX F
PrEP 101

Are you HIV-negative but at very high risk for HIV? Taken every day, PrEP can help keep you free from HIV.

What Is PrEP?

- PrEP, or pre-exposure prophylaxis, is daily medicine that can reduce your chance of getting HIV.
- PrEP can stop HIV from taking hold and spreading throughout your body.
- Daily PrEP reduces the risk of getting HIV from sex by more than 90%. Among people who inject drugs, it reduces the risk by more than 70%.
- Your risk of getting HIV from sex can be even lower if you combine PrEP with condoms and other prevention methods.

Is PrEP Right For You?

PrEP may benefit you if you are HIV-negative and **ANY** of the following apply to you.

You are a gay/bisexual man and

•have an HIV-positive partner.
•have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown–and you also
have anal sex without a condom, or
recently had a sexually transmitted disease (STD).

You are a heterosexual and

•have an HIV-positive partner.
•have multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown–and you also
don't always use a condom for sex with people who inject drugs, or
don't always use a condom for sex with bisexual men.

You inject drugs and

share needles or equipment to inject drugs.
recently went to a drug treatment program.
are at risk for getting HIV from sex.

Visit Your Healthcare Provider

To find out if PrEP is right for you.

Every 3 months, if you take PrEP, for repeat HIV tests, prescription refills, and follow-up.

If you don’t have a provider, visithttps://preplocator.org to locate one.

How Can You Get Help To Pay For PrEP?

Most private and state Medicaid plans cover PrEP. If you are on Medicaid, check with your benefits counselor.

If you have health insurance, you may receive co-pay assistance from drug manufacturers or patient advocacy foundations.

If you are without medical insurance, consider enrolling in an insurance marketplace, manufacturer patient assistance program, or your state’s Medicaid plan, if you are eligible for it.

Learn more about paying for PrEP at www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-paying-for-prep.pdf.

For more information please visit www.cdc.gov/hiv National Center for HIV/AIDS, Viral Hepatitis, STD, and TB PreventionDivision of HIV/AIDS Prevention

APPENDIX G

PRE/POSTEST

1. Before today, have you ever heard about PrEP?

___Yes
___No

2. Have you ever taken PrEP medication to prevent HIV infection after a high risk sexual exposure - before?

___Yes
___No

3. What medications are used in PrEP?

___ Atripla (efavirenz/Tenofovir/FTC
___ Complera (rilivirine/Tenofovir/FTC)
___ Truvada (Tenofovir/FTC) or Viread (Tenofovir)
___ Combivir (AZT/3TC)
___ Maraviroc (Selzentry)

4. Is there a vaccine for PrEP to help your body fight off the HIV infections for several years?

___ Yes
___ No

5. True or False: PrEP can be prescribed to HIV positive people.

___ True
___ False

6. How often should PrEP be taken (as recommended by CDC)?

___ Every day
___ only before sex
___ Weekly
___ Before and after sex
___ Once a month

7. True or False: PrEP is 100% effective in reducing HIV risk

___ True
___ False

8. What else should be used with PrEP to prevent HIV transmission? (check all that apply)

___ HIV testing
___ Lube
___ Juice
___ Candles for a romantic night
___ Condoms
___ Regular provider's appointments

9. If you take PrEP should you stop using condoms when having sex?

___ Yes
___ No

APPENDIX H

MEDICATION PILL LOG

Wake Forest University Physicians

MEDICATION DAILY SCHEDULE

Name:

DATE	Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Notes
 **Truvada (emtricitabine/ tenofovir)**								
Week 1								
Week 2								
Week 3								
Week 4								
Week 5								