EFFECT OF PRE-EXPOSURE PROPHLAXIS (PrEP) EDUCATION ON SEXUAL BEHAVIORS OF GAY AND BISEXUAL MEN

A Scholarly Project
submitted to the Faculty of the
Graduate School of Arts and Sciences
of Georgetown University
in partial fulfillment of the requirements for the
degree of
Doctor of Nursing Practice

By

Randulf Villanueva Erguiza, M.S.

Washington, DC
November 17, 2017
EFFECT OF PRE-EXPOSITION PROPHYLAXIS (PrEP) EDUCATION ON SEXUAL BEHAVIORS OF GAY AND BISEXUAL MEN

Randulf Villanueva Erguiza, M.S.

Thesis Advisor: Irene Jillson, Ph.D.

ABSTRACT

Pre-exposure prophylaxis (PrEP) is a drug that prevents the transmission of human-immunodeficiency virus (HIV), but not the transmission of other sexually-transmitted infections (STIs). Studies of PrEP use to prevent the transmission of HIV among gay and bisexual men (GBM) have demonstrated high risks for engagement in risk-compensating sexual behaviors, which increase their susceptibility to STIs. This study’s aims were to elicit understanding of the effect of PrEP education on sexual behaviors and STI rates of GBM, and to inform the development of evidence-based PrEP education. The quasi-experimental intervention study was based on Pender’s Health Promotion Model (HPM) as the theoretical framework and comprised two phases: a pre-post intervention assessment and a three-month follow-up. The knowledge, attitudes, and practices (KAP) of a purposive sample of GBM were measured in both phases, through in-person semi-structured interviews, an STI-PrEP Knowledge Questionnaire™, Sexual Risk Cognition Questionnaire (SRCQ), and self-reported STI status. The intervention comprised two brief Centers for Disease Control and Prevention (CDC) educational videos. Quantitative analyses included descriptive statistics and non-parametric tests. Analysis of open-ended questions was based on the hierarchical, editing style to generate categories and themes. Eight GBM participated in the first phase and four of them (50%) in the second, follow-up phase. Comparing the STI-PrEP questionnaire scores, there was a significant difference in scores between pre-intervention (Median = 13.50) and both post-intervention (Median = 15.00) and
three-month follow-up (Median = 14.75), \( p = .023 \), demonstrating that the improvement in STI-PrEP questionnaire scores was maintained at follow-up. The SRCQ yielded no significant change in sexual cognition between pre-intervention and follow-up, \( p = .461 \). There was a 25% decrease in the self-reported STI rate from baseline at pre-intervention to follow-up. Thematic analysis of the qualitative responses showed that PrEP use motivators include sexual pleasure, condom-less sex, and PrEP’s efficacy; PrEP education effects include improved informed decision-making and PrEP compliance. PrEP education improved knowledge, reduced STI rates, and had an effect on sexual intentions. Strengthened PrEP education in healthcare may improve sexual behaviors and STI rates utilizing the HPM and a multidisciplinary approach in implementing multimodal strategies in addressing sexual behaviors.

*Keywords:* bisexual, gay, gay and bisexual men, health education, MSM, PrEP, risk compensation, sex education, sexual behavior, STI
I dedicate the success of this study to the following individuals and groups:

The Lord, Almighty;

my family;

the LGBTQ community;

my former professors (MS and DNP) at Georgetown University;

Twelve12Pack;

fellow NPs and all health care providers;

Dr. John Rosselli (in memoriam);

and ethnic and racial minorities who experience health disparities.

Many thanks,

RANDULF ERGUIZA
ACKNOWLEDGEMENTS

The success I have reaped in completing the Doctor of Nursing Practice (DNP) degree at Georgetown University could not be realized without the leadership of Dr. Margaret Slota. As Director for the DNP program, Dr. Slota was instrumental in leading a ship in the right direction. More importantly, Dr. Slota’s tireless dedication to improving the program through active listening and flexibility deserves commendation.

My pursuit for advocating the group to which I belong – the LGBTQ community through a study about PrEP and GBM, could not have been possible without the guidance and tutelage of Dr. Irene Jillson. Right from the onset, Dr. Jillson made me realize of my worth in the community and how my study may create a difference to the health care community and to society. Dr. Jillson is the light which shone bright when I felt overwhelming struggles throughout my study. Dr. Jillson is the mentor any student would love to have.

The study could have not been improved without the inputs and wisdom imparted by Dr. Christopher King and Dr. Melody Wilkinson. I will be forever grateful for your dedication to my journey to learning and applying knowledge gained to the study of PrEP. Moreover, I would like to express gratitude to Dr. John Rosselli, Dr. Mallinson, Mr. Blake Johnson, Mr. Dalmacio Flores, and Mr. Stephen Perez for sharing their expertise in reviewing the STI-PrEP Knowledge questionnaire. To my family who is always a source of inspiration and motivation to make myself a better person, thank you so much.
# TABLE OF CONTENTS

Chapter I - Introduction ..................................................................................................................1  
Statement of Problem ..................................................................................................................3  
Significance of Problem ..............................................................................................................4  
Organizational Needs Assessment ...............................................................................................8  
Research Question ......................................................................................................................11  
Theoretical Framework ................................................................................................................11  
Iowa Model of Evidence-Based Practice .......................................................................................14  
Definition of Terms ......................................................................................................................15  

Chapter II - Review of Literature ...............................................................................................18  
Introduction to Search Criteria ....................................................................................................18  
Critique and Synthesis of Previous Evidence .............................................................................20  
Rationale for this Study ................................................................................................................36  
Research Study Aims ..................................................................................................................36  

Chapter III – Methods ................................................................................................................39  
Design and Implementation Framework and Plan ........................................................................39  
Project Sponsors and Resources .................................................................................................41  
Human Subjects Review ..............................................................................................................42  
Population .....................................................................................................................................44  
Educational Intervention ..............................................................................................................46  
Measurement Tools: Validity and Reliability .............................................................................47  
Outcome Measurements and Data Analysis Plan .......................................................................51
Chapter IV – Evaluation and Results ........................................................................................................54
   Analysis of Data ........................................................................................................................................54
   Sexually-Transmitted Infections-PrEP Knowledge Questionnaire .........................................................56
   Sexual Risk Cognition Questionnaire (SRCQ) ..........................................................................................58
   Sexually-Transmitted Infections (STI) Self-Report .................................................................................60
   Semi-Structured Interview ......................................................................................................................61
   Summary of Findings and Outcomes ....................................................................................................71
Chapter V – Discussion and Conclusions ..................................................................................................73
   Discussion of Findings ..........................................................................................................................73
   Strengths and Limitations ....................................................................................................................74
   Implications for Practice, Education, Research, and Policy Dissemination ........................................76
   Recommendations for Nursing Practice and for Further Study ............................................................77
Appendices ..................................................................................................................................................80
   Appendix A - Strength of Recommendation Taxonomy (SORT) .........................................................80
   Appendix B - Permission for Use of Strength of Recommendation Taxonomy .....................................81
   Appendix C - Sexually Transmitted Infections-PrEP Questionnaire ...................................................82
   Appendix D - Post-Educational Intervention Semi-Structured Interview ............................................84
   Appendix E - Follow-Up Survey Semi-Structured Interview ................................................................85
   Appendix F - Demographic Information Sheet .....................................................................................86
   Appendix G - Screening Questionnaire for Study Inclusion ..................................................................87
   Appendix H - Research Site Approval Letter .......................................................................................88
Bibliography ................................................................................................................................................89
LIST OF FIGURES

Figure 1  Flowchart of Data Collection Process ............................................. 51
Figure 2  Themes from Open-Ended Questions .............................................. 62
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>Socio-Demographic Characteristics of Sample</td>
<td>56</td>
</tr>
<tr>
<td>Table 2</td>
<td>STI-PrEP Knowledge Questionnaire Scores</td>
<td>57</td>
</tr>
<tr>
<td>Table 3</td>
<td>STI-PrEP Knowledge Questionnaire Score Analysis</td>
<td>58</td>
</tr>
<tr>
<td>Table 4</td>
<td>SRCQ Analysis</td>
<td>59</td>
</tr>
<tr>
<td>Table 5</td>
<td>Sexually-Transmitted Infections (STI) Self-Report</td>
<td>60</td>
</tr>
</tbody>
</table>
Chapter I - Introduction

The sexual health of gay and bisexual men (GBM) is an important facet of healthcare that warrants attention of clinicians, policymakers, and the general public. This chapter includes the introduction of pre-exposure prophylaxis (PrEP) to the United States (U.S.) healthcare system and the challenges it may present to GBM in terms of sexual beliefs, sexual behaviors, and sexually-transmitted infection (STIs) rates. The healthcare services organization that was the focus of the study is described, as is, the broad research approach. Lastly, the utilization of a theoretical framework and model of evidence-based practice (EBP) in working on the problem are described.

The presence of STIs among GBM is a concern for the members of the community and the healthcare clinicians who serve them. In 2016, the total number of reported cases of combined reportable STIs was the highest registered in the U.S. since 1941 (Centers for Disease Control and Prevention [CDC], 2017). In 2016, the CDC reported 27,814 cases of primary and secondary syphilis, 1,598,354 cases of chlamydia, and 468,514 cases of gonorrhea (CDC, 2017). In its 2016 report, the CDC highlighted that men accounted for 24,724 of 27,814 reported cases of primary and secondary syphilis. This represented a 15% increase in the rate among men, from 14 cases per 100,000 men in 2015 to 16 cases per 100,000 men in 2016. More specifically, 16,155 identified male cases of syphilis were accounted for gay, bisexual and other men who engage in sex with other men (MSM) where sex partner’s sex was known (CDC, 2017). In terms of gonorrhea, the rate among males increased from 139.7 to 170.7 cases per 100,000 among males from 2015 to 2016 (CDC, 2017). There is no assessment of gonorrhea cases attributed to
MSM over time because most jurisdictions do not report the sex of sex partner or the site of infection (CDC, 2017).

In the U.S., STIs are prevalent in all populations, although there are disparities with respect to rates. In 2016, the rate per 100,000 people of individuals with chlamydia was 497.3, gonorrhea was 145.8, and primary and secondary syphilis was 8.7 (CDC, 2017). The reported rates of STIs, specifically primary and secondary syphilis, showed an increasing trend from 2000 to 2016 (CDC, 2017). The rate of primary and secondary syphilis increased from 2.1 in 2000 to 8.7 in 2016 (CDC, 2017). Chlamydia and gonorrhea rates have also increased since 2000, from 251.4 and 128.7 respectively in 2000 to 497.3 and 145.8 in 2016 (CDC, 2017).

In 2015, CDC reports that human immunodeficiency virus (HIV), the STI which is the target of prevention by PrEP, continues to severely affect GBM. In CDC’s 2016 HIV Surveillance Report, there was no rate calculated by transmission category because denominator data were lacking (CDC 2016). In 2015, the CDC reported that 26,376 of 40,234 new HIV diagnoses were among GBM, which represents 67% of all new HIV infections (CDC, 2017). Young gay and bisexual adolescent men (aged 13 to 24) comprised 27% of new diagnoses among all GBM and 92% of new HIV diagnoses in their age group (CDC, 2017). The CDC recommends that MSMs who are sexually active have STI screenings at least once a year (CDC, 2014). CDC has not yet published statistics on the rate of STIs among people who are on PrEP.

The high prevalence of HIV is being addressed in part by the introduction of the PrEP for HIV-negative patients. Truvada, a PrEP daily medication developed to prevent transmission of HIV disease, was approved by the Federal Drug Administration (FDA) in 2012 (CDC, 2014). As PrEP seems to be promising in curbing HIV transmission, concerns have been raised about the possible risk-compensating sexual behavior, especially for GBM. Risk-compensating
behavior is the adoption of individual unsafe behaviors in response to reduced perceived risk from such risky behavior due to a new intervention or innovation (Wilde, 1994). People tend to behave more cautiously if their perception of risk or danger increases, and less cautiously when they feel ‘safer’ or more protected. Among the concerns is that STIs other than HIV may rise, borne out of risk compensating behavior.

The goal of this research study was to elicit an understanding of the knowledge, attitudes, and practices (KAP) among GBM PrEP patients with respect to the effects of PrEP on HIV and other STIs. Ultimately, the results of this research are intended to contribute to the reduction of HIV and other STI transmission, through increased awareness of risk compensating behaviors.

**Statement of Problem**

The most common STIs in the United States are HIV, genital herpes, syphilis, gonorrhea, chlamydia, and hepatitis B (CDC, 2016). The modes of transmission of STIs are unprotected vaginal, anal, or oral contact with an infected individual (CDC, 2016). These STIs are caused by bacteria, viruses, or parasites that enter the body of an uninfected individual. As these pathogens are foreign to one’s uninfected body, the immune system fights it through a process of inflammation. The inflammation causes manifestations such as pain, swelling, and redness (Public Health Agency of Canada, 2016).

The main aim of PrEP is to curb, if not to eliminate, the transmission of HIV among high-risk populations, including GBM who engage in MSM behavior (CDC, 2014). In 2012, the United States Food and Drug Administration (FDA) approved the use of the drug Truvada, a PrEP medication developed to prevent HIV only, not other STIs (CDC, 2014). PrEP was shown to reduce HIV transmission by 92% among participants who took the PrEP pill daily, based on
the iPREX trial-- a phase 3, randomized controlled trial (RCT) conducted in six countries including the U.S. and published in 2010 (CDC, 2014).

In identifying individuals or groups who may benefit from PrEP, the CDC has identified individuals who are at high risk for HIV as its target users. Prospective PrEP users are screened through assessment of sexual risk of acquiring HIV (CDC, 2014). Among MSMs, assessment of risky sexual behaviors includes the previous six-month history of: (1) having sex with either women or men, or both; (2) number of sex partners involving same sex; (3) frequency of condom-less receptive anal intercourse; (4) number of HIV-positive sex partners; (5) frequency of condom-less receptive anal intercourse with an HIV-positive man; and (6) use of methamphetamines (CDC, 2014).

A concern that has been raised is that the entry of PrEP into the market may increase unsafe sexual behaviors such as unprotected sex and multiple partners. The possible change in sexual behaviors may be borne out of the perception of total protection from STIs and HIV with PrEP use. The effectiveness of PrEP in limiting HIV transmission is corroborated by results of several international and national clinical trials which showed reduced HIV transmission by 92% or lower (CDC, 2014). This study is a contribution to the literature because it focused on the effect of PrEP education on the sexual behaviors and STI rates of adult GBM in California.

**Significance of Problem**

STIs are transmitted through unprotected sex. The practice of unprotected sex, a form of sexual risk compensation which is a concern among PrEP users, public health policy makers, clinicians, and researchers, needs to be explored (e.g., Calabrese & Underhill, 2015). The concern is that a person who is currently infected with STIs other than HIV is prone to HIV infection (CDC, 2016). Additionally, people who have HIV are prone to becoming infected with
other STIs when they engage in unsafe sexual practices such as unprotected sex, multiple sex partners, and injection drug use (CDC, 2016). The potential consequence of such behaviors is increased prevalence of STIs, which would include the multi-dimensional effects of the disease on the individual, the community, and the society. The potential unintended consequence among GBM on PrEP demonstrates the importance of educating PrEP patients about PrEP, STIs, and its transmission.

**Sexually-Transmitted Infections among MSM.** The four common STIs among MSM are: syphilis, gonorrhea, chlamydia, and anogenital herpes. According to the CDC (2017), the year 2016 showed an increase in three STIs: syphilis, gonorrhea, and chlamydia. Herpes, one of the STIs, is not routinely reported to the CDC (CDC, 2016). According to the CDC STI statistics in 2016, the rate of chlamydia has increased by 4.7% since 2015, the rate of gonorrhea increased by 18.5% since 2015, and primary and secondary syphilis increased by 17.6% since 2015 (CDC, 2017). These STIs are briefly described below.

**Syphilis.** Syphilis is a complex infection caused by Treponema pallidum, a spirochete which has the ability to infect almost all organs in the human body (Papadakis & McPhee, 2014). The disease is commonly transmitted during sexual contact, including oral sex. There are generally two stages of syphilis: primary (infectious) and late syphilis. Between these two stages is a symptom-free latent phase. A patient infected with syphilis initially develops a painless genital ulcer with indurated borders and regional lymphadenopathy. Unprotected sex with someone infected with syphilis has a transmission rate of 30%-50% (Papadakis & McPhee, 2014). The late syphilis phase is a destructive phase which can cause permanent disability as it attacks the cardiovascular and neurologic systems (Papadakis & McPhee, 2014).
**Gonorrhea.** Gonorrhea is an STI caused by a gram-negative diplococcus called Neisseria gonorrhoea. The disease is transmitted through unprotected sexual contact, including oral sex. For infected and symptomatic MSM, the initial presentation is dysuria and serous or milky penile discharge (Papadakis & McPhee, 2014). The infection may either regress to become chronic, or progress to involve organs including the epididymis, prostate, and periurethral glands. For MSM who engage in unprotected anal intercourse (UAI), rectal involvement occurs. When the disease becomes chronic, it may lead to prostatitis or urethral strictures (Papadakis & McPhee, 2014).

**Chlamydia.** Chlamydia is a disease caused by Chlamydia trachomatis types L1-L3 (Papadakis & McPhee, 2014). Transmission of the disease is through unprotected sexual intercourse, or through contact with exudates from a lesion. The presenting sign and symptom in males is an ulcerative lesion which sometimes goes unnoticed. Buboes form bilaterally on the inguinal area, which may lead to formation of draining sinuses with scarring (Papadakis & McPhee, 2014).

**Anogenital herpes.** Anogenital herpes is a disease caused by the herpes simplex type-2 virus (Papadakis & McPhee, 2014). The disease presents with grouped vesicles usually on the penile shaft, the labia, the buttocks, and the anogenital region (Papadakis & McPhee, 2014). Anogenital herpes is the most common source of pain on the genital regions to patients who are HIV-infected (Papadakis & McPhee, 2014).

**Costs.** The cost of STIs treatment other than HIV poses a burden to the patient, his family, and society. In the U.S., the estimated total medical cost related to STIs was $16 billion US dollars annually (in 2012 U.S. dollars) (CDC, 2016). This medical cost was based on an estimated 110 million total number of new and existing cases of STIs in 2008 among men and
women in the United States (CDC, 2013). If MSM, who contributed much to the spike of syphilis rate in 2016 (CDC, 2017), continue with risky sexual behaviors while on PrEP, the cost shouldered by individuals and other payers of medical care will increase. Additionally, since PrEP does not provide 100% prevention from HIV infection, the possible risk compensating sexual behaviors may increase the potential for the high risk population, including GBMs, to be infected with HIV. According to the CDC, the lifetime cost of HIV treatment was estimated in 2012 to be $326,500 (in 2012 dollars) per HIV-infected person. (Schackman et al., 2015). The corresponding effect on MSMs having to pay out-of-pocket (for insurance co-pay) for their STI and HIV medications will decrease their disposable income for other basic needs. Given the cost implications of STIs, it is therefore vital that sex education is targeted to patients who are taking PrEP or who have the intent to do so.

**Ethical perspective.** GBM are presented with several hazards of risk compensating behavior as a result of PrEP intake. The use of PrEP is in line with the concept of non-maleficence which is to avoid or prevent harm in any individual (Rainbow, 2002). By providing a medication such as PrEP, the healthcare provider is reducing the possible harm to GBM caused by HIV infection. However, it is also the obligation of health care providers to ensure that GBM are educated regarding their non-protection from other STIs while taking PrEP and to emphasize to patients that PrEP does not guarantee 100% protection from HIV. Such education and counseling, with specific, clear instructions, promotes beneficence. It is important to recognize that every patient has the right to an autonomous decision regarding his sexual behavior. It is, however, the responsibility of health providers and the community to provide individuals with the accurate information on the potential effects of risk compensation.
From a national perspective, the provision of subsidy by the government to make sure PrEP becomes available to high risk individuals follows utilitarian principles. The government decides to advocate an action, which promotes the greatest good to a greater number of individuals in the population (Velasquez, Andre, Shanks, & Meyer, 2012). There may be fewer individuals who are HIV-infected compared to other diseases. However, foresight is important to anticipate the possible epidemic which HIV and other STIs can create if transmission is not curbed. The multiplier effect of HIV and other STI transmission between sexually-active infected and non-infected MSM is high which merits consideration.

The problem of risk compensation and behavioral disinhibition among MSM who are on PrEP cannot be overstated. The 2016 CDC-published statistics on STIs, and specifically those concerning the increasing primary and secondary syphilis cases among GBM, should cause alarm to the lesbians, gay, bisexual, transgender, and questioning (LGBTQ) community, clinicians, and the government. If left unaddressed, society may face an STI epidemic which can be emotionally, financially, and socially costly to the individual, families, and society. The problem is not devoid of solutions. One possible solution is to contribute to averting STI epidemic through education of patients.

Organizational Needs Assessment

An HIV center located in Oakland, California was chosen as the site for the research study. The organization was established in 1987 as an affiliate of Sutter Health Alta Bates Summit (Sutter Health, 2016). The center offers services to males, females, and LGBTQ individuals for HIV, AIDS, and other STI screening, treatment, and management.

The research site has a project called Connecting Resources for Urban and Sexual Health (CRUSH). The CRUSH project is a $6 million grant from the California HIV/AIDS Research
Program (Bay Area News Group, 2014). The CRUSH project offered sexual health services to HIV high-risk East Bay residents. Moreover, CRUSH offered PrEP to HIV- negative gay and bisexual males in its center (CRUSH, 2016). The patients who were enrolled in the PrEP program were screened and provided with daily PrEP medication at no cost. Patients were routinely seen by the center, per CDC guidelines. The CRUSH project commenced in May, 2013 and ended in March, 2017, with 670 enrolled patients (AIDS Vaccine Advocacy Coalition [AVAC], 2016).

**Organizational assessment: applying the 7-S model.** The 7-S model of organizational assessment utilizes seven interdependent variables which are key in organization design and assessment (Reflect & Learn, 2016). The model takes into account both the “hardware” (structure and strategy) and the “software” (management style, staff, skills, shared values, and management style) (Reflect & Learn, 2016). According to the model, the “software” and “hardware” of the organization comprise the seven key areas for assessment and evaluation. The research site is described according to these seven variables and are noted as facilitators to the DNP study.

**Structure.** The clinic’s physical aesthetics is generally minimalist in style. Furthermore, the physical layout of the center emphasizes the center’s value for privacy. Specifically, each room has a sound-proof wall which conveyed privacy. This is important since utmost confidentiality and trust are values patients need.

**Strategy.** The mission of the organization is to “enhance the well-being of people in the communities we serve through a not-for-profit commitment to compassion and excellence in health care services” (Sutter Health Alta Bates Summit Medical Center, 2016). The organization’s mission is clear and is shared by all its stakeholders.
The achievement of the organization’s mission is based on its comprehensive services like primary care, access to clinical trials, consultation, and multidisciplinary support to patients who are living with HIV. Furthermore, the organization serves patients who are either HIV-negative or HIV-positive and the center provides multidisciplinary support to meet needs.

**Staff.** The research site is comprised of regular paid staff as well as volunteers. Individuals who are hired in the organization are expected to share the same core values which the organization promote. The center’s employees are very welcoming and they exude a very positive attitude in welcoming the study during introduction of the researcher to the staff.

**Skills.** To ensure competency among the organization’s staff with regard to clinical skills and sensitivity with respect to the client population, every employee undergoes technical skills training. In addition, the research division staff are provided with resources to attend training sessions or conferences to keep them abreast of issues affecting the organization’s clients.

**Management style.** The organizational structure is flat; observation demonstrated that there is an open door policy and an embracing atmosphere by the management to its employees. As the management is advocating for sensitivity to the needs of patients, they are expected to be equally sensitive to the needs of their staff, including volunteers. The organization has a box in the patient lounge for patient feedback and comments. The center also conducts a periodic evaluation survey to elicit feedback from its regular patients. The periodic evaluation survey is a very important tool in identifying loopholes in services.

**Shared values.** The manner of internalization of core professional values is important for this study. The organization’s core values of excellence and compassion are explicitly stated in its mission. The researcher’s observation noted consistent positive display of cheerful accommodation, respect, fun, privacy, and compassion.
**Building structure.** The building in which the research site is situated is a traditional box-type kind of structure. However, the lobby and its interiors showed a homey atmosphere and conveyed the feeling of being in a home.

**Research Question**

Utilizing the PICOT format where P identifies the population and problem, I stands for intervention to be used in the project, C stands for comparison group with the study if there is one, O identifies the outcome, and T identifies the time frame for the project (Melnyk & Fineout-Overholt, 2011), the following question is the foundation for this study: In GBM who are on PrEP, what is the effect of sex education on sexual behaviors and STI rates over three months?

**Theoretical Framework**

PrEP is being actively promoted to prevent transmission of HIV among high-risk GBM; however, concerns have been raised about the risky sexual behaviors that may compensate for the protection patients get from PrEP use. The occurrence of behavioral disinhibition and risk compensation opens the door to transmission of other STIs such as gonorrhea, herpes, syphilis, and chlamydia. It is important that possible behavioral disinhibition and risk compensation be addressed by health care providers to patients who are starting or who are on PrEP. Understanding the perceptual- cognitive and behavioral state of the patient and providing education to the patient with information about repercussions of sexual behaviors on his health were essential activities in the research study. Pender’s Health Promotion Model (HPM) was well-suited for the health education intervention used in this study.

In Pender’s HPM, health is perceived as a positive dynamic state rather than the absence of any illness or disease (Pender, 2011). Furthermore, Pender’s HPM recognizes the multidimensional nature of individuals as they interact with their external environment.
First key component. The individual characteristics and experiences comprise the first component of the HPM (Pender, 2011). The model recognizes that everyone is unique. This means that race, ethnicity, age, socioeconomic factors, and personality play a role in decision-making in subsequent actions. Moreover, HPM considers the repetition of past health behaviors. This component reflected the result of a longitudinal study of Rosario, Schrimshaw, and Hunter (2006) in New York City. The study showed that GBM who have lower self-esteem, who have history of child sexual abuse, and who have symptoms of anxiety reported more sexual partners in the 6-months assessment. These findings highlighted the importance of experiences and characteristics of individual.

Second key component. The behavior-specific cognitions and affect comprise the second key component of HPM (Pender, 2011). These variables, which relate to perception, affect, interpersonal influences, and commitment to act, can be modified through health provider’s intervention. For this study, the patient needed to perceive that there is a benefit to be derived from safe sex practices. Individualized health education is necessary to arrive at the goal of perceived benefits by the patient. The patient also needed to identify the perceived obstacles in pursuing safe sex behavior. The provider is well-positioned to explain comparisons of the personal, emotional, physiological, and psychological costs incurred between safe and unsafe sexual practices, contributing to a rational decision by the patient. The confidence level of the patient in making a safer sex decision must be considered as well. There are patients who have low self-esteem, which predispose them to engage in risky sexual behaviors as the study of Rosario et al. (2006) have shown. Moreover, it is essential that the existing interpersonal influences on the patient be recognized and considered when conducting behavioral counseling.
**Third key component.** The last component of the HPM is the behavioral outcome-health promoting behavior (Pender, 2011). For this study, the resulting decision to pursue safe sex practices and positive behavioral action is taken into consideration. This third component was measured as part of the follow-up phase of the study, which took place during the third month post-intervention and data collection, when participants self-reported sexual practices for the past three months.

**Assumptions of the HPM.** The HPM holds several assumptions (Pender, 2011):

1. Individuals are capable of actively regulating their behaviors.
2. Individuals are capable of self-reflection and competency assessment.
3. Individuals try to achieve a balance between change and stability. Individuals also seek for positive change or direction.
4. Individuals try to establish or create a situation or environment through which they can demonstrate their potentials.
5. Individuals are bio-psychosocially complex and they continuously interact with their external environment, change it, and get changed over a period of time.
6. Reconfiguration of interactive patterns between person and environment should be self-initiated. The action of self-initiation is important in seeking behavioral change.
7. Health professionals are part of a person’s interpersonal environment who has an influence on the person throughout his lifetime.

The HPM model was selected as a theoretical framework for the study because of its emphasis on recognizing the patient’s fields of experience, patient’s demographic characteristics, and patient’s capacity to decide on a healthy behavior. Furthermore, the inclusion of health professionals having influence on patients was a vital component that emphasizes providers’
ability to listen and educate patients about topics such as PrEP, STI, and risky sexual behaviors. Sex education was the intervention utilized in the study and outcome was measured on pre-intervention, post-intervention, and follow-up phases. The pre-intervention took into account the the first and second component: individual characteristics and behavior-specific cognitions and affect. The pre-intervention included information gathering from the participants. The post-intervention was a validation of the third component of HPM, which reflected on sexual intent. Moreover, the follow-up phase gathered information on sexual practices and self-reported STI status of participants.

**Iowa Model of Evidence-Based Practice**

Promoting quality care was one of the goals of the study, with a focus on use of the scientific process in problem-solving. The multidisciplinary approach needed to address the identified problem, combined with the needed scientific process in finding solutions to the problem, are in line with the framework of Iowa model of evidence-based practice (EBP). The study used the five-step Iowa EBP model from identification of problem to dissemination of results (Titler et al., 2001).

**Identification of Problem.** Using the Iowa model of EBP, the trigger for the study started with the identification of the clinical problem: the sexual behaviors and STI rates of GBM on PrEP. This problem-focused trigger was considered a priority of the research site, which primarily addresses the health of LGBTQ population.

**Forming a Team.** The next step was to form a team (Titler et al., 2001). The team comprised the researcher’s mentor, and the research site team (administrative manager, front desk staff, and project leader).
**Search for Related Literature.** After identifying the problem and forming a team, the next step was the collection of relevant and related literature (Titler et al., 2001). The literature search required to have the components of the study question. The most recent literature, published between 2006 to 2016, were included.

**Critique and Synthesis of Literature.** After gathering relevant literature, the selected articles or studies were critiqued and synthesized to determine if there existed a basis for study of the problem identified. A determination that research was to be conducted was based on the findings of the synthesized research literature. The thrust of the study was to generate new evidence and knowledge on the problem identified.

**Conducting Research Study.** The next step was to conduct the study. The results of the study will be shared with the research site with the purpose of providing direction based on the evidence found in the study.

**Dissemination of Study Findings.** The last step of the EBP process is to disseminate the results of the pilot study (Titler et al., 2001). It is the goal of the study to be able to disseminate findings with the end-goal of having the results adopted by organizations, or study be replicated on a larger scale.

**Definition of Terms**

The following terms are used in this research study with their corresponding operational definitions:

1. Bisexual – is a term used for a person who is sexually attracted to both women and Men (Merriam-Webster.com, 2016)

2. Gay – is a term used for a person who is sexually attracted to a person of the same sexual orientation (Merriam-Webster.com, 2016).
3. MSM – refers to men who engage in sex with men. This is a commonly used term when combining GBM in terms of sexual activity. This term will be used in the search for literature to combine GBM.

4. PrEP (Pre-Exposure Prophylaxis) – is a term used for the FDA-approved medication taken by individuals who are HIV-negative but are at high risk for contracting the HIV disease (CDC, 2016).

5. Sex Education - education about human sexual anatomy, sexual reproduction, sexual intercourse, and other aspects of human sexual behavior (Sciencedaily.com, 2016). Specifically, the sex education conducted in the study comprised information about PrEP and STIs. Furthermore, the sex education intervention was conducted on an in-person individual basis.

6. Sexual Behavior - person’s sexual practices - either engaging in heterosexual, bisexual, or homosexual activity (MedicalDictionary.com, 2016). Specifically, the sexual behaviors focused on the study encompassed safe sex behaviors and risk compensating sexual behaviors before and after educational intervention as measured by sexual behavior questionnaire, semi-structured interview, and self-reported STI status.

7. Sexually-Transmitted Infections (STI) – infections spread through sexual contact (Public Health Agency of Canada, 2016). In this study, the STI transmission was reflected on self-reported STI status of participants at three months, post-intervention. The STI test is part of the CDC guideline in managing PrEP patients (CDC, 2016).

**Conclusion.** The introduction of PrEP to the array of HIV prevention modalities has been seen as an important contribution to reducing HIV prevalence. There is however a concern with respect to the possible rise of STIs among those who are using PrEP, specifically syphilis.
More alarming has been the male syphilis cases attributed to MSM (CDC, 2017). The entry of PrEP in the market may pose a problem to GBM who are on PrEP in terms of possible increase of risky sexual behaviors, either due to lack of information or complacency. If STI rates are left uncurbed, STIs will pose problems to the health of patients and the society. It is an ethical obligation of health care providers and the government to promote good and avoid harm among GBM.

The research site, situated in Oakland, California, provides HIV and STI services to their population. Utilizing the Iowa model of EBP, the problem trigger was identified and a team was formed. The problem identified was the lack of standard sex education provided to PrEP patients, which may contribute to possible increase in STIs and risk compensating sexual behaviors.

Based on the identification of the problem, a PICOT statement was formulated: In GBM who are on PrEP, what is the effect of sex education on sexual behaviors and STI rates in three months? Pender’s HPM was selected as the theoretical framework for the sex education intervention targeting GBM at the research site. The HPM was chosen primarily because of its three components and assumptions, which were best appropriate in the design of educational intervention on the chosen population.
Chapter II - Review of the Literature

The review of the literature was based on available published and unpublished documents related to populations and issues involved in this study: GBM, PrEP, sexual behaviors, and STIs. The search for related or relevant literature was carried out using multiple databases to maximize results.

Introduction to Search Criteria

A comprehensive electronic search of literature was undertaken on Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medical Literature Analysis and Retrieval System (MEDLINE) PubMed and Ovid, Cochrane databases, and ONE Search from Georgetown University. Additionally, a manual search of bibliographies was also conducted. Terms used for the search were gay men, bisexual men, MSM, PrEP, STI, sexual behaviors, health education, and sex education. The search also included the elements of the PICOT question for the study. Inclusion criteria consisted of RCTs, non-RCTs, and full systematic reviews; free full text, abstract included; publication time between years 2006-2016; and English language.

Using PubMed MEDLINE, each of the search terms was used. Using gay men, the search yielded 11,476 articles. The search for the term bisexual men resulted in 3240 articles. Pre-exposure prophylaxis and sexual behavior were searched using the same process, yielding 2320 articles and 46,923 articles, respectively. Using sex education yielded 8157 articles, whereas using STI yielded 22,012 articles. Utilizing the Boolean search of the combined terms with AND yielded six relevant articles. However, no article was found when all search terms are combined with health education or sex education.
Using the CINAHL database, the search process was comparable. Using the term *gay men* yielded 352 articles, *bisexual men* yielded 101 articles, *MSM* resulted in 136 articles, and *PrEP* yielded 69 articles. Additionally, using the search phrase *sexual behaviors* garnered 187 articles, whereas *STI* resulted in 189 articles. Lastly, search phrases *sex education* and *health education* yielded 368 articles and 12,115 articles, respectively. Combining all search results on this database, excluding sex education and health education garnered one article. All the terms combined yielded no articles.

Searching on Ovid MEDLINE, the same process was followed. Using the term *gay men* and *bisexual men* resulted in 4,503 articles and 3,223 articles, respectively. Moreover, *MSM* yielded 7,551 articles, and *PrEP* garnered 4,999 articles. Additionally, search term *sexual behaviors* and *STI* resulted in 124,546 articles and 7,479 articles, respectively. Searching for *health education* yielded 457,652 articles, and *sex education* garnered 56,140 articles. Using Boolean search for all the terms with AND, except for health education and sex education, yielded 23 articles.

A search was carried out using the Cochrane Database of Systematic Reviews using the search modifier of *full systematic reviews*. The following were the terms that yielded results: *gay men* (3), *MSM* (27), *PrEP* (18), *sexual behaviors* (38), *STI* (61), *sex education* (24), and *health education* (307). Combining search terms yielded no article.

A parallel search conducted at Georgetown University (GU) library yielded comparable results: two relevant articles. After reviewing and evaluating the abstracts, and removing duplicated studies, 12 relevant articles were found to have satisfied the inclusion and exclusion search criteria.
Critique and Synthesis of Previous Evidence

The 12 articles that satisfied the inclusion and exclusion search criteria were included in this critical appraisal. The studies included one RCT (McCormack et al., 2016), three cohort studies (Chen, Snowden, McFarland, & Raymond, 2016; Liu et al., 2016; Perez-Figueroa, Kapadia, Barton, Eddy, & Halkitis, 2015), three mixed methods studies (Brooks et al., 2012; Hoff et al., 2015; Saberi et al., 2012), four descriptive studies (Brooks et al., 2011; Galea et al., 2011; Gamarel & Golub 2015; Grov, Whitfield, Rendina, Ventuneac, & Parsons, 2015), and one quality improvement project (Hilarie, 2015).

The critical appraisal of the literature used by the researcher was the Strength of Recommendation Taxonomy (SORT). The SORT allowed the researcher to rate an individual study’s quality and rate the body of evidence’s strength (Ebell et al., 2004). The SORT rates literature based on quality, quantity, and consistency. In terms of body of evidence, the studies showing consistent and good quality patient-oriented evidence were rated A-level of recommendation. On the other hand, a B-level of recommendation would mean an inconsistent or limited quality patient-oriented evidence. Lastly, a C-level of recommendation for a body of evidence would mean that the body of evidence was based on consensus, opinion, case series for studies for diagnosis, treatment, prevention, or screening (Ebell et al., 2004). Levels of evidence from one to three was rated on individual piece of evidence. An algorithm on the taxonomy is presented as Appendix A.

The 12 studies appraised revealed consistent findings or conclusions. Emerging themes found in the qualitative descriptive studies and cohort studies were: increase in condom-less use, increase in unprotected sex, and increase in risky sexual behaviors (Brooks et al., 2011; Brooks et al., 2012; Chen et al., 2016; Galea et al, 2011; Gamarel and Golub 2015; Grov et al., 2015;
Hoff et al., 2015; Liu et al., 2016; and Perez-Figueroa et al., 2015). The designs common among these research studies were qualitative descriptive and cohort. Due to limited studies available on current PrEP users including the elements of the PICOT question, only four studies (Chen et al., 2016; Hilarie, 2015; Liu et al., 2016; and McCormack et al., 2016) focused on current users of PrEP and two among these studies (Hilarie, 2015; and Liu et al., 2016) explored and examined the effect of an intervention on STI rates and sexual behaviors.

**Studies on current PrEP users: Condom-less use, sex education, and STI rates.**

Condom-less use by GBM was one of the common themes extracted from the body of literature involving current PrEP users. Since PrEP is relatively a new drug, there were only four studies which considered either sexual behaviors or condom use in correlation with actual use of PrEP, although it might be the case that there are numerous studies currently in progress regarding this topic. PrEP adherence, sexual behaviors, sero-adaptive strategies, and incidence of STIs were studied involving an RCT (McCormack et al., 2016), a cohort demonstration project (Liu et al., 2016), a longitudinal cohort study (Chen et al., 2016), and a quality improvement project (Hilarie, 2015).

A pilot-phase RCT called PROUD study was conducted by McCormack et al. (2016). The PROUD study was an open-label, pragmatic, RCT carried out in 13 sexual health clinics in England. This study assessed the effectiveness of PrEP among MSM who had condom-less anal sex (CAS) for the past 90 days. Efficacy was measured in terms of PrEP’s preventing HIV, adherence to PrEP, and risk compensation. The pilot-phase PROUD RCT had a projected sample of 500. Participants were randomly assigned to an immediate group who received PrEP at enrollment, and a deferred group who was given PrEP after one year of the study. Randomization was done through web-based access to a central computer-generated list with
variability in block sizes. The study achieved more than the projected sample: 544 study participants were recruited between November 29, 2012 to April 30, 2014.

In terms of the outcome measures of the pilot study of McCormack et al. (2016), the findings showed no difference in occurrence of STI between groups, although there were some risk compensating sexual behaviors suggested by participants but was not quantified. In terms of HIV incidence, the immediate group was found to have lower HIV compared to the deferred group. In terms of STI rate, 57% in the immediate group compared to 50% in the deferred group was diagnosed with an STI. The STIs diagnosed were commonly gonorrhea and chlamydia. Moreover, participants in the immediate group were found to have engaged in receptive anal sex with 10 or more partners without a condom compared to the deferred group. The increase in condom-less receptive anal intercourse while on PrEP was suggestive of risk compensation.

One limitation of the RCT by McCormack et al. (2016) was its failure to mention if a validated sexual behavior questionnaire was used in the pilot study. Additionally, participants were offered optional risk reduction sessions during their follow-up visits; which meant that not all participants received risk reduction intervention which may have an effect on reported sexual behaviors between those who opted to receive risk reduction sessions and those who opted not to attend risk reduction sessions. Two additional weaknesses of this RCT are: 1) the lack of data on reported sexual behaviors and PrEP adherence; and 2) the fact that the findings are not generalizable. The study is considered level 1 evidence based on SORT (Ebell et al., 2004) as the design and results provided good quality evidence patient-oriented evidence of a pilot phase RCT.

Liu et al. (2016) conducted a demonstration project in three metropolitan areas to assess sexual behaviors, PrEP adherence, STI incidence and HIV infections in a cohort of 437
transgender women and MSM over a 48-week study period. Data on sexual behaviors were assessed using interview questionnaire on every visit. Drug use and sexual behavior trends were assessed with Poison distribution models and generalized estimating equation logistics. The findings of the project showed that participants who initiated PrEP during the study engaged in condom-less receptive anal sex but remained stable from 65.5% at baseline to 65.6% at follow-up. There also was a decline in the mean number of partners engaging in anal sex from 10.9 to 9.3 persons. However, the incidence of STI remained high at 90 per 100 person-years but showed no increase over time. PrEP adherence was measured through self-reported adherence scale, pill counts, and medication possession ratio.

One weakness of this study (Liu et al., 2016) was its failure to specify the type of sampling procedure. The study focused on PrEP adherence, trends of sexual behaviors, STI rates, and drug use after a brief participant-centered counselling. However, the study did not include the perception of participants regarding PrEP and how perception affects their sexual behaviors before and after counselling. The study is considered level 1 evidence based on SORT (Ebell et al., 2004) as design and results provided good quality evidence patient-oriented evidence of a prospective cohort study utilizing brief client-centered counselling and periodic sexual behavioral assessments.

A longitudinal cohort study by Chen et al. (2016) was conducted to examine trends in condom-less anal sex partners, PrEP use, and sero-adaptive strategies of MSM in San Francisco, California. Time-location sampling yielded 2290 HIV-negative MSM over four waves: in 2004, 2008, 2011, and 2014. Chen et al utilized a standardized questionnaire developed by CDC to gather demographic data. PREP use for 12 months was made through self-report. The findings showed that pure serosorting (condom-less anal sex with person of the same serostatus)
increased sharply from 2011 to 2014 (29.6% to 39.9%), condom use decreased by 40% from 2011 to 2014 which coincides with PrEP initiation, and there was more than doubling of multiple CAS partners from 2004 to 2014.

An identified weakness of the Chen et al study (2016) was the time span of the study, covering periods without PrEP and a period when PrEP was introduced to health care. Hence, the increase in STI rates from 2004 to 2014 cannot be attributed to PrEP use since STI trends had been increasing prior to 2012, when PrEP was introduced. Furthermore, the study involved trends only and did not utilize an interventional tool to assess increases in STI rates or in CAS. Another weakness of the study was the inability to determine causality, which means that the increase in risky sexual behavior cannot be ascribed to PrEP. Moreover, the data on PrEP use was for 12 months, compared to self-reported sexual behavior which was collected for only six months. Another identified weakness of the study was the use of self-report of PrEP adherence by participants. Although this is a common method of research in behavioral health studies, it can be subject to respondent bias. One strength of the study, however, is its large sample size, although the researcher did not report the magnitude of treatment effect. Another contribution of the study is that it opened the door for more extensive studies on what leads MSM to risky behaviors while on PrEP, describing and analyzing current educational literature provided to patients in terms of emphasis on effect of sexual behaviors on STIs and HIV infection. This study merits a SORT level 2 evidence because it involved a retrospective study with limited quality patient-oriented evidence with poor-follow-up.

Hilarie (2015) implemented a PrEP education improvement (QI) project in a tertiary institution in San Francisco, California. The study’s aim was to improve safe sex practices and follow-up visit compliance of PrEP patients through standardized provider education. Sampling
strategy of the project’s three PrEP participants was unknown. The study’s intervention was through risk reduction classes by providers and educational materials given to the participants. The results were gathered through patient survey, peer-to-peer report, and data on new HIV and new STI rates. The result of the intervention showed 100% use of new educational materials by providers to patients, no new HIV cases, and no new STI cases approximately six months post-intervention.

An identified strength of the Hilarie (2015) study was its utilization of standardized, CDC-approved PrEP education to its patients. However, the study had several weaknesses. First, it failed to state explicitly IRB approval even though it involved personal identifiable information and data, specifically HIV and STI status of participants during the study. Second, the sampling strategy was not stated. Third, the results failed to show baseline statistics in terms of its claim that there was inadequate provider education on PrEP patients. Specifically, the study failed to quantify adequacy and inadequacy of patient education. Fourth, the project failed to assess and present reasons for lack of compliance with follow-up at baseline. Fifth, the project did not assess perceptions or evaluations of PrEP patients on patient education received post-risk reduction sessions. However, the transferability of its findings was promising, which can be translated to different healthcare institutions. Based on SORT (Ebell et al., 2004), this quality improvement project merits a level 3 evidence.

**Synthesis of current PrEP user studies.** The four studies showed some limitations and strengths in sampling and intervention design. The demonstration project conducted by Liu et al. (2016) failed to mention how sampling was carried out to avoid selection bias. It therefore failed to show any rigorous criteria to avoid confounding results (Pannucci and Wilkins, 2010). Sampling and recruitment were also problems with the study conducted by Hilarie (2015)
because the project did not mention how study participants were recruited for the QI project. On the other hand, the study of McCormack et al. (2016) used good sampling procedures, randomizing the assignment of participants in the pilot study. In the study conducted by Chen et al. (2016), the researchers used a CDC standardized questionnaire which had high validity and reliability.

The magnitude of treatment effect of the three of the four studies (Chen et al., 2016; Hilarie, 2015; and Liu et al., 2016), was uncertain, while the study of McCormack et al. (2016) was expected to have no magnitude of treatment effect because of the pilot nature of the study. Chen et al., 2016; Hilarie, 2015; and Liu et al., 2016 varied in their use of statistical analysis to assess the magnitude of treatment effect; none used odds ratio, relative risks, or other comparative measures to demonstrate magnitude of effect. Comparing similarity of findings to elicit consistency among group of studies (Ebell et al., 2004), three of the four studies (Hilarie, 2015; Liu et al., 2016; and McCormack et al., 2016) yielded inconsistent results with respect to STI rates. The study by Hilarie (2015) showed 0% in new STI cases at three to six months’ post-intervention; Liu et al. (2016) showed STI remaining high at 90 per 100 person-years at follow-up; McCormack et al. (2016) showed no significant differences in each group’s STI incidence or overall STI incidence between groups.

In terms of consistency of effect of education intervention, two studies (Liu et al., 2016 and Hilarie, 2015) showed inconsistent effect of educational interventions on STI and inconsistent findings on condom-less use. Chen et al. (2016) and McCormack et al. (2016) did not utilize any sex educational intervention in their respective studies. Overall, the body of evidence among the four studies involving PrEP patients merit class B strength of recommendation (Ebell et al., 2004) based on inconsistent patient-oriented evidence.
**Studies on prospective PrEP users: Fear for future risk compensation.** Eight of the 12 studies (Brooks et al., 2012; Brooks et al., 2011; Galea et al, 2011; Gamarel & Golub 2015; Grov, et al., 2015; Perez-Figueroa et al, 2015; Hoff et al., 2015; and Saberi et al., 2012) critiqued and synthesized were prospective studies in terms of future use of PrEP. They demonstrated consistency with respect to the findings regarding themes: probable increase in risky sexual behaviors (risk compensation) and condom-less anal intercourse with use of PrEP among GBM.

A mixed method study conducted by Hoff et al. (2015) in San Francisco and New York City examined the acceptability of PrEP use among individual and their partners, as well as condom use intentions with either primary or outside partner if individuals or partners were taking PrEP. The study included two independent sample groups of gay male couples in two distinct phases-the qualitative and quantitative phase. Stratified purposive sampling was used to recruit 219 couples. The results showed that within the context of PrEP use, 30% of HIV-negative male couples reported that they would not use condoms with their primary partners or outside partners as long as they were both on PrEP. Also, approximately 20% stated that they will not use condoms or decrease the frequency of condom use.

The qualitative phase of the study of Hoff et al. (2015) took place between March, 2011 and November, 2011 and the quantitative phase took place between June, 2012 and May, 2013. The outcome of the study posed a warning to GBM PrEP users who opt to engage in unprotected sex. One weakness of the study was that sampling was confined to GBM couples. However, the stratified purposive sampling employed was free of selection bias and was appropriate. Another study weakness was its failure to mention effect size of the sample. Moreover, in the published article, the researchers failed to state if tools use were validated and reliable and therefore did not demonstrate that the study’s findings could be replicated in a different setting. Based on the
limited quality patient-oriented evidence presented in this prospective mixed method study, the study merits a SORT level 2 evidence (Ebell et al., 2004).

Another study examined the predictors of intentions in adopting PrEP among HIV-negative MSM in primary partnerships (Gamarel and Golub, 2015). The cross-sectional study, conducted in New York City between January, 2012 and October, 2013, examined the impact of messaging and communication of PrEP on its adoption. It comprised 384 MSM, recruited and selected using snowball sampling methods. The tools utilized in data gathering were the Condom Use Motivation scale, the Intimacy Interference subscale, and the Risk Reduction subscale. Descriptive statistics, bivariate analyses, analysis of variance (ANOVA), and stepwise logistical regression were used in the statistical analyses of data.

The result of the study by Gamarel and Golub (2015) showed that 57.4% of participants who were likely to take PrEP engaged in CAS with their primary partner, and 73.2% of participants engaged in CAS with outside partners. These findings were important because unprotected anal intercourse existed without PrEP and the intention to take PrEP may reinforce their CAS behaviors. The CAS behavior may predispose the participants to more STIs, including HIV. There were several identified weaknesses of the study. First, the study failed to assess participants’ motivations in engaging in condom-less sex. Second, the study failed to conduct a pre-education assessment of PrEP adoption intentions and compare how PrEP adoption intentions change post-PrEP education. Third, the generalizability of the findings of the study was questionable due to its small sample size. Based on the limited quality patient-oriented evidence of a prospective cross-sectional study with poor follow-up, the study merits a SORT level 2 evidence (Ebell et al., 2004).
Another prospective longitudinal study, the Pillow Talk Project, examined the possible PrEP impact on safe sex practices, including condom use, among highly sexually active HIV-negative GBM and HIV-positive GBM (Grov et al., 2015). The study sample comprised 206 New York City GBMs who were identified as highly sexually active (having at least nine sexual partners 90 days prior to the study) and who were HIV-negative. The enrollment for the study began in February, 2011 and ended in June, 2013. There were 377 participants who enrolled but only 206 participants were HIV-negative. Tools used were a computer-assisted self-interview (CASI), the Temptation for Unsafe Sex Scale, the Safer Sex Self-Efficacy Questionnaire, and the Decisional Balance for Sex without Condoms instrument. Results of the study showed that the participants who were willing to take PrEP had higher odds of recent CAS. Furthermore, there were only 10% of the participants who stated that they might engage in CAS. Men who planned to engage in CAS perceived greater benefits from CAS. Although statistically not significant, the findings suggested trends between willingness to start PrEP and perceived impact of PrEP on condom use. Specifically, 47.9% of participants who were willing to take PrEP felt that condom use would decrease, compared to 65.5% of participants who expressed the likelihood of an increase in condom use when on PrEP, and 41.1% of participants who stated that PrEP use would not have impact on their use of condoms.

The study by Grov et al. (2015) had some limitations and weaknesses. First, the study did not specify the type of sampling procedure it used. Second, the article reporting the study findings did not sufficiently describe the intervention, including not mentioning the type of PrEP information provided to participants. The amount and type of information shared with participants may have impacted on their responses regarding their willingness to take PrEP at the same time as engaging in CAS. Although some of the reported findings were statistically
significant, given the small sample size, generalizability cannot be made. The extrapolation of the findings is moderately strong as it lacks thorough descriptive data and it has a small sample size for transferability. Based on the limited quality patient-oriented evidence of a longitudinal descriptive study, the study merits a SORT level 2 evidence (Ebell et al., 2004).

Perez-Figueroa et al (2015) carried out a to explore attitudes and perceptions of PrEP among a subsample of 200 HIV-negative young MSM (YMSM) recruited from a prospective cohort parent study conducted in New York City from February, 2012 to November, 2012. A purposive sampling approach was used to recruit and select the study participants. There were no PrEP users at the time of the assessment. The mode of data collection was through semi-structured interviews including both open-ended and closed-ended questions with the participants. Thematic analysis was used in coding, sorting, and comparing interview transcripts.

One of the themes generated by the Perez-Figueroa et al. (2015) study was regarding one of the barriers to successful implementation of PrEP. A number of participants stated the potential for risk compensation and behavioral disinhibition if the participants’ partners use PrEP. The study showed that there was a fear for possible risk compensating behavior which may arise from the YMSM participants’ possible sense of protection. The credibility of the study is moderately strong, as the researchers used several strategies to ensure the rigor of the study methods. These strategies included peer debriefing, independent and collaborative coding of transcripts, examination of negative cases in the refinement of themes, and provision of decisional audit trail (Perez-Figueroa et al., 2015).

One weakness of the study (Perez-Figueroa et al., 2015) was that the YMSM who participated were not necessarily considered high risk for HIV. Consequently, the results cannot be extrapolated on target users of PrEP- the high risk group for HIV infection. Based on the
limited quality patient-oriented evidence, prospective cohort study merits a SORT level 2 evidence (Ebell et al., 2004).

A mixed methods study conducted by Brooks et al. (2012) among 25 GBM couples in serodiscordant relationships (couple with positive and negative HIV serostatus) in Los Angeles, California focused on participants’ current sexual practices, possible adoption and acceptability of PrEP, and sexual behavior intentions with PrEP adoption. Participants were provided with PrEP information through a brief tutorial prior to a semi-structured interview. The study showed that 60% of the participants stated that future adoption of PrEP would allow abandonment of condom use to prevent HIV and 64% of the participants stated likelihood for possible increase in engagement in risky sexual behaviors. The study concluded that the use of PrEP among GBM may lead to risk compensation by taking on risky sexual behaviors while taking on PrEP. The findings suggest that HIV-negative GBM who were involved in a serodiscordant relationship may have potential for risk compensation upon initiation with PrEP.

One problem with Brooks et al. (2012) study was that its failure to report the the sampling strategy used. The researchers also did not describe how the PrEP information shared with participants was developed. In addition, the qualitative data may have had compromised credibility as there was no cross-checking of the transcriptions to allow confidence of data obtained. In this manner, the qualitative finding’s dependability was questionable. The small sample size and the exploratory nature of the study may limit generalizability of the findings. Based on the limitations of the study, it merits a SORT level 2 evidence (Ebell et al., 2004).

In a mixed method study conducted by Saberi et al. (2012), the researchers examined seroconcordant and serodiscordant male couple’s concerns regarding PrEP providers, PrEP awareness, and correlates of PrEP uptake by HIV-negative member. The researchers used
snowballing sampling to recruit 328 participants comprising 164 couples in San Francisco, California. Qualitative methods were used in conduct of interviews with open-ended questions; a quantitative questionnaire focusing on PrEP was also used utilizing Computer Assisted Personal Interviewing (CAPI) and Computer Assisted Self-Interviewing (ACASI) procedures. Results showed that one of the most frequently stated reasons for hesitancy in taking PrEP was possible risk compensation, including behavioral disinhibition and specifically decrease condom use. The likelihood of a participant taking PrEP is positively correlated to condom-less anal intercourse.

The Saberi et al (2012) study also had several limitations. The study was limited to couples, which may have yielded different results with regard to perceived sexual behavioral risk in tandem with PrEP use than a study that would have included GBM who are engaged in a couple relationship and those who are single. In terms of the PrEP questionnaire used in the study, it failed to mention the questionnaire’s content validity. The study, primarily exploratory and formative, may not be generalizable and representative of the MSM population. Based on the limited quality patient-oriented evidence, the longitudinal mixed methods study merits a SORT level 2 evidence (Ebell et al., 2004).

A descriptive study by Brooks et al. (2011), researchers identified factors that may facilitate or impede future adoption of PrEP among GBM who were in HIV-serodiscordant relationships. There were 25 couples in the study in Los Angeles, California. A Grounded theory approach was used as its theoretical framework. Purposive sampling was used in the study. The data collection tool was semi-structured and individual interviews. Prior to the interviews, the concept of PrEP was explained and a description on how PrEP use will prevent HIV infections was provided. Themes were generated through the modified grounded theory
approach. One of the themes generated showed that one motivator of PrEP use was the opportunity to engage in unprotected sex with their serodiscordant partner. The finding was important for current and future review of education to PrEP patients. However, only concept of PrEP and its action in preventing HIV were discussed and failed to include PrEP limitations in terms of non-protection from other STIs. Furthermore, the researchers failed to mention source of PrEP information or how information was developed. Over-all, the credibility of the study’s findings and data is strong; however, the findings may not have high extrapolation and generalizability due to its small sample size. Based on the limited quality patient-oriented evidence, this descriptive study merits a SORT level 2 evidence (Ebell et al., 2004).

A pilot descriptive study on the acceptability of PrEP among MSM, transgenders (TG), and female sex workers (FSW) who were considered at an elevated risk for HIV was undertaken in Lima, Peru by Galea et al. (2011). A convenience sample 45 individuals comprising female sex workers, TG, and MSM participated in seven focus groups. A semi-structured focus group guide was used, eliciting information regarding participant’s awareness and characteristics of PrEP, community and social concerns, and participants’ perceived behavioral effect as a result of future PrEP use. One of the themes generated from the focus groups was the behavioral changes after starting PrEP. Findings reveal that MSM and TG believed that there would be a decrease in condom use or potential sexual risk disinhibition as a consequence of PrEP use. One weakness of the study was its limited transferability of findings because of the small sample size, and the use of convenience sampling, which risks selection bias. Based on the limited quality patient-oriented evidence, descriptive study merits a SORT level 2 evidence (Ebell et al., 2004).

**Synthesis of prospective studies involving future PrEP use.** In terms of quantity of the eight studies discussed, the results pointed to consistent findings in terms of risk compensating
behaviors and decreased condom use. There was consistency in the results of four studies (Galea et al, 2011; Gamarel & Golub, 2015; Perez-Figueroa et al., 2015; Saberi et al., 2012) in terms of condom-less use should PrEP be taken by the participants and their partners. These results highlight the probable increase in sexual risky behaviors when taking PrEP. Moreover, in two prospective studies, an increase in risky sexual behaviors accompanying PrEP use among GBM was yielded (Brooks et al., 2012 & Hoff et al., 2015). The studies of Brooks et al. (2011) and Grov et al. (2015) showed consistent results showing risk compensation and condom-less anal intercourse.

In terms of sampling, the eight studies was not large enough to demonstrate statistical significance and consequently to show generalizability of the results. Despite the lack of sample size, the eight research studies were generally of good quality. Consequently, good quality provided confidence in the robustness in the body of evidence in terms of prospective users of PrEP considering that there exist few studies involving actual users of PrEP in relation to sexual behaviors and STIs. Moreover, the consistency in findings in terms of possible behavioral disinhibition and risk compensation, specifically decrease in condom use, added to the strength to the body of evidence. Overall, the quantity rating of the eight studies was found to be consistent.

Overall, with respect to quality, the eight studies are considered SORT level B. The eight studies consisted of three mixed methods study (Brooks et al., 2012; Hoff et al., 2015; Saberi et al., 2012), two cohort studies (Gamarel & Golub, 2015 and Perez-Figueroa et al., 2015), and two descriptive studies (Galea et al, 2011 and Grov et al., 2015). All studies were approved by an Institutional Review Board (IRB). The sampling of most of the studies was considered adequately rigorous. However, one study, by Gamarel and Golub (2015), used snowballing in a
setting in which purposive sampling could have been used. The other studies used purposive sampling (Brooks et al., 2011; Brooks et al., 2012; Hoff et al., 2015; Perez-Figueroa et al., 2015; Saberi et al., 2012), convenience sampling (Galea et al, 2011), and telephone recruitment-stratified purposive sampling (Grov et al., 2015).

In terms of analytic tools used, the qualitative descriptive studies (Galea et al, 2011; Gamarel & Golub, 2015; and Grov et al., 2015) used rigorous transcribing and coding before thematic analyses was carried out. The other studies used validated and reliable tools or subscales such as Safer Sex Self-Efficacy Questionnaire, Decisional Balance for Sex with Condoms, Temptation for Unsafe Sex Scale, Condom Use Motivational Scale, Intimacy Interference Subscale, Sexual Pleasure Subscale, Pleasure Reduction Subscale, and Risk Reduction Subscale. It was very important that the studies used validated and/or reliable tools when those were available, to lend more credibility to the findings.

**Over-all rating of the body of evidence.** Based on individual ratings of studies using the SORT critique of level of evidence, two out of 12 studies merited a rating of SORT level 1, nine studies merited rating of SORT level 2, and one study was rated as SORT level 3 (Ebell et al., 2004). The quality of the twelve studies was generally of SORT level 2, with eight out of 12 studies were generally prospective but with poor follow-up.

In terms of the body of evidence, the 12 studies showed limited quality patient-oriented evidence, which merits B strength of recommendation. The 12 published articles provided key recommendations for clinicians regarding diagnosis and treatment (Ebell et al., 2004). Moreover, although the studies generally had limited patient-oriented evidence, they pointed to results with recommendation on how to strengthen PrEP among its target users to reduce morbidity and consequently a better quality of life. The recommendations made were based on
consistent findings from at least one RCT, three mixed method studies, four cohort studies, three descriptive studies, and one QI project. Some of the recommendations were based on eight studies of the prospective use of PrEP and the possible change in behaviors with future PrEP intake. The eight studies, therefore, did not show realistic measure outcomes but rather hypothetical. On the other hand, there were four studies which showed the actual effect of PrEP on sexual behaviors (Chen et al., 2016; Hilarie, 2015; Liu et al., 2016; and McCormack et al., 2016).

**Rationale for this Study**

The study was focused on GBM, a vulnerable population. The sexual practices of GBM are prone to exposure to STIs, including HIV. There were only two studies (Hilarie, 2015 and Liu et al., 2015) which showed the use of sex education with the actual use of PrEP. However, the findings were inconsistent, with one study (Hilarie, 2015) being judged to be poor in design and methodology. The study by Liu et al. (2016) showed that STI rates remained stable but high with PrEP use, whereas the project by Hilarie (2015) yielded 0% STI transmission with PrEP patients. The study of McCormack et al. (2016) showed increased report of risk compensating sexual behaviors but STI rate was statistically insignificant between groups. Therefore, a research gap existed which warranted the conduct of a research study in order to generate knowledge or evidence on the effect of sex education on sexual behavior and STI rates of GBM who are on PrEP.

**Research Study Aims**

The health care providers are an essential partner in the promotion of health and prevention of disease. The study had the following aims: (1) to carry out a health care educational intervention focusing on STI and PrEP education on GBM; (2) to demonstrate
knowledge performance of an STI and PrEP education pre-intervention, post-intervention, and at follow-up; (3) to demonstrate change in thought processes of participants in relation to condom use and engagement in HIV risk sexual practices through a validated and reliable sexual cognition tool; (4) to show possible change of STI rate from pre-intervention to follow-up; and (5) to identify individual PrEP perception, expressed sexual intentions, and reported current sexual behaviors of GBM.

Given the study aims, it was the goal of the study to create, initiate, implement, and disseminate the findings of the study to the research site, to the LGBTQ population, and to the health care industry. It is hoped that the findings will be a springboard in incorporating educational emphasis on STIs and its transmission to GBM who are on PrEP. Although the study had GBM as its sample, it was also the goal of the study that the findings will be used for any individual who is engaged in high risk sexual behaviors. In the end, the study findings should raise awareness, promote health and wellness, and prevention of HIV and other STIs through sex education.

**Conclusion.** Sexual behaviors by GBM determine their susceptibility to being infected with STIs, including HIV. The introduction of PrEP to non-HIV infected individuals give added protection to GBM from getting infected with STIs. The dynamics interplaying among factors such as sexual behaviors, PrEP, and STIs cannot be understated. The consistent themes found among the relevant studies, were probable increase in condom-less use, increase in unprotected sex, and increase in risky sexual behaviors. However, only two of the 12 studies addressed changes in sexual behaviors with the use of an educational intervention (Hilarie, 2015 and Liu et al., 2016).
There were only two studies that used sex education intervention, either risk reduction sessions or brief patient counseling, in addressing sexual behaviors (Hilarie, 2015 and Liu et al., 2016). However, findings in the two studies showed inconsistent result in terms of STI rates of the participants. The gap is evident on the need for a sex education component in addressing sexual behaviors of GBM who are on PrEP. Lack of information given to patients may lead to an increase in STIs while on PrEP. Addressing the research gap about sex education as an intervention is therefore important, necessary and may reduce the incidence of STIs.
Chapter III – Methods

This chapter describes how the research study was designed and implemented to explore the effects of PrEP education on the sexual behaviors and STI rate of GBM. It specifies the research design, project sponsors, human subjects review, study sample, data collection instruments and methods, and data analysis.

Design and Implementation Framework and Plan

The results of the critique and synthesis of literature showed an evident research gap in terms of existing study regarding educational intervention’s effect on the sexual behaviors and STI rates of GBM on PrEP. It was this existing research gap which led the investigator to conduct a research study to explore and generate new knowledge regarding GBM on PrEP. A mixed-method study involving one group, exploratory and quasi-experimental pre- and post-test research was deemed necessary to maximize the knowledge generated from this study. The study sample was selected using purposive methods.

The rationale for a mixed-method approach was based on the fact that PrEP is relatively new and maybe less understood which requires exploration through the qualitative approach (Polit & Beck, 2008). The qualitative data may also support and provide explanation of the quantitative data (Polit & Beck, 2008); in the case of this study, these would be results of the standardized instruments used.

Philosophical assumption. The study aimed at focusing on the research problem by utilizing all approaches in understanding the challenges of GBM on PrEP. Mixed-method approach was used in gathering data gaining more understanding of the problem. The researcher was also not focused on one system of philosophy. Instead, the researcher took assumptions
from both quantitative and qualitative approaches. This approach reflected the pragmatic worldview that guided the researcher in this study (Creswell, 2013). Although the study was not focused on one system of research philosophy, the study intervention was guided by Pender’s HPM which focused on three components: the individual’s characteristics and experiences, the behavior-specific cognitions affect, and behavior outcome-health promoting behavior (Pender, 2011).

**Strategies of inquiry.** The approach to undertaking the study utilized a concurrent mixed methods strategy of inquiry, focusing on sexual behaviors and STI rates before and after the intervention. In this method of inquiry, qualitative and quantitative data derived from the research tools were converged to yield a more comprehensive analysis of the research problem. Both qualitative and quantitative data were gathered concurrently, and results were integrated to generate a meaningful interpretation of study results (Creswell, 2013).

**Research methods.** The study involved two sessions. The first session included the pre-intervention survey, the intervention, and the post-intervention survey. The second session, which coincided with participant’s routine three-month follow-up appointment with their PrEP provider, comprised the follow-up survey.

**First session.** The first session of the study was conducted in March, 2017. It was during the first session that participants were screened for inclusion and exclusion criteria. Once the subjects qualified for inclusion in the study, the subjects were informed about the study, including the study’s risks and benefits. Participants were then asked to provide verbal informed consent to be included in the study. Once participants consented to participate, a demographic paper survey was administered. The selected participants who satisfied the inclusion and exclusion criteria, were then asked to complete the pre-intervention assessment. The researcher
then conducted the educational intervention, which involved the playing of the educational video to each participant in a research room. The post-educational intervention assessment took place immediately after the educational intervention. In addition to that, an informational brochure from CDC was given to participants after the interview. The total estimated length of time to complete the pre-educational intervention survey (the paper questionnaire) was approximately 10 minutes; the total amount of time to complete the post-interventional survey (the paper questionnaire and the semi-structured interview) was approximately 15 minutes.

Second session. The second session was conducted three months after the first session (June, 2017). The participants completed the follow-up paper survey and then proceeded with the individual semi-structured interview. In addition to the questions posed in the interview, the participants self-reported their STI status for the previous three months after the first session. The total amount of time to complete the follow-up assessment (the paper questionnaire and the semi-structured interview) was approximately 20-25 minutes.

Project Sponsors and Resources

The sponsor for the study, the research site, was a valuable partner in this undertaking. The researcher collaborated with the site on recruitment and selection of study participants. Moreover, the site allowed the use of a small room in which to conduct the intervention and interviews so that privacy of patients was protected. The use of a room was important, but this may have resulted in loss of space for use of the research site’s other activities regarding their operation—in other words, this might have been an opportunity cost for the research site, although they did not specifically report that this was the case. In terms of selection of subjects, the research site allowed the recruitment of participants from its enrolled patients in its CRUSH project.
There were important individuals who instrumental in the study’s success, and thus who were key human resources. First, the administrative director was pivotal in its role in approving the conduct of the study in their organization. Furthermore, the CRUSH project director was important since he handled the pool of PrEP enrollees (and prospective ones). The medical assistants at the research site were also valuable as they provided space for the researcher at the front desk to invite participants.

Other needed resources for the study were considered. The physical space or room used for the study subject, the good lighting, and a private room were provided during the study. Other resources used were: an audio recorder for the interview and a laptop for the sex education video. Moreover, gift cards as incentive for participants were given to study subjects after completing each session of the study. Other non-financial resources needed for the study included library use from Georgetown University, mentor’s inputs and guidance, and expert panels’ inputs. Importantly, fact that we did not use patient data from the research site or restriction contributed to the minimal resources required and facilitated a more protected study.

**Human Subjects Review**

**Institutional Review Board.** The sample of the study involved a vulnerable group, the GBM. Moreover, the study also used essential de-identified personal identifiable information of the subjects. The study presented no more than probable minimal risk to human subjects. The study was conducted only with approval of the GU IRB and the approval of the research site. The research site approved the GU IRB being the agency of record without going through the site’s IRB because the center restricted any use or sharing of its data.

**Informed consent.** The sample was obtained with an effective verbal informed consent and underwent a two-step process in the informed consent process. The first step was the
provision of essential information about the study. The participant was given the opportunity to ask questions about the study and his participation. The second step was the verbalization that stated the voluntary consent process took place. The consent was only an agreement by the participant to take part in the study and the participant may withdraw anytime from the study, or may refuse to answer questions any time during the study (Collaborative Institutional Training Initiative [CITI], 2016). The study used an approved consent form by GU’s IRB and with concurring approval of research site’s administrative director.

Privacy and confidentiality. Rigorous steps were taken to ensure the participant’s confidentiality and privacy. Participants were able to read a disclosure in the consent form regarding questions which were sensitive and may be intrusive, like sexual behaviors. Furthermore, the informed consent stated the need for essential personal identifiable information like ethnicity, age, and gender, but were de-identified. Also, self-reported STI status of participants was needed during study’s pre-intervention and follow-up session. Only required personal identifiable information was gathered from participants. The subjects were also informed of the written stipulation on the consent form of their option to skip answering questions if it made them uncomfortable. Moreover, the participants’ identities or their identification in participating in the study were de-identified to protect their privacy. In terms of communication with the participants, physical addresses were not used for correspondence.

In terms of protecting confidentiality, the subjects were informed that their identities were protected from being deduced from data. The personal identifiable information was assigned with pseudonyms chosen by the participants. Also, participants were informed that pseudonyms will be used when data will be utilized for presentations or publications. Moreover, the subjects were also informed through the verbal informed consent on the individuals who will
have strict access on the data. Upholding privacy and confidentiality is paramount in protecting human subjects.

**Promoting ethical practice.** The participants, during the consent process, were given information about potential risks and benefits of the study. The respect for autonomy was always observed by giving the subjects the authority to decide on matters concerning their inclusion and participation in the study. Specifically, their right to refuse answering questions which they found uncomfortable or intrusive were upheld. In addition, subjects were given the opportunity to withdraw at any time during the course of the study. The protection of subjects’ privacy and confidentiality, as well as the goal of reduced STI transmission and the practice of safe sex practices, were in line with the ethical principles of beneficence and non-maleficence.

The risks and benefits of participating in the study were stated on the verbal informed consent which included possible questions which may elicit sensitivity, distress, or embarrassment. It was emphasized that no personal identifiable information will be used, that subjects can withdraw any time during the study, that access to all data collected from interviews or questionnaires were limited to specific members of the study team, and that data collected were to be stored in a locked cabinet and computer encrypted.

**Population**

The study’s population of focus comprised adult GBM. The sample for the study were sourced from the research site’s PrEP project which comprised people who were taking PrEP.

**Setting and subjects.** The research site was selected because it enrolls GBM in its Oakland, California site in its PrEP program. The subjects for the study were recruited in March 2017; they were invited to participate in both the first session in March 2017 and the second session in June 2017.
**Inclusion and exclusion criteria.** The inclusion criteria for the study were GBM; age 18 years and older; qualified for PrEP regimen; writes, reads, and speaks English in 6th grade level; compliant with PrEP regimen (maximum of two missed doses per week in three months of PrEP use but with four consecutive days of intake). The guide on the number of missed dosing was based on Cell PrEP study showing 98% protection from HIV after four consecutive days of PrEP intake among non-HIV infected men (Seifert et al., 2014); and no current diagnosis of other STIs. The following are the exclusion criteria for the study: non-compliance with PrEP regimen at baseline and follow-up through self-report (three missed doses per week); visually-impaired or hearing-impaired; and unable to give verbal consent.

**Recruitment.** Recruitment was carried out through two methods: 1) distribution of an invitation flyer to prospective participants during PrEP registration at the front desk of research site in March, 2017; and 2) provision of a group talk to prospective study sample who was initiating on PrEP at the research site. Individuals who registered at the front desk for initiation of PrEP were informed by the researcher of the study. The prospective participants were then asked if they were interested in joining a group invitational talk by the researcher. Once the prospective participant agreed to do so, the time and assigned room was given to the prospective participants.

For the individual invitations, the researcher was given a working space at the front desk of the research site. Prospective participants registering at the front desk, either as a new or current PrEP patient, were introduced to the researcher. The participants were given the information flyer and a brief description of the study. As prospective participants agreed to participate, each individual was brought to the assigned research room. It was during this first session with the researcher that prospective participants were screened for inclusion and
exclusion criteria. Once the prospective participant qualified for inclusion in the study, the individual was informed about the study and its risks and benefits. Participants were then asked to provide verbal informed consent if they wanted to be included in the study. Once subjects consented to participate, a self-completed demographic survey was given to the subjects. The planned provision of group invitational talk to prospective participants did not take place due to lack of number of participants to be grouped for an invitational talk.

**Study sample.** A total of 25 GBM was initially targeted for recruitment during their scheduled visit for the PrEP program. The sample comprised eight GBM patients taking PrEP and initiating PrEP. The research was a pilot study and hence, no power analysis was conducted to consider effect size. The sample size is acceptable for purposes of a qualitative pilot study.

**Educational Intervention**

The sexual education intervention was in line with HPM’s three key components: (1) each individual is unique; (2) behavior-specific cognitions and affect; and (3) and behavioral outcome-health promoting behavior (Pender, 2011). There were two videos from CDC which were used in the study. The first video was a two-minute fifty-one seconds educational tool entitled: “PrEP – an HIV prevention option”, talks about PrEP and instructions to PrEP current or prospective patients (CDC, 2016). The video talked about basic information about PrEP, provided information about access to PrEP, and briefly discussed about self-assessment for prospective patients if PrEP was the right medication to use (CDC, 2016). The second video was a three-minute thirty-second sex education tool entitled, “What is it? Be Smart. Be Well” (CDC, 2017), talked about different STIs, what the different types are and how these are transmitted. The video discussed the most common STIs like gonorrhea, syphilis, and herpes, the common signs and symptoms of these common STIs, and susceptibility to HIV and other complications.
arising from non-treatment (CDC, 2017). The total duration of the two educational videos was approximately six minutes.

**Measurement Tools: Validity and Reliability**

The study included pre- and post-intervention tools designed to gather information on patient’s knowledge about STIs, sexual behavior cognitions, self-perceived risk and sexual behaviors, intent to practice safe sex, and past three months’ sexual behavior. These tools were administered in both sessions (March, 2017 and June, 2017) of the study. Also, the inclusion of an open-ended semi-structured interview was designed to gather, supplement, and explain information from the written questionnaire.

One of the tools developed and used for the study was the STI-PrEP knowledge questionnaire. The questionnaire comprised 15 questions about STI and PrEP. The content of the questions was extracted from the brief CDC educational videos used as intervention in the study. To ascertain the content validity of the questionnaire, a panel of five experts on HIV, STI, and PrEP reviewed and evaluated the questions. After review of the video and questions, the five panel of experts recommended on rewording of few questions, streamlining the language and choices used in the survey, and applying consistency with multiple choice-type of questions. One of the expert reviewers commented that from a content perspective, the questions were good (J. Rosselli, personal communication, December 7, 2016). Moreover, the questionnaire was found to be factually consistent with the educational videos (D. Flores, personal communication, December 7, 2016).

**STI and PrEP knowledge test.** The STI knowledge questionnaire was a new tool developed from the educational intervention. There exist validated questionnaire tools about STIs, but there was no available tool yet in addressing combined knowledge about STI and PrEP.
The questions sought to specifically measure knowledge of participants based on the content of the educational intervention. The questions were directly extracted from the videos so that no question or information sought was not provided by the educational video. The questionnaire had combination of PrEP and STI questions. There were 15 questions in Likert-like format (see Appendix C for STI-PrEP knowledge questionnaire). The questionnaire was reviewed by five panel of experts in terms of its content validity. Furthermore, the questionnaire will be piloted on this study’s sample. Specifically, the questionnaire was administered on the pre-intervention survey, post-intervention survey, and follow-up survey.

**Sexual Risk Cognitions Questionnaire (SRCQ).** This scale was used in the assessment of cognitive thought processes associated with condom use (Shah et al., 1997). The tool, developed by Shah et al. (1997) was initially used in London with 343 homosexual adults sample in an RCT. The reliability of the SRCQ was a Cronbach alpha (SCRQ-22) – 0.91 (Shah et al., 1997). The questionnaire consisted of 22 core items (SRCQ-22) with six subsections. There were subsections in the questionnaire, with each subsection comprising 8-13 question items.

The basis of the validity of SRCQ was the relationship of the constructs with self-reported sexual behavior among MSM who comprised 70% of the study’s sample (Shah et al., 1997). The subsequent result showed the reliability of SCRQ-22 in the assessment of cognitions related to HIV risk sexual behaviors in the sample population. The SCRQ tool’s result in the study indicated its reliability in measuring sexual behaviors as important determinants of safe and unsafe behavior. The study used a subset of the tool comprising of 12 Likert-like questions with a range of five to 60. The higher the score of a participant, the higher is the propensity to engage in HIV risky sexual behaviors. The SRCQ was administered on the pre-intervention survey and follow-up survey. The results of the SRCQ were intended to demonstrate possible
change in cognition in relation to HIV risk sexual behaviors and condom use by the participants. The researcher was granted permission for the use of SRCQ tool by the publisher.

**STI self-report.** All PrEP patients were tested for STI on their three-month follow-up based on CDC guidelines (CDC, 2014). The participants self-reported their STI history for the past three months prior to inclusion in the study and three months post-intervention. The STI result of the study sample was one of the outcome measures of the study.

**Semi-structured, open-ended interview.** The semi-structured post-educational intervention interview had eight open-ended questions (see Appendix D for post-educational intervention interview questions):

1) What motivated you to start PrEP;
2) What do you believe will encourage you to continue to take PrEP;
3) Do you believe that you have enough information about PrEP to know what are sexually healthy practices while you are using PrEP? If not, what more information would you need;
4) After learning information about PrEP and STIs, how do you intend to sexually behave;
5) Please tell me what you believe are the factors that impact on your engagement in sexual behavior.;
6) What will motivate you to engage in sexually healthy behavior; that is, to engage in protected sexual activities;
7) Please tell me about how you believe that you will engage in healthy sexual behavior now that you will be on PrEP.; and
8) What else would you like to tell me about how you feel about being on PrEP or starting PrEP?

During the follow-up session interview, participants were asked with five open-ended questions (see Appendix E for follow-up session interview questions):

1) What is the effect of the educational videos you watched during the first session on your sexual behavior;

2) Can you describe your sexual behavior for the past three months;

3) What motivates you to remain or change your sexual behavior;

4) What is your view on PrEP in preventing other STDs; and

5) In your view, what will urge you to practice unsafe sex behaviors in the future?

The interview questions were designed to elicit information about PrEP motivation, reason for starting PrEP, current sexual behavior, and effect of education intervention on the participants. The questions were important components of the qualitative aspect of the study because of the themes which were generated from the study sample’s lived experiences.
**Outcome Measurements and Data Analysis Plan**

**Outcome measurements.** The socio-demographic characteristics were measured in terms of descriptive statistics. The statistics included mean scores and standard deviations, frequencies, and percentages for demographic variables. The data were then presented in a table format to show demographic characteristics and differences among the sample from the study.

The STI-PrEP knowledge questionnaire, which measured STI and PrEP knowledge of the participants was measured pre-intervention and post-intervention during the first session, and was also measured during the follow-up session. Non-parametric tests and descriptive statistics were used to identify any changes in score and to show any significant change in scores with one group taking the same test during pre-intervention, post-intervention, and follow-up session, if there be any. The results of the STI-PrEP knowledge questionnaire were intended to achieve one
of the research study’s aim: to demonstrate knowledge improvement of STI and PrEP through educational intervention. Another test, the SRCQ, used descriptive statistics and non-parametric test for the 12-item subset questions conducted during pre-intervention and during follow-up session. The result of the SRCQ was one of the research study’s aim: to demonstrate change in thought processes of participants in relation to condom use and engagement in HIV risk sexual practices.

The open-ended question interview was aimed at generating qualitative data and creating themes. The interview was digitally recorded and transcribed verbatim. Transcripts were checked for accuracy and was uploaded in Dedoose, a web-based application used in integrating, managing, and analyzing qualitative and mixed methods data (Dedoose, 2017). The researcher used a hierarchical thematic analysis approach in identifying themes from the transcript (Braun and Clark, 2006; Strauss & Corbin, 1998). Key text and their definitions were extracted from the interview guide and multiple reading of transcripts. Exemplar text were identified by the researcher and another expert from the study team. The PI was the coder of interviews. The codes were then entered into the Dedoose, together with associated text segments. The text segments were then sorted to general categories, where emerging global themes, organizing themes, and basic themes were identified. Descriptive statistics were used for the overall sample.

The STI status of the participants was gathered through self-report. STI history for previous three months prior to the study, and subsequent three months after intervention were reported by participants. Descriptive statistics were used to describe percentage of participants who have had history of STI and compared it to sample’s STI status post-intervention. The demonstration of possible change of STI rate post-intervention was one of the study’s aims.
**Data management.** The data gathered from the questions and interviews were highly confidential. The subjects did not use real names but instead used a chosen pseudonym of their own. The pseudonym was assigned a number code which was used in data processing. The data are always confidential, not anonymous. The pieces of information are very delicate as it also included some de-identified (pseudonym used) information. To protect the participant’s privacy, confidentiality, and integrity, the use of de-identified information through pseudonyms and codes were explained to participants. The data collected was placed in a locked briefcase, in a locked cabinet, and encrypted computer. Only the researcher had access to the data. Moreover, the PI, who was the encoder of the interviews only had access to the recorded interview and were individually labeled with their pseudonyms.
Chapter IV - Evaluation and Results

The effectiveness of the study’s intervention is measured by the findings from the study’s data collection and analysis. The purpose of this chapter of the study is to present analysis of the data utilizing appropriate statistical techniques where appropriate to provide information on the strengths and weaknesses of the intervention in relation to the research study’s aims. The analysis of results allows for meaningful interpretations, and subsequently an impetus for recommendations for future study.

Analysis of Data

Statistical Package for the Social Science (SPSS) version 24.0 was used for this study (Statistical Package for the Social Science [SPSS], 2017). Socio-demographic characteristics were described using univariate, descriptive statistics. Continuous variables such as age, STI-PrEP scores, and SRCQ scores used means, medians, and standard deviations to describe the data. Additionally, non-parametric tests were used in further describing the SRCQ and STI-PrEP data. Nominal variables such as ethnicity, sexual orientation, relationship status, education, and PrEP status used percentages to describe the data.

Demographic information was gathered during the pre-intervention phase from the purposive sample of GBM who showed interest during the recruitment phase. There were no demographic data gathered during follow-up phase since participants in the follow-up phase took part in the pre-post-intervention phase. The socio-demographic data included age, ethnicity, relationship status, educational level, and sexual orientation.

A summary of the socio-demographic characteristics of the participants for the study is displayed on Table 1. There was a total of eight participants for the pre-post-intervention phase.
From these number of participants, four (50%) participants completed the follow-up phase of the study. The mean age of participants in pre-post-intervention was 25.25 years ($SD = 3.45$, median = 26.50, range = 20-29), whereas the mean age of participants in the follow-up phase was 25 years ($SD = 2.51$, median 27, range 20-29) at the time of pre-post-intervention. Among the eight participants in pre-post-intervention phase, seven (87.5%) were on PrEP, and one (12.5%) was about to start PrEP at the time of pre-post-intervention phase of the study.

The majority (seven, or 87.5%) of the participants in the pre-post-intervention phase belonged to ethnic minorities: five (37.5%) African-American, one (12.5%) Asian, one (12.5%) Hispanic Latino, Mixed (African-American-Hispanic/Latino) (25.0%) and one (12.5%) White. Seven (87.5%) of the participants identified as homosexual and one (12.5%) identified as bisexual. Five (62.5%) of the participants had some college education, two (25%) finished college education, and one (12.5%) finished high school. In terms of relationship status, seven (87.5%) of the participants were single, and one (12.5%) was in a committed relationship at the time of the pre-post-intervention phase. Among the participants who proceeded with the follow-up phase, three months after the pre-post-intervention phase, two (50%) were Mixed (African-American-Hispanic/Latino), one (25%) was Asian, and one (25%) was African-American of ethnicity.

Although the sample taken from the population of GBM who were taking or starting PrEP was small (n = 8), it was sufficient for this pilot study, although it does not allow for generalization of findings. It is not appropriate to conduct power analysis in a pilot of this type.
Table 1

Socio-Demographic Characteristics of Sample

<table>
<thead>
<tr>
<th>Categories</th>
<th>Pre-Post Intervention Phase</th>
<th>Follow-Up Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=8</td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>3</td>
<td>37.5</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>Hispanic Latino</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>White</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>Mixed (African-American &amp; Hispanic/Latino)</td>
<td>2</td>
<td>25.0</td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bisexual</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>Homosexual</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>Relationship Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>In a relationship</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>College Graduate</td>
<td>2</td>
<td>25.0</td>
</tr>
<tr>
<td>Some College</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>High School Graduate</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>PrEP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently taking</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>Starting</td>
<td>1</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Sexually-Transmitted Infections-PrEP Knowledge Questionnaire

The STI-PrEP questionnaire consists of 15 multiple choice questions administered to participants during pre-intervention, post-intervention, and follow-up phase. The questions were derived from the two, brief educational videos from CDC, and was content validated by five subject experts. The range of scores of the eight participants (n = 8) in the pre-intervention was nine to 14, whereas during post-intervention, range was improved from 12 to 15. There was an
immediate improvement in the scores post-intervention, with five out of eight (62.5%) participants achieving 100% scores compared to baseline. During the follow-up phase, the range of scores for the four participants (n = 4) was 14 to 15. Table 2 shows the individual scores of the participants in the pre-intervention, post-intervention, and follow-up phase.

Table 2

STI-PrEP Knowledge Questionnaire Scores

<table>
<thead>
<tr>
<th>Participant</th>
<th>Pre-Intervention</th>
<th>Post-Intervention</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>12</td>
<td>15</td>
<td>DNF*</td>
</tr>
<tr>
<td>02</td>
<td>11</td>
<td>12</td>
<td>DNF</td>
</tr>
<tr>
<td>03</td>
<td>13</td>
<td>13</td>
<td>DNF</td>
</tr>
<tr>
<td>04</td>
<td>9</td>
<td>15</td>
<td>DNF</td>
</tr>
<tr>
<td>05</td>
<td>13</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>06</td>
<td>14</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>07</td>
<td>14</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>08</td>
<td>13</td>
<td>14</td>
<td>14</td>
</tr>
</tbody>
</table>

Note: The highest possible score for the questionnaire is 15
DNF* = did not follow-up

Based on the small sample size on follow-up phase (n = 4), non-parametric tests were used. Friedman test was used to compare the STI-PrEP questionnaire scores at pre-intervention, post-intervention, and follow-up phase. The scores of four participants showed significant difference between pre-intervention (Median = 13.50), post-intervention (Median = 15.00), and follow-up phase (Median = 14.50), Friedman $X^2(2) = 7.54, p = .023$. The analysis used an alpha of 0.05 as cut-off for statistical significance.

One of the research study’s aim was to show how an STI-PrEP educational intervention improves the knowledge of PrEP users immediately post-intervention and at three-month follow-
The mean score of participants during the post-intervention (n = 8) showed a 15.11% immediate improvement in mean scores from pre-intervention (12.38 = pre-intervention, 14.25 = post-intervention). The CDC educational intervention appears to have improved the knowledge of four participants at post-intervention, and maintained at follow-up (13.50 = pre-intervention, 14.75 = post-intervention, and 14.50 = follow-up). Table 3 shows the STI-PrEP analysis for the pre-intervention, post-intervention, and follow-up phase.

Table 3

STI-PrEP Knowledge Questionnaire Score Analysis

<table>
<thead>
<tr>
<th>STI-PrEP Questionnaire</th>
<th>M</th>
<th>SD</th>
<th>Median</th>
<th>X^2(2), p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention (n = 8)</td>
<td>12.38</td>
<td>1.69</td>
<td>13.00</td>
<td></td>
</tr>
<tr>
<td>Post-Intervention (n = 8)</td>
<td>14.25</td>
<td>1.67</td>
<td>15.00</td>
<td></td>
</tr>
<tr>
<td>Pre-Intervention who went for Follow-up (n = 4)</td>
<td>13.50</td>
<td>0.58</td>
<td>13.50</td>
<td></td>
</tr>
<tr>
<td>Post-Intervention who went for Follow-up (n = 4)</td>
<td>14.75</td>
<td>0.50</td>
<td>15.00</td>
<td></td>
</tr>
<tr>
<td>Follow-up (n = 4)</td>
<td>14.50</td>
<td>0.58</td>
<td>14.50</td>
<td>7.54, p = .023</td>
</tr>
</tbody>
</table>

Sexual Risk Cognition Questionnaire (SRCQ)

The SRCQ used in this study was a 12-item Likert-like type of questionnaire subset of the SRCQ. The SRCQ assessed the frequency of thought process of participants associated with condom use and HIV risk sexual behavior. SRCQ also measured sexual behaviors as determinant of unsafe sexual behaviors (Shah et al., 1997). The participants choose among the following Likert-like options: (1) Never have thought; (2) Very occasionally had thought; (3) Occasionally had thought; (4) Frequently had thought; and (5) Very frequently had thought. The
maximum score for the SRCQ subset questionnaire is 60. The reliability of this tool, based on eight participants, has a Cronbach alpha = .76. This value indicates adequate reliability of SRCQ (alpha of >.75 is considered adequate).

The SRCQ was administered on pre-intervention and on follow-up. Comparing SRCQ scores between pre-intervention and follow-up, Wilcoxon Signed Ranks test was used. The SRCQ scores showed no significant change in cognition from pre-intervention (Median = 19.5) to follow-up (Median = 20.5), Wilcoxon Z = -.378, p = .705. Since there were only four participants at follow-up, caution is advised in generalizing results.

An aim of the research study is to measure changes of cognition associated with condom use and unsafe sexual behaviors. The SRCQ is the tool which elicited this measure in the study. The possible range of score is from five to 60. The higher the score each participant obtains, the higher is the participant’s propensity to engage in unsafe sexual behavior. The result from the SRCQ is compared with self-reported sexual behaviors and self-reported STI status on follow-up. Table 4 shows the SRCQ analysis from pre-intervention phase to follow-up phase.

### Table 4

**SRCQ Analysis**

<table>
<thead>
<tr>
<th>SRCQ</th>
<th>M</th>
<th>SD</th>
<th>Median</th>
<th>Z, p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention (n = 8)</td>
<td>21.0</td>
<td>5.60</td>
<td>20.50</td>
<td></td>
</tr>
<tr>
<td>Pre-Intervention for those with</td>
<td>20.0</td>
<td>5.70</td>
<td>19.50</td>
<td></td>
</tr>
<tr>
<td>Follow-up (n = 4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up (n = 4)</td>
<td>20.50</td>
<td>3.11</td>
<td>20.50</td>
<td>-.378, p = .705</td>
</tr>
</tbody>
</table>


Sexually-Transmitted Infections (STI) Self-Report

Information regarding three-month STI history of participants prior to the pre-post-intervention, and at three-month follow-up were gathered through participant’s self-report. One of the aims of the study was to measure self-reported STI status of participants at follow-up. The STI rates at pre-intervention and at follow-up were analyzed with reported sexual behavior, PrEP perception, and effect of PrEP education on sexual behaviors.

Among the eight participants in the pre-post-intervention phase, five (62.5%) reported having been diagnosed and treated with STI other than HIV. Four from these five participants who have STI history in the past three months proceeded with the follow-up session. Among the four participants in the follow-up phase, three (75%) were diagnosed with an STI for the three months preceding the follow-up phase, after the pre-post-intervention. The data showed a 25% decrease in incidence of STI among the follow-up participants after the pre-post-intervention in the study. A summary of the STI historical data of participants on pre-post-intervention and follow-up phase is shown in Table 5.

Table 5

*STI Self-Report*

<table>
<thead>
<tr>
<th>Categories</th>
<th>Pre-Post Intervention Phase</th>
<th>Follow-Up Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=8</td>
<td>%</td>
</tr>
<tr>
<td><strong>STD History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Intervention (n = 8)</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>Post-Intervention (n = 8)</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>Pre-Intervention for those with Follow-Up (n = 4)</td>
<td>4</td>
<td>100.0</td>
</tr>
<tr>
<td>Post-Intervention for those with Follow-Up (n = 4)</td>
<td>4</td>
<td>100.0</td>
</tr>
<tr>
<td>Follow-Up (n = 4)*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: * = The follow-up data are STI diagnoses for the past three months after the pre-post-intervention
**Semi-Structured Interview**

The interview of participants comprised eight open-ended questions during post-intervention, and five open-ended questions during the follow-up phase. The questions were intended to elicit personal views and experiences about: (1) motivations in taking PrEP; (2) adequacy of information about PrEP and STIs; (3) factors affecting sexual behaviors; (4) sexual beliefs and intentions; (5) effect of PrEP intervention on their sexual behaviors; and (6) perceptions about PrEP after intervention.

The qualitative data were thematically analyzed utilizing the hierarchical method. The results of analysis were ultimately categorized into global themes, organizing themes, and basic themes. The answers gathered from the participants during the interview intend to elicit meaning from participants’ experiences and beliefs post-intervention and during follow-up. The participants’ insights about PrEP, STI, and sexual behaviors intend to provide understanding into personal beliefs and experiences of gay and bisexual men on PrEP. Figure 2 shows identified global themes, and organizing themes from the interview.
Figure 2. Themes from Open-ended Questions

**PrEP in the eyes of patients.** PrEP was being taken or was to be taken by the participants during the pre- and post-intervention phase. Key themes which were drawn from the interview were motivations in taking PrEP and personal perception about PrEP. In both post-intervention and follow-up phase, the effect of PrEP education to participants was a key theme.

**PrEP intake motivators.** The majority of the participants (five out of eight) during the pre-and post-intervention phase expressed sexual benefits of PrEP, PrEP’s efficacy, and self-care
improvement as primary motivators for taking PrEP. Additionally, fear of HIV and the presence of resources, information and access to PrEP were reasons for starting and continuing PrEP.

**Sexual benefits.** Five out of eight participants in the pre-post-intervention phase mentioned sexual benefits as one of the main motivators for starting or remaining on PrEP. One participant stated: “What motivated to start PrEP was uhm the fact that I could have barrier-free sex, without barriers, natural condomless sex” (Participant 1, personal communication, March 17, 2017). The five participants stated of desire not using condoms for sex and believed that PrEP provides reassurance of not contracting HIV even with barrier-free sex. As one participant stated: “…now there may be times that I don’t use condoms so you know that reassurance…” (Participant 2, personal communication, March 20, 2017).

**PrEP’s efficacy.** The participants mentioned PrEP’s being approved by FDA, indicating that it reduces the risk of HIV transmission. HIV prevention is one key aspect of PrEP which motivates the participants to continue taking the drug. Having knowledge about PrEP’s effect on the body, one participant stated, “I think that benefit outweighs the risk of liver damage, uhm, considering it has been in trials and has been approved by the FDA for a long time” (Participant 3, personal communication, March 20, 2017).

**Fear of HIV.** One of motivator of taking PrEP was the fear of HIV infection in three out of eight of participants. One individual explained his fear: “I uhm am very fearful of HIV, I think it is really really terrible to have it. I know that there are drugs nowadays to manage HIV and people can be undetectable but that is something I just don’t want to worry about…” (Participant 3, personal communication, March 20, 2017). Participants addressed their fear by taking PrEP, a drug which is marketed with effectiveness in preventing HIV transmission.
Self-care. The majority of the participants (five out of eight) expressed self-care as one of the primary reasons for taking PrEP. Three of eight participants believe that PrEP gives an individual good state of mind, and consequently, makes the participants have better sexual decisions. One participant explained: “The fact that I know I am going to be okay or better than okay and that its gonna be fine’ (Participant 4, personal communication, March 23, 2017). With PrEP preventing HIV transmission, an individual remains sexually healthy in that aspect and therefore able to continue an active life. Being HIV-free, PrEP continues to give majority of the participants (five out of eight) a feeling of security. One participant talked about self-care as PrEP motivator: “…I just wanted to take care of myself and have a responsibility of taking care of myself’ (Participant 4, personal communication, March 23, 2017).

Availability and access to PrEP. The availability and access to PrEP resources were considerations for two out of eight participants: “…For me personally the easy access that I have to it, uhm the resources that are available to me within my community to keep this successful” (Participant 1, personal communication, March 17, 2017). Affordability was one factor in access to PrEP, based on the response of one participant.

Perception about PrEP. Decisions of participants in starting or continuing PrEP were based on how PrEP was perceived. There were four basic themes generated from post-intervention and follow-up interviews: (1) the role of PrEP in disease prevention; (2) PrEP rationalizing sexual decisions; (3) PrEP creates public stigma on its users; (4) PrEP affects mental and emotional health; and (5) PrEP as an innovation. Among these themes, the impact of PrEP on emotional and mental well-being was mentioned by all participants in the pre-post-intervention phase. Furthermore, the perception of PrEP’s role in disease prevention was shared by six out of eight participants.
Role of PrEP in disease prevention. One participant during the post-intervention interview noted the essence of ongoing studies about providing PrEP education. “I guess the purpose of studies is like education on PrEP” (Participant 5, personal communication, March 21, 2017). During the follow-up phase, one basic theme which all participants (4) viewed PrEP was as a drug not preventing STIs other than HIV. One participant stated how PrEP works and PrEP’s limitation: “The role of PrEP is to guard against HIV transmission. It provides, when taken regularly, provides like 96% protection against the virus and I know that it does not protect against gonorrhea, chlamydia, herpes” (Participant 1, personal communication, June 16, 2017).

PrEP rationalizes sexual decisions. Given the knowledge of the basic use and limitations of PrEP, half of the participants shared views that PrEP rationalizes sexual decisions. One participant explained his view about increasing STI rates and correlating it with intake of PrEP during post-intervention interview:

“… Like people on PrEP like incur like STDs at a higher rate because they are having more barrier-free sex or natural sex. And I think that is part of it. Like of course, because they were never able to have this type of sex before or for free of like oh if i’m gonna catch this thing, that is a death sentence. I don’t know where this is going but ah like in the political scheme like I know there were some resistance to having PrEP and Truvada because “oh it will just gonna spread gonorrhea and chlamydia more” and I think that is part of like the learning curve like for culture… like speaking numbers-wise, numbers are gonna go up and I think that is natural but it’s not a negative, that’s all” (Participant 1, personal communication, March 17, 2017).

During the follow-up interview, increased risk-taking was verbalize by one participant: “Well, PrEP prevents HIV but not other STDs, I don’t really correlate. I think I am willing to take more of a risk that I’ll get STI but I think it depends on the moment who I am with and how
I feel” (Participant 2., personal communication, June 12, 2017). Contrasting increased risk-taking was one view held by one participant about PrEP promoting safe sex: “It only helps with HIV what is why I use condoms” (Participant 5, personal communication, June 15, 2017).

**PrEP creates public stigma.** One theme which arose from participants in both interview sessions was the concern about public stigma which PrEP creates: “It’s like there is an interesting stigma in the community that people who are on PrEP, like there is an association on people who are on PrEP being sluts. That is the current perception” (Participant 5, personal communication, March 21, 2017).

**PrEP is good for mental and emotional health.** There is a favorable perception on PrEP’s effects on participants’ mental and emotional health. The benefits spanned from feeling good about oneself while taking PrEP and consequently, enabled the PrEP user to make better decisions, gave more peace of mind, and made one feel more at ease. As one participant acknowledged the positive benefits of PrEP on his mental and emotional well-being:

“It just makes me feel safer and secure and by the sexual decision I make…my mental health is a big factor. Yeah because when I feel good about myself then I will have like healthier practices and when I don’t feel good about myself, you know I’m gonna like be able to be reckless” (Participant 6, personal communication, March 16, 2017).

**PrEP as an innovation.** As PrEP is a relatively new drug and prevents HIV transmission, three out of eight participants viewed PrEP as an innovation. Participants talked about the change in HIV survival comparing it during the 1980’s when HIV diagnosis was a death sentence. As one participant stated:

“PrEP I think is one of the most like greatest ideas or greatest creation that somebody can come up with… there’s a lot of things that people won’t tell people because probably of how
they feel if they will pass it that they are positive or something like that” (Participant 4, personal communication, March 23, 2017).

**Effect of PrEP education.** The participants’ views on how the PrEP education intervention affected their sexual decisions and behaviors was one theme extracted from the interviews. The question about effect of PrEP education was asked during post-intervention and follow-up phase. PrEP education has affected the participants in both knowledge and sexual behavior decisions they made.

*PrEP education improves knowledge.* Six out of eight participants in the post-intervention interview believed in having improved knowledge after the PrEP-STI educational videos. With adequacy of information, participants also added the need for PrEP testing and the need for discussion with partner about sexual history and status before making any sexual decisions. Furthermore, one participant emphasized what he learned from the educational video: “…HIV is easier to be transmitted if you have another STI. I have heard about that before but it is not something I normally think about” (Participant 3, personal communication, March 20, 2017).

*PrEP education affects sexual decisions.* One benefit from PrEP education was how it affected sexual behavior decisions of the participants. During the follow-up interview, two out of four participants emphasized the importance of information in making decisions: “…It kinda served as a reminder…armed with that information so I can make informed decisions” (Participant 1, personal communication, June 16, 2017). While PrEP education served to facilitate informed decisions, two of the four participants reported having no change in sexual behavior, with one participant stated: “A little bit more cautious in terms of how I engage with
people quickly and sexually… I have been taking PrEP every single day” (Participant 2, personal communication, June 12, 2017).

**Sexual being of PrEP patients.** The second major theme from participants’ interviews elicited the sexual being of PrEP patients. From this theme, sexual and behavioral intentions, safe sex and unsafe sex motivators, factors affecting sexual behaviors, and current sexual behaviors drawn as key messages. The sexual facet of an individual on PrEP is very important as it can provide information on what sexually motivates PrEP patients and how these motivators affect sexual behaviors.

**Sexual behavior intentions.** During the post-intervention interview -- after participants were given education about PrEP and STIs -- participants shared their intentions regarding sexual behavior.

*Likely sexual decision when taking PrEP.* The most likely sexual decisions which PrEP participants will make were split between intention to engage in safer sex and the intention not to change current sexual practice or behavior (four out of eight participants in each option). Illustrating this, one participant stated: “…be safe and be careful while you are having sex. Keep using condoms even if you are on PrEP” (Participant 7, personal communication, March 20, 2017). The participants who expressed of not changing their sexual behaviors did not mean engaging in unsafe sex.

*Personal benefits and limitations from PrEP.* As one participant narrated: “I like to protect myself … I feel like my sexual behavior is the same but I’m on PrEP now so that will be the only difference about that like having added protection. I know PrEP doesn’t help in preventing other STDs” (Participant 4, personal communication, March 23, 2017). The statement of Darrell recognized the limitations which PrEP offers.
Essence of communicating with partners. Some participants acknowledged the essence of communicating with partners and the mental benefits participants get from PrEP: “…not because I am on PrEP that I am invincible, I think it does make me a little bit more confident in getting some thing” (Participant 2, personal communication, March 20, 2017).

Safe sex motivators. It is important to know what drives or influences the PrEP participants in engaging in safe sex. The motivators provide an understanding of the reasons that PrEP patients engage in different sexual behaviors.

Public and personal issues about HIV and other STIs. Notably, public and personal issues about HIV and STI was a major factor (six out of eight participants) in engaging in safe sex. As one participant shared: “There is no PrEP for herpes” (Participant 3, personal communication, March 20, 2017). The statement also acknowledged PrEP’s limitations in the spread of STIs and sharing the information to friends are sufficient motivator to practice safe sex. Other public issues driving participants into safe sex are the ongoing antibiotic resistance to gonorrhea and high incidence rates of STIs. In terms of personal issue, one’s experience with an STI provided a lesson on unsafe sex practices to a participant.

Caring about oneself and for others. One basic theme elicited from the interview about safe sex motivator was caring about oneself and for others. Three out of eight participants stated the importance of taking care of oneself and others. As one participant narrated: “…the engagement I would say, just to see this generation now to care enough about myself, and about the people around myself” (Participant 7, personal communication, March 20, 2017). Another type of motivator for safe sex is recognizing preference of one’s partner: “If a guy prefers that I use condoms, I will use condom” (Participant 8, personal communication, March 23, 2017).
**Unsafe sex motivators.** What drives unsafe sex practices is crucial information in understanding actual sexual behaviors and STI rates of gay and bisexual men. External factors and personal circumstances were key themes generated from the theme.

*External factors motivate unsafe sex.* Breakthroughs in medicine was stated to be an influence in engaging in unprotected sex. One participant stated: “More breakthroughs in medicine, if they come up with something to like prevent chlamydia, gonorrhea, that would be fantastic” (Participant 1, personal communication, June 16, 2017).

*Personal factors motivate unsafe sex practice.* Personal factors like attraction, libido, personal sex preference, and relationship status were personal issues identified by participants which promote unsafe sex practice. As one participant explained: “Being in a relationship will motivate me to engage in unprotected sex, committed. Or when the guy is extremely hot that I will never get a chance with him again” (Participant 2, personal communication, June 12, 2017).

*Factors affecting sexual behaviors.* Certain triggers influenced change in sexual behaviors of the participants like current STI research, personal preference, self-care issue, PrEP protection, and adequacy of PrEP and STI information. Moreover, easy access to PrEP facilitates change in behavior and encourages regular testing with providers. In terms of environment as an influence, education which PrEP users get from studies or from groups influence behaviors. One participant shared the effect of accessibility in three ways: “Access to sexual partners, that I want to have sex with, access to condoms which I believe I always have which is great. Access to PrEP” (Participant 3, personal communication, March 20, 2017).

*Current sexual behaviors.* After participants were exposed to an educational behavior, current sexual behaviors were elicited during the follow-up interview. The current sexual behavior is important as it may denote change from previous sexual behavior or remained in
their previous sex practices. Half of the participants (two out of four) reported having multiple sex partners with unprotected sex. The other half of participants practiced safe sex and specified condom use. One participant expressed: “…the past month I’ve gone like on a rampage, with multiple partners. They have been unprotected, orally and anally” (Greg, personal communication, June 16, 2017). This contrasts with another participant’s comment on safe sex practice: “…just more cautious in terms of how I am having sex protected or unprotected. I have used condoms more compared to before I got information from this study” (Participant 2, personal communication, June 12, 2017).

The themes generated from the interview highlighted factors motivating intake of PrEP: improving self-care, fear, and sexual benefits. Moreover, PrEP education improved knowledge and affected sexual decisions. The participants’ perception about PrEP highlighted how PrEP’s role in preventing disease, how public stigma is perceived by PrEP users, and how PrEP becomes a justification for their sexual decisions, were viewed by PrEP users. The themes also revealed what motivated PrEP users in engaging into safe or unsafe sex, how PrEP education shaped their sexual intentions, and how different factors affect sexual behaviors.

Summary of Findings and Outcomes

The use of a video of PrEP-STI education among PrEP users showed improvement in knowledge from baseline based on significant change in scores among participants in both pre-post-intervention measurement and in participants who followed-up. The use of non-parametric test in analyzing the three sets of PrEP-STI scores of participants who followed-up was able to demonstrate the significant change in test performance of basic PrEP and STI concepts. The SRCQ median scores, however, did not show any significant change among participants from post-intervention to follow-up based on the non-parametric test used. The SRCQ result
demonstrated no change of thought process related to condom use and HIV sexual risk behaviors. However, based on self-reported STI status, there was a decrease in STI rate for PrEP users who followed-up.

The two broad themes generated from the semi-structured interview were general PrEP perception and sexual behavior. In terms of PrEP, the participants expressed reasons for getting motivated in taking PrEP, and verbalized PrEP education’s effect on their knowledge and sexual decisions. Furthermore, PrEP was perceived as a means of preventing disease, an avenue of public stigma on users, and a basis for sexual decisions. After education about PrEP, participants were identified to have varied safe sex and unsafe sex motivators, sexual behavior intentions, triggers in sexual behaviors, and current sexual behaviors.

**Conclusion.** The results of data collection and analysis has yielded an understanding of the effect of PrEP and STI education among participants who were on PrEP. Statistical analyses of data had shown statistically significant improvement of knowledge about PrEP and STI. The significance was supported by the thematic analysis which generated interview themes from the open-ended questions. While there was no significant change in cognition about condom use and HIV sexual behavior, thematic analysis had shown perceptual and actual changes in participants’ sexual behaviors, as well as reduction in STI incidence during follow-up. The final chapter of the study will discuss the importance of the study, the limitations of the study, and the implication for practice, research, and policy, and the directions for future studies.
Chapter V - Discussion and Conclusions

Discussion of Findings

In this study, research was conducted on current and commencing PrEP users among GBM, ages 18 and older, recruited from an HIV and PrEP center in Oakland, California. The aim was to investigate the effect of PrEP education on the sexual behaviors and STI rates of gay and bisexual men. STI-PrEP scores, SRCQ scores, and self-reported STI status were analyzed together with themes identified from open-ended questions included in a semi-structured interview.

Application of Health Promotion Model. The first component of HPM, individual characteristics and experiences, were data gathered about socio-demographic profile of participants, and most specifically, their sexual practices, their PrEP and STI knowledge, and STI status prior to the educational intervention. At baseline, knowledge about PrEP and STI was relatively lower than post-intervention (Mean = 12.38 for eight participants and 13.50 for four participants who followed up). For STI status, all of the four participants who followed-up had 100% STI history for three months prior to intervention.

The PrEP-STI education was a tool in stimulating self-assessment of current knowledge and current sexual behaviors of the participants. There was a significant change in PrEP and STI knowledge scores from baseline and maintained at follow-up ($X^2(2) = 7.54, p = .023$). Furthermore, the lessons learned from the educational videos elicited participants’ ability to perceive benefits of PrEP and safe sex.

In terms of behavior-specific cognitions and affect, the post-intervention interview further elicited perceived benefits of PrEP as means for disease prevention, and as a means of
facilitating informed decisions, caution, and PrEP compliance (four out of eight participants). Although SRCQ scores did not significantly change from pre-intervention to follow-up ($Z = -0.378, p = .705$), mean scores from pre-intervention to follow-up were low ($20 = $pre-intervention, $20.5 = $follow-up) indicating low propensity of thought process in engaging into HIV sexual behaviors. There was consistency in perceived self-efficacy in engaging in a safer sex behavior. Extracting from the interviews, the majority of the participants (six out of eight) expressed the impact of emotional and mental status in sexual decisions. In terms of sexual intentions and behaviors, participants have identified intrapersonal (adequacy of information and caring for self) and external factors (public stigma, high incidence of STI, antibiotic resistance, STI research, and PrEP limitations) in motivating them in certain sexual behavior. The last component of HPM, behavioral outcome-health promoting behavior, the self-reported STI status of four participants have shown a 25% decrease in STI incidence from baseline. Moreover, two out of four (50%) participants during follow-up have been practicing caution and using condoms more frequently which indicated improved practice of health-promoting behavior.

**Strengths and Limitations**

The result of this research study should be interpreted within its identified strengths and limitations. First, the research is a pilot study conducted in just one research site and with a small sample size. The research site has a total of 380 enrolled PrEP users in its program, which was a study that started in 2013 and culminated its study in March, 2017. A total of 25 enrolled PrEP users were scheduled at the research site during pre- and post-intervention date. Only eight invitees from the PrEP users expressed intent to participate in this study. Moreover, the convenience sampling and selection bias limited the ability to generalize results. Second, the target population was strictly among individuals who identified themselves as GBM and did not
include everyone who qualifies for PrEP, per CDC guideline. PrEP was introduced to the market to target individuals at high risk for HIV, which includes any individual who has relationship with an HIV-positive person, any individual who is not in a monogamous relationship, heterosexual persons who engage in unprotected sex with individuals of unknown HIV status with high risk for HIV infection, and individuals who use injected drugs and have shared needles with others (CDC, 2017). A larger sample from all groups identified as high-risk for HIV may not yield the same knowledge scores, sexual behavior cognition scores, STI status and history, PrEP perception, and sexual behavior decisions.

Third, the study of change of sexual behaviors was limited to a three-month follow-up among the participants coinciding with their PrEP follow-up visit. The change of sexual behaviors and sustained level of STI rate may very well be measured on prolonged periods of study and multiple follow-ups (3-month, 6-month, 12-month follow-ups) and not limited to a single time point at three months. However, the study is dependent on the short length of research time structured in the study program. Fourth, the intervention was limited to two brief educational videos. The short six-minute educational intervention was intended to simulate a 20-minute visit of a PrEP patient with a primary provider. However, sexual behaviors, sexual thought processes, STI-PrEP knowledge, and STI rates can be addressed through different modalities such as motivational interviewing, behavioral counseling, and risk reduction strategies.

Fifth, a limitation in this study was the inclusion of a mix of current PrEP users and PrEP starters. The repercussion of a mixed sample may have affected baseline knowledge scores about STI and PrEP as evidenced by high mean scores of participants. Sixth, the STI rates were all through self-report. A larger study would give generalizable effect of PrEP education on STI
rates. On the other hand, one strength of the study was the use of a mixed method approach to study PrEP perception, effect of PrEP education, sexual intentions, sexual motivations, and current sexual behaviors of PrEP patients. The quasi-experimental exploratory study also allowed the researcher to support and complement quantitative data with in-depth narratives from the semi-structured interviews.

**Implications for Practice, Education, Research, and Policy Dissemination**

PrEP is a new HIV-prevention strategy for identified high-risk patients. PrEP implementation, however, presents challenges in both patients and health care. Most notably, the role of PrEP in a patient’s sexual behavior and consequently STI rates are concern for health care and society as well. Preventing STI, including HIV, through healthy sexual behaviors among PrEP users is a primary goal of health care, education, research, and policy.

Primary care and other PrEP clinics are the conduits for prevention services among PrEP users. Primary care is therefore in a position to implement a comprehensive, feasible, and sustainable program for PrEP users. A focus on increased KAP of primary care clinicians is instrumental to achieve significant reductions in STI incidence and risky sexual behaviors. The increased awareness in prescribing PrEP in primary care settings have increased to 66% in 2015, three years after PrEP was introduced (Smith, Mendoza, Stryker, & Rose, 2016). The willingness to prescribe by primary care clinicians to at least one high-risk group was 91% (Smith et al., 2016). The acceptability and willingness of primary care clinicians to provide or offer PrEP is needed so that access to PrEP by eligible patients is facilitated. Nurses, in collaboration with health care team, have key role in implementing risk reduction strategies during multiple follow-up visits of PrEP patients. Additional training and education may be necessary to accomplish this nursing-specific task.
Research provides backbone in generating new knowledge and evidence-based interventions in practice. Most studies published about PrEP implementation were qualitative studies and were focused on identifying barriers to PrEP uptake (Scholl, 2015). The review of literature showed very few studies which demonstrated effects of PrEP education or behavioral interventions on sexual behaviors, knowledge, and STI rates among PrEP users. As STI rates have increased, specifically syphilis among MSM (CDC, 2016), research studies on effective interventions in addressing sexual behaviors and STI rates among PrEP users are necessary.

The World Health Organization (WHO) (2015) published a policy brief in 2015 stating the need to offer antiretroviral prevention pill to all populations at risk for HIV infection (incidence of HIV greater than three per 100 person-years in the absence of PrEP). The WHO policy brief is in line with CDC guidelines for PrEP (CDC, 2014). However, Silapaswan, Krakower, and Mayer (2016), in its narrative review, showed low implementation of PrEP nationwide. The low implementation is due to limited number of healthcare providers trained to prescribe and implement PrEP in their settings (Silapaswan et al., 2016). With increase in PrEP-related provider training, access to PrEP by at-risk populations is facilitated. There is a need for mandatory training to health practitioners by clinics or health setting providing PrEP.

**Recommendations for Nursing Practice and for Further Study**

The exploratory, interventional mixed methods pilot study was intended to gather data to provide understanding of the important role of PrEP education on sexual behaviors and STI rates of patients at-risk for HIV and are taking PrEP. The use of PrEP by HIV-negative patients is relatively new practice and therefore an understanding of high-risk sexual behaviors for HIV is imperative. The risk-compensating sexual behaviors expressed by participants during the
interviews, as well as STI diagnoses on both study phases highlighted the need for a multi-disciplinary approach in addressing these phenomena.

Primary care providers are faced with consultation time limits with each patient. The issue about time limitation does not guarantee adequate coverage of information needed by PrEP patients. Limited studies show effective implementation of PrEP in primary care setting (Scholl, 2015). Nurses, including advanced practice registered nurses (APRNs), as members of the multidisciplinary health team, can be instrumental in providing health interventions to PrEP patients in multiple health settings. The multimodal approach in addressing issues of PrEP patients can be addressed through STI-PrEP education, motivational interviewing, and risk reduction interventions.

The implementation of structured evidenced-based interventions (EBI) is needed in PrEP clinics. The EBI is in line with the CDC practice guidelines (CDC, 2014) which recommended the use of video-based interventions such as the intervention used in this study which can be used at the waiting room allowing maximization of clinician’s time. Additionally, tailoring risk-reduction education to individual PrEP patient by identifying patient’s risky sexual behaviors and mutually setting goals may help reduce risk-compensating behaviors arising from PrEP and consequently reducing STI, including HIV. CDC guidelines also recommended use of repeated but brief counseling sessions during multiple visits of PrEP patients for follow-up visits (CDC, 2014). The CDC guidelines should be adopted by PrEP clinics utilizing a multidisciplinary team-based approach in consideration of limited time visits of patients with primary care providers.

The findings of this study facilitate an understanding of the promising effectiveness of PrEP education in curbing STI rates and promoting healthy sexual behaviors among patients.
However, a larger scale study with adequate sample consisting of all groups identified as high risk for HIV and utilizing multimodal approach in behavioral risk reduction is recommended.

**Conclusion.** The use of PrEP education in understanding its effect on sexual behaviors and STI rates among GBM delivered promising results in the limited context of this pilot project. Utilizing the HPM and a multidisciplinary approach in implementing multimodal strategies in addressing sexual behaviors are recommended based on existing CDC clinical practice guidelines for PrEP. Future research employing larger sample, including all identified groups needing PrEP, and utilizing multimodal approach in behavior risk reduction can be helpful in expanding knowledge about PrEP and its effect on users.
Appendix A

Strength of Recommendation Taxonomy (SORT)

Figure 1. Strength of Recommendation Taxonomy (SORT)

In general, only key recommendations for readers require a grade of the “Strength of Recommendation.” Recommendations should be based on the highest quality evidence available. For example, vitamin E was found in some cohort studies (level 2 study quality) to have a benefit for cardiovascular protection, but good-quality randomized trials (level 1) have not confirmed this effect. Therefore, it is preferable to base clinical recommendations in a manuscript on the level 1 studies.

<table>
<thead>
<tr>
<th>Strength of recommendation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Recommendation based on consistent and good-quality patient-oriented evidence.*</td>
</tr>
<tr>
<td>B</td>
<td>Recommendation based on inconsistent or limited-quality patient-oriented evidence.*</td>
</tr>
<tr>
<td>C</td>
<td>Recommendation based on consensus, usual practice, opinion, disease-oriented evidence,* or case series for studies of diagnosis, treatment, prevention, or screening.</td>
</tr>
</tbody>
</table>

Use the following table to determine whether a study measuring patient-oriented outcomes is of good or limited quality, and whether the results are consistent or inconsistent between studies.

<table>
<thead>
<tr>
<th>Study quality</th>
<th>Diagnosis</th>
<th>Treatment/prevention/screening</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1—good-quality patient-oriented evidence</strong></td>
<td>Validated clinical decision rule SR/meta-analysis of high-quality studies High-quality diagnostic cohort study†</td>
<td>SR/meta-analysis of RCTs with consistent findings High-quality individual RCTs: All-or-none study§</td>
<td>SR/meta-analysis of good-quality cohort studies Prospective cohort study with good follow-up</td>
</tr>
<tr>
<td><strong>Level 2—limited-quality patient-oriented evidence</strong></td>
<td>Unvalidated clinical decision rule SR/meta-analysis of lower-quality studies or studies with inconsistent findings Lower-quality diagnostic cohort study or diagnostic case-control study§</td>
<td>SR/meta-analysis of lower quality clinical trials or of studies with inconsistent findings Lower-quality clinical trials: Cohort study Case-control study</td>
<td>SR/meta-analysis of lower-quality cohort studies or with inconsistent results Retrospective cohort study or prospective cohort study with poor follow-up Case-control study Case series</td>
</tr>
<tr>
<td><strong>Level 3—other evidence</strong></td>
<td>Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series for studies of diagnosis, treatment, prevention, or screening</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

_consistency across studies_

| Consistent | Most studies found similar or at least coherent conclusions (coherence means that differences are explainable) or if high-quality and up-to-date systematic reviews or meta-analyses exist, they support the recommendation Considerable variation among study findings and lack of coherence or if high-quality and up-to-date systematic reviews or meta-analyses exist, they do not find consistent evidence in favor of the recommendation |
| Inconsistent | |

*—Patient-oriented evidence measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, and quality of life. Disease-oriented evidence measures intermediate, physiologic, or surrogate end points that may or may not reflect improvements in patient outcomes (e.g., blood pressure, blood chemistry, physiologic function, pathologic findings).†—High-quality diagnostic cohort study: cohort design, adequate size, adequate spectrum of patients, blinding, and a consistent, well-defined reference standard.§—High-quality RCT: allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (greater than 80 percent).§—In an all-or-none study, the treatment causes a dramatic change in outcomes, such as antibiotics for meningitis or surgery for appendicitis, which precludes study in a controlled trial.

Appendix B

Permission for Use of Strength of Recommendation Taxonomy

Mark H Ebell <ebell@uga.edu> 10/23/16

to Jay, me

That’s fine with me. I don’t think you need formal permission from the publisher (American Academy of Family Physicians) for a dissertation. You would need their permission (which they would no doubt grant) if you intend to publish the figure itself in a new publication. My co-author Jay Siwek is faculty at Georgetown in Family Medicine and is editor of American Family Physician.

Best,

Mark

From: Randulf Erguiza <rve5@georgetown.edu>
Date: Saturday, October 22, 2016 at 4:32 PM
To: Mark H Ebell <ebell@uga.edu>
Subject: Permission to use SORT (and as appendix)

Jay Siwek <siwekj@georgetown.edu> 10/23/16

to Mark, me

Hi Randulf

Yes, I think it’s fine to use the SORT evidence-rating system, and include the algorithm in an appendix, citing its source. (Note: this system was co-published in several medical journals; it’s okay to just cite one of them, such as the one from AFP: http://www.aafp.org/afp/2004/0201/p548.html

Good luck with your dissertation.

Hoya Saxa!

Jay

Jay Siwek, MD
Professor and Vice Chair
Department of Family Medicine
Editor, American Family Physician
Georgetown University Medical Center
Preclinical Science Bldg., Suite LM9-E
3900 Reservoir Road, NW
Washington, DC 20007
Academic Office: 202-687-1600
AFP Editorial Office: 913-906-6205
AFP Editorial fax: 913-906-6086
Personal email: siwekj@georgetown.edu
AFP email: afpjournal@aafp.org
AFP website: http://www.aafp.org/afp
Appendix C

Sexually-Transmitted Infection-PrEP Questionnaire

SEXUALLY TRANSMITTED INFECTION-PrEP QUESTIONNAIRE

It may take approximately ten minutes to complete this activity. Should you have any questions, I will be nearby so that you can come to ask me the questions. Should you feel any discomfort with any question or need help with it, feel free to inform me at any point during the session. Please be reminded that you are free to withdraw or continue with the study any time without consequences.

INSTRUCTIONS: This is a mixed multiple choice question and true or false questionnaire. Circle the letter (or option) corresponding to your answer. Please answer each question.

1. PrEP is a medication which prevents transmission of:
   a) HIV
   b) All sexually-transmitted infections
   c) HIV, Gonorrhea, and Chlamydia

2. For the PrEP pill to be effective, it should be taken (select one only):
   a) Every day
   b) Every other day
   c) Once a week

3. What is the MOST EFFECTIVE way to prevent HIV transmission?
   a) Abstaining from sex will prevent HIV transmission
   b) Use of PrEP to prevent HIV transmission
   c) Use of condom will prevent HIV transmission

4. Follow-up visit with health providers at the PrEP clinic is scheduled (select one only):
   a) Every month
   b) Every 3 months
   c) Every 6 months

5. The MOST COMMON side effect of PrEP is (select one only):
   a) Chest pain
   b) Constipation
   c) Mild headache
   d) Other, specify

6. Taking PrEP may affect which body organ(s)? (select all that apply):
   a) Heart
   b) Liver
   c) Kidney
   d) Lungs
   e) Other, specify:

7. Sexually transmitted infections are transmitted:
   a) Through oral sex
   b) Through anal sex
   c) All of the above

8. Which of these STDs is curable? (select one only)
a) STD caused by bacteria  
b) STD caused by virus  
c) No STDs are curable

9. Which disease(s) can be prevented with the use of condom? (select one only)  
a) HIV, Herpes, Syphilis  
b) HIV, Gonorrhea, Chlamydia  
c) HIV, Herpes, HPV

10. Which STD may cause blisters either on your mouth, genitals, and anus? (select all that apply)  
a) HIV  
b) Gonorrhea  
c) Herpes

11. Gonorrhea and chlamydia can cause: (select one only)  
a) Discharge from the penis  
b) Blisters on the mouth, anus, and penis  
c) Discharge from the penis and blisters on the mouth, anus, and penis

12. Which STD(s) cause(s) sores, ulcers, or rashes and can spread throughout the body? (Select all that apply)  
a) Gonorrhea  
b) Syphilis  
c) Chlamydia

13. Hepatitis B can be transmitted through sex  
a) True  
b) False

14. HIV can be transmitted through sexual contact. The risk is 2 to 5 times higher in the presence of other STDs.  
a) True  
b) False

15. Anyone who has sex is at risk for acquiring STD  
a) True  
b) False
Appendix D

Post-Educational Intervention Semi-Structured Interview

POST-EDUCATIONAL INTERVENTION INTERVIEW

Thank you for completing the paper survey. The next step of this session will be an interview containing nine questions. As you have agreed, the interview will be audio-recorded for the purpose of transcribing word by word of your answers so that a meaningful analysis of answers by all participants can be done. We will continue to use your pseudonym and the numeric code assigned to it on the form. Should you feel any discomfort in answering the questions, please feel free to inform me.

1. What motivated you to start PrEP?

2. What do you believe will encourage you to continue to take PrEP?

3. Do you believe that you have enough information about PrEP to know what are sexually healthy practices while you are using PrEP? If not, what more information would you need?

4. After learning information about PrEP and STDs, how do you intend to sexually behave?

5. Please tell me what you believe are the factors that impact on your engagement in sexual behavior?

6. What will motivate you to engage in sexually healthy behavior; that is, to engage in protected sexual activities?

7. Please tell me about how you believe that you will engage in healthy sexual behavior now that you will be on PrEP?

8. What else would you like to tell me about how you feel about being on PrEP or starting PrEP?

   What else would you like to tell me about your thoughts about sexual behavior while you are on PrEP.

9. Have you been diagnosed with any STD in the past three months?  ____ YES  ____ NO
Appendix E

Follow-Up Survey Semi-Structured Interview

FOLLOW-UP INDIVIDUAL INTERVIEW

Thank you for completing the paper survey. The next step of this session will be an interview containing nine questions. As you have agreed, the interview will be audio-recorded for the purpose of transcribing word by word of your answers so that a meaningful analysis of answers by all participants can be done. We will continue to use your pseudonym and the numeric code assigned to it on the form. Should you feel any discomfort in answering the questions, feel free to ask.

1. What is the effect of the educational videos you watched during the first session on your sexual behavior?
2. Can you describe your sexual behavior for the past three months?
3. What motivates you to remain or change your sexual behavior?
4. What is your view on PrEP in preventing other STDs?
5. In your view, what will urge you to practice unsafe sex behaviors in the future?
6. STD STATUS: Did you have an STD for the last 3 months? ____ YES ____ NO
7. PREP STATUS: Did you miss any day of PrEP pill? ____ YES ____ NO
Appendix F
Demographic Information Sheet

PRE-EXPOSURE PROPHYLAXIS EDUCATION’S EFFECT ON SEXUAL BEHAVIOR
OF GAY AND BISEXUAL MEN
Randulf Erguiza, MS, NP, FNP-BC, NP-C
rve5@georgetown.edu

DEMOGRAPHIC INFORMATION

Please fill out the demographic information on this form. As with all other information collected, strict confidentiality will be maintained. Your real name will be used by the researcher only to identify you for the next session. It will NOT be used for the study. Instead, only the pseudonym that you select will be used.

Should you have any questions, feel free to ask the researcher at any time during the session.

NAME: ______________________
PSEUDONYM: ______________________
DATE OF BIRTH: ______________________

ETHNICITY: Select all that apply:

White
Black or African American
American Indian or Alaska Native
Asian
Native Hawaiian or Other Pacific Islander

SEXUAL ORIENTATION: Lesbian Homosexual/Gay Bisexual Transgender Questioning

RELATIONSHIP STATUS:

Single Married with Female Married with Male Divorced
In a monogamous relationship In an open relationship Widowed

EDUCATIONAL STATUS:

Doctorate Masters College Some College
High School Some High School Grade School No education

Do not fill out information below

PSEUDONYM: ______________________ Numeric Code Assigned: __________

DATE OF NEXT PRE-EXPOSURE PROPHYLAXIS (PrEP) APPOINTMENT: __________
Appendix G
Screening Questionnaire for Study Inclusion

PRE-EXPOSURE PROPHYLAXIS EDUCATION’S EFFECT ON SEXUAL BEHAVIOR
OF GAY AND BISEXUAL MEN
Randulf Erguiza, MS, NP, FNP-BC, NP-C
Georgetown University
rve5@georgetown.edu

Prospective Study Subject No. ________

SCREENING QUESTIONS FOR STUDY INCLUSION

1. Are you 21 years of age or older? ________
2. Do you feel comfortable engaging in a conversation in English? ________
3. Do you believe that you will be able to respond to a survey in English? ________
4. Are you starting pre-exposure prophylaxis (PrEP) or are you already taking PrEP? ________
   Starting on PrEP ________ Already on PrEP
5. If wishing to start on PrEP, did you qualify to take PrEP? ________ YES ________ NO
Appendix H
Research Site Approval Letter

Randall Erguiza, MS, NP, FNP-BC, NP-C
rwe5@gseu.edu
831-915-0227

January 13, 2017

Anthony Sillemon, Psy.D., MSW
Administrative Manager
East Bay AIDS Center
Alta Bates Summit Medical Center
Oakland, California 94609

Dear Dr. Sillemon,

I am writing to request your approval or authorization to conduct a research study for my Doctor of Nursing (DNP) study at your facility. I am a board-certified Family Nurse Practitioner and currently a student in the DNP program at Georgetown University. My research study focuses on the effect of pre-exposure prophylaxis (PrEP) education on sexual behaviors and sexually-transmitted infections (STI) rates among gay and bisexual males on PrEP. The East Bay AIDS Center is my chosen site for the study because of its reputation of giving holistic care among our lesbians, gays, bisexuals, transgender, and questioning population (LGBTQ).

The research study will be conducted over a four-month period with the first session on February, 2017, and the next session will be in May, 2017, coinciding with the patients’ three-month follow-up with their PrEP provider. Participants for the study will include approximately 22 patients aged 18 and older who are either on PrEP or who will initiate on PrEP. Prospective participants will undergo initial screening by the unscreened principal investigator (PI) to make sure inclusion criteria are met for participation.

Each participant will receive $20 worth of visa card for each completed session. The PI will be doing recruitment among prospective study subjects and EBAC medical staff will not participate in active recruitment of study sample. Recruitment will be through invitation-only flyer which will be distributed to prospective participants at the front desk.

Also, a group invitation-only short talk can be done for prospective participants who are initiating PrEP. No patient data will be gathered from electronic medical records, nor data sharing will be undertaken. Any relevant personal data coming from the participant will be treated with strict confidentiality and shall be deleted or destroyed once data analysis is done. Each participant will be assigned their chosen pseudonym with a corresponding numeric code.

Lastly, informed consent will be undertaken by the PI.

In lieu of the aforementioned DNP research study, I would like to seek approval from your esteemed office to undertake this study at EBAC. I further request that I will be given a research study room for 7 days for each session to ensure privacy of patient is observed. Moreover, I request for a table, two chairs, and electrical outlet in the room to facilitate my study.

Georgetown University’s Institutional Review Board will oversee the project development, methodology and research to ensure that all protocols, including patient’s rights and confidentiality are strictly observed. Additionally, I will be subject to any restrictions required by your institution.

Thank you in anticipation of your immediate approval of my request.

Sincerely,

Randall Erguiza, MS, NP, FNP-BC, NP-C

Approved by:

Anthony Sillemon, Psy.D., MSW
EBAC Administrative Manager

Date
Bibliography


https://www2c.cdc.gov/podcasts/videowindow.asp?f=805709&af=v


Collaborative Institutional Training Initiative (CITI). (2016). Biomedical research conduct of research – Basic course. Retrieved from
https://www.citiprogram.org/members/index.cfm?pageID=50


Evidence-based practice in nursing and 


https://deepblue.lib.umich.edu/bitstream/handle/2027.42/85350/HEALTH_PROMOTION_MANUAL_Rev_5-2011.pdf?sequence=1&isAllowed=y


