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Optimizing HIV PrEP Implementation in the Primary Care Setting

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Abstract

Despite compelling evidence behind the efficacy of pre-exposure prophylaxis (PrEP) in preventing human immunodeficiency virus (HIV) acquisition and its introduction in 2012, the prescription of PrEP has remained low (Silapaswan, Krakower, & Mayer, 2016). At the Asian and Pacific Islander Wellness Center (API), an urban primary care clinic in San Francisco, suboptimal PrEP implementation was related to a lack of standardized practice and routine HIV risk screening for PrEP provision. A doctorate of nursing (DNP) project was implemented to initiate a standardized HIV risk screening protocol for identifying HIV risk and PrEP eligibility to increase PrEP implementation at API. The impact of this protocol demonstrated an increase in the PrEP implementation cascade, particularly in HIV risk identification, PrEP offer, and evaluation of at-risk patients for PrEP uptake (initiation). During implementation of the HIV risk screening protocol, however, inconsistent clinical staff compliance with the routine screening tool led to an inadequate increase in PrEP offer for patients who tested positive for a sexually transmitted infection (STI). This indicates a need for further reinforcement of standardized practice and clinical staff education on the importance of combining HIV risk screening and PrEP, with emphasis on the significant risk for HIV infection associated with positive STI, to effectively promote patient outcomes. Implications for further research include validation of the HIV PrEP screening tool used in the HIV risk screening protocol as a model for PrEP implementation in the primary care setting.

Keywords: PrEP implementation, PrEP delivery, PrEP demonstration project, primary care, pre-exposure prophylaxis, HIV prevention, HIV risk screening, PrEP screening tool, PrEP implementation model

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Introduction

In 2012, the combination antiretroviral drug, tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), was federally approved in the United States (US) for use as pre-exposure prophylaxis (PrEP) for preventing HIV infection (Centers for Disease Control and Prevention, 2014). PrEP is the first drug of its kind to prevent HIV acquisition in high-risk populations, proven to be up to 92% effective (CDC, 2014). While such evidence is a promising start, the lack of widespread dissemination of the literature and practice guidelines limits its impact. Currently, there is a need for increased implementation of the evidence, via standardized practice models, in primary care settings providing care to at-risk populations (Silapaswan et al., 2016). The Asian and Pacific Islander Wellness Center (API), an urban federally qualified health center (FQHC) located in an HIV endemic area, provides care for an at-risk patient population that would benefit from PrEP. This DNP project proposed to optimize PrEP implementation at API through standardization of clinical practice with an emphasis on increasing routine HIV risk screening, which can serve as a model applicable to other primary care settings.

Problem Description

Although HIV can be managed as a chronic illness in the United States for those who have healthcare access and respond to antiretroviral treatment, it remains a serious preventable communicable disease. In 2015, 39,513 persons were newly diagnosed with HIV in the United States (CDC, 2016). As of June 2016, there are 16,030 people living with HIV in San Francisco (San Francisco Department of Public Health, 2016). Because HIV is endemic in San Francisco, an independent, volunteer-led, multi-sector consortium called the *Getting to Zero San Francisco* initiative established its mission to achieve UNAIDS's (United Nations program on HIV/AIDS)

vision of zero new HIV infections, zero HIV deaths, and zero HIV stigma by 2020 (Getting to Zero San Francisco, 2015) (United Nations program on HIV/AIDS, 2011).

API is a non-profit, urban primary care clinic in the Tenderloin district of San Francisco that serves a disenfranchised patient population, consisting of lesbian, gay, bisexual, transgender and queer (LGBTQ), and low-income people of color. As of April 2016, an estimated 61% of patients had substantial risk for acquiring HIV due to intravenous drug use, commercial sex work, being in an HIV serodiscordant relationship, or inconsistent safe sex practices (T. Do, personal communication, February 25, 2016). Prior to this DNP project, API did not have an established PrEP implementation protocol or a standardized screening process for HIV risk.

At API, the following process describes clinic workflow. Per routine, the medical assistants (MAs) room the patient, collect vital signs, and perform routine health screenings, such as the PHQ-2 and -9, AUDIT-C (Appendix A), and sexual history assessment. The results are documented into the electronic health record (EHR) and reported to the nurse practitioners (NPs) or physician before they assess the patient. Due to a lack of standardization specifying the health screenings associated with the type of patient encounter, health screenings were performed inconsistently. For example, the sexual history assessment was conducted for many patient encounters but was often missed for straightforward visits, particularly STI testing. Although the sexual history assessment screen in the EHR collected important information about sexual risk behavior, it did not flag HIV risk. Without appropriate clinical staff training to use the sexual history information to assess for HIV risk, the screen was ineffective for identifying at-risk patients who qualify for PrEP.

PrEP implementation consists of the following steps, also known as a “cascade” (B. Turner, personal communication, April 6, 2016). The first step is screening for HIV risk per

CDC guidelines (Appendix B) (CDC, 2014). Once an at-risk patient is identified, the second step is PrEP offer, which involves the provider discussing and offering PrEP as an HIV prevention method. After a patient accepts PrEP offer, the third step is PrEP evaluation. Evaluation involves laboratory testing and physical examination to confirm that a patient is eligible, in other words safe, to start PrEP. The final step in the cascade is PrEP uptake, which is the prescription and patient initiation of PrEP.

It is important to note that PrEP uptake can be limited by the financial cost of TDF/FTC. The drug cost of PrEP is approximately $13,000 per patient per year (CDC, 2015). Depending on a patient's health insurance plan, the cost of PrEP may not be fully covered, posing a barrier to receiving a prescription for and initiating PrEP. At API, such financial barriers to PrEP are resolved by the PrEP case manager, now PrEP navigator, by connecting patients with the Gilead Sciences (the pharmaceutical company that manufactures TDF/FTC) financial assistance program and copay cards, or Medi-Cal health insurance coverage. Medi-Cal covers the entire cost of PrEP (T. Do, personal communication, May 9, 2016).

Baseline data collected on the clinical practice of PrEP implementation at API demonstrated that only 48% of patients with a history of sexual HIV risk, and 35% of patients at risk for acquiring HIV due to testing positive for an STI were offered PrEP (Appendices B and C). These results revealed a considerable gap between the CDC's PrEP clinical practice guidelines and actual clinical practice (CDC, 2014). The lack of standardized HIV risk screening during API's PrEP implementation is a contributing factor to this gap in practice. This is significant because screening is the first step to prevention or treatment.

Available Knowledge

Review of evidence: efficacy of PrEP for HIV prevention. A significant amount of peer reviewed, placebo-controlled, randomized controlled trials (RCTs) demonstrate the effectiveness of PrEP in preventing at-risk patients from acquiring HIV. The following evidence from the World Health Organization (WHO) (2012) and the CDC (2014) suggest a strong impact in protection rates against HIV when using PrEP. A literature review was completed to study the methodology of PrEP trials and success rates, which summarized the evidence supporting PrEP. The literature was retrieved from the provider resources folder located in API's intranet, and from searching the following key words on the CINAHL database: *PrEP, pre-exposure prophylaxis, HIV prevention*. A critique of the reviewed literature was performed using the Johns Hopkins Nursing Evidence Based Practice (JHNEBP) Research Evidence Appraisal instrument (Appendix D).

The WHO (2012) conducted a meta-analysis of eight RCTs using TDF or TDF/FTC for PrEP among the following populations and settings: a. heterosexual serodiscordant couples (in which one partner is living with HIV) in Kenya and Uganda; b. heterosexual women and men in Botswana; c. women at higher risk of contracting HIV in Kenya, South Africa and Tanzania; d. men and transgender women who have sex with men from the landmark "iPrEX" study conducted in Peru, Ecuador, Brazil, Thailand, South Africa, and the US. TDF/FTC's effectiveness in reducing HIV infection and its relationship with medication adherence were analyzed. The result demonstrated 92% effectiveness in preventing HIV infection among participants maintaining high medication adherence, as evidenced by their detectable serum TDF/FTC level (WHO, 2012). The WHO study involved 14,951 participants. Results validated that TDF/FTC for PrEP is 90-92% effective in preventing HIV infection in persons practicing

high medication adherence. The CDC (2014) repeated this meta-analysis, also including a RCT of 2,411 intravenous drug users (IDUs) in Bangkok, which produced similar results, thus confirming PrEP's effectiveness. The CDC then created the PrEP clinical practice guidelines using this data.

The WHO (2015) later conducted another meta-analysis of 12 trials, supporting the effectiveness of PrEP among serodiscordant couples, heterosexual men and women, men who have sex with men (MSM), IDUs, and transgender women. These trials took place in Africa, Asia, Europe, South America and the US. These results established that TDF/FTC for PrEP is effective in reducing risk for HIV infection with high medication adherence, regardless of age, gender, antiretroviral regimen, and mode of sexual transmission (WHO, 2015).

Additional information on PrEP recommendations. Additionally, the WHO (2015) performed a qualitative literature review on administering PrEP to explore the cost-effectiveness, equity, and acceptability of PrEP. The financial cost-effectiveness of PrEP varies depending on the relative cost of PrEP versus HIV treatment. In terms of the demographic incidence of HIV, preventing HIV transmission and keeping persons HIV-negative is invaluable to communities. PrEP promotes equitable health outcomes of persons and their sexual partners, as well as access to sexual health services during follow-up. Acceptability refers to how much the recommendation of PrEP use is accepted by the patients who are affected by it and the healthcare providers who can implement it (WHO, 2015). Widespread acceptability was reported across multiple at-risk populations. Based on the results of this study, the WHO (2015) updated its guidelines and now highly recommends starting PrEP not only for high-risk patients, but also for patients with substantial risk for HIV infection per CDC guidelines (Appendix B). Substantial risk for HIV infection is defined as meeting at least one of the following criteria in MSM,

heterosexual, and IDU populations: HIV-positive sexual or injecting partner; recent bacterial STI; high number of sex partners; history of inconsistent or no condom use; commercial sex work; located in high-prevalence area or network; sharing injection equipment; and recent intravenous drug treatment but currently injecting (CDC, 2014). Therefore, the WHO recommends expanding PrEP uptake to a wider patient population.

Review of evidence: PrEP implemenation. Although significant evidence proves the efficacy of PrEP in preventing HIV acquisition, a limited amount of studies demonstrating how to best implement PrEP in the primary care setting exists (Scholl, 2015). The literature search for this review of evidence was conducted using the CINAHL database by searching the following key words: *PrEP implementation, PrEP demonstration project, PrEP implementation model, HIV risk screening, PrEP screening, primary care, and HIV prevention*. The search yielded few relevant articles about PrEP implementation, let alone in the primary care setting. No studies of models for practicing PrEP implementation specifically in the primary care setting were generated. A critique of the reviewed literature was also conducted using the JHNEBP Research Evidence Appraisal instrument (Appendix E), confirming that most of the literature consisted of qualitative studies identifying barriers to PrEP implementation, and implications for practice (Scholl, 2015).

While no studies of PrEP implementation in the primary care setting were obtainable in the literature search, studies performed in STI clinics demonstrate PrEP implementation models targeting MSM. At a Rhode Island STD Clinic, PrEP implementation involved offering PrEP education for every MSM patient presenting for STI testing, regardless of reported risk factors, followed by a brief questionnaire assessing patient interest in PrEP, and a scheduled appointment –for those who reported interest –with a provider for PrEP evaluation and initiation (Chan et al.,

2016). Results across the PrEP implementation cascade reported that 60% expressed interest in PrEP after receiving education; of whom 22% completed PrEP evaluation; and 81% of whom actually initiated PrEP (Chan et al., 2016). Overall, only 10% of the targeted MSM initiated PrEP. The results are primarily related to patients' low HIV risk perception, indicating the importance of emphasizing individual HIV risk factors to increase PrEP implementation.

Aiming to assess the feasibility and acceptability of implementing PrEP to MSM and transgender women in the STI clinic and community health center setting, the US PrEP demonstration project targeted these high-risk populations (Cohen et al., 2015). "The Demo Project" implemented PrEP at STI clinics in San Francisco and Miami, and at a community health center in Washington, D.C. At the San Francisco STI clinic, providers used the clinic's standardized HIV risk assessment, routinely administered to all MSM & transgender women, to identify eligible patients for referral to participate in the study. MSM and transgender women who requested PrEP were also referred for study participation –as "self-referrals"–if risk criteria were met. In Miami, MSM and transgender women were informed about PrEP and the study. All interested patients were referred to the PrEP team for prescreening prior to study participation. While at the D.C. community health center, study staff directly approached MSM and transgender women seeking HIV and STI screening to offer them the opportunity for prescreening and participation in the study. Of the 557 participants enrolled, 60.5% completed PrEP uptake. The participants' demographic factors, behavioral risk characteristics, HIV risk perception, and interest in PrEP were analyzed. Results show that PrEP uptake was high across demographic factors and clinic sites. This indicated high levels of willingness to take PrEP if patients accept its efficacy as an HIV prevention method, and if PrEP is provided at low or no cost (Cohen et al., 2015). Although targeting only MSM and transgender women, the

standardization of the prescreening intervention proved effective in recruiting participants and producing high levels of PrEP uptake.

Most of the articles published on PrEP implementation models are qualitative studies that identify barriers to increasing PrEP uptake (Appendix E). In a study of community FQHCs in southeastern Florida, clinical staff perspectives on PrEP implementation were assessed (Doblecki-Lewis & Jones 2016). The results were clear, that cultural stigma surrounding HIV and sexual risk behaviors; concerns regarding documentation status, health insurance, and financial cost; clinical staff knowledge of PrEP, and discomfort with discussing sexual history and HIV risk screening contribute to the low implementation of PrEP despite serving high-risk patient populations.

There is low PrEP implementation nationwide according to the narrative review conducted by Silapaswan et al. (2016). Only a minority of at-risk persons who could benefit from PrEP is taking it due to a limited number of healthcare practitioners trained to provide PrEP. Addressing this barrier requires increased patient access to PrEP. Therefore, the authors suggest that primary care practitioners should be the primary providers of PrEP because it is a preventative health intervention for otherwise healthy individuals.

However, there are conflicting perspectives among healthcare providers regarding who is best fit to provide PrEP and which healthcare setting is most appropriate for PrEP implementation (Hoffman et al., 2016). For example, Hoover, Ham, Peters, Smith and Bernstein (2016) suggest that PrEP is best implemented in STI clinics because of the shared sexual risk behaviors related to acquiring HIV and other STIs, and persons infected with a bacterial STI are more susceptible to HIV infection. Furthermore, STI clinics disproportionately provide services for high-risk patient populations. Some primary care providers reported preference for HIV

specialists, who are experts on antiretroviral therapy and HIV transmission, to serve as PrEP providers (Hoffman et al., 2016). Meanwhile, some HIV specialists argue that HIV-negative patients are not going to seek their services. Therefore, the wide net for health screenings cast in the primary care setting supports that primary care providers are uniquely qualified for prescribing PrEP (Hoffman et al., 2016). The lack of a unanimous stance on where PrEP belongs in healthcare poses a significant barrier to its widespread dissemination. Further research using implementation science is needed to determine the most effective setting for PrEP implementation (Hoffman et al., 2016).

Although it is currently unclear which healthcare setting–STI clinics, community health centers, HIV specialists, or primary care – is most appropriate for providing PrEP, the qualitative studies in this review of evidence offer implications for practice to address barriers to PrEP implementation. According to Doblecki-Lewis, and Jones (2016), Silapaswan et al. (2016), and Hoffman et al. (2016), increasing provider knowledge of PrEP is the most common recommendation across qualitative studies. Raifman, Flynn, and German (2016) identify that provider knowledge is especially important as patient awareness of PrEP was found to be unassociated with most healthcare contact. Training and guidelines are needed to support provider discussion with patients about sexual history and PrEP. Furthermore, improved methods for identifying at-risk patients who qualify for PrEP via routine sexual history/gender identity questions are recommended to optimize PrEP implementation in the primary care setting (Silapaswan et al., 2016).

Additional information on HIV risk screening in primary care. Because PrEP is a preventative intervention that requires prescreening, it should be considered similar to other preventative health services (Silapaswan et al., 2016). As with all routine screenings that are

offered in primary care, such as AUDIT-C for alcohol dependence and PHQ-2 and -9 for depression and suicide (Appendix A), HIV risk screening for PrEP implementation can also be provided in this setting (Smith, Pals, Herbst, Shinde, & Carey, 2012).

In 2006, the CDC recommended the expansion of HIV screening to non-targeted ("opt-out") routine HIV testing in all healthcare settings in the US (Haukoos et al., 2011). However, non-targeted HIV testing was not widely adopted in clinical practice, especially in primary care, because such large-scale screening is not cost-efficient (Haukoos et al., 2011). In 2007, the US Preventative Services Task Force (USPSTF) recommended targeted (among high-risk populations) HIV screening as the primary method of HIV testing (Haukoos et al., 2011). As a compromise between the conflicting recommendations, the Denver HIV risk score, derived from targeted HIV screening, was internally and externally validated by Haukoos et al. (2011). The results of the study confirmed efficacious applicability of this HIV risk assessment tool across healthcare settings, including non-targeted settings such as primary care.

The most current USPSTF recommendation for routine HIV screening in the primary care setting states that one-time testing for HIV infection can begin at age 15 through age 65 with repeat testing for those identified as at risk for HIV infection, engaged in risky behaviors, and who live or receive medical care in a high-prevalence setting (US Preventative Services Task Force, 2013). Because there is insufficient evidence to determine standard HIV testing intervals, a reasonable approach is to screen high-risk groups at least annually, and at-risk groups every 3-5 years (USPSTF, 2013). However, there is no recommendation for HIV risk screening. HIV risk screening in primary care can determine appropriate HIV testing intervals for individuals based on identified HIV risk factors, as supported by the results of the Denver HIV risk score study (Haukoos et al., 2011). Therefore, the Denver HIV risk score study supports the feasibility of

increasing PrEP implementation in primary care through HIV risk screening. As preventative health is one of the tenants of primary care, and the first step in prevention is screening, primary care is the appropriate setting for routine HIV risk screening and PrEP implementation.

Smith et al. (2012) developed and validated a screening tool for identifying high-risk MSM, for whom PrEP is appropriate, called the HIV Incidence Risk Index for MSM (HIRI-MSM). The index included the following seven items: a. age; b. number of sex partners in the past six months; c. number of times receptive anal intercourse performed in past six months; d. number of HIV-positive sex partners; e. number of times insertive anal intercourse performed; f. number of times methamphetamines used in the past six months; g. use of "poppers" in the past six months? A cut-off score of 10 was found to be predictive of HIV acquisition with a sensitivity of 84% and a specificity of 45%. Although the HIRI-MSM is a valid screening tool targeting only MSM, the study of the index suggests widespread use for prioritizing at-risk patients for PrEP (Smith et al., 2012). Therefore, expansion of an MSM-targeted screening tool to other at-risk populations represents a model by which PrEP implementation in the primary care setting can be increased.

Rationale

The core of this DNP project consisted of changing API's PrEP implementation practice by developing and implementing an HIV risk screening protocol by educating clinical staff, employing an HIV PrEP screening tool, and integrating the change into routine clinical practice. One theoretical framework used in the development of this project is the *Diffusion of Innovation Theory* popularized by Everett Rogers (Kaminski, 2011). This theory represents the process that occurs as people adopt a new practice. Over time, the innovative practice is diffused amongst the population until a saturation point is reached, and the majority adopts the new practice as status

quo. This theory is applicable to innovations in healthcare and health informatics (Angeles, Dolovich, Kaczorowski & Thabane, 2014). The HIV risk screening protocol will diffuse among the clinical staff at API, and has the potential to be adopted by other primary care clinics in San Francisco if this DNP project's model for PrEP implementation is disseminated.

The *Awareness to Adherence Model*, which states that provider compliance with clinical practice guidelines is dependent upon the following steps: awareness, agreement, adoption, and adherence (Freed, Pathman, Konrad, Freeman, & Clark, 1998). This model well describes the way in which this project will bring awareness of the CDC (2014) PrEP clinical practice guidelines through educating and training API providers and clinical staff on HIV risk identification and following the HIV risk screening protocol. The API providers and clinical staff will agree to follow the new HIV risk screening protocol after understanding its rationale and benefits to their patient population. Adoption of the HIV risk screening protocol into routine clinical practice should be effective due to API's small size and few organizational barriers. The author will be available to reinforce routine screening tool use to achieve adherence.

Specific Aims

The aim of this DNP project was to improve HIV prevention in a primary care setting over a period of six months by increasing clinical staff identification of patients with substantial risk for HIV, per CDC guidelines, through the implementation of a standardized HIV risk screening protocol, as evidenced by increasing PrEP offer and evaluation for initiating TDF/FTC for PrEP by 50% (Appendix F). The goal is to optimize HIV prevention at primary care clinics in order to contribute to the *Getting to Zero San Francisco* initiative.

Methods

Interventions

The primary intervention employed to change current practice and improve PrEP implementation at API is the development of a standardized HIV risk screening protocol that uses an HIV PrEP screening tool in the EHR. This will be accomplished by educating clinical staff to routinely identify patients at risk for acquiring HIV who should be offered PrEP. The HIV PrEP screening tool integrates the sexual history assessment with HIV risk screening to streamline clinical practice. The following objectives describe the methods of the HIV risk screening protocol:

1. Establish a standardized screening process: as patients are roomed, the MAs use the HIV PrEP screening tool to assess for HIV risk and qualification for PrEP offer for each establish new patient, STI testing, and annual physical exam patient encounter, and report results to the providers.
2. Educate all clinical staff on routine HIV risk identification, per CDC criteria, using the HIV PrEP screening tool and the new screening process.
3. Develop a standardized HIV PrEP screening tool and integrate it into the EHR (Appendix G) to assist clinical staff in increasing identification of patients at substantial risk for HIV acquisition, and subsequently increase PrEP offer and evaluation.
4. Develop clinical decision support tools in the EHR (Appendix H) to supplement the optimization of PrEP implementation: a PrEP evaluation order set linked to ICD-10 diagnostic codes related to STI screening and treatment, and a PrEP evaluation progress note template. The PrEP evaluation order set triggers providers to implement PrEP and decreases EHR related burden for ordering evaluation and follow-up, and it includes a

link to provider guidelines and patient education materials. The PrEP evaluation progress note template streamlines and standardizes the documentation of PrEP evaluation.

5. Educate providers on accessing the PrEP clinical decision support tools.
6. Evaluate clinical staff comprehension with post-education tests (Appendix I).
7. Launch the HIV risk screening protocol for clinical practice at API.
8. Reinforce change by following up with clinical staff on HIV risk screening protocol compliance –the routine utilization of the HIV PrEP screening tool per the established screening process.

Gap analysis. Prior to initiating this DNP project, a gap analysis (Appendix J) of API's clinical practice of PrEP implementation was conducted through observation of clinical practice and a baseline clinical data assessment (Appendix C). Based on observations of clinical practice, a lack of standardization specifying the health screenings to be conducted for the type of patient encounter was noted. Consequently, the sexual history assessment was performed inconsistently. Furthermore, the sexual history assessment screen did not identify HIV risk despite the relevant information it collected. Without appropriate clinical staff training to use sexual history information to assess for HIV risk, the screen was ineffective for identifying at-risk patients who should be offered PrEP. Additionally, differences in provider preference on which clinical staff conducted health screenings (providers themselves or the MAs), and the high rate of clinical staff turnover further contributed to inconsistencies in practice.

The baseline clinical data assessment was conducted by collecting and analyzing clinical data from December 7, 2015 through April 8, 2016. Patient lists were generated from the following data categories: STI treatment medications ordered, ICD-10 code Z11.3 (encounter for screening for infections with a predominantly sexual mode of transmission), and STI lab tests

ordered. The author performed individual patient chart reviews to identify those who qualified for PrEP based on testing positive for an STI or sexual HIV risk (per CDC guidelines), and if they were offered PrEP. The data analysis yielded the following gaps in identifying and offering PrEP to patients with substantial risk for acquiring HIV per CDC guidelines. Of the patients with a history of sexual HIV risk, 48% were offered PrEP (Appendix C). Of those who tested positive for an STI, 35% were offered PrEP. Therefore, a significant gap exists between the number of at-risk patients who qualify for PrEP and the number of these patients who were actually offered PrEP. According to this gap analysis, it was determined that API's PrEP implementation guidelines could benefit from a change in practice through this DNP project.

Gantt narrative. This DNP project timeline took place from March 2016 to February 2017 (Appendix K). In March 2016, the author visited API and spoke to Dr. Tri Do, the chief medical officer (CMO), about the clinic's needs. By the end of April 2016, the author selected the DNP project topic after researching evidence-based literature on PrEP and conducting a gap analysis of API's PrEP implementation practice. June through September 2016 was spent designing the HIV risk screening protocol –the implementation of an electronic screening tool into clinical practice. The development of the HIV PrEP screening tool, the first critical milestone, and the additional PrEP clinical decision support tools were completed in September 2016. The second milestone, clinical staff education was delayed by one month due to scheduling conflicts, and was instead completed in October 2016. Subsequently, the HIV PrEP screening protocol was launched on November 1, 2016, postponing the third milestone by one month. The fourth and final milestone, evaluation of the intervention and its measurable outcomes, started in January 2017 and was completed in February 2017.

SWOT analysis. The following SWOT analysis describes API's strengths, weaknesses, opportunities, and threats that have the potential to affect the implementation of this DNP project (Appendix L).

Strengths. API's compassionate and culturally sensitive environment, its small organizational size, FQHC status, and its specific patient population (LGBTQ and low-income people of color) represent strengths. Because both the patient population and API staff share similar backgrounds as LGBTQ community members and/or people of color, the culture at API produces a trusting environment that is open to change for improvement. Since it is a small organization, there is minimal bureaucratic pushback. Rather, the author receives support, such as access to invaluable resources, from Dr. Blair Turner, the lead NP who supervised this DNP project, and Dr. Do, the CMO/physician. FQHC status also contributes to API's strengths because federal funding reduces financial limitations to providing care. Furthermore, API's patients represent the at-risk population that qualifies for PrEP. Therefore, this DNP project is appropriate and relevant. These strengths promote this DNP project's capability to improve the clinic's PrEP implementation.

Weaknesses. The small size of API, high clinical staff turnover rate, and the outdated EHR system represent weaknesses. Although API's small organizational size is a strength because it produces less resistance to change, its small size as a free-standing clinic also represents a weakness. Since the clinic is not part of a larger health care system, it had few standardized protocols and policies. During protocol development there were constant workflow changes, resulting in difficulty establishing new protocol into routine. Additionally, the clinical staff turnover rate is high because nurses and MAs are often volunteers or hired temporarily from an agency, so new staff are constantly being trained. API's EHR system represents another

weakness because it is inefficient and has limited ability to capture clinical data. Difficulty navigating the EHR was expected to pose problems in this DNP project during the baseline assessment and evaluation. Therefore, project implementation was expected to face difficulties with technology and adherence to change in practice.

Opportunities. The FQHC status API received in December 2015 creates the opportunity to provide preventative care to more patients, and potentially meet the federally required EHR meaningful use standards of promoting patient health outcomes (C. Ong-Flaherty, April 7, 2016). FQHC status opens the clinic's doors to more patients in the community, which represents an opportunity to optimize HIV prevention efforts through PrEP implementation. Because the patient population is at risk for acquiring HIV, this DNP project also has the opportunity to produce potentially significant implications in public health by reducing HIV transmission and improving patient outcomes in the community, which contribute to the *Getting to Zero San Francisco* initiative. Patient health outcomes currently measured by EHR meaningful use standards include scheduled immunizations, and flu and pneumonia vaccinations; and in acute care for example, sepsis and heart failure (C. Ong-Flaherty, April 7, 2016). HIV prevention, however, has not yet been established as a patient health outcome for meaningful use. If established as a measurable outcome in the future, this DNP project can potentially help API contribute to its meaningful use of the EHR by using an electronic HIV PrEP screening tool.

Threats. Patient refusal of PrEP due to cultural stigma, financial cost, and low HIV risk perception represent threats. One of the barriers to PrEP uptake is cultural stigma. This cultural stigma stems from pre-existing stigma around HIV, but specifically depicts patients taking PrEP as "Truvada whores" (Calabrese & Underhill, 2015). Another barrier to PrEP uptake is financial cost. While some health insurance plans, such as Medi-Cal, cover the entire cost of PrEP, others

do not (T. Do, personal communication, May 9, 2016). Although API has a PrEP navigator to connect patients with financial access to PrEP, the process of acquiring financial resources still delays PrEP uptake. During this time waiting for financial coverage for PrEP, patients may change their minds or not return to care. Low HIV risk perception is the main reason MSMs at a Rhode Island STI clinic declined PrEP, representing an individual-level barrier to PrEP uptake (Chan et al., 2016). For these reasons an identified at-risk patient may refuse PrEP evaluation, and an eligible patient may refuse to initiate PrEP. Such threats may affect the PrEP implementation cascade, and subsequently, this DNP project's measurable outcomes.

Cost/benefit analysis. Because of API's limited budget, this DNP project was created to be without financial cost to API by utilizing available resources within the organization. API's full time equivalent (FTE) budget was not available to the author, so estimated costs are based on equivalent San Francisco Department of Public Health job wages for each staff member's hourly wage. The estimated cost of this DNP project is $2,156.54, which consists of approximate FTE employee hours spent by the following API staff members in project implementation: the CMO, lead NP, volunteer NP, MAs, clinical data specialist, EHR system consultant, PrEP case manager, clinical operations manager, and director of nursing (Appendix M). The author absorbed the majority of this DNP project's cost as an unpaid resource responsible for project development and management. Therefore, project costs were absorbed into API's FTE budget.

For other primary care clinics looking to adopt the HIV risk screening protocol, the cost would primarily consist of FTE employee hours spent during clinical staff education, a project manager to lead the implementation of the protocol, and potential information technology assistance for integration into the EHR system. Based on *Glassdoor's* database of salary reports, the average hourly wage for a project manager consultant is approximately $42.52 (Glassdoor,

2017). Including staff FTEs, as estimated above, and the cost to hire a project manager, the total estimated cost for a primary care clinic to implement the HIV risk screening protocol is $6,408.54 (Appendix M).

By preventing HIV infection, this DNP project produces a significant benefit of cost-avoidance of HIV management (Appendix M). HIV antiretroviral treatment costs approximately $20,000 upwards per patient per year (CDC, 2015). The medication cost of PrEP is $13,000 per patient per year. If all of API's suspected at-risk patients (232) acquired HIV and required HIV antiretroviral treatment, the estimated minimal cost of treatment is $4,640,000 per year. If started on PrEP and HIV infection is prevented instead, the estimated cost is $3,016,000 per year. This represents a potential cost avoidance of an estimated $1,624,000 per year.

By expanding PrEP implementation, this DNP project also produces a return on investment (ROI) unique to the API clinic in the form of increased health insurance reimbursements. Under its new FQHC status, API qualifies for Medi-Cal reimbursement at the rate of $25 per patient per month for total cost of care (T. Do, personal communication, May 9, 2016). Based on the total estimated at-risk patients (232), assuming they are new to care and Medi-Cal coverage, and are started on PrEP, API can potentially receive an estimated reimbursement of $69,600 in one year (232 patients x $25 x 12 months per year) at this reimbursement rate (Appendix N). This does not account for new Medi-Cal patients as API continues to expand, nor future reimbursements from other health insurance plans as new contracts are established. Thus, the estimated ROI is conservative and is promising for a new FQHC clinic. It is important to clarify that initiating PrEP for established Medi-Cal patients does not create additional reimbursement. However, PrEP care does require frequent follow-up, which would keep patients in care, contributing to patient, and thus reimbursement, retention.

Responsibility/communication plan. The planning involved in this DNP project required extensive interdisciplinary responsibility and continuous communication (see Appendix O for work breakdown and Appendix P for communication plan). Inter-professional collaboration for this project occurred primarily between the author, Dr. Turner and clinical staff, and the author's DNP committee. Working directly with Dr. Turner, the author was responsible for the development, management, implementation, and evaluation of the project. Dr. Turner and Dr. Do provided assistance, serving as clinical experts of API's patient population and HIV prevention. As API's lead NP and CMO, they provided authorization for this DNP project and changes to clinical practice on site (see letter of support in Appendix Q). The clinical data specialist assisted the author with retrieving data from the EHR, while the University of San Francisco (USF) health informatics student intern provided assistance with data analysis, for the baseline clinical data assessment. To assist the author with the cost/benefit analysis, the clinical data specialist reported the approximate patient census for 2016. The API PrEP case manager, whose role is to support PrEP patients and conduct outreach to introduce PrEP to the community, provided invaluable advice for the appropriate approach to screening patients for HIV risk and offering them PrEP. The clinical staff were educated and trained on the HIV risk screening protocol. As the lead NP, Dr. Turner was considerably involved in this DNP project by providing supervision, developing the HIV risk screening protocol with the author, and educating the other providers.

Additionally, collaboration with the City Wide PrEP NP, who works for the San Francisco Department of Public Health to assist primary care clinics in San Francisco with their PrEP implementation needs through education and training, was planned for educating API's clinical staff. The following PrEP experts were also interviewed to research local PrEP

implementation models during the design of the HIV risk screening protocol: the Gilead Sciences assistant director of medical sciences for the west coast region, and local representative; and the PrEP program managers at San Francisco City Clinic and Strut.

Study of the Intervention

After launching the HIV risk screening protocol, methods for assessing the effectiveness of implementation and success of the HIV risk screening protocol were performed (Appendix R). First, the clinical staff post-education test scores were evaluated. Not only did the tests assess the clinical staff's comprehension of the HIV risk screening protocol, HIV risk identification and PrEP offer; they assessed the effectiveness of the educational training. Next, the author collected three months of post-intervention clinical data from the EHR, starting from the launch date of the HIV risk screening protocol on November 1, 2016 through February 1, 2017. Analysis of clinical data from relevant patient encounters (STI testing, establish new patient, and annual physical exam) evaluated staff compliance with the routine utilization of the HIV PrEP screening tool per the established screening process. The author further analyzed the data for appropriate completion of the PrEP implementation cascade to assess the effect of the HIV risk screening protocol on improving API's clinical practice of PrEP implementation.

Measures

Primary outcomes. The following primary outcomes were used to assess the effectiveness of the HIV risk screening protocol based on improvement from baseline clinical practice, as evidenced by an increase by 50% across the PrEP implementation cascade:

1. To increase PrEP offer to 72% of patients with sexual HIV risk, compared to the baseline of 48% of patients with sexual HIV risk that were offered PrEP.

2. To increase PrEP offer to 53% of patients tested positive for an STI, compared to the baseline of 35% of patients tested positive for an STI that were offered PrEP.
3. To increase PrEP evaluation to 53% of patients offered PrEP, compared to the baseline of 35% of patients offered PrEP that completed evaluation.
4. To increase PrEP uptake to 42% of patients evaluated and eligible for PrEP, compared to the baseline of 28% of PrEP eligible patients that were prescribed TDF/FTC.

Secondary outcomes. The following secondary outcomes were used to assess the effectiveness of implementing the HIV risk screening protocol:

1. To achieve effective clinical staff educational training as evidenced by post-education test scores of 80%.
2. To achieve adequate clinical staff compliance with using the HIV PrEP screening tool as evidenced by a screening rate of 80% for each STI testing, establish new patient, and annual physical exam patient encounter.

Maximizing internal and external validity. In order to maximize internal and external validity, the percentage of identified at-risk patients offered PrEP, the percentage of patients offered PrEP who completed PrEP evaluation, and the percentage of patients evaluated and eligible for PrEP who completed PrEP uptake were calculated and analyzed. Comparing these baseline and post-intervention percentages more accurately reflects the effect of the HIV risk screening protocol on the PrEP implementation cascade. Because the HIV PrEP screening tool asks similar questions as the internally validated Denver HIV risk score, it can be inferred that it is also a valid tool for identifying HIV risk (Haukoos et al., 2011). Unlike the Denver HIV risk score, the HIV PrEP screening tool does not produce a numerical score to detect HIV risk.

Therefore, statistical testing is needed to confirm the validity of the HIV PrEP screening tool. As the HIV PrEP screening tool asks questions specific to HIV risk criteria, it represents a reliable tool for identifying patients at risk for acquiring HIV.

External validity of the HIV PrEP screening tool was maximized by incorporating HIV risk and PrEP screening with sexual history assessment into one standardized screening tool. The HIV PrEP screening tool is applicable to other primary care clinics in San Francisco because sexual history assessments are conducted routinely in primary care, as should HIV risk screening in San Francisco where HIV is endemic (SFDPH, 2016). Therefore, streamlining both processes maximizes the HIV PrEP screening tool's external validity. As previously mentioned, the HIV PrEP screening tool asks similar questions as the Denver HIV risk score, which was also externally validated, inferring the external validity of the screening tool (Haukoos et al., 2011). Therefore, the HIV PrEP screening tool can be employed across patient populations and healthcare settings in the US. However, statistical testing is needed to confirm the tool's external validity.

Instruments for assessment. The instruments used to assess the effectiveness of the HIV risk screening protocol were API's EHR system and Microsoft Excel (Appendix R). Because the HIV PrEP screening tool was implemented and pertinent clinical data is documented into the EHR system, the use of the EHR was required for the collection of clinical data analyzed for evaluation. Microsoft Excel was used to perform the data analysis to assess intervention effectiveness by calculating percentages and creating graphs to compare baseline and post-intervention results (Appendix S).

Assuring validity of assessment instruments. Microsoft Excel is a valid instrument because it is a data-analyzing software program that functions independently of API's EHR

system. Potential data entry error in Excel was addressed by re-checking electronically entered totals multiple times for calculating pertinent values. However, human error in counting numbers and entering data in Excel was still possible. The EHR has insufficient validity because of its inconsistencies in retrieving clinical data. Meticulous clinical data collection was conducted to assure data quality and accuracy. To ensure as complete a set of data as possible, multiple data searches were performed, in line with the clinical data specialist's instructions during the baseline clinical data assessment, which generated patient lists from the following search categories: STI testing, establish new patient and annual physical exam patient encounters, and STI lab orders. From each list, the author performed individual patient chart reviews to identify at-risk patients who qualify for PrEP, per CDC guidelines, and if PrEP offer, evaluation and uptake were completed. To maintain consistency in data analysis method, duplications were managed and deleted, and patients previously started on PrEP or living with HIV were excluded from the sample, as performed in the baseline clinical data assessment.

Analysis

Only quantitative analytical methods were used in the evaluation of this DNP project, for which quantified measurable outcomes were developed. Microsoft Excel, a long-standing software program widely used in accounting, statistics, and sciences, was the software used to analyze both the baseline and post-intervention clinical data. Through Excel, the results for each measure were calculated as percentages, for which graphs were generated. Graphs comparing baseline and post-intervention results revealed the effects of the HIV risk screening protocol (Appendix S). While graphs displaying the clinical staff post-education test scores and HIV PrEP screening tool compliance rates demonstrated the effectiveness of implementing the HIV risk screening protocol.

Ethical Considerations

Ethical considerations directly involved in the author's DNP project implementation and evaluation include patient privacy and potential conflict of interest. Patient privacy was protected by strict adherence to the Health Insurance Portability and Accountability Act (HIPAA). While this project was not research, per Institutional Review Board (IRB) guidelines, a waiver was filed (Appendix F). The capture of clinical data from the EHR was conducted only at API within a secure network. Patient names and personal information were excluded during the analysis of clinical data for evaluation of the intervention. The author reports no personal or financial conflicts of interest because her work is unpaid, and she is not affiliated with the pharmaceutical company that manufactures TDF/FTC, public health departments, research or other HIV and PrEP related organizations.

Implications for the ethical practice of PrEP implementation in primary care are recognized by this DNP project. In accordance with the American Nurses Association Ethical Standards and the Jesuit values of the University of San Francisco, the responsibilities of the clinician and the healthcare site were examined. Providers must educate patients and weigh the risks versus benefits of taking PrEP to practice beneficence and non-maleficence (Rowniak & Portillo, 2013). To practice justice, providers must also serve as diligent patient advocates by connecting disenfranchised, at-risk patients to social services necessary to access PrEP. Furthermore, providers must fulfill their role as fiduciary stewards, and consider the financial impact on the healthcare system and society while deciding whether to provide PrEP to a patient (Atherton, Blodgett & Atherton, 2011) (Buck, 2016). Despite well-intentioned attempts, providers must accept that their efforts to provide the best HIV prevention methods may still be

blocked by forces outside of their control, such as patient autonomy and limited access to necessary resources (Rowniak & Portillo, 2013).

Results

Primary Outcomes

Comparing baseline and post-intervention clinical data evaluated the effectiveness of the HIV risk screening protocol (Appendix S). An increase by 50% from baseline was the established target across the PrEP implementation cascade. The results demonstrated positive effects:

1. At baseline, 48% of patients with sexual HIV risk were offered PrEP. After implementation of the HIV risk screening protocol, 81% of at-risk patients were offered PrEP, exceeding the target goal of 72%.
2. At baseline, only 35% of patients who tested positive for an STI were offered PrEP. At post-intervention, 56% of these patients were offered PrEP, surpassing the target percentage of 53%.
3. At baseline, 35% of patients who were offered PrEP completed PrEP evaluation. After project implementation, 56% of these patients were evaluated for PrEP initiation, also exceeding the target percentage of 53%.
4. At baseline, PrEP uptake for patients evaluated and eligible for PrEP was noted at 28%. The post-intervention rate of 36% demonstrated an increase, but did not meet the target goal of 42%.

Secondary Outcomes

The following secondary outcomes assessed the effectiveness of the implementation of the HIV risk screening protocol (Appendix T).

1. Adequate clinical staff comprehension and effective educational training as evidenced by post-education test scores of 80%: Both of the two MAs and one of the two providers completed their respective post-tests. The MAs' test scores were 94% and 56%, averaging 75%. The provider scored 75%.
2. Adequate clinical staff compliance with screening tool use as evidenced by a compliance rate of 80% for each of the following patient encounters:
    a. STI testing: 53% (n = 26)
    b. Establish new patient: 74% (n = 62)
    c. Annual physical exam: 100% (n = 1)

Discussion

Summary

Although the outcomes for PrEP offer and evaluation exceeded their respective target percentages, the exact percentage targets for PrEP uptake and the secondary outcomes were not met. Nonetheless, the aim to increase clinical staff identification of patients with substantial risk for acquiring HIV, and subsequent increase in PrEP offer and evaluation for PrEP initiation were still achieved. Project evaluation highlighted the importance of communication and reinforcing change for effective improvement of clinical practice as targeted. Streamlining the sexual history assessment and HIV risk screening into one standardized screening tool proved successful in improving the clinical practice of PrEP implementation at API, as evidenced by increased percentages across the PrEP implementation cascade. By sharing the HIV risk screening protocol with the City Wide PrEP NP, the PrEP implementation model demonstrated by this DNP project can be used by other primary care clinics in San Francisco. For clinics with limited EHR capacities, the HIV PrEP screening tool can be converted into paper format. Ample clinical staff

education and instruction on establishing a standardized screening process is essential for effective optimization of PrEP implementation.

Interpretation and Limitations

The HIV risk screening protocol produced improvement across primary outcomes, exceeding the target percentage of increase except for PrEP uptake (Appendix S). This is related to pending health insurance coverage limiting PrEP uptake. If these patients had health insurance coverage and received their prescriptions, 100% of those who cleared evaluation would have completed PrEP uptake. Specifically measuring improvement in the gap in PrEP implementation for patients who tested positive for an STI is an especially important clinical outcome. Although PrEP offer increased by 60%, PrEP uptake for patients who tested positive for an STI did not improve from baseline because patients declined PrEP initiation (Appendix U), indicating the need for extensive and continuous patient discussions about PrEP. Often left unaddressed in baseline clinical practice, testing positive for an STI indicates HIV risk. Previous studies have shown that MSM in San Francisco who are diagnosed with rectal gonorrhea or chlamydia more than once within two years are eight times as likely to acquire HIV; and in Florida, women with syphilis were at the highest risk for subsequent diagnosis of HIV infection (Hoover et al., 2016). As 56% of patients tested positive for an STI were offered PrEP, and the HIV PrEP screening tool was used in 53% of STI testing patient encounters at post-intervention, reinforcement of HIV risk screening protocol compliance is warranted to promote patient outcomes.

The results of the secondary outcomes also demonstrated unmet target percentages. Because the average score for both MAs and the one provider who completed their post-education tests was 75%, as opposed to the target score of 80% each, the effectiveness of the clinical staff education was inadequate. This is related to limited time for clinical staff education,

and a scheduling conflict that prevented the City Wide PrEP NP from providing education as initially planned. A clinical staff compliance rate of 80% for screening tool use in STI testing (53%) and establish new patient (74%) encounters was not met (Appendix T). Although the annual physical exam patient encounter received a 100% clinical staff compliance rate, there was only one documented case over the course of the post-intervention period (n = 1). Therefore this result is unreliable. These unmet outcomes demonstrate the unsatisfactory effectiveness of implementing the HIV risk screening protocol. Furthermore, API recently established additional protocols to meet FQHC standards. Multiple changes in practice and the high rate of clinical staff turnover, requiring frequent new employee training, resulted in clinical staff not following the HIV risk screening protocol and the subsequent inadequate compliance rate for using the HIV PrEP screening tool. Better clinical staff education, communication, and HIV risk screening protocol reinforcement could have prevented the inadequate results of the secondary outcomes.

Additionally, the percentages of patients with substantial HIV risk at baseline (61%) and post-intervention (38%) were calculated and compared to address potential changes to the patient population and provide context for the results of the primary outcomes (Appendix V). The noted difference in the percentage of patients with substantial HIV risk indicates a lower-risk patient population for acquiring HIV at post-intervention. The decrease in at-risk patients consequently affects the number of patients who qualify for PrEP offer, and subsequently evaluation and uptake. The internal validity of this DNP project may have been compromised by this decrease in the patient population's HIV risk.

It is necessary to reiterate the limitations within API's EHR system, namely the inconsistencies in its capacity to retrieve clinical data. Despite the aforementioned measures to assure internal validity, technological limitations may still have affected both baseline and post-

intervention clinical data collection, and thus evaluation results. Although not all target outcomes were met, the HIV risk screening protocol can still be a viable model for increasing PrEP implementation in primary care, as supported by the studies of the Denver HIV risk score and HIRI-MSM (Haukoos et al., 2011) (Smith et al., 2012).

Conclusions

The HIV risk screening protocol produced improvement in API's clinical practice of PrEP implementation by increasing PrEP offer, evaluation, and uptake. The minimal estimated cost of the project, and significant cost avoidance and ROI, via health insurance reimbursement estimates, demonstrate the HIV risk screening protocol's cost-efficiency. Similar to other brief screening tools used in primary care, the HIV PrEP screening tool for identifying HIV risk and PrEP offer represents a useful clinical tool in the primary care setting, especially those in endemic areas, for optimizing PrEP implementation and improving HIV prevention.

Implications for practice and future research were derived from the implementation of this DNP project. Because STI infection represents one of the HIV risk criteria per CDC guidelines, as patients with a history of STI infection have a higher susceptibility for acquiring HIV, it is important to note the severity of the potential consequences of not capturing these patients for PrEP offer (CDC, 2014) (Hoover et al., 2016). To effectively optimize PrEP implementation in the primary care setting, as well as further improve clinical practice at API, the relationship between STI testing/treatment and HIV risk screening for PrEP offer must be emphasized and reinforced to clinical staff. Implications for future research include the opportunity to evaluate the effectiveness of the HIV risk screening protocol if implemented at other San Francisco primary care clinics; validate the HIV PrEP screening tool; and assess the

HIV risk screening protocol's impact on San Francisco's HIV transmission rate and contribution to *Getting to Zero San Francisco*.

Other Information

Funding

No internal or external funding was provided for any part in this DNP project, as its costs were absorbed into API's FTE budget. Therefore, funding played no major role in its design, implementation, and interpretation.

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Appendix A

Definition of Terms

API: Asian and Pacific Islander Wellness Center

AUDIT-C: Alcohol Use Disorders Identification Test - Consumption

CDC: Centers for Disease Control and Prevention

CMO: Chief Medical Officer

DNP: Doctorate of Nursing Practice

EHR: Electronic Health Record

FQHC: Federally Qualified Health Center

FTE: Full Time Equivalent

HIRI-MSM: HIV Incidence Risk Index for Men who have Sex with Men

HIPAA: Health Insurance Portability and Accountability Act

HIV: Human Immunodeficiency Virus

IDU: Intravenous Drug User

IRB: Institutional Review Board

JHNEBP: Johns Hopkins Nursing Evidence Based Practice

LGBTQ: Lesbian, Gay, Bisexual, Transgender, Queer

MA: Medical Assistant

MSM: Men who have Sex with Men

NP: Nurse Practitioner

PHQ: Patient Health Questionnaire

PrEP: Pre-exposure Prophylaxis against HIV Infection

RCT: Randomized Controlled Trials

ROI: Return on Investment

STI: Sexually Transmitted Infection

TDF/FTC: Tenofovir Disoproxil Fumarate/Emtricitabine

UNAIDS: United Nations Program on HIV/AIDS

USF: University of San Francisco

US: United States

WHO: World Health Organization

Appendix B

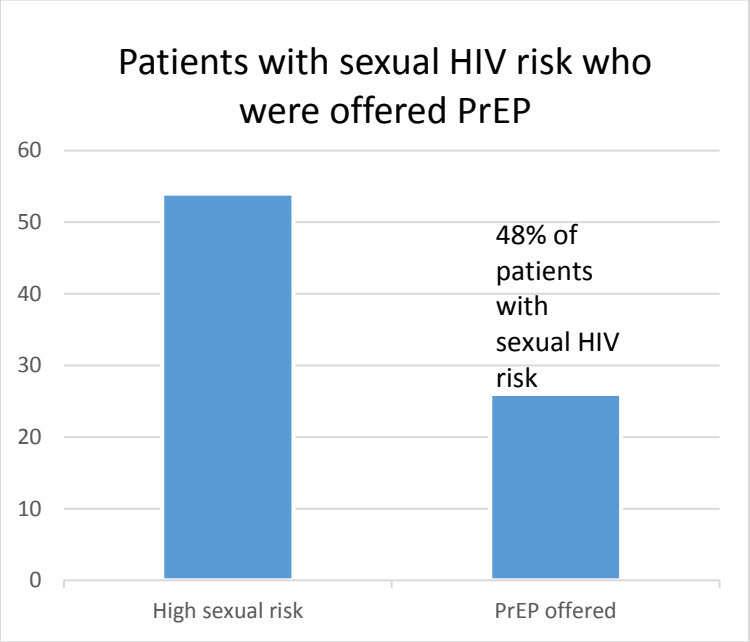
CDC Guidelines for Detecting Substantial Risk for Acquiring HIV

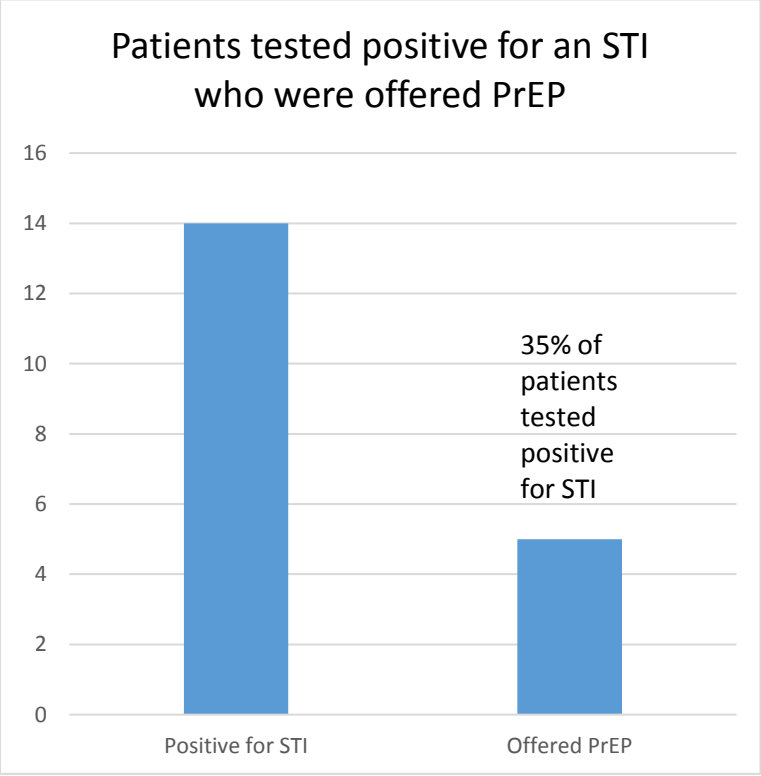
Men who have sex with men	Heterosexual men and women	Injection drug users
HIV-positive sexual partner	HIV-positive sexual partner	HIV-positive injecting partner
Recent bacterial STI	Recent bacterial STI	Sharing injection equipment
High number of sex partners	High number of sex partners	Recent drug treatment (but currently injection)
History of inconsistent or no condom use	History of inconsistent or no condom use	
Commercial sex work	Commercial sex work	
	In high-prevalence area or network	

*Note: Adapted from the Centers for Disease Control and Prevention. (2014). *Preexposure prophylaxis for the prevention of HIV infection in the United States: A clinical practice guideline.* Retrieved from: https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

Appendix C

Baseline Clinical Data Assessment





* Note: Based on data from chart reviews of medical encounters for ordered STI testing from December 7, 2015 to April 8, 2016 (n =88).

Appendix D

PrEP Efficacy Evidence Tables using JHNEBP Research Evidence Appraisal

Citation	Conceptual Frame-work	Design/ Method	Sample/ Setting	Major Variables	Measurement	Data Analysis	Findings	Appraisal
WHO (2012). *Guidance on Pre-Exposure Oral Prophylaxis (PrEP) for Serodiscordant Couples, Men and Transgender Women Who Have Sex with Men at High Risk of HIV: Recommendations for Use in the Context of Demonstration Projects.* World Health Organization: Geneva, Switzerland.	Development of clinical practice recommendations	Meta-analysis	N = > 8,000 Trial 1: 6-county iPrEx trial in MSM/TGF. Trial 2: women at higher risk of HIV Kenya, South Africa, Tanzania. Trial 3: heterosexual men and women in Botswana. Trial 4: Partners PrEP: HIV-1 serodiscordant couples in Kenya & Uganda. Trial 5: The VOICE trial of Women in Uganda, South Africa, &	Trial 1: TDF/FTC in MSM/TGF & HIV acquisition. Trial 2: daily PO TDF/FTC in African women at higher risk of HIV. Trial 3: daily PO TDF/FTC in heterosexual men and women. Trial 4: daily PO TDF & daily PO TDF/FTC among HIV-1 serodiscordant couples in Kenya and Uganda. Trial 5: Women in Uganda, South Africa, & Zimbabwe. Daily PO TDF; daily PO TDF/FTC; daily topical TDF gel, vs. placebos	Trial 1: HIV infection rates, measurable serum drug levels indicating medication adherence. Trial 2: HIV infection rates. Trial 3: HIV infection rates. Trial 4: Plasma TDF levels, indicating medication adherence, HIV conversion rates. Trial 5: HIV infection rates.	Systematic reviews of effectiveness, safety, GRADE profile analysis, reviews of values & preferences of potential users & consultations w/ key scientists, implementers & peer reviewers. The Guidelines Steering Group, the full Guidelines Development Group, ^ the External Review Group conducted the analysis.	Trial 1: 44% HIV acquisition reduction. Trial 2: inconclusive d/t poor adherence. Trial 3: reduced risk of HIV infection by 63%. Trial 4: 67% overall effectiveness w/ TDF; 75% overall effectiveness w/ TDF/FTC. With higher levels of adherence: TDF 86% effective; TDF/FTC 90% effective. Trial 5: unfinished.	Meta-analysis of RCTs Limitations: Medication adherence, inconclusive results from 2 RCTs. Strength of Evidence: Level 1 Quality A
Centers for Disease Control and Prevention (2014). *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline.* US Public Health Service.	Development of clinical practice guidelines	Meta-analysis	MSM iPrEX Trial n=2,499 US MSM Safety Trial n=400 Hetero M/W Partners PrEP n=4,758 TDF2 N=1,219 Hetero W FEM-PrEP N=2,120 West African Trial n=936 VOICE n=3,0109 IVDU BTS n=2,411	TDF/FTC TDF TDF & TDF/FTC TDF/FTC TDF/FTC TDF TDF & TDF/FTC TDF	HIV Infection rates, medication adherence.	N/A Summary of completed clinical trials	Efficacy Est (95% CI) iPrEX: 44% US MSM: NR Partners PrEP TDF: 67% TDF/FTC 75% TDF2:62% FEM-PrEP: 6% West African Trial: 65% VOICE TDF: 50% TDF/FTC: 4% BTS: 49% Efficacy by med adherence (blood detection of drug) iPrEx: 92% Partners PrEP: TDF: 86% TDF/FTC: 90% TDF2: TDF 85% FEM-PrEP: NR VOICE: NR	Meta-analysis of RCTs Limitations: Medication adherence, loss to follow-up, Heterosexual women trials stopped early Strength of Evidence: Level 1 Quality A

PrEP Efficacy Evidence Tables using JHNEBP Research Evidence Appraisal (continued)

Citation	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables	Measurement	Data Analysis	Findings	Appraisal
WHO (2015). *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV.* World Health Organization: Switzerland.	Comprehensive revision of 2013 guidelines based on new evidence & lessons from implementation through June 2015 via Clinical Guideline Development Group.	Guideline based on: Systematic Review & meta-analysis Qualitative Literature Reviews External peer review	14 RCTs, 3 observational studies, studies in accordance w/ PRISMA reporting guidelines Settings: Trials conducted in India, Indonesia, Kenya, Peru, Portugal, Ukraine, Zambia and Zimbabwe.	HIV infection Guideline recommendation based on the following criteria: Rationale & supporting evidence Benefits vs harm Cost & cost-effectiveness Equity & acceptability Feasibility Implementation considerations Research gaps.	HIV infection in TDF vs TDF/FTC vs placebo. PrEP effectiveness in high adherence group (>70% serum drug detection) vs moderate adherence (41-70% drug detection) vs low adherence group (<40% drug detection). Drug resistance to FTC in HIV + subjects (= low).	Studies reviewed & recommendations developed using GRADE method Results: PrEP trials containing TDF = effective in reducing risk of HIV infection, regardless of age, gender, regimen (TDF VS TDF/FTC), & mode of infection. Significant HIV reduction in high and moderate adherence group; no effect in low adherence group.	New recommendation replaces the previous WHO recommendations on PrEP and enables the offer of PrEP to be considered for people at substantial risk of acquiring HIV rather than limiting the recommendation to specific populations, including during pregnancy.	Meta-analysis of RCTs Qualitative literature review Limitations: Medication adherence, & systematic review used was an unpublished study Strength of Evidence: Level 1 & 3 Quality A

Appendix E

PrEP Implementation Evidence Tables using JHNEBP Research Evidence Appraisal

Citation	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables	Measurement	Data Analysis	Findings	Appraisal
Chan, P. A., Glynn, T. R., Oldenburg, C. E., Montgomery, M. C., Robinette, A. E., Almonte, A., … Nunn, A. S. (2016). Implementation of preexposure prophylaxis for human immunodeficiency virus prevention among men who have sex with men at a New England sexually transmitted diseases clinic. *Sexually Transmitted Diseases, 43*(11), 417-422.	Analysis of gaps in PrEP imple-menta-tion cascade.	Demonstration project Method: Every MSM seeking STD related services were offered education on PrEP. If agreeable, they were provided PrEP education. Their interest in PrEP was then assessed. For those interested in PrEP, follow-up was conducted to schedule an appointment with a provider for evaluation to initiate PrEP. For those who kept their provider appointments and met PrEP criteria, they were prescribed PrEP. Brief questionnaire assessed reasons behind patients' lack of interest or refusal to initiate PrEP.	New England Sexually Trans-mitted Diseases Clinic N=234 MSM.	Lack of interest. Lack of patient acceptabilit y of PrEP.	Number of participants included in the following steps of the PrEP implementa-tion cascade: Educated about PrEP; interested in PrEP; received follow-up contact; scheduled provider appointment; attended provider appointment; initiated PrEP (received Rx).	Bivariate and multi-variable logistic regress-ion models to examine predict-ors of PrEP initiation.	Educated about PrEP: 234 Interested in PrEP: 56% Received follow-up scontact: 53% of those interested Scheduled provider appointment: 51% of those who followed up Attended provider appointment: 77% of those who schduled an appointment Initiated PrEP (rceived Rx): 95% of those who attended the appointment Reasons for lack of interest in PrEP: 37% low HIV risk perception; 10% more time to consider; 7% concern about side effects; 3% financial barriers Reason for not scheduling an appointment: low HIV risk perception	Non-experiment-al study Limitations : low HIV risk perception, lack of provider knowledge about PrEP. No control group. Strength of Evidence: Level 3 Quality C
Cohen, S. E., Vittinghoff, E., Bacon, O., Doblecki-Lewis, S., Postle, B. S., Feaster, D. J.,…Liu, A. Y. (2015). High interest in preexposure prophylaxis among men who have sex with men at risk for HIV infection: baseline data from the US PrEP demonstration project. *Acquired Immune Deficiency Syndrome, 68*(4), 439-448.	Assess-ment of PrEP delivery in munici-pal health care settings.	Prospective, longitudinal open-label cohort study. Method: MSM and transgender women were targeted and prescreened for referral to participate in the study, then screened for PrEP eligibility, followed by completion of a detailed interviewer-administered questionnaire on demographics and sexual and drug-use behaviors. Those who cleared PrEP screening were "enrolled" for PrEP initiation and received TDF/FTC at no cost for 48 weeks.	N= 557 STD clinics in San Francis-co & Miami: MSM & trans-gender women. Comm-unity health center in Washing-ton, DC: MSM & trans-gender women.	PrEP eligibility criteria. Screening participants for PrEP. Enrollment of participants in study. PrEP uptake. Socio-demograph-ics, & sexual & drug use behaviors. HIV risk perception. Prep awareness.	Participant enrollment, HIV risk behaviors, PrEP awareness, interest in PrEP.	Multi-variable Poisson regress-ion model assessed predict-ors of enroll-ment. Multi-variable descript-ive statistical analyses of partici-pant character-istics.	Participants who were self-referred, those with previous PrEP awareness, and those reporting > 1 episode of anal sex with an HIV-positive partner in the last 12 months were more likely to enroll. 98% of enrolled participants were MSM. At baseline, 63.5% of MSM reported condomless receptive anal sex in the previous 3 months. Overall, interest in PrEP is high among a diverse population of at-risk MSM when offered at STD or community health clinics.	Qualitative study Limitations : no control group Strength of Evidence: Level 3 Quality B

PrEP Implementation Evidence Tables using JHNEBP Research Evidence Appraisal (continued)

Citation	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables	Measurement	Data Analysis	Findings	Appraisal
Doblecki-Lewis, S., & Jones, D. (2016). Community federally qualified health centers as homes for HIV preexposure prophylaxis: perspectives from south Florida. *Journal of the International Association of Providers of AIDS Care, 15*(6), 522-528.	Focus group study to explore the feasibility, acceptability, and uptake of PrEP in an endemic area.	Qualitative study of focus group discussion themes Method: 6-7 staff members from each clinic were interviewed. Brief demographic background information was collected, and focus group discussions were moderated by a study investigator using a semi-structured guide.	N= 22 clinic staff 4 community health centers in southeastern Florida, 3 of which are FQHCs.	Staff perceptions of: PrEP implementation practice; PrEP interest among patients; PrEP acceptability among patients and providers; concerns and barriers to PrEP.	Themes derived from focus group discussions.	Audio recordings of focus group discussions were transcribed. Transcripts uploaded to Dedoose version 5.0.11 for analysis. Open coding of transcripts further developed themes. Coded transcripts were reviewed by study team members, resolving differences by discussion and mutual agreement, for accuracy.	Themes surrounding PrEP: need for increased provider knowledge about PrEP; perception of low PrEP demand among patients; cost and risk assessment as perceived barriers to PrEP; concerns about adherence and risk compensation.	Qualitative study. Limitations: potential bias from arbitrary theme development by study team members compromises validity. Strength of evidence: Level 3 Quality C
Silapaswan, A., Krakower, K., & Mayer, K. H. (2016). Pre-exposure prophylaxis: a narrative review of provider behavior and interventions to increase PrEP implementation in primary care. *Journal of General Internal Medicine, 32*(2), 192-198.	Practice recommend-ations	Narrative review Method: Previous qualitative studies of provider behavior, attitudes, and intentions toward PrEP provision were summarized to develop practice recommendations to optimize PrEP in the primary care setting.	Multiple studies. Exact number nor specified.	Provider behavior, attitudes, and intentions toward PrEP provision.	Barriers to PrEP "real world" effectiveness. Potential unintended clinical consequences. Purview Paradox.	Summarizes findings from previous studies, otherwise not specified.	Barriers to PrEP: PrEP efficacy & medication adherence; provider logistics; potential unintended clinical consequences (ARV drug resistance PrEP drug toxicity); behavioral disinhibition & STIs. Purview Paradox: HIV specialists have higher PrEP awareness than PCPs. Practice recommendations: Increase provider education & training on PrEP. Optimize medication adherence and PrEP acceptability through community engagement. Improve identification of appropriate patients for PrEP.	Meta-synthesis. Limitations: Methods not discussed. Unknown sample size. Low internal validity. Strength of Evidence: Level 3 Quality C

PrEP Implementation Evidence Tables using JHNEBP Research Evidence Appraisal (continued)

Citation	Conceptual Frame-work	Design/ Method	Sample/ Setting	Major Variables	Measure-ment	Data Analysis	Findings	Appraisal
Hoover, K. W., Ham, D. C., Peters, P. J., Smith, D. K., & Bernstein, K. T. (2016). Human immunodeficiency virus prevention with preexposure prophylaxis in sexually transmitted disease clinics. *Sexually Transmitted Diseases*, *43*(5), 277-282.	Models of Practice	Commentary Method: summary of evidence regarding PrEP efficacy and higher risk of HIV infection related to STD infection. Models of PrEP implementation in STD clinics are described.	Sample: n/a Setting: STD clinics	PrEP uptake in the US has been low.	STD infection as objective biological markers for HIV risk.	n/a	High-risk patient populations disproportionately seek care at STD clinics, and STD infections increase the susceptibility for HIV acquisition, therefore STD clinics are the optimal setting for PrEP implementation. Recommendations: Model 1: PrEP services provided directly at STD clinic. Model 2: STD clinic captures PrEP eligible patient and provides referral to a PrEP provider in the community.	Meta-synthesis. Limitations: no trials studied. Method not discussed. No evaluation of effectiveness of models for practice. Strength of Evidence: Level 3 Quality C
Hoffman, S., Guidry, J. A., Collier, K. L., Mantell, J. E., Boccher-Lattimore, D., Kaighobadi, F., & Sandfort, T. G. (2016). A clinical home for preexposure prophylaxis: diverse health care providers' perspectives on the "Purview Paradox." *Journal of the International Association of Providers of AIDS Care*, *15*(1), 59-65.	Multi-disciplin-ary interview-ing	Qualitative study of interview data. Method: practicing clinicians who provide care for MSM, IDUs, & high-risk heterosexual women were recruited & provided education on PrEP. Extensive interviewing (1-1.5 hrs) of each participant was conducted by study coinvestigators or project director about the following topics: PrEP knowledge; prescribing guidelines; prior experience prescribing PrEP; skills needed to implement PrEP in one's practice & anticipated challenges; perceptions of peers' opinions of PrEP; intentions to implement PrEP, & to whom; anticipated training needs; preferences for continuing education modalities.	N = 30 providers: 24 MDs, 4 NPs, 2 PAs. Setting: greater New York metro-politan area.	Purview Paradox: who should provide PrEP? (HIV specialists vs. PCPs).	Interviews were transcribed and coded for global topics.	Final codes were applied to documents using a computer-ized qualitative program (Atlas.ti), after which coding reports were produced for each global code. Coding grids were derived from the reports to identify participant character-istics.	A diverse group of participants favored PrEP implementation in non-HIV specialty settings, but were divided on whether they thought primary care providers could achieve all the skills and services espoused with PrEP provision.	Qualitative study. Limitations: potential bias since interview content was coded by study team members, which compromises internal validity. Strength of Evidence: Level 3 Quality C

PrEP Implementation Evidence Tables using JHNEBP Research Evidence Appraisal (continued)

Citation	Conceptual Frame-work	Design/ Method	Sample/ Setting	Major Variables	Measurement	Data Analysis	Findings	Appraisal
Raifman, J. R., Flynn, C., & German, D. (2017). Healthcare provider contact and pre-exposure prophylaxis in Baltimore men who have sex with men. *American Journal of Preventative Medicine*, 52(1), 55-63.	Dissemin-ation of PrEP awareness	Qualitative data analysis Method: data from the 2014 MSM wave of National HIV Behavioral Surveillance (NHBS) in Baltimore were collected and analyzed for exposures to healthcare versus community based organization (CBO) contacts and PrEP awareness.	N = 401 MSM Setting: 2014 Baltimore NHBS data.	PrEP awareness related to healthcare vs CBO contacts.	Exposures to healthcare vs CBO contacts: 1. Seeing a healthcare provider in the past 12 mo; 2.Having a usual source of care; 3.Being out to a healthcare provider; 4.Receiving HIV testing from healthcare provider; 5.Getting tested for HIV; 6.Getting tested for STI; 7.Testing positive for an STI; 8.Participating in individual HIV prevention counseling; 9.Participating in group HIV prevention counseling; 10.Receiving free condoms from an HIV CBO; 11. Receiving free condoms from an LGBT CBO.	Stata, version 12, was used to conduct analyses: associations between healthcare contacts and PrEP awareness were estimated via logistic regression models controlling for age, race and education, and clustering by venue. Additional comparative analyses between PrEP and other HIV prevention intervention were conducted with HIV testing as an outcome. Healthcare provider and CBO contact regarding HIV testing in the past year was evaluated. Lastly, statistical analysis	Visiting a healthcare provider in the past 12 mo, receiving an HIV test from a provider, and having an STI test in the past 12 mo were not significantly associated with PrEP awareness. PrEP awareness was positively associated with being out to a healthcare provider ($p<0.001$); being tested for HIV ($p=0.023$); & receiving condoms from an HIV/AIDS CBO ($p=0.001$). HIV testing was significantly associated w/ most forms of healthcare contact. Healthcare providers are providing HIV testing to MSM, but not PrEP.	Meta-synthesis Limitations: no quantitative data as it was a qualitative study, but otherwise thoroughly assured internal validity. Strength of Evidence: Level 3 Quality A
Haukoos, J. S., Lyons, M. S., Lindsell, C. J., Hopkins, E., Bender, B., Rotham, R. E., … Byyny, R. L. (2011). Derivation and validation of the Denver human immunodeficiency virus (HIV) risk score for targeted HIV screening. *American Journal of Epidemiology*, *175*(8), 838-846.	HIV risk screening tool	Screening tool development; internal & external validation. Method: Denver HIV risk score derived from analysis of prospectively collected data from routine assessment patient information required for HIV testing, producing HIV risk prediction model. Internal validity established, then externally tested at a different healthcare site in	Deriva-tion sample: 92,635, of which 504 HIV-pos. Setting: Denver Metro Health Clinic (STD clinic). Validation sample: 22,983 Setting: University of Cincinnati Medical Center ER.	Demographic character-istics, symptoms, STI hx, sexual hx, specific sexual practices & condom use, gender of sexual contacts, previous HIV testing hx, other risk factors for HIV transmission. Confirmed HIV infection served as the outcome/ dependent variable.	Predictive value of variables; predictive ability of Denver HIV risk score model; predictive HIV prevalence vs observed HIV prevalence.	Derivation: Denver HIV risk model development: multi-variable logistic regression, bivariate statistical testing, Akaike's Information Criterion for global test of good fit, statistical analysis of predictive ability of variables. Internal validity: 10-fold cross- validation & calibration by graphically comparing predicted HIV prevalence w/ observed HIV prevalence. External validity: data managed w/ Microsoft Access. Statistical analyses: SAS, version 9.2; Stata, version 10.1; SPSS, version 18. Markov chain Monte Carlo approach - to promote validity of results. Bootstrapping approach to estimate 95% CI for regression coefficients of final model.	Final Denver HIV risk score included predictive variables: age, gender, race/ethnicity, sex w/ a male, vaginal intercourse, receptive anal intercourse, IDU, & past HIV testing. HIV prevalence for the following scores: <20: 0.31% 20-29: 0.41% 30-39: 0.99% 40-49: 1.59% 50 and up: 3.59% (95% CI each). Denver HIV risk score accurately categorizes patients into groups with increasing probabilities of HIV infection.	Derivation: Meta-synthesis External validation: Quasi-experimental study. Limitations: qualitative data within variables r/t patient answers. High quality data analysis: multiple software & approaches assured internal & external validity. Strength of Evidence: Levels 3 & 2 Quality A

PrEP Implementation Evidence Tables using JHNEBP Research Evidence Appraisal (continued)

Citation	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables	Measure-ment	Data Analysis	Findings	Appraisal
Smith, D. K., Pals, S. L., Herbst, J. H., Shinde, S., & Carey, J. W. (2012). Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *Journal of Acquired Immune Deficiency Syndromes, 60*(4), 421-427.	Brief HIV risk screening tool	Prospective data analysis for screening tool development, followed by internal validation. Method: Analysis of data from 2 existing large data sets from HIV prevention trials that enrolled HIV-uninfected MSM in the US, collected risk behavior data and HIV test results every 6 mo, & that had at least 100 HIV seroconversions over the course of the trial. MSM in active and control arms of the trial data sets were included. Questionnaires used in both data set trials were reviewed to select screening questions. Point scores for the index were developed. The final screening tool model was developed: HIV Incidence Risk Index for MSM (HIRI-MSM).	VAXGEN 004 RCT data set N = 4,643 HIV-uninfected MSM from 57 US sites Project EXPLORE RCT data set N = 4,295 HIV-uninfected MSM from 6 US cities.	Age In past 6 months: Sexual behavior (# sex partners, # times of unprotected receptive anal sex; # times of unprotected insertive anal sex, each by reported HIV status of partner). Non-injection substance use (poppers, amphetamines, hallucinogens, cocaine, or sildenafil). Any self-reported STI. Residence in one of the top 10 metropolitan statistical areas in the US ranked by HIV prevalence.	Predictive ability of variables	Generalized estimating equations were used to fit logistic regression models to adjust for over-time correlation in variables. Statistical analysis of predictive ability of each variable. Bootstrap and backward elimination procedure were used to select variables for the final model, which included only those with P<0.05 statistical significance. Multiplication of regression coefficients for each by 10 and rounded to the nearest integer was conducted to develop point scores for the index. Point values for all variables in the model were summed to establish a high-risk MSM index score. Different score cut-offs established by computing sensitivity, specificity, and area under ROC curve.	Final logistic regression model for HIRI-MSM included: Age; During past 6 mo: Total # of male sex partners; total # of HIV-positive male sex partners; number of times of unprotected receptive anal sex w/ a male partner of any HIV status; Number of times of insertive anal sex w/ an HIV-positive male partner; use of poppers; use of amphetamines. Area under ROC curve: 0.74 Index scores range from 0-47 Score of 10 & up has sensitivity of 84% & specificity of 45%, levels appropriate for a screening tool.	Meta-synthesis Limitations: no trial to assess implementation of HIRI-MSM. Lacks external validity Strength of Evidence: Level 3 Quality A

Appendix F

Statement of Determination

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DNP Statement of Non-Research Determination Form

Student Name: Cara Padilla-Nalagan

Title of Project: Improving HIV prevention among populations at substantial risk for acquiring HIV by optimizing PrEP delivery in the urban primary care setting.

Brief Description of Project:

A) Goal:

The goal of this project is to improve HIV prevention at primary care clinics in line with the Getting to Zero San Francisco program.

Aim Statement:

To improve HIV prevention by increasing clinical staff identification of patients at substantial risk for HIV per CDC guidelines and provider offer of Truvada for PrEP in the urban primary care setting.

B) Description of Intervention:

Objectives:

1. Develop a screening tool for clinical staff to improve identification of patients at substantial risk for HIV and increase provider offer of Truvada for PrEP at an urban primary care clinic by September 6, 2016.
2. Educate clinical staff on the use of the screening tool and evaluate staff comprehension by September 16, 2016.
3. Implement the screening tool at an urban primary care clinic by October 1, 2016.
4. Evaluate clinical staff compliance of the use of the screening tool of at least 80% of all medical encounters at an urban primary care clinic by February 1, 2017.
5. Evaluate consistency in provider practice of offering Truvada for PrEP to patients at substantial risk for HIV as identified by the screening tool by February 1, 2017.

Statement of Determination (continued)

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

C) How will this intervention change practice?

This intervention will change practice by standardizing current practice to improve adherence to the CDC's 2014 PrEP clinical practice guidelines.

D) Outcome measurements:

1. Education post-test for clinical staff on screening tool comprehension by September 16, 2016.
2. Measure screening tool compliance through percentage of screening tool use for every medical encounter by January 8, 2017.
3. Increase by 50% of eligible patients to whom providers offer Truvada for PrEP compared to the baseline data of 48% by January 8, 2017.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)

☑ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐ This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title:	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	✓	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	✓	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	✓	

Statement of Determination (continued)

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ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	✓	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	✓	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with *USF SONHP*.	✓	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	✓	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients. If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	✓ ✓	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print):
Cara Padilla-Nalagan

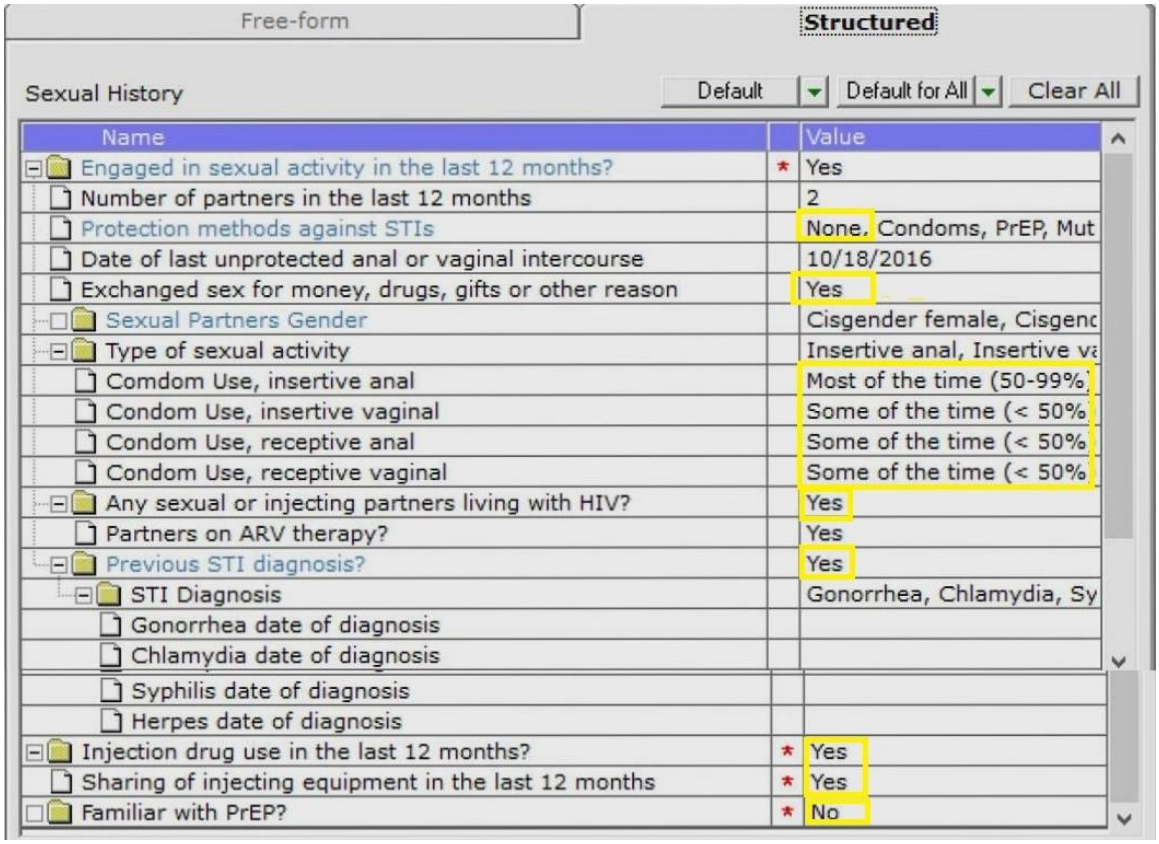
Signature of Student: Cara Padilla-Nalagan **DATE** 6/1/2016

SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print):
Chenit Ong-Flaherty

Signature of Supervising Faculty Member (Chair): **DATE** 6/1/2016

Appendix G

HIV PrEP Screening Tool Implemented into the EHR

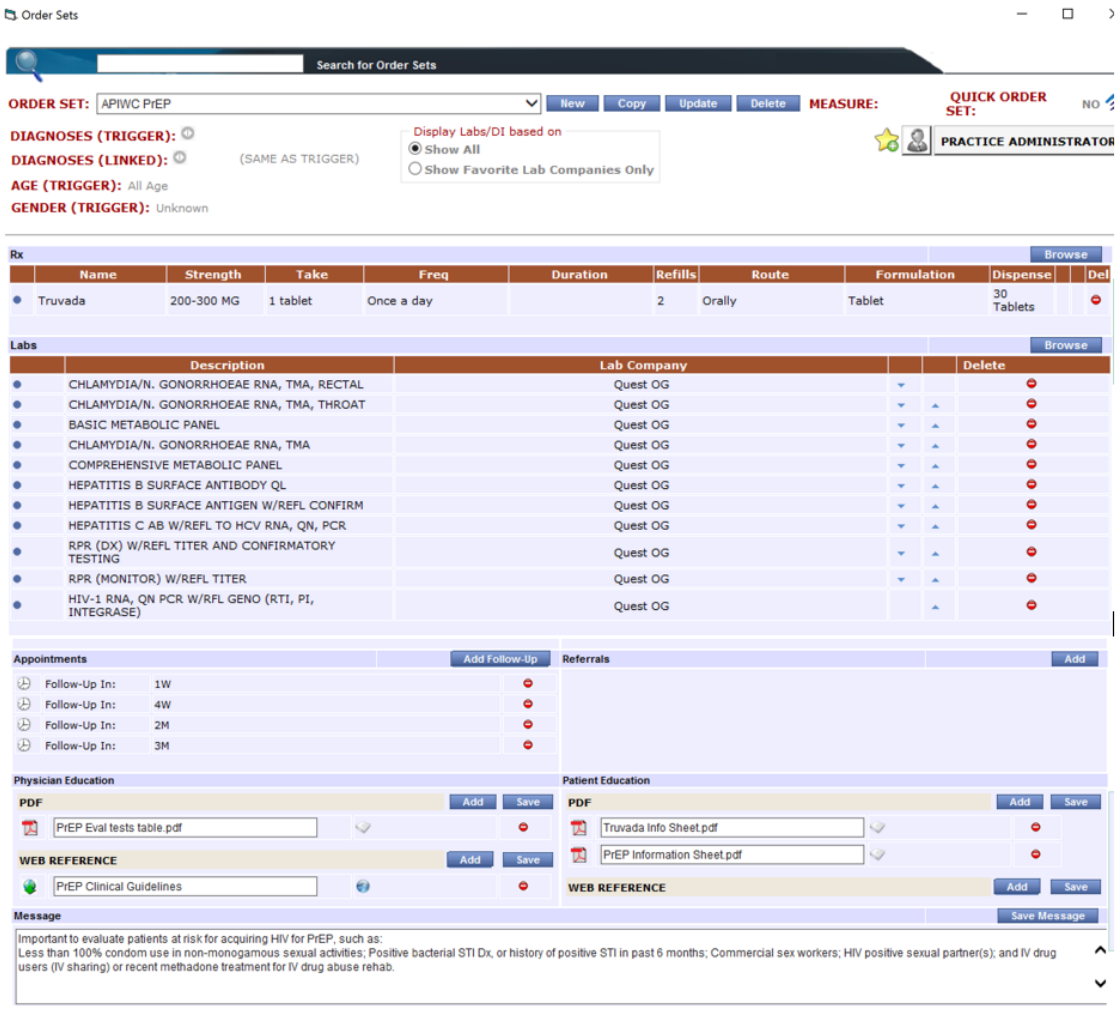


*Note: Highlighted answers indicate HIV risk and PrEP offer/discussion of PrEP

Appendix H

Clinical Support Tools Implemented into the EHR

PrEP order set linked to STI-related ICD-10 diagnoses:



Clinical Support Tools Implemented into the EHR (continued)

PrEP evaluation progress note template:

Current Medications
None

Past Medical History
Denies history of renal and bone disease

Social History
Sexual History:
Sexual History
Engaged in sexual activity in the last 12 months? *Yes* _
Injection drug use in the last 12 months? *No*
Familiar with PrEP? *Yes*
Drugs/Alcohol:
Drugs
Have you used drugs other than those for medical reasons in the past 12 months? *Yes*

Allergies
.

Review of Systems
General/Constitutional:
Patient denies Fever, chills, night sweats, weight loss, myalgias, lymphadenopathy.
Ophthalmologic:
Patient denies Visual changes.
ENT:
Patient denies Sore throat, oral lesions.
Respiratory:
Patient denies SOB, cough, wheezing.
Cardiovascular:
Patient denies Chest pain, palpitations, edema.
Gastrointestinal:
Patient denies Abdominal pain, N/V/D, loss of appetite, rectal pain, itching or burning.
Genitourinary:
Patient denies Dysuria, hematuria, penile discharge, genital lesions, scrotal pain or swelling.
Musculoskeletal:
Patient denies Joint pain.
Skin:
Patient denies Rash, lesions or skin changes.
Neurologic:
Patient denies Headache.

Reason for Appointment
1. PrEP Evaluation.

History of Present Illness
Primary Care:
PrEP Screening Tool
Engaged in sexual activity in the last 12 months? _
PrEP:
PrEP History
Motivation *Concerned about personal HIV risk* _
HIV Risk *Inconsistent condom use, IVDU, HIV positive partner (s), STI diagnosed in last 6 months*
Ever prescribed PrEP previously? *No*
Ever prescribed PEP? *Yes*
Date /
Most recent HIV test /
Previously screened for STDs (GC/CT, syphilis, Hep B/C)? *Yes*
Most recent screen /
Engaged in primary care? *Yes*

Examination
General Examination:
GENERAL APPEARANCE: alert, pleasant, well nourished, well developed, in no acute distress.
EYES: BOTH EYES, sclera non-icteric, upper eyelids normal, lower eyelids normal.
ORAL CAVITY:
Exam: *gums normal, mucosa moist, no lesions*

THROAT: pharynx without exudate or erythema, tonsils 1+ without exudate or erythema.
LYMPH NODES: no cervical adenopathy, no inguinal lymphadenopathy.
SKIN: warm and dry, good turgor, no rashes, no suspicious lesions.
HEART: regular rate and rhythm, S1, S2 normal, no S3, S4, no murmurs, rubs, gallops.
LUNGS: clear anteriorly and posteriorly, good air movement, no wheezes, rales, rhonchi.
ABDOMEN: rounded, normoactive bowel tones, soft, nontender, nondistended, liver edge not palpable, liver non-tender.
RECTAL EXAM: no external hemorrhoids or lesions, no red blood.
MALE GENITOURINARY: testes descended bilaterally, no hydrocele, no penile lesions or discharge, no testicular mass or tenderness.
NEUROLOGIC: alert and oriented, cooperative with exam.
PSYCH: good eye contact, judgement and insight good, mood/affect full range, speech clear, thought process logical, goal directed.

Assessments
1. Contact with and (suspected) exposure to other viral communicable diseases - Z20.828 (Primary)
2. Encounter for screening for infections with a predominantly sexual mode of transmission - Z11.3

Treatment
1. Contact with and (suspected) exposure to other viral communicable diseases
Start Truvada Tablet, 200-300 MG, 1 tablet, Orally, Once a day, 30, Refills 2
LAB: COMPREHENSIVE METABOLIC PANEL
PROCEDURE: VENIPUNCT, ROUTINE*
Notes: Counseled on PrEP indications, efficacy, limitations, dosing and potential side effects. Counseled on importance of consistent, daily adherence, time to protective effect. Reminded that protection is limited to HIV infection and is not 100% effective. Encouraged continued condom use for protection against other STI. Labs today.

2. Encounter for screening for infections with a predominantly sexual mode of transmission
LAB: Rapid HIV 1/2 Antibody Rapid
LAB: CHLAMYDIA/N. GONORRHOEAE RNA, TMA, RECTAL
LAB: CHLAMYDIA/N. GONORRHOEAE RNA, TMA, THROAT
LAB: RPR (DX) W/REFL TITER AND CONFIRMATORY TESTING
LAB: HEPATITIS B SURFACE ANTIGEN W/REFL CONFIRM
LAB: HEPATITIS B SURFACE ANTIBODY QL
LAB: HEPATITIS C AB W/REFL TO HCV RNA, QN, PCR
LAB: CHLAMYDIA/N. GONORRHOEAE RNA, TMA
PROCEDURE: VENIPUNCT, ROUTINE*
Notes: Full STD screening panel today. Counseled on risk and harm reduction. Condoms offered.

Procedure Codes
3300 Rapid HIV test
99401 P/M COUNSEL, INDIV 15 MIN
36415 VENIPUNCT, ROUTINE*

Follow Up
1 Week (Reason: PrEP Initiation)

Appendix I

Clinical Staff Post-Education Tests

Medical Assistant Test:

HIV Risk Screening Protocol

1. Which of the following are signs that indicate eligibility for PrEP? (Highlight all that apply)
    - □ Recent STI diagnosed in the past 6 months
    - □ Current STI diagnosis
    - □ 80% condom use for vaginal and/or anal sexual intercourse
    - □ Illicit drug use
    - □ Multiple sexual partners of known HIV -negative status
    - □ Multiple sexual partners with 100% condom use
    - □ Monogamous relationship with HIV-positive sexual partner
    - □ Injection drug use without equipment sharing and uses clean needles only
    - □ History of syphilis from 10 years ago
    - □ Monogamous relationship with HIV-negative partner
    - □ HIV-negative injecting partner
    - □ Exchanges sex for rent
    - □ Transgender woman who is asexual
    - □ HIV-positive injecting partner
2. True or False: At the end of the sexual health assessment, always ask the patient if they have heard of PrEP. (Highlight answer)
    a. True
    b. False
3. After conducting the sexual health assessment, what do you do next? (Highlight answer)
    a. Report results of the patient's sexual health assessment to the provider at huddle.
    b. State whether or not the patient is eligible for PrEP and ask the provider to discuss PrEP with the patient.
    c. Both a & b

Clinical Staff Post-Education Tests (continued)

Provider Test Part 1:

HIV Risk Screening Protocol

1. Which of the following are signs that indicate eligibility for PrEP? (Highlight all that apply)
    - □ Recent STI diagnosed in the past 6 months
    - □ Current STI diagnosis
    - □ 80% condom use for vaginal and/or anal sexual intercourse
    - □ Injected drug use
    - □ Multiple sexual partners of known HIV -negative status
    - □ Multiple sexual partners with 100% condom use
    - □ Monogamous relationship with HIV-positive sexual partner
    - □ Injection drug use without equipment sharing and uses clean needles only
    - □ History of syphilis from 10 years ago
    - □ Monogamous relationship with HIV-negative partner
    - □ HIV-negative injecting partner
    - □ Exchanges sex for rent
    - □ Transgender woman who denies sexual activity in the last 12 months
    - □ HIV-positive injecting partner
2. True or False: At the end of the sexual health assessment, always ask the patient if they have heard of PrEP, unless they are already on PrEP. (Highlight answer)
    a. True
    b. False
3. After a patient's STI test result comes back positive, what do you do next? (Highlight answer)
    a. Treat the STI
    b. Discuss PrEP (and document)
    c. Both a & b
4. What is the purpose of integrating the sexual health assessment with PrEP eligibility screening? (Highlight answer)
    a. To make using ECW more complicated to use.
    b. To identify PrEP eligible patients.
    c. To ultimately increase PrEP uptake among patients at risk for acquiring HIV infection.
    d. b & c

Clinical Staff Post-Education Tests (continued)

Provider Test Part 2:

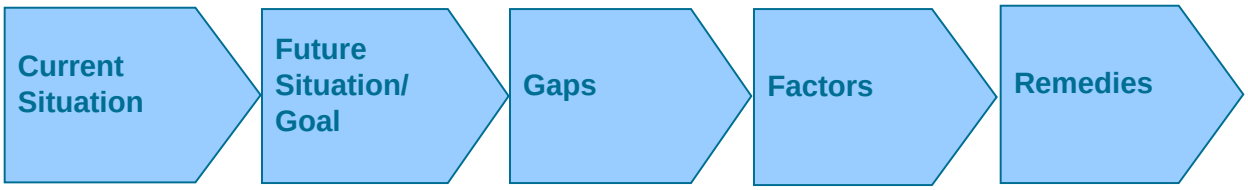
Clinical Decision Support Tool: Triggered PrEP Order Set

1. True or False: When sexual health risk related ICD-10 diagnoses codes are entered, the PrEP evaluation order set will be triggered. (Highlight answer)
    a. True
    b. False

2. How do you access the triggered PrEP evaluation order set? (Highlight answer)
    a. Do nothing, it will automatically appear.
    b. Click on the "stop sign" button that will turn red on the upper right corner of the ECW screen.
    c. Enter each order for PrEP evaluation individually.
3. Where is the "stop sign" button for accessing triggered order sets located? (Highlight answer)
    a. It will pop up in the center of the ECW screen.
    b. It will turn green in the left corner of the ECW screen.
    c. It will turn red in the right corner of the ECW screen.
4. What is the purpose of the triggered PrEP order set? (Highlight answer)
    a. To make ordering everything required for PrEP evaluation easier and more streamlined.
    b. To make ECW more complicated to use.
    c. To ultimately increase PrEP uptake among patients at risk for acquiring HIV infection.
    d. Both a & c

Appendix J

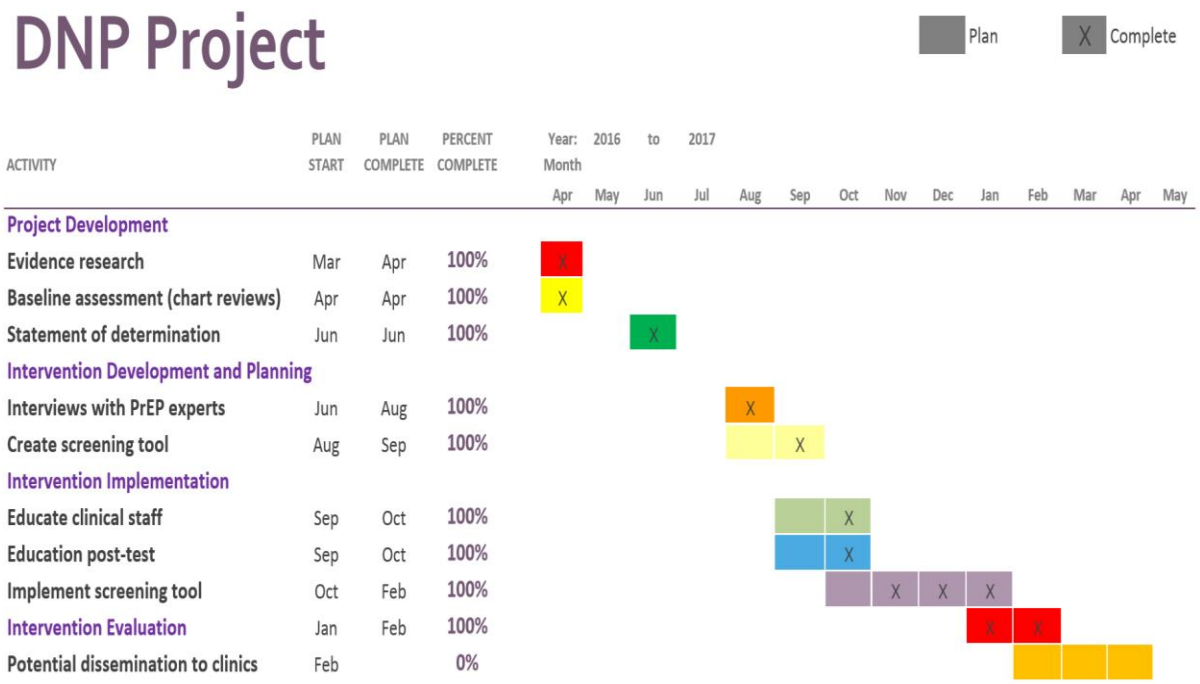
Gap Analysis



Inconsistent clinical practice of HIV risk screening. No standardized practice for PrEP implementation.	Standardized process for HIV risk screening and PrEP implementation. 100% of patients at risk for acquiring HIV are identified and offered PrEP for HIV prevention.	48% of patients with history of sexual HIV risk are offered PrEP. 35% of patients tested positive for an STI are offered PrEP. *Note: See baseline clinical data assessment in Appendix C	Lack of standardization of clinical practice that specifies routine health screenings to be conducted for the type patient encounter. Provider preference on which clinical staff performs routine health screenings: providers vs. MAs. High rate of clinical staff turnover.	Standardized screening tool for sexual history assessment and HIV risk. Standardized HIV risk screening protocol that utilizes screening tool for specified patient encounters.

Appendix K

Gantt Chart



Appendix L

SWOT Analysis

Strengths	**Weaknesses**
• Compassionate and culturally sensitive environment • Small organizational size • FQHC status • Patient population represents at-risk population eligible for PrEP • Chief medical officer and lead provider support	• No standardized protocols • Many changes to clinic workflow • Outdated EHR • High rate of clinical staff turnover
Opportunities	**Threats**
• At-risk patient population • FQHC status: more primary care patients • Screening tool implementation using EHR system potentially contributes to meaningful use for possible future HIV prevention standard • Improve patient outcomes in HIV prevention • Implications for public health safety: *Getting to Zero San Francisco*	• Patient refusal of PrEP • Cultural stigma • Financial cost of PrEP • Low HIV risk perception

Appendix M

DNP Project Cost Summary

Costs Absorbed into the Asian and Pacific Islander Wellness Center FTE Budget			
API staff member	Estimated hourly wage (FTE)[1]	Number of hours spent on project	Subtotal cost (FTE)
CMO/Physican	$93.48	2	$280.44
Lead NP	$71.61	20	$1,432.20
Volunteer Nurse Practitioner	$0	0.33 (20 min)	$0
Medical Assistant (4)	$31.66	0.33 (20 min)	$41.79
Director of Nursing	$67.00	0.33 (20 min)	$22.11
PrEP Case Manager	$30.00	1	$30.00
EHR System Consultant	$55.00	2	$110.00
Clinical Data Specialist	$30	8	$240.00
DNP Author/Project Manager	$0	163	$0
Estimated cost of DNP project			**$2,156.54**
Cost for Primary Care Clinics to Implement HIV Risk Screening Protocol			
Staff leader for implementation	Estimated hourly wage of project manager (FTE)[2]	Number of hours anticipated to be spent on project implementation	Subtotal cost (FTE)
Project Manager	$42.52	100	$4,252.00
Estimated cost of for primary care clinics Clinical staff costs ($2,156.54) + project manager			**$6,408.54**

[1]API staff wage estimates from equivalent City and County of San Francisco public health job listings. Retrieved from http://www.jobaps.com/SF/

[2]Project manager wage estimate based on average salary for project manager consultant in San Francisco reported by *Glassdoor*. Retrieved from https://www.glassdoor.com/Salaries/project-management-consultant-salary-SRCH_KO0,29.htm

DNP Project Cost Summary (continued)

Cost-Avoidance Estimate	
HIV management costs	$20,000+ per patient per year[1]
Estimated HIV management costs for the reported 16,002 people living with HIV in San Francisco at the end of 2015[2]	Estimated cost of $320,040,000 spent in 2015 if every person was on HIV antiretroviral treatment
Estimated total cost of HIV management if all 232 patients suspected at-risk acquired HIV infection[3]	A minimum of $4,640,000 per year
Cost of PrEP	$13,000 per patient per year[1]
Estimated total cost of PrEP for all 232 patients suspected at risk for HIV acquisition[3]	$3,016,000 per year
Estimated cost avoidance by starting all 232 suspected at-risk patients on PrEP[3]	A minimum of $1,624,000 per year

[1]Centers for Disease Control and Prevention. (2015). HIV cost effectiveness. Retrieved from http://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html

[2]San Francisco Department of Public Health. (2015). *HIV Semi-annual surveillance seport.* Retrieved from https://www.sfdph.org/dph/files/reports/RptsHIVAIDS/HIV-SemiAnnualReport122015.pdf

[3] Estimated number of at-risk patients based on approximate 2016 unique patient census of 381 as reported by API's clinical data specialist (C. Ong-Flaherty, personal communication, April 5, 2017).

Appendix N

Budget Return on Investment Plan

Medi-Cal reimbursement rate to API: $25 per patient per month per year[1]

Percentage of patients at risk for HIV acquisition	61%[2]
Approximate total number of patients at end of 2016	381[3]
Estimated number of patients suspected at risk for acquiring HIV	232

Medi-Cal reimbursement estimate if all at-risk patients are new to care and Medi-Cal coverage are started on PrEP:
232 patients x $25 x 12 months per year= **$69,600** in one year

*Note: Estimate based on assumption that the 232 at-risk patients are new to care and Medi-Cal coverage. Established Medi-Cal patients who initiate PrEP would not produce additional reimbursement cash flow, but for PrEP follow-up would keep them in care, contributing to patient and reimbursement retention. Minimal reimbursement estimate. Does not include other health insurance plan reimbursement rates.

[1] Per API's CMO. (T. Do, personal communication, May 9, 2016).

[2] Based on baseline clinical data assessment.

[3] Based on approximate 2016 unique patient census as reported by API's clinical data specialist (C. Ong-Flaherty, personal communication, April 5, 2017).

Appendix O

Work Breakdown Structure by Person

Stakeholder	Project Role	Item/Event	Special Instructions
Dr. Tri Do Chief medical officer API physician	Authorization	Change in practice approval	Review and approve project and screening tool intervention
DNP co-chairs: Drs. Chenit Ong-Flaherty and Prabjot Sandhu DNP committee: Dr. Stefan Rowniak	Authorization, guidance, critique and assessment of implementation and evaluation.	DNP project approval	Assist and support with development and approval of DNP project.
Dr. Blair Turner Lead NP	Supervision and guidance of project	Change in practice: HIV risk screening protocol	Provide supervision, assistance, and support for development of project.
DNP author/Project manager: Cara Nalagan	Project developer, manager, and evaluator	Change in practice: HIV risk screening protocol	Develop, implement, and evaluate HIV risk screening protocol to optimize PrEP implementation.
EHR system consultant, clinical data specialist and USF health informatics student intern	EHR system navigation	Baseline clinical data assessment, electronic screening tool	Assist with using EHR system to conduct baseline clinical data assessment, and with development of screening tool into the EHR.
PrEP case manager	Intervention design	Change in practice	Provide input for designing appropriate HIV risk screening protocol.
Gilead Sciences assistant director of medical sciences for the west coast region, and local representative	Intervention design	Change in practice	Provide input for designing appropriate HIV risk screening protocol.
San Francisco City Clinic and Strut PrEP program managers	Intervention design	Change in practice	Provide input for designing appropriate HIV risk screening protocol.
City Wide PrEP NP	Intervention design, clinical staff education, and potential dissemination	Change in practice	Provide input for designing appropriate HIV risk screening protocol, assist with clinical staff education, and potentially disseminate protocol to other primary care clinics in SF.
Clinic providers and staff (MD, NPs, RNs, MAs, clinic operations manager, director of nursing)	Intervention recipients	Change in practice	Learn and follow HIV risk screening protocol to increase identification of patients at risk for acquiring HIV and increase provider offer of PrEP.

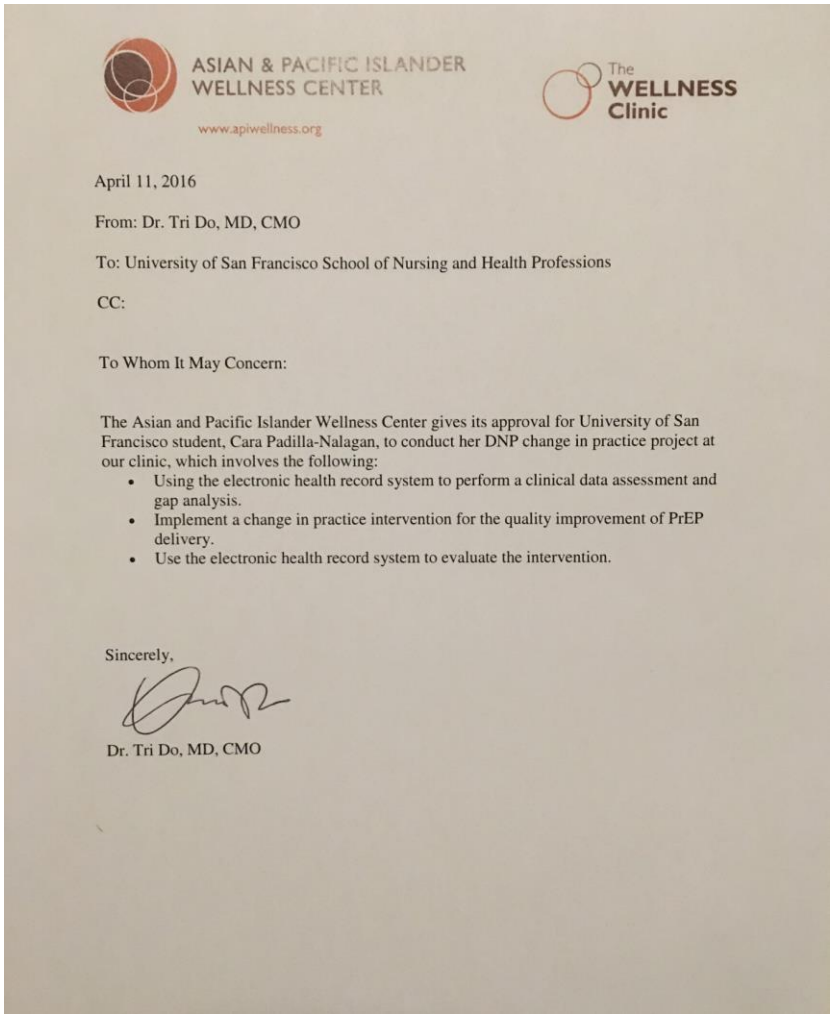
Appendix P

Communication Plan by Item/Event

Item/Event	Purpose	Audience	Date/ Frequency	Who is Responsible	Authority & Release
Brainstorm	Develop appropriate HIV risk screening protocol	Dr. Turner, DNP committee, Gilead Sciences support representatives, San Francisco City Clinic and Strut PrEP managers, City Wide PrEP NP, PrEP case manager, and the author	May 31, 2016 to September 6, 2016	The author and Dr. Turner	Dr. Turner (lead NP) and Dr. Do (CMO)
EHR system navigation	Baseline clinical data assessment, Development of HIV PrEP screening tool in the EHR system	Dr. Turner and the author	August 7, 2016 to September 6, 2016	Clinical data specialist, EHR system consultant, Dr. Turner, and the author	Dr. Turner (lead NP) and Dr. Do (CMO)
Implementation of HIV risk screening protocol	Increase identification of patients at risk for acquiring HIV and increase provider offer of PrEP.	Clinical staff & providers	October 16, 2016 to February 1, 2017	The author and Dr. Turner	Dr. Turner (lead NP) and Dr. Do (CMO)
Evaluation	Evaluate effectiveness of intervention	Clinical staff and providers	January 9, 2017 to February 5, 2017	The author	Dr. Turner (lead NP) and Dr. Do (CMO)

Appendix Q

Authorization



ASIAN & PACIFIC ISLANDER WELLNESS CENTER
www.apiwellness.org

The WELLNESS Clinic

April 11, 2016

From: Dr. Tri Do, MD, CMO

To: University of San Francisco School of Nursing and Health Professions

CC:

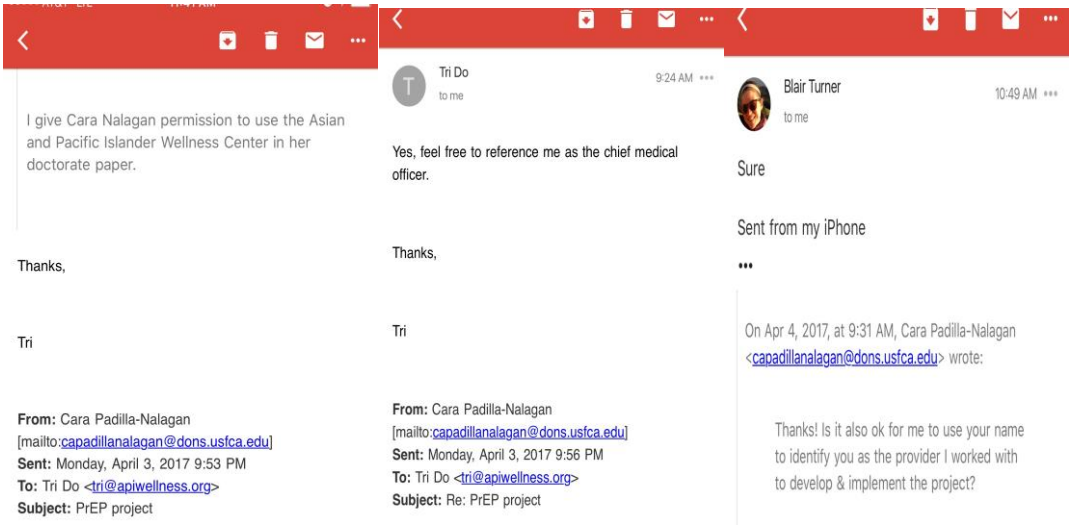
To Whom It May Concern:

The Asian and Pacific Islander Wellness Center gives its approval for University of San Francisco student, Cara Padilla-Nalagan, to conduct her DNP change in practice project at our clinic, which involves the following:

- Using the electronic health record system to perform a clinical data assessment and gap analysis.
- Implement a change in practice intervention for the quality improvement of PrEP delivery.
- Use the electronic health record system to evaluate the intervention.

Sincerely,

Dr. Tri Do, MD, CMO



I give Cara Nalagan permission to use the Asian and Pacific Islander Wellness Center in her doctorate paper.

Thanks,

Tri

From: Cara Padilla-Nalagan [mailto:capadillanalagan@dons.usfca.edu]
Sent: Monday, April 3, 2017 9:53 PM
To: Tri Do <tri@apiwellness.org>
Subject: PrEP project

Tri Do to me 9:24 AM

Yes, feel free to reference me as the chief medical officer.

Thanks,

Tri

From: Cara Padilla-Nalagan [mailto:capadillanalagan@dons.usfca.edu]
Sent: Monday, April 3, 2017 9:56 PM
To: Tri Do <tri@apiwellness.org>
Subject: Re: PrEP project

Blair Turner to me 10:49 AM

Sure

Sent from my iPhone

On Apr 4, 2017, at 9:31 AM, Cara Padilla-Nalagan <capadillanalagan@dons.usfca.edu> wrote:

Thanks! Is it also ok for me to use your name to identify you as the provider I worked with to develop & implement the project?

Appendix R

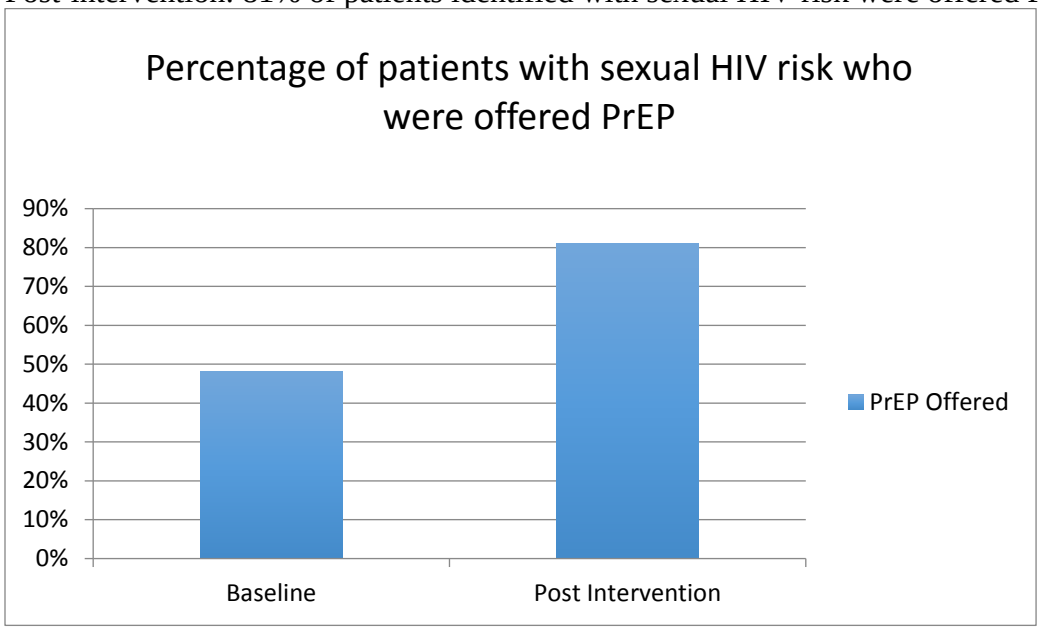
Evaluation Plan

Deadline	Evaluation	Method
October 23, 2016	Clinical staff comprehension of HIV risk identification and screening tool use	Screening tool post-education test with a passing score of 80%
February 1, 2017	Clinical staff compliance rate of 80% for routine screening tool use	Retrieve clinical data from the EHR system and use Microsoft Excel to calculate the percentage of screening tool use per STI testing, establish new patient, and annual physical exam patient encounter
February 1, 2017	An increase by 50% in PrEP offer for patients with sexual HIV risk, and for patients tested positive for an STI compared to baseline An increase by 50% in PrEP evaluation for patients offered PrEP, and in PrEP uptake for eligible patients compared to baseline	As evidenced by the data captured by the screening tool and by individual chart reviews in the EHR and analyzed in Microsoft Excel by calculating percentages and generating graphs, repeated in a similar method used in the baseline clinical data assessment
February 5, 2017	HIV risk screening protocol	Complete evaluations and summarize results using Microsoft Excel to calculate percentages and generate graphs to compare baseline and post-intervention results

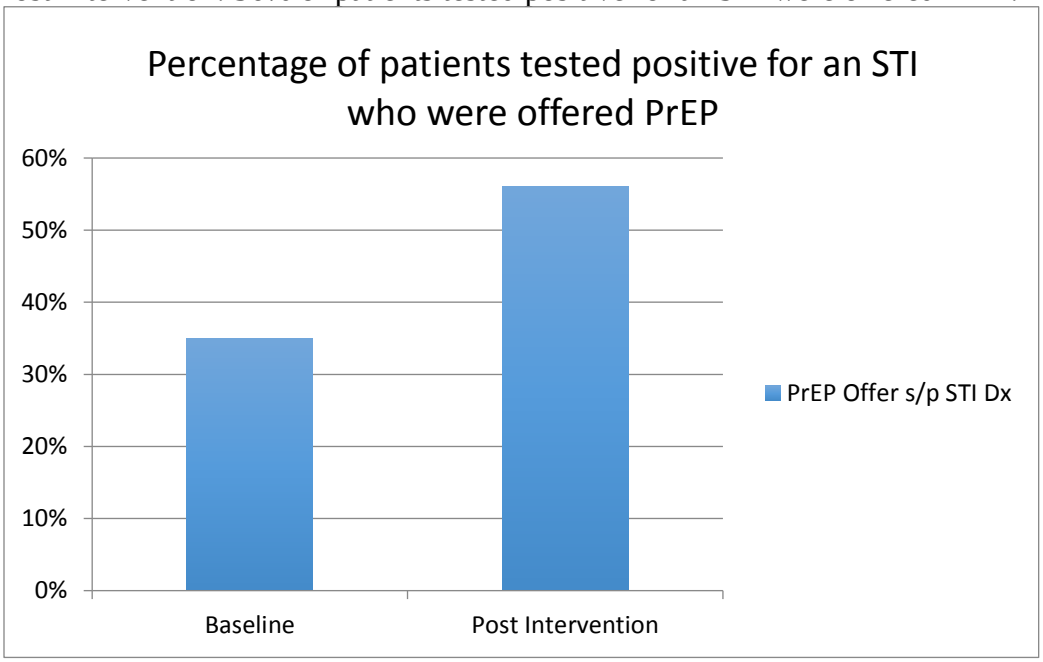
Appendix S

Results of Primary Outcomes

1. Baseline: 48% of patients identified with sexual HIV risk were offered PrEP.
   Target: 72%
   Post-intervention: 81% of patients identified with sexual HIV risk were offered PrEP.

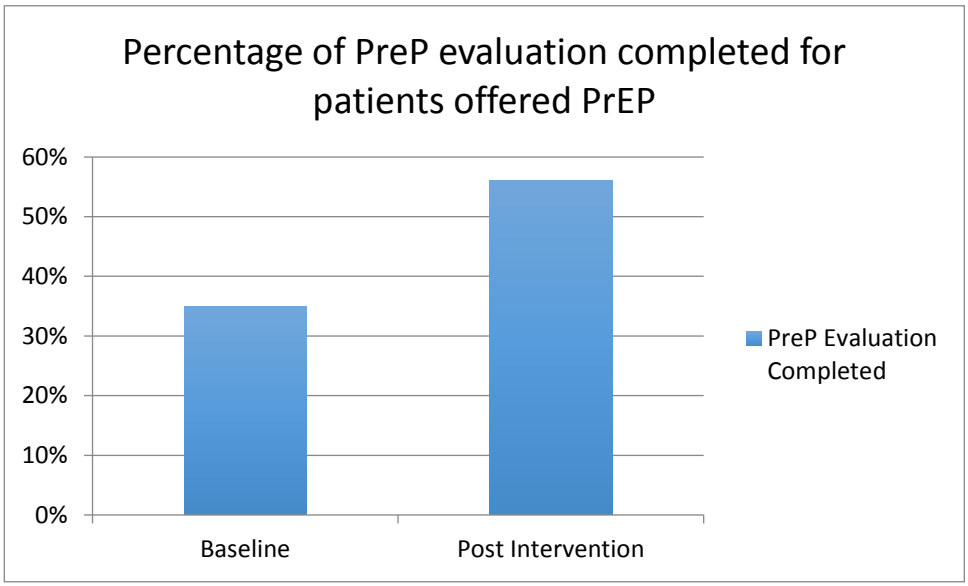


2. Baseline: 35% of patients tested positive for an STI were offered PrEP.
   Target: 53%
   Post-intervention: 56% of patients tested positive for an STI were offered PrEP.

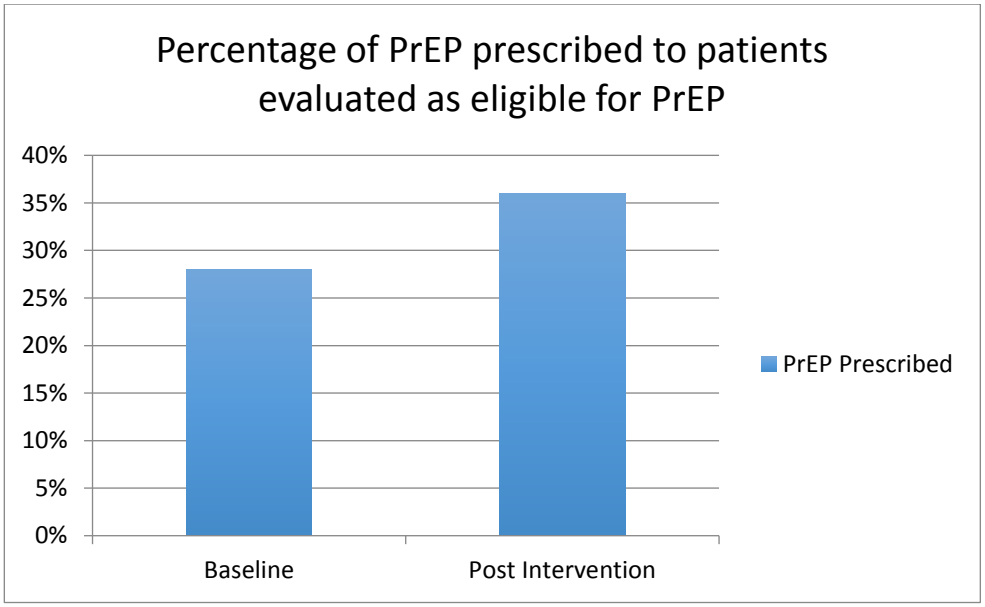


Results of Primary Outcomes (continued)

3. Baseline: 35% of patients offered PrEP completed PrEP evaluation.
   Target: 53%
   Post-intervention: 56% of patients offered PrEP completed PrEP evaluation.



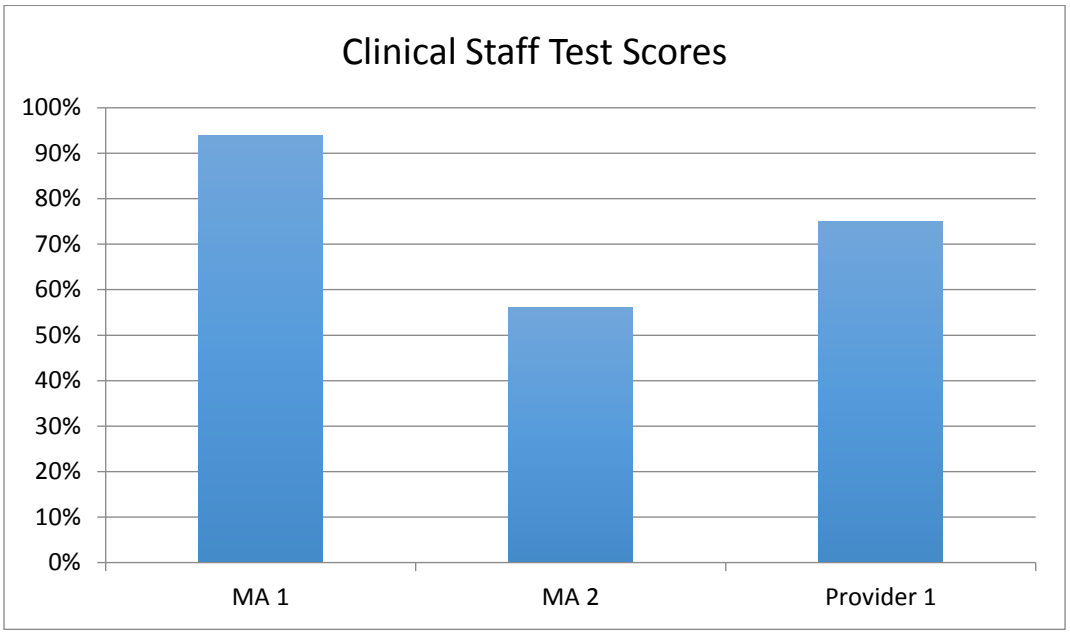
4. Baseline: 28% of patients evaluated as eligible for PrEP completed PrEP uptake.
   Target: 42%
   Post-intervention: 36% of PrEP eligible patients were prescribed TDF/FTC for PrEP.



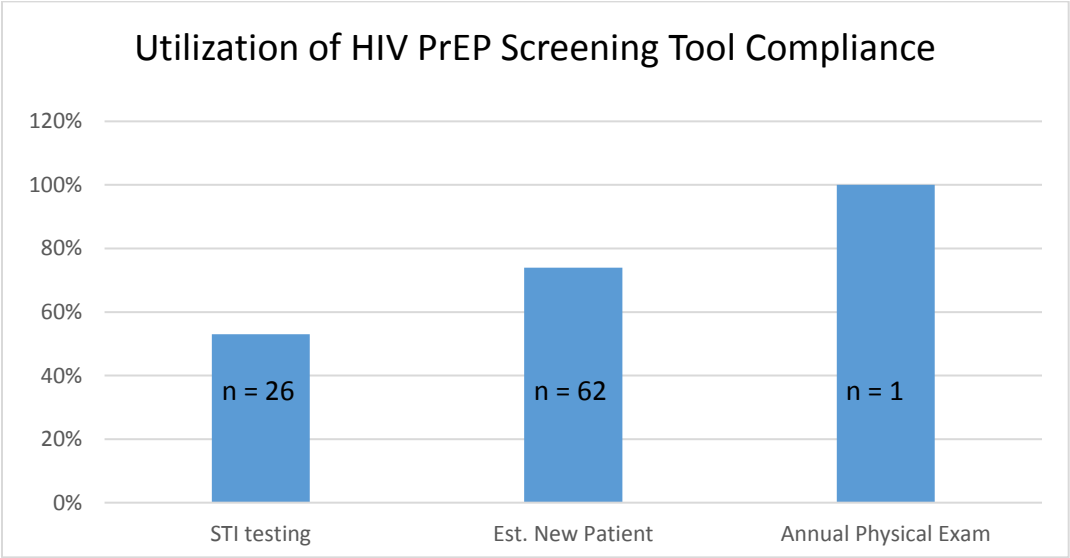
Appendix T

Results of Secondary Outcomes

1. Clinical staff comprehension of HIV risk identification and screening tool use as evidenced by a post-test score of at least 80%: MA1 scored **94%**; MA2 scored **56%**; and Provider 1 scored **75%**

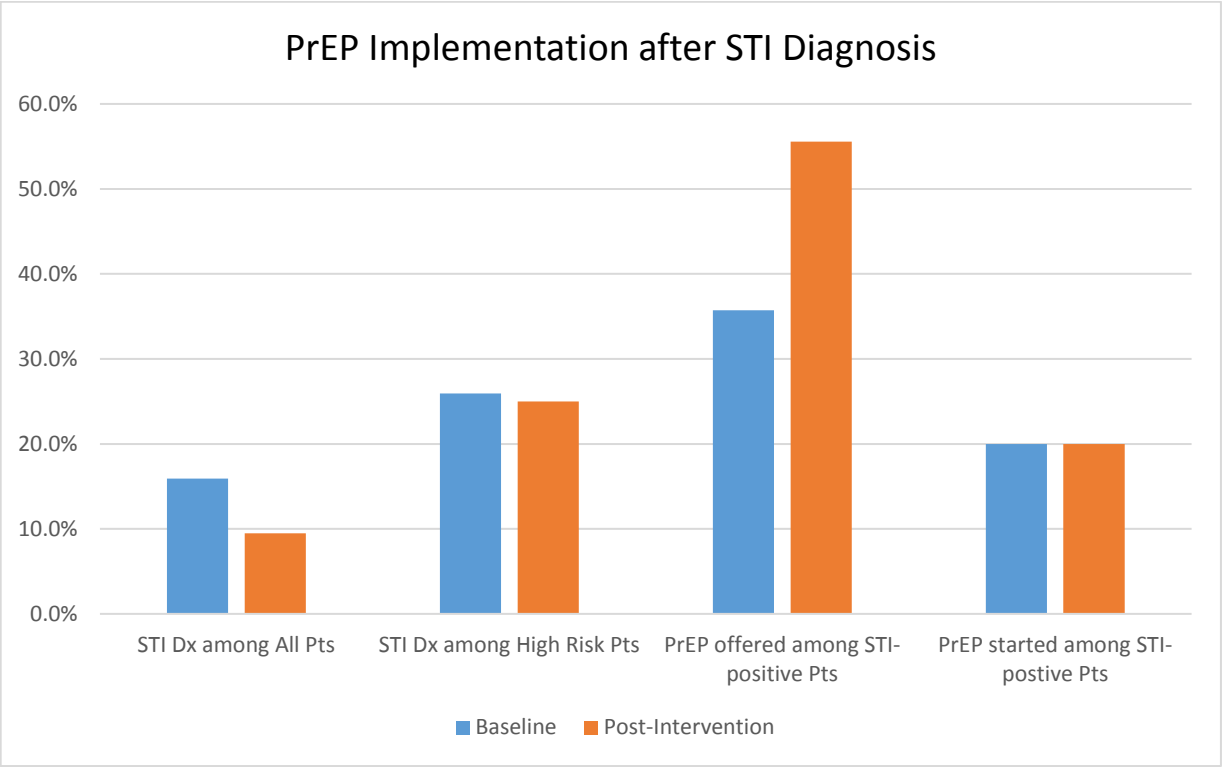


2. Clinical staff compliance rate for routine HIV PrEP screening tool use of 80% for each STI testing, establish new patient, and annual physical exam patient encounter: **53%, 74%,** and **100%**, respectively



Appendix U

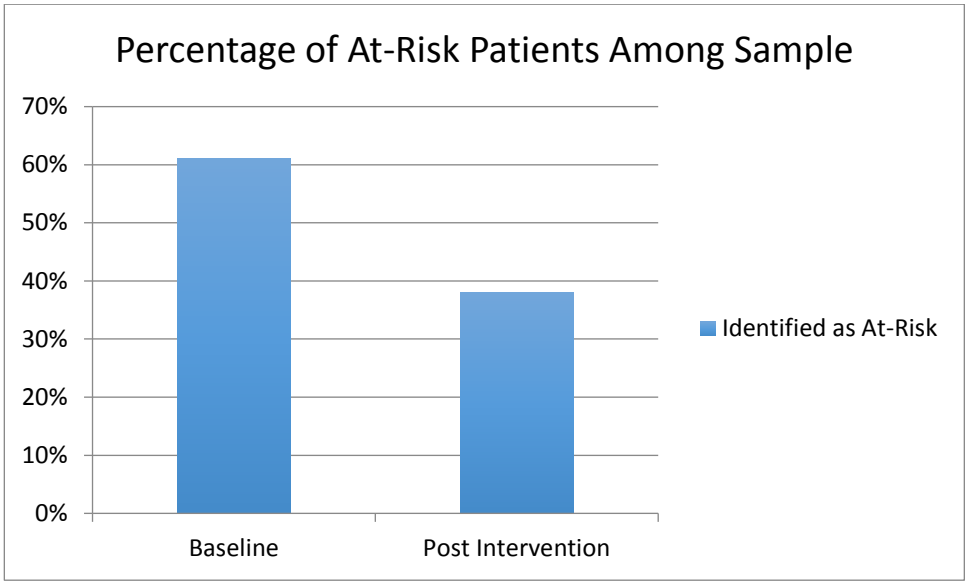
Comparison of PrEP Implementation Cascade for Patients Tested Positive for an STI at Baseline and Post-Intervention



*Note: Only one out of five post-intervention patients agreed to initiate PrEP after evaluation; the rest declined PrEP uptake.

Appendix V

Comparison of Patient Population HIV Risk at Baseline and Post-Intervention



*Baseline patient sample over a four-month period of data collection n= 88. Post-Intervention patient sample over a three-month period of data collection n=95.