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Using the Consolidated Framework for Implementation Research to Investigate Daily Pre-exposure Prophylaxis (emtricitabine/tenofovir DF) Implementation via Community-based HIV Testing Sites in Florida

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Using the Consolidated Framework for Implementation Research to Investigate Daily Pre-exposure Prophylaxis (emtricitabine/tenofovir DF) Implementation via Community-based HIV Testing Sites in Florida

by

DeAnne E. Turner

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a concentration in Community and Family Health College of Public Health University of South Florida

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Keywords: PrEP, sexual health, HIV prevention, theory

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DEDICATION

This dissertation is dedicated to the many people living with HIV in the United States and worldwide; my participants who dedicate their time and energy to HIV care and prevention; and my friends and family who have been an amazing support system.
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I would like to acknowledge the 150 participants and 48 organizations who took part in the study. Without their participation, this study would not be possible. Additionally, my friends and family have been an amazing support system throughout this process. I am also thankful to have received funding for my dissertation work from the University of South Florida College of Public Health and Graduate School. Finally, I would like to acknowledge my major professor, Dr. Stephanie Marhefka, and my committee members Drs. Daley, Wang, and Shore for their support and feedback throughout this process.
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ABSTRACT

Background: Pre-exposure prophylaxis (PrEP) is a daily pill that can reduce a person’s chances of acquiring HIV. HIV testing and counseling is a critical point during which non-clinical staff could intervene, discuss and/or refer clients for PrEP. However, not all HIV testing/counseling staff take part in PrEP implementation in the same way. This study investigated: 1) the underlying PrEP implementation subgroups of staff who perform HIV testing and 2) PrEP implementation as a function of key constructs from the Consolidated Framework for Implementation Research (CFIR).

Methods: This study was a mixed methods concurrent triangulation design, in which qualitative and quantitative data were collected concurrently and data were triangulated during analysis and interpretation. Latent Class Analysis (LCA) was performed using MPlus.v.8 on a sample of 150 HIV testing/counseling staff in Florida. The LCA technique groups participants based on similarities in how they answer a predetermined set of questions (here, five items related to PrEP-implementation behaviors). The final LCA model and corresponding latent classes were determined based upon fit indices and theoretical interpretation. Two generalized linear mixed models were conducted to estimate PrEP implementation as a function of key variables from the CFIR. A total of 22 interviews were completed and data were analyzed thematically.

Results: A LCA with four models was conducted—containing 1, 2, 3 or 4 classes, respectively. Based on consideration of fit statistics and theoretical relevance, a 3-class LCA was selected. Class one (labeled “Universal”; 42%; n=62) includes HIV testing/counselors who were PrEP advocates; “Universal” participants were likely to talk about PrEP with clients, regardless of client eligibility, and likely to share physical information about PrEP (e.g. brochures). Class two
(labeled “Eligibility Dependent”; 33%; n=48) includes staff who were most likely to discuss PrEP if they believed their client met the indications for PrEP. Staff in Class 3 (labeled “Limited”; 25%; n=37) spoke to clients about PrEP inconsistently. Several variables under the CFIR have a statistically significant association with PrEP implementation among HIV testing staff, including race, sexual orientation, relative priority, and available resources. Qualitative data revealed the importance of available resources, cosmopolitanism, and leadership in PrEP implementation within community-based HIV testing sites.

Conclusions: Not all HIV testing and counseling staff discuss PrEP with clients. Some staff differentially discuss PrEP based on eligibility, or inconsistently talk to clients about PrEP. Understanding implementation subgroups can assist in training and program development. Furthermore, understanding the factors that could affect PrEP implementation (e.g. availability of PrEP-related resources) may help organizations to better prepare HIV testing staff to more seamlessly implement PrEP education and referrals.
SECTION 1: INTRODUCTION

Statement of Problem

HIV as a Public Health Problem

Recent estimates from the Centers for Disease Control and Prevention (CDC) suggest that approximately 1.2 million people in the United States are living with HIV (CDC, 2015). Although the annual number of newly diagnosed HIV cases has declined in the last decade, there were still nearly 40 thousand people newly diagnosed with HIV in 2014 (CDC, 2015). These new diagnoses have disproportionately affected Black (44% of new diagnoses) and Hispanic (23% of new diagnoses) Americans, women (19% of new diagnoses), and gay, bisexual, and other men who have sex with men (MSM; 67% of new diagnoses) (CDC, 2015).

Florida has particularly alarming rates of HIV – consistently ranking among the top states for both new HIV infections and cumulative number of people living with HIV (CDC, 2017; FDOH, 2016a). As with the nation, Blacks and Hispanics, as well MSM, have a higher incidence and prevalence of HIV in the state than other demographic groups (FDOH, 2018b). Such high rates of HIV incidence and prevalence make Florida an important location for HIV prevention work.

Although HIV can now be well controlled by active engagement in care and medication adherence, it is still an incurable infection with significant consequences to the immune system (CDC, 2015). Moreover, when left untreated, HIV can progress to Acquired Immune Deficiency Syndrome (AIDS) – marked by a decreased CD4 count (i.e. under 200 cells/mm) or the presence of an AIDS-defining opportunistic infection (i.e. an infection such as tuberculosis or Kaposi sarcoma that takes opportunity of the body’s weakened immune system) (CDC, 2015;
NIH, 2017). An HIV diagnosis also means taking daily medications for the duration of life – which can be further complicated by changing insurance policies and social benefits, medication resistance, and medication side effects (CDC, 2015). Such health effects and the alarming rates of HIV act to remind us that HIV prevention is still an important public health problem that needs to be addressed.

**The State of HIV Prevention**

HIV prevention has long been categorized into structural, social-behavioral, and biomedical approaches. In a large-scale review, Rotheram-Borus and colleagues (2009) found that more than 140 interventions were available, and efficacious, in promoting HIV risk-related behavior change; however, some interventions may only be designed for niche populations or available within certain regions of the United States. Biomedical prevention methods include the non-behavioral methods of HIV prevention, such as those directly affecting the biological transmission of the virus. Until recently, biomedical HIV prevention was largely centered around prevention of mother to child transmission and treatment as prevention (TasP). Although these methods have been effective at reducing the incidence of HIV over the past several decades, more is needed to completely eliminate the spread of the virus.

**Pre-exposure Prophylaxis for HIV Prevention**

Daily use of emtricitabine/tenofovir disoproxil fumarate (TDF/FTC; often referred to by its brand name, Truvada®) used for PrEP (henceforth, PrEP) has been introduced as an innovative way to curb the spread of HIV. This method of HIV prevention includes daily use of antiretroviral medication by HIV-negative individuals who are at high risk of acquiring HIV (CDC, 2014, 2016d). Researchers tend to agree that combination prevention – including biological, structural, and socio-behavioral prevention methods – is the key to furthering the success of HIV prevention (Kippax & Stephenson, 2012; Koblin, Andrasik, & Austin, 2013; McNairy & El-Sadr, 2014; Rotheram-Borus, Swendeman, & Chovnick, 2009; Underhill, Operario, Skeer, Mimiaga, &
Mayer, 2010). This is because, even with the evolution of efficacious biomedical prevention options, there exists a social side of prevention – including promoting initiation and adherence to the biological methods, partner-based communication, and the need for behavioral counseling or interventions (Rotheram-Borus et al., 2009; Underhill, Operario, Skeer, et al., 2010).

**PrEP Efficacy**

Pharmacological efficacy studies investigating PrEP have included tenofovir disoproxil fumarate (referred to as TDF), a combination of tenofovir-emtricitbine (referred to as TDF/FTC); some studies have also compared these two formulations for the use of PrEP (Jiang et al., 2014; Spinner et al., 2016). This study refers to TDF/FTC as PrEP and its use as a daily, oral dose, as this is the formulation currently approved by the Food and Drug Administration (FDA). Studies of on-demand, or intermittent, PrEP use (PrEP used only immediately before and after a potential HIV exposure) and other drug formulations used as PrEP are ongoing (Spinner et al., 2016) and are not yet approved by the United States’ FDA; as such, their implementation is not directly studied in this dissertation.

PrEP efficacy has varied across studies, with systematic reviews reporting efficacy to be between 44 to 86%; when adjusted for adherence (and thus, concentration of the drug actually in the blood), reported efficacy has been higher, varying between 74 to 92% (Spinner et al., 2016). This has led many governmental agencies to market PrEP as up to 92% effective (CDC, 2016f). Some agencies also refer to 99% efficacy, the highest possible efficacy when PrEP is taken every day as intended (Anderson et al., 2012).

Through the current dissemination of PrEP (as a daily, oral pill), studies have found that drug concentrations are greatest in the rectal tissue, followed by blood and vaginal/cervical tissue (Anderson et al., 2012); and thus, PrEP may have a greater protective effect for anal sex when compared to vaginal sex. It is also important to note that studies vary in their findings of PrEP efficacy – with at least one study reporting that PrEP use was not efficacious.
(Marrazzo et al., 2015). These studies, and the researchers’ rationale for low PrEP efficacy, will be reviewed in the following paragraphs, and have led to important guidelines regarding the level of adherence needed to achieve the maximum effect of HIV risk reduction (Murnane et al., 2013). Although a comprehensive literature review can be found in Appendix A, key efficacy results by risk category are briefly described below.

**Efficacy among Men who have Sex with Men and Transgender Women**

Perhaps one of the best known and most commonly cited PrEP efficacy trials is the iPrEx study, which occurred over four continents, enrolling 2499 MSM and transgender women in a randomized control trial (Grant et al., 2010). This study reported that Truvada reduced the incident rate of HIV by 44% (Grant et al., 2010). In a secondary data analysis, Anderson et. al. (2012) reported the rate of risk reduction varied based upon the number of PrEP doses participants took each week; when PrEP was taken twice a week participants were 76% less likely to contract HIV, when taken four times a week participants were 96% less likely to contract HIV, and when taken seven days a week – as recommended – participants were 99% less likely to contract HIV (Anderson et al., 2012). These researchers also reported that the rate of efficacy in the iPrex trial would likely have been greater if participant had better rates of adherence.

**Efficacy among Heterosexuals and Opposite-Sex Partners**

A recent systematic review indicated that several randomized control trials have investigated PrEP efficacy among heterosexual men and women (Jiang et al., 2014). These studies included sexually active women, heterosexual couples, and serodiscordant couples (Jiang et al., 2014). The efficacy achieved across these studies ranged widely, including rates of 65% (high risk women), 62% and 73% (heterosexual discordant couples), 6% (women), and 63% (heterosexual men and women). Some studies have reported lower rates of efficacy for PrEP. The FEM PrEP study among African women found PrEP to not be efficacious.
(Marrazzo et al., 2015). The study cites low adherence as a possible reason for the findings, but points to an important need to better understand adherence of PrEP in real-world scenarios.

The Partners PrEP study was a randomized, double-blind, placebo controlled clinical trial of nearly 5000 serodiscordant heterosexual couples throughout Kenya and Uganda, examining the use of TDF/FTC and TDF alone as PrEP (Baeten et al., 2012). This study resulted in such significant efficacy results (overall 67% protection with TDF; 75% efficacy with TDF/FTC) (Baeten et al., 2012; Donnell et al., 2014) that the placebo arm of the study was discontinued (Donnell et al., 2014). These protective results were found in both men and women. In subsequent analyses, Donnell et al. (2014) examined the treatment arm of the study, comparing the 29 cases in which seroconversion occurred with 196 randomly chosen participants from those who did not seroconvert. Researchers found that the concentration of PrEP in the blood of those who did not convert was consistently high; among those who seroconverted the concentration of PrEP in the blood was only high in 5 of the 29 seroconverters. Thus, in the majority of participants who converted to a positive HIV serostatus, adherence to PrEP was likely low (Donnell et al., 2014).

**Efficacy among Injection Drug Users**

There is limited clinical data available assessing the efficacy of PrEP among injection drug users. Only one clinical trial (a randomized, double-blind, placebo-controlled trial), the Bangkok Tenofovir Study, assessed the efficacy of PrEP among injection drug users (Choopanya et al., 2013). The trial was conducted in Thailand among 2413 men and women who had injected drugs in the past year (Choopanya et al., 2013). Findings resulted in a nearly 50% reduction in HIV incidence; 17 participants (of 1204 in the study arm) and 33 participants (of 1209 in the control arm) seroconverted during the study. When participants with low (or not present) levels of PrEP were removed from efficacy analyses, the efficacy in the treatment arm increased to 73.5%.
Guidance and Recommendations for PrEP Use

PrEP is supported by a wide array of international and governmental agencies – such as the WHO (Hodges-Mameletzis, Dalal, Msimanga-Radebe, Rodolph, & Baggaley, 2018; World Health Organization, 2015) and CDC (CDC, 2014; The White House Office of National AIDS Policy, 2015; U.S. Public Health Service, 2014, 2015). These agencies are similar in that they support, or provide suggested guidelines, for PrEP implementation. As in all public health implementation, guidelines are a great start, but only the beginning of creating systematic organizational change (Bhattacharyya, Reeves, & Zwarenstein, 2009). It is also important to note that PrEP is not the right choice for everyone. These guidelines suggest indications for beginning PrEP, but this is just one option for HIV prevention.

Early guidance from the WHO in 2012 found PrEP clinical trials to be promising, and encouraged demonstration projects for serodiscordant couples, MSM, and transgender women – populations with particularly high rates of HIV and with a higher than average chance of being exposed to HIV (World Health Organization, 2012b). The WHO officially recommended PrEP for MSM in 2014, following the successful efficacy trials within this population, and expanded this recommendation to all high risk populations in 2015 following more comprehensive efficacy trials (World Health Organization, 2015). The WHO recommendations, much like the CDC recommendations described in the next paragraph, emphasize that PrEP is recommended only when combined with other prevention methods, such as condom use and behavioral counseling. PrEP has also been included as an important option within the WHO report Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples: recommendations for a public health approach (World Health Organization, 2012a).

In 2011, the CDC published interim guidelines for PrEP use (Smith et al., 2011), followed by comprehensive guidelines recommending the use of PrEP, alongside condom use

**U.S. Population Meeting PrEP Indications and Using PrEP**

Recent data suggest that over one million people in the U.S meet the clinical indications for PrEP (Smith et al., 2015). This includes nearly 25% of sexually active MSM, 19% of injection drug users, and 0.5% of heterosexual adults (Smith et al., 2015). However, far fewer adults are accessing PrEP. Although there is no comprehensive database of PrEP users, estimates suggest that at least 77,000 (AIDSvu & Emory University Rollins School of Public Health, 2018), or even upwards of 100,000 (Mera Giler, 2017) people are using PrEP – a number that has continued to rise since the FDA approval of PrEP in 2012 (AIDSvu & Emory University Rollins School of Public Health, 2018). In Florida, these rates are estimated to be 32 per every 100,000 people (AIDSvu & Emory University Rollins School of Public Health, 2018). While this is a great start, PrEP has yet to reach many communities. Available data suggests that those most likely to be using PrEP are middle and older aged adults who are White and male (Snowden, Chen, McFarland, & Raymond, 2016). This may be because, although PrEP is now recommended among a variety of HIV prevention options for at-risk populations (Liu et al., 2014; Mayer et al., 2013), many individual, structural, and community-level barriers limiting the success of PrEP initiatives still exist.

**Current State of PrEP Research**

To date, many aspects of social-behavioral PrEP research have been investigated. Such studies have examined: client willingness to use PrEP (Goedel, Halkitis, Greene, & Duncan, 2016; Gredig, Uggowitzer, Hassler, Weber, & Niderost, 2016; Grov, Rendina, Whitfield, Ventuneac, & Parsons, 2016; Hoots, Finlayson, Nerlander, & Paz-Bailey, 2016; Karuga et al., 2016; Kesler et al., 2016; Kuo et al., 2016; Levy et al., 2017), adherence (Daughtridge, Conyngham, Ramirez, & Koenig, 2015; Hosek et al., 2013; Marcus et al., 2014; Shrestha &
Willingness to Use, and Acceptability of, PrEP

Studies have found that many people who meet the indications for PrEP are willing to consider using it. In one study of nearly 2,000 people considered possible candidates for PrEP across seven countries, willingness to use PrEP was found to be at least moderately high (Eisingerich et al., 2012). Additionally, such willingness has increased with time for many populations at greatest risk of acquiring HIV (Patrick et al., 2017). However, knowledge of, and willingness to take, PrEP varies based on demographic and behavioral factors. These factors will be discussed in greater detail below.

MSM and Transgender Women. The majority of social-behavioral PrEP research has focused on MSM and transgender women, due to the disparate rates of HIV that occur in these populations. Knowledge and acceptance of PrEP among MSM and transgender women has increased over time, as noted in a systematic review of 33 studies conducted between 2008 and 2012 (Young and McDaid, 2014). Since this systematic review was published, similar trends of increasing knowledge and acceptability of PrEP have been found (Grov, Rendina, Whitfield, Ventuneac, & Parsons, 2016; Patrick et al., 2017). Of course, gay, bisexual, and other men who have sex with men, as well as transgender women, are not a homogenous group; neither is their acceptance and knowledge of PrEP. Studies have noted varied acceptability of PrEP ranging from 28 to 80% among MSM, as stated in a systematic review by Young & McDaid (2014). Among MSM and transgender women, studies have yielded mixed results regarding the role demographic characteristics (e.g. race) may have on willingness to take PrEP (Young & McDaid, 2014). For example, in an analysis based on 2011 data collected in New York City,
interest in taking PrEP varied significantly based upon race and ethnicity: Latino men expressed the most interest in PrEP (over 70% interested), followed by Black men (just under 70% interested), and lastly White men (less than 40% interested) (Mantell et al., 2014). Golub, Gamarel, Rendina, Surace, and Lelutiu-Weinberger (2013) noted a different trend when measuring racial differences in the acceptance of PrEP. These findings suggest that men who were Black and Latino rated the concerns and barriers to PrEP use higher than their White counterparts. Various other studies have highlighted mixed findings about the role race, and other demographic characteristics, have in PrEP awareness, acceptance, and knowledge (Metz et al., 2017). More research is needed to better understand the role demographic characteristics may have on these factors (Hannaford et al., 2018). Regardless of awareness, acceptance, or knowledge, as stated earlier, available data suggests White middle and older aged men are the most likely to be prescribed and taking PrEP (Snowden et al., 2016). This variation in PrEP uptake by race and ethnicity may further exacerbate the disparities in HIV rates in minority populations (Galindo et al., 2012; Snowden et al., 2016).

Women and Heterosexual Couples. Lower rates of PrEP awareness among women, compared to MSM, have been cited throughout the literature (Auerbach, Kinsky, Brown, & Charles, 2015; Garfinkel, Alexander, McDonald-Mosley, Willie, & Decker, 2016) . Data have suggested that despite this limited knowledge of PrEP, women in the U.S. may find PrEP an acceptable and worthwhile intervention after being informed about the risks and benefits of its use (Auerbach et al., 2015; Flash et al., 2014; Rubtsova, Wingood, Dunkle, Camp, & DiClemente, 2013; Sales et al., 2018). PrEP also provides another method of safe conception for serodiscordant couples, sometimes referred to as PrEP-C (Heffron, Pintye, Matthews, Weber, & Mugo, 2016; Lampe, Smith, Anderson, Edwards, & Nesheim, 2011; Mack, Odhiambo, Wong, & Agot, 2014; Matthews, Baeten, Celum, & Bangsberg, 2010; Matthews et al., 2014; Matthews, Smit, Cu-Uvin, & Cohan, 2012; Ngure et al., 2016; Whetham et al., 2014) or

**Injection Drug Users.** Compared to other risk groups, limited research has been conducted on PrEP and injection drug users. This dearth of research was noted in a 2014 review of PrEP implementation among injection drug users, citing limited empirical research on the topic beyond the initial efficacy trials (Escudero, Lurie, Kerr, Howe, & Marshall, 2014). Injection drug users are perhaps the population least aware of PrEP. A Washington, D.C. based study found that out of over 300 participants surveyed in 2012, only 13% had heard of the use of ARVs to prevent HIV (Kuo et al., 2016). Other studies have also found low rates of willingness to use PrEP, averaging about 30% (Escudero, Kerr, Wood, et al., 2015).

Demographic characteristics may also play a role in willingness to use and acceptance of PrEP among people who inject drugs. Page et al. (2015) suggest that women who are injection drug users are told about, or screened for, PrEP less often than their male counterparts. Additionally, Des Jarlais et al. (2015) call for a need to address injection drug users who are from minority groups, as this population is most at risk for HIV transmission via injection drug use.

**Facilitators of, and Barriers to, PrEP Use**

Common facilitators of and barriers to PrEP use exist across all populations. Reasons for interest in PrEP have included desires to: protect oneself against HIV, reduce the associated fears of contracting HIV, and have condomless sex with less fear (Young & McDaid, 2014). The most salient barrier to PrEP use is cost, or anticipated cost (Auerbach et al., 2015; Falcao et al., 2016; Flash et al., 2014; Geary & Bukusi, 2014; Kuo et al., 2016). However, several studies of MSM actively engaged in PrEP care found that medication costs are not a significant barrier to its continued use (Chan et al., 2016). Awareness of the availability of free or low-cost medication, as well as access to healthcare and HIV testing, has also been noted as a facilitator of PrEP use (Golub et al., 2013). Additional concerns noted in the literature have included fear of the related side effects (Auerbach et al., 2015; Brooks et al., 2011; Falcao et al., 2016; Flash
et al., 2014; Geary & Bukusi, 2014; Golub et al., 2013; Idoko et al., 2015; Mack et al., 2014; Mantell et al., 2014; Scholl, 2016; Young & McDaid, 2014) and related stigma associated with using PrEP (Auerbach et al., 2015; Flash et al., 2014; Geary & Bukusi, 2014; Idoko et al., 2015; Mack et al., 2014). Concerns related to the pharmacodynamics of PrEP have also emerged in the literature, including doubts regarding the efficacy of PrEP (Auerbach et al., 2015; Falcao et al., 2016; Golub et al., 2013) and fear of potential for drug resistance if a person was to acquire HIV after using PrEP (Golub et al., 2013). Although drug resistance has been noted as a concern from people meeting the indications for PrEP, research has found that the contribution of PrEP to drug resistance is low (Dimitrov et al., 2016; Hurt, Eron, & Cohen, 2011; Parikh & Mellors, 2016; van de Vijver & Boucher, 2010; van de Vijver et al., 2013; Weis et al., 2016). Use of PrEP by someone who is unknowingly living with HIV is a contributor to this low, but notable, resistance development (Abbas, Hood, Wetzel, & Mellors, 2011; Parikh & Mellors, 2016).

Barriers and facilitators that are unique to particular risk populations have also been noted in the literature. For example, men have noted specific concerns with the availability of PrEP (Brooks et al., 2011; Hannaford et al., 2018; Young & McDaid, 2014) – a concern reaching beyond cost and related to the concern about who can, or will, prescribe PrEP. This concern was not noted in other populations, perhaps because other populations are less likely to be aware of PrEP. Additional unique concerns have emerged from serodiscordant couples. Some studies have found concerns within serodiscordant partnerships regarding the possible stigma brought not only to the individual, but to the relationship, due to PrEP use (Idoko et al., 2015; Mack et al., 2014); for example, PrEP use may “out” the partner living with HIV or cause others to judge the partner taking PrEP. Additionally, promoting PrEP use within the injection drug use population comes with a unique set of challenges. Given that some injections drug users are transient or experience time in jail or prison, adherence may be a particularly important barrier to regular PrEP use (Martin et al., 2015). Preliminary results have indicated that PrEP
adherence may differ based on the type of injection drug being used (Martin et al., 2015); thus, programs may need to be tailored to specific populations within the injection drug use community. Stakeholders have also noted concerns regarding how PrEP may affect the uptake of other harm reduction activities, by limiting the conversation about other HIV prevention strategies for injection drug users—such as rehabilitation or needle exchange programs (Escudero et al., 2014; Kuo et al., 2016).

Provider Knowledge of PrEP

Provider awareness, knowledge, and prescribing practices regarding PrEP have varied across specific types of clinical providers. Several studies have found that, compared to doctors specializing in HIV or infectious diseases, general medical providers were less aware, less informed, and less likely to prescribe PrEP to their clients (Krakower & Mayer, 2016; Krakower et al., 2015; Mimiaga, White, Krakower, Biello, & Mayer, 2014). It has been suggested that, although HIV care providers primarily serve people living with HIV, these providers may be important in disseminating PrEP to people who are at a high risk of HIV infection with a negative serostatus—largely because they are already familiar with the medication, side effects, and speaking openly about HIV with clients. However, HIV care providers may not see many people not known to be living with HIV, thus limiting their available reach for PrEP dissemination (Pinto, Berringer, Melendez, & Mmeje, 2018). This juxtaposition of 1) HIV care providers being a well-informed outlet for PrEP dissemination, yet not seeing clients who would be eligible for PrEP and 2) primary care doctors seeing clients who might be eligible, but not being comfortable prescribing PrEP has been coined the “purview paradox” (Pinto et al., 2018). Beyond HIV care providers, other provider types have also been studied to assess PrEP awareness and knowledge. A study of over 1000 infectious disease doctors not specializing in HIV found that while most had heard of PrEP, the majority (91%) had never prescribed it (Karris, Beekmann, Mehta, Anderson, & Polgreen, 2014). Moderate rates of PrEP knowledge were found in studies
of generalist in several U.S. based states (Krakower & Mayer, 2012; Krakower, Oldenburg, et al., 2015; White, Mimiaga, Krakower, & Mayer, 2012). Lower rates of PrEP knowledge have been reported in military-based healthcare providers (Hakre et al., 2016) and family planning providers (38% of providers being able to define PrEP) (Seidman, Carlson, Weber, Witt, & Kelly, 2016). Therefore, clients may, or may not, be hearing about PrEP from their doctor, depending on the provider(s) they see.

Acceptance and awareness of PrEP have appeared to increase in providers since the release of the CDC PrEP Guidelines in 2014 (Krakower & Mayer, 2016; Smith, Mendoza, Stryker, & Rose, 2016). However, despite this general increase acceptance and awareness, there may be differential prescribing practices of PrEP (Adams & Balderson, 2016; Calabrese et al., 2017; Krakower & Mayer, 2016). For example, some prescribers are more comfortable addressing PrEP for HIV risk associated with sex than for HIV risk associated with injection drug use (Adams & Balderson, 2016; Krakower & Mayer, 2016). A 2015 study found that providers may differentially offer PrEP to clients within certain risk populations, such as prescribing to only those at highest possible risk for HIV transmission – MSM in serodiscordant partnerships (Adams & Balderson, 2016; Smith et al., 2015), or have biases in prescription by race – such as greater willingness to prescribe PrEP to White, compared to Black, patients due to a belief that Black men would engage in condomless sex if prescribed PrEP (Calabrese, Earnshaw, Underhill, Hansen, & Dovidio, 2014). Moreover, there are mixed findings regarding if PrEP awareness and knowledge alone result in increased prescribing practices, with some researchers finding that PrEP knowledge was associated with a greater likelihood of prescribing PrEP (Blumenthal et al., 2015) and others noting that PrEP knowledge was unlikely to result in an increase in prescribing practices (Krakower & Mayer, 2016). Therefore, it is important to examine other factors that may affect prescribing practices. These findings may also suggest the importance of promoting PrEP outside of providers’ offices (Smith et al., 2015; Underhill et
Increasing the Reach of PrEP

To best reach the populations in need, researchers have suggested that PrEP information delivery and referral (i.e. PrEP implementation) should occur in a diverse array of settings, including emergency room departments, primary care doctors, and infectious disease specialist sites (Smith et al., 2015; Underhill et al., 2014; Underhill, Operario, Mimiaga, et al., 2010; Underhill, Operario, Skeer, Mimiaga, & Mayer, 2010); however, not all of these settings have been extensively explored for PrEP implementation. A notable amount of research has been conducted within sexually transmitted disease clinics, as well as an array of non-generalists’ sites. A study of Lesbian-Gay-Bisexual-Transgender (LGBT) clinics in Boston suggests that PrEP referral and prescription may be higher in LGBT focused settings than in generalist offices (Krakower, Maloney, Grasso, Melbourne, & Mayer, 2016). Smith et al. (2016) conducted a study of 175 community-based organizations (CBOs), both clinical and non-clinical in nature, and examined the knowledge and infrastructure for PrEP implementation at these sites. While the organizations were knowledgeable about PrEP, non-clinical CBOs felt ill-equipped for PrEP, with some indicating they did not know where they would refer a client if the client was interested in talking to a clinical provider about PrEP (Smith et al., 2016). Participants indicated that informational materials for clients and a financial resource guide would assist them in such implementation. Although few non-clinical CBOs in the study were actively participating in PrEP implementation, these agencies were still interested in being involved via referral, community education, or interventions (Smith et al., 2016). There remains a need to further explore PrEP implementation outside of providers’ offices, specifically in sites accessible to a variety of at-risk populations. One potentially underutilized time to promote the discussion of PrEP, and possible referral for a prescriber visit, is during HIV testing.
Theoretical Considerations

Theory and HIV Prevention

Theory is important in public health to guide both research and practice. Prestwich et al. (2014) noted in a meta-analysis that few researchers apply specific theoretical constructs when evaluating or conceptualizing interventions; instead, they may not use theory at all, or only mention the theory as a guiding framework. Yet, interventions driven by theory are statistically more likely than those not driven by theory to have large effect sizes (Prestwich et al., 2014). In public health, theory is often organized by the levels of Social Ecological Model, noting the interplay between the different levels: intrapersonal, interpersonal, organizational, community, and societal (Coreil, 2010). Fishbein (2000) suggests that despite the numerous theories available, there are a limited number of constructs that truly affect behavior change, among them: beliefs, skills, intentions, attitudes, norms, and self-efficacy. However, these constructs are used across a large number of theories, and all of these constructs have been previously applied within the field of public health.

Theory has long been applied to HIV prevention and care. Many of these theories have been used to investigate HIV prevention and sexual health behavior change. In 2007, Noar identified 13 theories that were most commonly used to predict HIV-related behavior change: Health Belief Model, Theory of Reasoned Action, Theory of Planned Behavior, Integrated Model, Social Cognitive Theory, Transtheoretical Model, AIDS Risk Reduction Model, Information Motivation, Behavioral Skills Model, Multiple Domain Model, Extended Parallel Process Model, Protection Motivation Theory, Theory of Gender and Power, and Precaution Adoption Process Model. The similarities between many of these theories can often make it difficult to select a single theory to use. Researchers suggest several steps to select which theory to apply: examine the aims of the study, relevant literature, inapplicable theories, and
investigate what theories have been applied to the population being studied in the past (Noar, 2007).

**PrEP Implementation and Existing Theories and Frameworks**

PrEP is relatively novel to HIV prevention and entered research as a biomedical innovation. This is likely why much of the available PrEP research is driven by pharmaceutical and biomedical schemas, rather than theories common in public health research and practice. Now that the efficacy of PrEP has been well established, social science is bridging the gap to address behavior change, initiation, adherence, and a number of other behaviorally driven concepts that must be understood in order for PrEP implementation to be successful.

PrEP implementation is broad - encompassing many aspects of PrEP. Implementation here consists of factors affecting the initiation and success of PrEP programs, as well as the barriers and facilitators to running such programs. This study addresses the implementation of PrEP within HIV testing sites. Of the constructs included in the HIV prevention literature, and those already applied to PrEP implementation research, two major themes emerge: organizational characteristics relevant to PrEP implementation within HIV testing sites and the behavior change process among staff performing HIV testing, with regard to PrEP knowledge and implementation practices.

Some theories have already been applied to the study of PrEP and PrEP implementation. In a study of nearly 1500 African American and White women, Rubtsova, Wingood, Dunkle, Camp, and DiClemente (2013) applied the Health Belief Model to examine participants’ willingness to use PrEP, and possible barriers that may affect PrEP use. The strength in this theoretical application is the identification of intrapersonal level barriers and beliefs regarding PrEP, but its weaknesses lie in the lack of consideration regarding the organizational and contextual factors critical to implementation. Other researchers have applied theory to the behaviors and prescribing practices of providers. As part of the Adolescent
Medicine Trials Network, researchers investigated providers’ attitudes toward adolescent PrEP use (PrEP for adolescents was not yet approved by the FDA at the time of the study) (Mullins et al., 2015; Mullins, Zimet, Lally, & Kahn, 2016). These researchers used semi-structured interviews guided by the Theory of Planned Behavior and Diffusions of Innovations, largely noting the adaptations that providers would make to the adolescent application of PrEP, compared to how they disseminated PrEP-related information to adults (Mullins et al., 2015; Mullins, Zimet, Lally, & Kahn, 2016). Through application of these theoretical frameworks, researchers were able to identify barriers at the client, provider, organizational, and community levels; however the discussion of organizational and community level barriers were limited and specific to youth, and may not be experienced by organizations serving adults (Mullins et al., 2015; Mullins et al., 2016). These findings were further limited because the relationship between the theoretical constructs, the study results and discussion are not explicitly stated (Mullins et al., 2015; Mullins et al., 2016). Krakower and Mayer (2016) conducted a systematic review guided by the Diffusion of Innovations to describe the diffusion of PrEP throughout the healthcare field. This review focused on identification of early adopters in the implementation of PrEP. Although the researchers used the Diffusion of Innovations to discuss adopter categories and to hypothesize the uptake of providers prescribing PrEP, they did not utilize the other variables within the Diffusion of Innovations, such as attributes of the innovation (including the constructs of relative advantage, compatibility, complexity, trialability, and observability), communication channels, the innovation decision process, and the social system (Rogers, 2010). The theoretical application most relevant to this study is that of Walsh & Petroll (2016). Their outcome was measured both as prescription, and discussion about PrEP – the latter of which is most relevant to the role HIV testers could provide in PrEP promotion. These researchers applied the Information-Motivation-Behavioral Skills Model to examining the factors affecting PrEP implementation among primary care providers. Among providers in 10 major U.S. cities,
they found that knowledge and motivation could predict providers’ discussion and prescription of PrEP; and that these factors were mediated by the self-perceived level of skill that the provider has to discuss and prescribe PrEP (Walsh & Petroll, 2016). Other studies, although not explicitly using a theory, have relied on terminology reminiscent of theoretical constructs. For example, Krakower, Oldenburg, et al. (2015) describe their PrEP related survey items as covering “awareness, knowledge of normative guidance, prescribing practices and intentions, and perceived barriers to providing PrEP” (p. 4), which could be perceived as some of the constructs within the Theory of Planned Behavior and Health Belief Model, but the researchers do not describe the relationships between these constructs.

Implementation, Organizational, and Community Theories and Frameworks Applied to PrEP

Theories addressing organizational, community, and societal factors may have an important role in PrEP implementation, but to date are only briefly mentioned in the literature and used in the research. These factors include the organizational readiness to adopt such an innovation, community acceptance of PrEP, related health communication campaigns, and policies. Jaspal and Nerlich (2016) applied Social Representation Theory to address the hope and risk that PrEP represents in the media, particularly when advertised to MSM. Social Representation Theory posits that people create schemas for new, unfamiliar, ideas; these schemas then affect how ideas are perceived by others; in short, societal views of new ideas can either make the ideas more concrete or dichotomize them to create conflicting sides of an issue (Jaspal & Nerlich, 2016; Rateau, Moliner, Guimelli, & Abric, 2011). Social Representation Theory was used to guide data collection and analyses, but the study was also specific to the United Kingdom culture in which the study took place, and its application was not relevant to barriers occurring within organizations or during HIV testing (Jaspal & Nerlich, 2016).

Similarly, Spieldenner (2016) examined social representation of PrEP use among MSM by applying Queer Theory and Quare Theory to examine the operationalization of the term “PrEP
Whore,” which has been used in the MSM community to describe men using PrEP. This stereotype stigmatizes men who took PrEP as overtly sexual and only engaging in condomless sex; however, more recently, the term has turned into a term of empowerment emphasizing that PrEP enables sexual expression (Spieldenner, 2016). A few researchers have also applied social justice theories to PrEP research. Researchers have used the Public Health Stewardship Framework (which includes both public health and equity outcomes) to examine the ethical issues in providing ARV medication for PrEP and TasP (Haire & Kaldor, 2013).

The application of a specific implementation theory (beyond the Diffusion of Innovations, which can be applied at both the organizational and intrapersonal levels of the Social Ecological Model) is a missing component in the literature. Specifically, no studies have used theory to investigate real world implementation or to identify the organizational characteristics necessary for successful PrEP implementation within publicly funded HIV testing sites. Although the need to study PrEP through an implementation lens is clear, there is still an entire field of theories, models, and frameworks from which to choose. Several researchers have attempted to provide guidance on selecting the most appropriate implementation framework to use in a given scenario (Hanson, Self-Brown, Rostad, & Jackson, 2016; Nilsen, 2015; Tabak, Khoong, Chambers, & Brownson, 2012). Nilsen (2015) describes five types of models, frameworks, or theories that could address the various phases of implementation research, including process models, determinant frameworks, classic theories, implementation theories, and evaluation frameworks. Both process models and evaluation frameworks have a temporal significance, and are most appropriately applied at the onset (process models) or conclusion (evaluation frameworks) of a particular phase of implementation (Nilsen, 2015). The remaining theory types (determinant frameworks, classic theories, implementation theories) are collectively used to describe the factors that may affect implementation. Implementation theories are those newly developed by implementation researchers, while classic theories are applications of more established theories – such as Social Cognitive Theory or the Information Motivation Behavioral
Change Model – applied to implementation. While both provide a foundation for the study of implementation, the former (implementation theories) are novel and often lack well defined constructs. On the other hand, classic theories often lack the ecological perspective needed for implementation in an organizational setting. Nilsen (2015) describes determinant frameworks as:

Types (also known as classes or domains) of determinants and individual determinants, which act as barriers and enablers (independent variables) that influence implementation outcomes (dependent variables). Some frameworks also specify relationships between some types of determinants. The overarching aim is to understand and/or explain influences on implementation outcomes, e.g. predicting outcomes or interpreting outcomes retrospectively (Table 1).

Hanson et al. (2016) typifies implementation theories differently, and perhaps more broadly, as: stages of implementation frameworks; consolidation and core component frameworks; organizational support frameworks; and planning frameworks. Stage frameworks and planning frameworks are often temporal in nature and may be best suited for studies that investigate the entire range of the diffusion, dissemination, and implementation spectrum (e.g. EPIS).

Consolidation and core component frameworks may address a broad range of determinants and factors affecting implementation, as derived from prior implementation science theories, models, and frameworks; however, this classification also includes frameworks designed for evaluation (e.g. REAIM). Furthermore, Tabak et al. (2012) explain that while some theories, models, and frameworks can be applied across the dissemination to implementation spectrum, others are best suited for a specific phase of the process (i.e. dissemination only or implementation only). These researchers suggest that additional consideration in model selection should include which level(s) of the Socioecological Model the study intends on examining; the development or flexibility of the model constructs; and the field from which the study originates.
The Consolidated Framework for Implementation Research (CFIR) is a synthesis of nearly 20 implementation theories and frameworks (Damschroder et al., 2009). CFIR guides the study of real-world implementation by providing a framework and underlying constructs that commonly affect implementation. CFIR could be classified as a determinant framework (Nilsen, 2015) and consolidation and core component framework (Hanson et al., 2016) – which are thought to be helpful when examining the facilitators and barriers to an implementation outcome. The framework addresses the implementation phase of the diffusion-dissemination-implementation spectrum – such as the PrEP implementation outcomes occurring within HIV testing sites. The CFIR has five overarching domains: Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process (Damschroder et al., 2009) – each containing constructs found in the literature to influence implementation in other settings (i.e. settings which are not specifically HIV testing sites). A full description of the rationale for the use of CFIR domains and constructs can be found in Appendix C and below under Application of CFIR to HIV Prevention.

Review of CFIR

CFIR has been described as a meta-theory drawing upon many constructs within the field of implementation science (Damschroder et al., 2009). The framework is comprised of five overarching domains: Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process of implementation – each with its own associated constructs (see Table 1.1).
CFIR aligns well with measures of theoretical evaluation. The framework is clear and, although it contains a large number of domains and constructs, was created with the intention of providing a succinct framework for implementation research. Strengths of the framework include its application to implementation science and the synthesis of preexisted constructs which have already been defined. Clarity of precision is measured by the conceptual and operational development of the framework (Goodson, 2010). Conceptually, CFIR was developed to provide a concise framework for implementation research (Damschroder et al., 2009). The constructs were drawn from implementation theories that provide a foundation for their use and development. The development of operationalization of CFIR is ongoing in the literature (Damschroder, 2016). The CFIR technical assistance team (Damschroder, 2016) has created a qualitative interview guide template, touching on the specific constructs of each CFIR domain. Quantitative measurement is less developed, although many CFIR constructs have been mapped to Organizational Readiness for Change Assessment (ORCA) for measurement.
purposes (Helfrich, Li, Sharp, & Sales, 2009). Although the development of additional CFIR quantitative measures is considered ongoing (Damschroder, 2016; Liang et al., 2015), researchers have not defined relationships between constructs. This weakness is acknowledged by Damschroder (2016). However, the researchers also suggest that domains and constructs of the framework can be used in part or whole as appropriate, suggesting there may not be a need for defined ties between measures. **Testability** measures the ability and ease of which replication of the theoretical application can be tested (Goodson, 2010). The degree to which the framework can be consistently tested across studies is strongly related to the operationality of its constructs. As the constructs are further operationalized, so will the framework’s ability to be tested. **Abstraction level and explanatory power** are two inter-related constructs that describe the applicability of the theory to a variety of phenomenon, circumstances, and populations (Goodson, 2010). Due to the nature of the framework, rooted in implementation, it is applicable to the implementation of a variety of phenomenon. Similarly, the framework is meant to take context into account, making it applicable to a variety of situations and populations. **Parsimony** describes the degree to which the framework simply explains its constructs and theoretical basis (Goodson, 2010). Perhaps due to the complexity of implementation, the framework contains numerous domains and constructs, making it lack parsimony in the strictest sense. However, the framework was rooted in the need to synthesize existing constructs and provide common terminology. This may suggest that compared to other implementation science frameworks and theories, CFIR could be considered parsimonious. **Formal development** of a theory is described as how well a theory has been articulated and tested in its application (Goodson, 2010). In the case of CFIR, the framework was developed in 2009 and is relatively novel (Damschroder et al., 2009). The **heuristic value** of the framework is rooted in its ability to generate additional research (Goodson, 2010). CFIR is meant to be applied to implementation research and, as such, may develop and improve new ways to
implement programs (in this case discussing PrEP during HIV testing). It may also help to refine new research and assist in determining the best way to implement intervention programs in the real world, as well as the best way to assess potential implementation challenges and strategies.

**Theoretical Application**

**Application of CFIR to HIV Prevention**

Little is known about the context of PrEP implementation specifically during HIV testing. To investigate this unique setting for PrEP implementation, the CFIR will be used, including the domains: Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process; these domains and constructs can be viewed in full in Table 1.1. Because PrEP is relatively novel compared to other HIV prevention methods, little is known regarding how the characteristics of PrEP (CFIR domain Intervention Characteristics) may affect its institutionalization. Additionally, PrEP is rooted in a history of biomedical development, which has the potential to lend itself to distrust if not marketed successfully. Characteristics of the organizations providing HIV testing (CFIR domain Inner Setting) and the political climate surrounding HIV prevention (CFIR domain Outer Setting) may also be critical to real world PrEP implementation. Characteristics of the Individuals performing HIV testing, such as their age, understanding of PrEP, and personal values may also cause variation in PrEP implementation. Although guidelines to determine clinical indications of PrEP now exist, provider views may still be biased. Furthermore, although external PrEP guidelines have been developed by the CDC, internal policies may not have been developed at community clinics or AIDS Service Organizations (ASOs) involved in performing HIV testing. Information is needed regarding the factors that affect PrEP implementation, as well as the perceived barriers to, and facilitators of, PrEP implementation in this setting. Such information will assist in planning the rollout of PrEP.
implementation in HIV testing locations, and in overcoming obstacles to providing access to HIV prevention via PrEP.

Although the strengths outweigh the weaknesses, there are some weaknesses of utilizing the CFIR as the guiding framework for this study. The theory focuses on specific constructs, but not the relationship between these constructs; this also limits the ability for the theory to be empirically tested (Damschroder et al., 2009). Additionally, CFIR is a framework and not an explicit theory, limiting the explanatory nature of the constructs (Nilsen, 2015). However, relationships between the domains and constructs may not be necessary in this study, as this is one of the first studies to investigate the facilitators and barriers specific to the staff providing HIV testing. Preliminary information, as collected in a study such as this, may be needed before relationships are drawn between the variables to better understand the state of PrEP implementation within HIV testing sites.

**Aims and Research Questions**

There is a paucity of research regarding the specific role *staff who perform HIV testing* may have in PrEP implementation. Existing studies have only utilized HIV testing sites for recruitment of clients who may be eligible for PrEP (Flash et al., 2018; Gallagher et al., 2014; King, et al. 2014), and have not focused on the role that staff performing HIV tests have in PrEP implementation. Publicly funded HIV testing sites are an ideal location for PrEP implementation because these sites often provide services free of charge, regardless of if a person has health insurance - unlike many other health care services. Additionally, such locations routinely collect information on sexual risk behavior during the testing process, and may provide an easy outlet for PrEP implementation. A study of providers who were early adopters of PrEP (in this study identified by peer referral for working in PrEP implementation during 2014 to 2015) found that support staff were an important part of PrEP implementation – citing their ability to educate, counsel, and assist with financial resources (Calabrese et al., 2016). Staff performing HIV
testing could be one group of support staff to bridge the gap between PrEP information delivery and clinical prescription. Additionally, researchers examining practice viewpoints of PrEP implementation also suggested the possibility of providing PrEP linkages during HIV testing campaigns (Jay & Gostin, 2012; King et al., 2014; Mayer, Grinsztejn, & El-Sadr, 2016).

CFIR provides unique insight into the implementation of PrEP. Although provider and client views have been examined in research, there are few studies that examine the implementation of PrEP with a theoretical basis (Krakower, Beekmann, Polgreen, & Mayer, 2016; Mullins, Lally, Zimet, & Kahn, 2015; Mullins, Zimet, Lally, & Kahn, 2016; Rubtsova et al., 2013; Walsh & Petroll, 2016). Unlike other theories used in the literature thus far, CFIR focuses specifically on implementation and the context in which it occurs.

To address this paucity, this study explores the facilitators of and barriers to PrEP implementation via community-based publicly funded HIV testing sites in Florida, as well as key characteristics associated with implementing PrEP within this setting. To do this the following aim and research questions were explored:

Study Aim: Describe the context of PrEP implementation/non-implementation in organizations providing HIV testing in Florida.

Research Question #1: What, if any, PrEP implementation subgroups exist among staff providing HIV testing in Florida?

Research Question #2: What characteristics of the individual are associated with PrEP implementation during HIV testing, as guided by the constructs of CFIR?

Research Question #3: What inner and outer setting factors are associated with PrEP implementation during HIV testing, as guided by the constructs of CFIR?
<table>
<thead>
<tr>
<th>Research Question</th>
<th>Hypotheses</th>
<th>Related Analyses</th>
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<tbody>
<tr>
<td>Research question 1: What, if any, PrEP implementation subgroups exist among staff providing HIV testing in Florida?</td>
<td>Within the population of HIV testing staff, subpopulations exist based on PrEP implementation behaviors.</td>
<td>Descriptive Statistics</td>
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<td>Latent Class Analysis</td>
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<tr>
<td>Research question 2: What characteristics of the individual are associated with PrEP implementation during HIV testing, as guided by the domain of CFIR (i.e. characteristics of the individual)?</td>
<td>High levels of PrEP knowledge, PrEP-related self-efficacy, prior/current PrEP use, and positive personal PrEP motivations and beliefs will be associated with high levels of PrEP implementation, when controlling for key organizational factors. Low levels of PrEP knowledge, PrEP-related self-efficacy, and negative personal PrEP motivations and beliefs will be associated with low levels of PrEP implementation when controlling for key organizational factors.</td>
<td>Descriptive Statistics</td>
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<td></td>
<td></td>
<td>Generalized Linear Mixed Model [Distribution: Multinomial; Logit Link]</td>
</tr>
<tr>
<td>Research question 3: What inner and outer setting factors are associated with PrEP implementation during HIV testing, as guided by the domains of CFIR?</td>
<td>A belief that clients need the option for PrEP (patient needs and resources); cosmopolitanism; pro-PrEP internal policy and incentives, structural characteristics, networks and communications, culture, tension for change, compatibility, relative priority; a positive learning climate; and PrEP-related available resources, and access to knowledge and information will be positively associated with high levels of PrEP implementation; while a belief that clients do not have a need for the option of PrEP (patient needs and resources); limited cosmopolitanism; anti-PrEP internal policy and incentives, structural characteristics, networks and communications, culture, tension for change, compatibility, relative priority; a negative learning climate; and a lack of PrEP-related available resources, and access to knowledge and information will be negatively associated with high levels of PrEP implementation.</td>
<td>Descriptive Statistics</td>
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<td></td>
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<td>Generalized Linear Mixed Model [Distribution: Multinomial; Logit Link]</td>
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<td></td>
<td>Thematic Analysis</td>
</tr>
</tbody>
</table>

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Overview of Study Design

This study utilized a mixed methods concurrent triangulation design (Creswell, 2013), in which the qualitative data and quantitative data were collected concurrently to fully understand the study aim, to describe the context of PrEP implementation/non-implementation in organizations providing HIV testing in Florida. A concurrent strategy was used for both feasibility and to allow concurrent data interpretation. This approach included the advantages of both qualitative and quantitative methods – providing a holistic view of PrEP implementation during HIV testing. Collecting both qualitative and quantitative data was particularly important in this study because PrEP implementation research is relatively novel compared to other HIV prevention methods; thus, the literature providing insight to interpret the findings is limited.

This study consisted of a quantitative assessment with staff who provide publicly funded, community-based, HIV testing in Florida. The quantitative assessment was used to determine the most common facilitators of, and barriers to, PrEP implementation, as well as the factors associated with PrEP implementation during HIV testing. The quantitative assessment utilized the CFIR domains of Intervention Characteristics, Inner Setting, Outer Setting, and Characteristics of Individuals. Semi-structured qualitative interviews were used to further describe the most salient implementation constructs, focusing on the facilitators of, and barriers to, PrEP implementation within each CFIR domain. The results were examined through an integrated analysis.

Dissertation Format

The following dissertation is written in a manuscript format. The following sections are included: Section 1: This section contains an introduction to the dissertation and the theoretical underpinnings of the research. A brief overview of the study methodology is also included.
Section 2: This section consists of Manuscript 1, “I'm obligated as somebody who's doing HIV prevention and testing to talk to somebody about this”: A latent class analysis identifying the underlying PrEP implementation behaviors of staff performing HIV testing in community-based HIV testing sites in Florida. The primary research question addressed in this manuscript is: Research question 1: What, if any, PrEP implementation subgroups exist among staff providing HIV testing in Florida?

Section 3: This section consists of Manuscript 2, “It's sort of all falling into place … before I felt like educating people about PrEP was like talking about the tooth fairy”: A mixed methods study examining the intrapersonal, organizational and external factors affecting PrEP implementation within community-based HIV testing sites in Florida. This manuscript answers two research questions: 1) What characteristics of the individual are associated with PrEP implementation during HIV testing, as guided by the construct of CFIR (Characteristics of the Individual)? and 2) What inner and outer setting factors are associated with PrEP implementation during HIV testing, as guided by the constructs of CFIR?

Section 4: This section consists of additional analyses not directly related to the research questions presented, but rather the larger context of PrEP implementation within HIV testing sites.

Section 5: This section consists of an overarching discussion, conclusion, and public health implications of the research presented.

To assist in ease of reading, a list of acronyms and terms used throughout the dissertation are included in Table 1.3 below.
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<tr>
<td>ARV</td>
<td>Antiretroviral Medication</td>
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<td>ASO</td>
<td>AIDS Service Organization</td>
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<tr>
<td>CBO</td>
<td>Community-based Organization</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CFIR</td>
<td>Consolidated Framework for Implementation Research</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>FLDOH</td>
<td>Florida Department of Health</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>LGBT</td>
<td>Lesbian-Gay-Bisexual-Transgender</td>
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<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>MSM</td>
<td>Men who have sex with men; In the HIV literature this term encompasses gay, bisexual, and other men who have sex with men</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
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<tr>
<td>NNT</td>
<td>Number need to treat</td>
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<tr>
<td>ORCA</td>
<td>Organizational Readiness for Change Assessment</td>
</tr>
<tr>
<td>PARHIS</td>
<td>Promoting Action on Research Implementation in Health Services Framework</td>
</tr>
<tr>
<td>PEP</td>
<td>Post-exposure prophylaxis; PEP is a 28 day medication that can be started within 72 hours after HIV exposure to prevent HIV</td>
</tr>
<tr>
<td>PrEP</td>
<td>Pre-exposure Prophylaxis; The proposed study refers to combination TDF/FTC (either Truvada® or generic formulation) as PrEP, and its use as a daily, oral dose, as this is the prescription currently approved by the Food and Drug Administration (FDA)</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
</tr>
<tr>
<td>TasP</td>
<td>Treatment as Prevention; A method by which people living with HIV are on medication and become virally suppressed, resulting in a substantially decreased likelihood of HIV transmission</td>
</tr>
<tr>
<td>TDF/FTC</td>
<td>Emtricitabine/tenofovir disoproxil fumarate – the formulation of the medication used for PrEP</td>
</tr>
<tr>
<td>Truvada</td>
<td>A brand name medication used in the treatment and prevention of Human Immunodeficiency Virus; composed of the formulation Tenofovir/Emtricitabine Disoproxil Fumarate</td>
</tr>
<tr>
<td>TGW</td>
<td>Transgender women</td>
</tr>
<tr>
<td>U.S.</td>
<td>United States</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
SECTION 2: “I'M OBLIGATED AS SOMEBODY WHO'S DOING HIV PREVENTION AND TESTING TO TALK TO SOMEBODY ABOUT THIS”: A LATENT CLASS ANALYSIS IDENTIFYING THE UNDERLYING PREP IMPLEMENTATION BEHAVIORS OF STAFF PERFORMING HIV TESTING IN COMMUNITY-BASED HIV TESTING SITES IN FLORIDA

Introduction

Pre-exposure prophylaxis (PrEP) has been approved by the Food and Drug Administration (FDA), and is recommended by the Centers for Disease Control and Prevention (CDC) (CDC, 2014; The White House Office of National AIDS Policy, 2015; U.S. Public Health Service, 2014, 2015) and World Health Organization (WHO) (World Health Organization, 2012b, 2015) as one method to assist in the prevention of HIV. By taking a daily pill of Tenofovir/Emtricitabine Disopoxil Fumarate (often referred to by the brand name, Truvada®), a person can reduce his or her risk of HIV by up to 92% (CDC, 2016f; Spinner et al., 2016). Despite the development and recommended use of this prevention method for at risk populations, many people are still unaware of PrEP (Chapman Lambert, Marrazzo, Amico, Mugavero, & Elopre, 2018; Eaton et al., 2017; Garnett et al., 2018; Walters, Reilly, Neaigus, & Braunstein, 2017).

In the complicated United States healthcare system, it is unclear who is responsible for ensuring patients are informed about HIV prevention and PrEP. Partnering with medical providers may be a natural first step to disseminate information related to PrEP. Acceptance and awareness of PrEP has appeared to increase in medical providers since the release of the CDC PrEP Guidelines in 2014, but many providers are still unaware of PrEP (Krakower & Mayer, 2016; Smith, Mendoza, Stryker, & Rose, 2016). Additionally, factors beyond awareness affect whether medical providers talk to their clients about, or prescribe, PrEP. Studies have found that some medical providers may differentially discuss PrEP based on how at-risk they perceive their patient to be (Adams & Balderson, 2016; Calabrese et al., 2014; Krakower &
Mayer, 2016). Additional research has shown that providers may not be fully aware of their patients’ sexual histories or behaviors (Krakower & Mayer, 2012; Thrun, 2013). For instance, studies among MSM have found that some men may not be “out” to their provider (i.e. voluntarily open with their provider about their sexual orientation) (Arrington-Sanders et al., 2016; Mehta et al., 2011). This is particularly important because some findings have suggested that being “out” to a provider about sexual orientation is associated with awareness of PrEP (Raifman, Flynn, & German, 2016; Watson, Fish, Allen, & Eaton, 2018). Patients not being “out” to their providers about their sexual orientation may further complicate PrEP implementation because providers may not be aware of the HIV-related risk behaviors in which these patients engage. Therefore, providers may not adequately assess which patients would most benefit from PrEP and may not provide adequate counseling. Given these shortcomings, locations outside of providers’ offices must also be utilized to increase knowledge and awareness of PrEP (Mayer, Chan, R, Flash, & Krakower, 2018; Smith, Dearing, Sanchez, & Goldschmidt, 2013; Underhill et al., 2014; Underhill, Operario, Mimiaga, Skeer, & Mayer, 2010; Underhill, Operario, Skeer, et al., 2010).

Although it is clear a multi-faceted approach is needed to successfully implement PrEP (Mayer et al., 2018; Smith et al., 2013; Underhill et al., 2014; Underhill, Operario, Mimiaga, et al., 2010; Underhill, Operario, Skeer, et al., 2010), locations outside of traditional medical provider offices have been underexplored. Alternative locations such as community-based organizations, pharmacies, and clinics specializing in treating sexually transmitted infections have been suggested as possible locations to expand PrEP implementation. Depending on the location and clinical availability, these sites could participate in at least one or more of the following: education, counseling, referral, or screening for a possible prescription (Mayer et al., 2018; Mayer et al., 2016; Smith et al., 2013; Underhill et al., 2014; Underhill, Operario, Mimiaga, et al., 2010; Underhill, Operario, Skeer, et al., 2010). Moreover, studies investigating the role of
non-clinical staff in PrEP implementation have found that such staff may be important to education and counseling efforts (Calabrese et al., 2016; Smith et. al., 2016), as well as navigating the available resources for PrEP-related financial assistance (Calabrese et al., 2016). A recent systematic review even suggested the need to study the integration of PrEP education into routine HIV testing procedures (Mayer et al., 2018). However, the perspectives of staff performing HIV testing have not yet been studied.

Counseling during the HIV testing process could be a critical point during which non-clinical staff could intervene and discuss PrEP as an option for HIV prevention, or refer people to organizations providing PrEP, (Mayer et al., 2018). HIV testing sites are focused on serving people who are uninfected, or do not yet know they are living with HIV. Staff at such sites already ask sensitive questions about sexual risk behavior during pre-test counseling. For example, in Florida, the DH1628 Laboratory Request Form completed with each publicly funded HIV test requires that counselors ask clients about risk factors, including both sexual risk factors and risks associated with injection drug use (FDOH, 2012). Yet, little is known about the specific factors affecting PrEP implementation (i.e. discussing PrEP or referring clients to an organization providing PrEP) during the HIV testing process.

It is likely that many HIV testing staff discuss PrEP with their clients, but such staff may not discuss PrEP in the same way, and some staff may not include PrEP in their counseling discussion. Building on prior research examining the role of non-clinical staff in PrEP implementation (Calabrese et al., 2016; Smith et. al., 2016), this study investigates the role that staff performing HIV testing have in PrEP implementation, answering the research question: What, if any, PrEP implementation subgroups exist among staff providing HIV testing in Florida?
Methods

Study Design

This study utilized a mixed methods concurrent triangulation design (Creswell, 2013) to investigate the unobserved subgroups of staff who provide HIV testing in Florida, and how these characteristics impact the role of staff in PrEP implementation. In this study, PrEP implementation is described as the degree to which PrEP is discussed and/or a referral to a prescriber occurs during HIV testing. Data were collected and analyzed concurrently and triangulated during data analysis and interpretation. The study was approved by the Institutional Review Board of the University of South Florida (Appendix G). A waiver of written informed consent was received and participants provided informed consent within the electronically delivered survey.

Data collection

Participants were recruited via email to complete an online assessment administered through Qualtrics that lasted approximately 15-20 minutes. Contact information for publicly funded HIV testing sites in Florida is freely available on the Internet. Each community-based (i.e. not located within the department of health) publicly funded testing site was contacted via email with a request to share the survey with staff who perform HIV testing and counseling. Unsuccessful attempts and requests for no further contact were logged daily. Organizations were contacted up to four times (i.e. a pre-notice, followed by up to 3 additional contacts that include the survey link) (Dillman, 2011). At the end of the quantitative assessment, participants were asked if they would like to enter a raffle for one of three $50 gift cards, and if they would be willing to be contacted for the qualitative portion (i.e. in-depth interviews) of the study. Interview participants were selected from those who indicated interest by quota sampling to ensure inclusion of participants with a diverse range of PrEP implementation experiences. Participants who took part in the qualitative interview received a $20 gift card.
Measures

The study outcome was PrEP implementation, with PrEP implementation categories determined by a Latent Class Analysis (LCA). The LCA was based upon how clients answered a pre-determined set of questions regarding multifaceted PrEP implementation, with specific questions to follow: Overall, how often do you talk to clients about PrEP when testing/counseling for HIV?; I talk to clients about PrEP every time I test for HIV; I talk to clients about PrEP when I think they might be eligible (meet the indications to start taking PrEP); I give physical information about PrEP (such as pamphlets, flyers, and written contact information for PrEP friendly providers) to clients during HIV testing/counseling; Overall, how often do you give clients physical information about PrEP (such as pamphlets, flyers, and written contact information for PrEP friendly providers) during HIV testing/counseling? All items were categorical in nature and measured in a 5-point scale (see Table 2.3 in results). The in-depth interview guide was based on CFIR guidance provided on the CFIR technical assistance website (Damschroder, 2016). [A full list of quantitative and qualitative items can be found in Appendices C and E.]

Sample Size

A total of 150 participants from 48 organizations were included in quantitative analysis. The qualitative sample size was based on thematic saturation, when no new themes emerge from the data (Guest, Bunce, & Johnson, 2006). Saturation was reached at 22 participants.

Data analysis

Quantitative data were exported from Qualtrics (Qualtrics, 2017) into SPSS v.24 (SPSS, 2011). Data were cleaned and examined for suspicious and repeat responses. Forty-nine participants were excluded from analysis: 12 did not meet inclusion criteria, thus were unable to continue on to the survey and an additional 18 did not proceed past the consent. Nineteen participants completed between 34-55% of the survey. These participants had not yet completed demographic questions, so it was not possible to compare their demographic
information to those who completed the survey in its entirety. However, when comparing key
variables (e.g. existence/non-existence of a PrEP policy), these participants did not appear to
be drastically different than the analytic sample. Additionally, 21 IP addresses were listed more
than once. This was expected based upon internet configuration, as some organizations may
have a shared IP address between their employees. These responses were determined to be
from unique participants based upon investigation into survey answers and demographic
characteristics. Additionally, no names, phone numbers, or emails of participants who entered
the gift card raffle, or agreed to future contact, were duplicated. Descriptive statistics of the
remaining analytic sample were conducted.

Latent Class Analysis (LCA) (Heck, Thomas, & Tabata, 2013; McCutcheon, 1987) was
used to determine PrEP implementation groups. The LCA was performed using MPlus v.8
(Muthén & Muthén, 2015). All other analyses were performed using SPSS v.24 (SPSS, 2011).
The LCA technique groups participants based on similarities in how they answer a
predetermined set of questions. Five items were included in the LCA (full items depicted in table
2.3 under “results”), asking participants to rank the degree to which they participated in a
number of dissemination activities related to PrEP. These activities included referring clients to
a place where they could learn more about PrEP and/or providing clients with resources about
PrEP. All items were categorical and were each measured on a 5-point scale. The final LCA
model and corresponding latent classes were determined based upon fit indices (BIC [Bayesian
Information Criterion] and LMR [Lo-Mendell-Rubin]) and theoretical interpretation (Nylund,
Asparouhov, & Muthén, 2007). In interpreting BIC, the lower the score the better fit of the model.
For LMR, it is suggested that researchers find the model which produces a non-significant LMR
value, and use one less class (k-1) (Nylund et al., 2007). Theoretical interpretation (i.e.
consideration of how participants responded to the items in the LCA, as they relate to the
existing literature) was also considered (Nylund et al., 2007).
Qualitative interviews were transcribed, verified by the primary author to ensure correct transcription, imported into MaxQDA (Kuckartz, 2007) and analyzed thematically (Guest, MacQueen, & Namey, 2011). The primary author segmented all transcripts based on topic. An initial codebook was created based on the CFIR guidelines and emerging codes that arose while conducting the interviews listening to the audio and verifying transcription accuracy. Two researchers trained in qualitative data analysis coded the same transcript independently before discussing revisions and edits for the codebook. The same researchers coded an additional transcript to refine the codebook. Following agreement on the codebook, four transcripts were independently coded to calculate interrater reliability (IRR). At this first attempt the overall Kappa was K=.75. The same two coders reviewed these transcripts, discussed interpretation and clarification of codes, and again attempted IRR with 4 new transcripts. IRR was reached, with an overall K=.86. The remaining transcripts (n= 12) were coded by the primary author. Trustworthiness of the qualitative data was examined using Guba’s model of trustworthiness of qualitative research (Guba, 1981; Krefting, 1991; Lincoln & Guba, 1986).

Integration of the qualitative and quantitative findings was performed. During data collection and analysis, connecting occurred via using the quantitative data to identify participants for the qualitative phase (Creswell, 2013; Creswell, Klassen, Plano Clark, & Smith, 2011). Data were also merged after data collection, a technique that involves combining the quantitative and qualitative data sets (Creswell et al., 2011; Fetters, Curry, & Creswell, 2013). During data interpretation a narrative approach (where integration of the two data sources was woven throughout the interpretation), and utilization of joint display of data (displaying the quantitative and qualitative portions of the study within the same section and noting how they build upon each other) were used to integrate the data (Fetters et al., 2013).
**Results**

**Participant Characteristics**

A total of 150 staff providing HIV testing (participants) from 48 organizations were included in analysis. Participants were an average of 41.4 years old, ranging in age from 20 to 73 years (Table 2.1). The sample was fairly diverse in terms of gender (53.7% male; 43.6% female) and sexual orientation (48.3% heterosexual; 40.9% homosexual). Just over half of participants indicated their race as White, while just over 20% indicated being Black. While most participants worked fulltime at their organization (78.1%), some worked part time (10.1%) or volunteered (11.8%). Notably, nearly 20% (19.3%) of participants were living with HIV.

### Table 2.1

<table>
<thead>
<tr>
<th>Table 2.1</th>
<th>Participant Characteristics (N=150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range)</td>
<td>41.4±14.1 (20-73)</td>
</tr>
<tr>
<td><strong>Gender</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td>Male</td>
<td>80 (53.7)</td>
</tr>
<tr>
<td>Female</td>
<td>65 (43.6)</td>
</tr>
<tr>
<td>Transgender female to male</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Another gender</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td><strong>Sexual Orientation</strong>&lt;sup&gt;b&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td>Heterosexual (Straight)</td>
<td>72 (48.3)</td>
</tr>
<tr>
<td>Homosexual (Gay/Lesbian)</td>
<td>61 (40.9)</td>
</tr>
<tr>
<td>Bisexual</td>
<td>7 (4.7)</td>
</tr>
<tr>
<td>Another Sexual Orientation</td>
<td>5 (3.4)</td>
</tr>
<tr>
<td><strong>Race</strong>&lt;sup&gt;c&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td>White</td>
<td>77 (51.3)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>35 (23.3)</td>
</tr>
<tr>
<td>Asian</td>
<td>6 (4.0)</td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Native Hawaiian/Pacific Islander</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>50 (33.3)</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td>n (%)</td>
</tr>
<tr>
<td>Full time</td>
<td>118 (78.7)</td>
</tr>
<tr>
<td>Part time</td>
<td>13 (8.7)</td>
</tr>
<tr>
<td>Volunteer</td>
<td>19 (12.7)</td>
</tr>
<tr>
<td><strong>Prescriber (employed in position that involves prescribing medicine)</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td></td>
<td>4 (2.7)</td>
</tr>
<tr>
<td><strong>Ever taken PrEP</strong>&lt;sup&gt;e&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td></td>
<td>20 (13.4)</td>
</tr>
<tr>
<td><strong>Currently on PrEP</strong>&lt;sup&gt;f&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td></td>
<td>14 (9.6)</td>
</tr>
<tr>
<td><strong>HIV status</strong>&lt;sup&gt;e&lt;/sup&gt;</td>
<td>n (%)</td>
</tr>
<tr>
<td>Living with HIV (HIV positive)</td>
<td>29 (19.5)</td>
</tr>
<tr>
<td>Not living with HIV (HIV negative)</td>
<td>120 (80.3)</td>
</tr>
</tbody>
</table>

<sup>a</sup> No participant identified as transgender male to female. One participant selected “prefer not to answer”. One participant skipped the question. N=149

<sup>b</sup> Two participants indicated “not sure” and two indicated “prefer not to answer”. One participant skipped the question. N=149

<sup>c</sup> Participants could select all races/ethnicities that applied. Some participants did not select a race, and only selected Hispanic ethnicity

<sup>d</sup> One participant skipped the question N=149

<sup>e</sup> One participant selected “prefer not to answer” N=149

<sup>f</sup> One participant selected “prefer not to answer”. Three participants skipped the question N=146
Qualitative interview participants (N=22) were similar to the larger sample, with slight variations. These participants were slightly younger, and more likely to be White and/or male than the full sample. The average qualitative participant was 37.4 years (range: 21-64), 63.6% White, 63.6% male, 54.5% heterosexual, and 18.2% living with HIV.

**Classes of PrEP Implementation**

A total of four models were conducted using LCA—each containing 1, 2, 3 or 4 classes, respectively (Table 2.2). The 1 class and 4 class models each had higher BIC values than the 2 class and 3 class models, respectively; the 2 class and 3 class models were further investigated. Although the 2 class model had the best model fit as determined by the BIC criteria, the 3 class model had the better fit when considering LMR and theoretical interpretation. Based on consideration of fit statistics and theoretical relevance, a 3 class LCA was selected and used for all further analyses.

<table>
<thead>
<tr>
<th>Number of classes</th>
<th>AIC</th>
<th>BIC</th>
<th>aBIC</th>
<th>LMR p value</th>
<th>Entropy*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1967.987</td>
<td>2027.796</td>
<td>1964.505</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>1798.022</td>
<td>1920.629</td>
<td>1790.883</td>
<td>p &lt; .001</td>
<td>0.961</td>
</tr>
<tr>
<td>3*</td>
<td>1750.482</td>
<td>1935.889</td>
<td>1739.687</td>
<td>p=0.0098</td>
<td>0.914</td>
</tr>
<tr>
<td>4</td>
<td>1733.269</td>
<td>1981.475</td>
<td>1718.818</td>
<td>p=0.1392</td>
<td>0.938</td>
</tr>
</tbody>
</table>

*Entropy was not considered for fit or the decision of the number of latent classes, but is here for reference.

As a model approaches 1.0, it approaches full delineation of latent classes, referred to as entropy (Celeux & Soromenho, 1996); entropy for the LCA was .914. After reviewing the classes, or grouping of participants, each group was assigned a label to be used throughout analysis and data reporting. The name of each label was determined based on the characteristics of their latent class. The class labeled *Universal* was labeled as such because this group indicated talking about PrEP with all or most of the clients they see, as well as handing out PrEP-related materials regularly. Thus, class one (42%; n=62) included staff performing HIV testing who were PrEP advocates; these participants were highly likely to talk
about PrEP with their clients, regardless of client eligibility. This group was also most likely to
give their clients physical information about PrEP – such as pamphlets, flyers, and written
contact information for PrEP friendly providers. Class two (33%; n=48) were staff who often
talked to clients about PrEP, but were most likely to discuss the prevention method if they felt
their client was eligible, thus referred to as Eligibility Dependent. This group also provided
physical materials to clients, but not as consistently as participants in the Universal group. Class
3 (25%; n=37) was the most discriminate group with regards to PrEP implementation – they
sometimes spoke to clients about PrEP, but not as systematically as those in the Universal or
Eligibility Dependent groups. This group will be referred to as Limited. This group was also the
least likely group to provide physical information about PrEP, such as brochures or referral
cards.

The latent classes were often triangulated via qualitative data. In qualitative interviews,
some members of the Universal group stated that they believed everyone should be aware of
PrEP, regardless of their current level of risk. Participants in the Universal group often confirmed
discussing PrEP with clients on a frequent basis, such as “I'm obligated as somebody who's
doing HIV prevention and testing to talk to somebody about this [PrEP]. (Participant 113)” or “I
think is great because it's a resource that everyone should know about. Regardless if you don't
use it [PrEP] or use it, you know, if you know someone that can use it, you can always
recommend them to it (Participant 116)”. This theme was less present in the Eligibility
Dependent group and not present in the Limited group.
Table 2.3. Categorical distribution of final latent class model

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Response Categories</th>
<th>Latent Class 1</th>
<th>Latent Class 2</th>
<th>Latent Class 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Universal (42%)</td>
<td>Eligibility Dependent (33%)</td>
<td>Limited (25%)</td>
</tr>
<tr>
<td>Overall, how often do you talk to clients about PrEP when testing/counseling for HIV?</td>
<td>I never do this</td>
<td>0.000</td>
<td>0.000</td>
<td>0.055</td>
</tr>
<tr>
<td></td>
<td>Very rarely</td>
<td>0.000</td>
<td>0.021</td>
<td>0.164</td>
</tr>
<tr>
<td></td>
<td>Some of the time</td>
<td>0.018</td>
<td>0.114</td>
<td><strong>0.532</strong></td>
</tr>
<tr>
<td></td>
<td>Most of the time</td>
<td>0.019</td>
<td><strong>0.780</strong></td>
<td>0.249</td>
</tr>
<tr>
<td></td>
<td>Every time</td>
<td><strong>0.963</strong></td>
<td>0.085</td>
<td>0.000</td>
</tr>
<tr>
<td>I talk to clients about PrEP every time I test for HIV</td>
<td>Strongly disagree</td>
<td>0.050</td>
<td>0.000</td>
<td>0.107</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>0.000</td>
<td>0.079</td>
<td><strong>0.527</strong></td>
</tr>
<tr>
<td></td>
<td>Neither</td>
<td>0.000</td>
<td>0.221</td>
<td>0.366</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>0.243</td>
<td><strong>0.700</strong></td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>Strongly agree</td>
<td><strong>0.708</strong></td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>I talk to clients about PrEP when I think they might be eligible (meet the indications to start taking PrEP)</td>
<td>Strongly disagree</td>
<td>0.080</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>0.016</td>
<td>0.021</td>
<td>0.055</td>
</tr>
<tr>
<td></td>
<td>Neither</td>
<td>0.048</td>
<td>0.000</td>
<td>0.165</td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>0.181</td>
<td>0.337</td>
<td><strong>0.479</strong></td>
</tr>
<tr>
<td></td>
<td>Strongly agree</td>
<td><strong>0.674</strong></td>
<td><strong>0.642</strong></td>
<td>0.301</td>
</tr>
<tr>
<td>I give physical information about PrEP (such as pamphlets, flyers, and written contact information for PrEP friendly providers) to clients during HIV testing/counseling</td>
<td>Strongly disagree</td>
<td>0.064</td>
<td>0.000</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>0.024</td>
<td>0.054</td>
<td>0.326</td>
</tr>
<tr>
<td></td>
<td>Neither</td>
<td>0.091</td>
<td>0.088</td>
<td><strong>0.415</strong></td>
</tr>
<tr>
<td></td>
<td>Agree</td>
<td>0.337</td>
<td><strong>0.609</strong></td>
<td>0.152</td>
</tr>
<tr>
<td></td>
<td>Strongly agree</td>
<td><strong>0.483</strong></td>
<td>0.249</td>
<td>0.079</td>
</tr>
<tr>
<td>Overall, how often do you give clients physical information about PrEP (such as pamphlets, flyers, and written contact information for PrEP friendly providers) during HIV testing/counseling?</td>
<td>I never do this</td>
<td>0.000</td>
<td>0.041</td>
<td>0.055</td>
</tr>
<tr>
<td></td>
<td>Very rarely</td>
<td>0.064</td>
<td>0.022</td>
<td>0.328</td>
</tr>
<tr>
<td></td>
<td>Some of the time</td>
<td>0.165</td>
<td>0.398</td>
<td><strong>0.590</strong></td>
</tr>
<tr>
<td></td>
<td>Most of the time</td>
<td>0.256</td>
<td><strong>0.539</strong></td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>Every time</td>
<td><strong>0.515</strong></td>
<td>0.000</td>
<td>0.027</td>
</tr>
</tbody>
</table>
Eligibility Dependent participants often brought up concerns regarding the side effects of PrEP that seemed to highlight the need for a more selective discussion of PrEP based on risk criteria, such as “Like I said, if you're married and you have one partner, then you're taking PrEP to damage your liver or your kidneys, and so on and so on. It doesn't make sense [to use PrEP]. (Participant 103)” or “We have many people that we know are in serodiscordant relationships, so we want to help them (Participant 107).” In essence, these participants weighed the pros and cons of PrEP for their client and determined if PrEP should be discussed based upon their client’s level of risk.

In LCA the Limited group was found to have inconsistent discussions about PrEP. This lack of systematic rationale for PrEP implementation was captured by the varied qualitative responses within this group. This group discussed concerns regarding PrEP but did not have salient qualitative rationale for why they did, or did not, discuss PrEP with clients.

Discussion

This study sought to understand PrEP implementation at community-based HIV testing locations in Florida. A latent class analysis revealed three distinct classes of PrEP implementation—Universal, Eligibility Dependent, and Limited. Entropy was found to be 0.914 (approaching 1), indicating delineation between classes (Celeux & Soromenho, 1996). Qualitative data were triangulated with quantitative data, and provided additional information and characterization of these classes.

While staff who provide HIV testing may share some similar characteristics, they are a heterogenous population with regards to the specific ways that they take part in PrEP implementation. Using the LCA approach (Heck et al., 2013; McCutcheon, 1987) allowed for the grouping of participants into mutually exclusive sub-groups within the larger population of staff who provide HIV testing. This approach takes the complex nature of PrEP implementation into account; unlike other approaches that may split participants based on a score or percentage.
ranking, the LCA considers the specific combinations of PrEP-related implementation activities (Heck et al., 2013; McCutcheon, 1987).

Participants in the Limited group were inconsistent in their PrEP implementation behaviors, despite the state of Florida HIV testing manual describing the importance of linkage to prevention resources, including PrEP (FDOH, 2018a). These findings may also speak to the need for targeted interventions for HIV testing staff with characteristics of the Limited group. From a public health perspective, there is a need for these participants to change their PrEP implementation behaviors to those similar to the Eligibility Dependent or Universal groups. Participants in both the Universal and Eligibility Dependent groups meet the standards of the Florida Department of Health testing procedures in that they are able to provide linkages and may be able to provide client-centered risk assessments during the counseling process (FDOH, 2018a). The understanding of what it means to provide client-centered risk assessments could be one differentiating factor between these groups. Participants in the Eligibility Dependent group may feel that discussing PrEP with clients they believe would not meet the indications for PrEP diverts from the recommendation of client-centered counseling. It is also important to note that the level of risk HIV testing staff perceive a client to have may not always be accurate. Clients may not be fully truthful with the staff providing the HIV testing service (Sheon, Lee, & Facente, 2010); similarly, the staff providing testing may make assumptions about the client based on the way he or she presents themselves or demographic characteristics (Adams & Balderson, 2016a; Calabrese et al., 2014; Calabrese & Underhill, 2015). Thus, while some participants in the Eligibility Dependent group may be accurately determining which clients could benefit from knowing about PrEP, other HIV testing staff within the Eligibility Dependent group may be missing the opportunity to tell clients about a potentially valuable prevention method. While the Universal participants may be sharing information about PrEP with those who do not meet the indications, (unlike the Eligibility Dependent participants) they are not missing clients who may benefit from the innovation. By sharing this information with all clients, participants in
the *Universal* group are also increasing the general community-level knowledge of PrEP, which in turn may reduce associated stigma.

This study is not without limitations. The study was limited to community-based organizations within one state in the southern United States. Some aspects of PrEP implementation may vary geographically, as studies have found slower PrEP uptake among some populations (Elopre, Kudroff, Westfall, Overton, & Mugavero, 2017) and high rates of HIV-related stigma in the southern United States (Darlington & Hutson, 2017). The lack of validated scales measuring PrEP implementation led to a literature driven development of relevant items; however, use of latent class analysis provided some strength to the outcome variable. Literature-driven development of items used in LCA has been used in other understudied contexts (Laska, Pasch, Lust, Story, & Ehlinger, 2009).

There are many strengths in this study. The study is rooted in an implementation science framework that has been used extensively in the literature (Birken et al., 2017; Damschroder et al., 2009); however, has been underutilized the field of PrEP implementation. Additionally, it is a mixed methods study that triangulates the quantitative and qualitative findings to provide a comprehensive look at PrEP implementation during HIV testing. This study may have implications for training and program development related to PrEP implementation, such as providing targeted skill-based training for participants in the *Limited* group or additional resources to *Eligibility Dependent* participants. Finally, this study also took place in a state with high HIV prevalence and incidence, Florida (FDOH, 2016a). Much can be learned from PrEP implementation in Florida, as it is geographically and ethnically diverse, as well as entering a statewide push for PrEP implementation. This study is among the first to examine PrEP implementation from the perspective of staff who provide HIV testing to the clients. These findings may help organizations in determining the best way forward in providing training for PrEP implementation in the future.
SECTION 3: “IT’S SORT OF ALL FALLING INTO PLACE ... BEFORE I FELT LIKE EDUCATING PEOPLE ABOUT PREP WAS LIKE TALKING ABOUT THE TOOTH FAIRY”: A MIXED METHODS STUDY EXAMINING THE INTRAPERSONAL, ORGANIZATIONAL AND EXTERNAL FACTORS AFFECTING PREP IMPLEMENTATION WITHIN COMMUNITY-BASED HIV TESTING SITES IN FLORIDA

Introduction

Pre-exposure prophylaxis (PrEP) has been found to effectively reduce HIV acquisition by approximately 90% (Anderson et al., 2012; CDC, 2016f; Spinner et al., 2016). Following successful efficacy trials, PrEP was approved by the Food and Drug Administration and recommended for at-risk populations by several key public health entities, including the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) (CDC, 2014; The White House Office of National AIDS Policy, 2015; U.S. Public Health Service, 2014; World Health Organization, 2012a, 2012b, 2015). However, to date, there has been slow uptake of PrEP (Scholl, 2016). There has been a focus on the role that medical providers have in PrEP implementation (Krakower & Mayer, 2016; Smith, Mendoza, Stryker, & Rose, 2016), and for good reason. A medical provider is needed to prescribe PrEP. Yet, there are some limitations to relying on medical providers as the only staff responsible for PrEP implementation, among them the struggle or disinterest some medical providers have in discussing sexual health with their patients (Krakower & Mayer, 2012; Thrun, 2013). However, additional sites – such as STI clinics, pharmacies, and community-based organizations - could be utilized to disseminate PrEP-related education and support (Mayer et al., 2018; Smith et al., 2013; Underhill et al., 2014; Underhill, Operario, Mimiaga, et al., 2010; Underhill, Operario, Skeer, et al., 2010).

HIV testing sites offer alternative locations in which PrEP implementation could occur (Mayer et al., 2018); in these settings PrEP implementation is conceptualized as PrEP education and/or referral to a place where a PrEP prescription could take place. Many HIV
testing sites can be accessed regardless of insurance coverage and operate on a walk-in basis. Additionally, staff providing HIV testing already speak with clients about their sexual risk behaviors and HIV prevention. Thus, PrEP implementation at HIV testing sites may be important for reaching clients who may meet the indications for PrEP.

Research regarding HIV testing and PrEP has focused on the client – the person receiving the HIV testing and counseling (Hevey, Walsh, & Petroll, 2018; Kwan & Lee, 2018; Parsons, John, Whitfield, Cienfuegos-Szialay, & Grov, 2018; Wilton et al., 2016). For example, studies have examined the frequency in which clients already on PrEP have continued to get tested for HIV; testing for HIV every three to six months is suggested per the CDC guidelines for PrEP. (Hevey et al., 2018; Parsons et al., 2018). Researchers have recruited clients from within HIV testing sites and investigated the interest these clients have in PrEP (Kwan & Lee, 2018). One study assessed the role of HIV testing sites in linkage to PrEP, but again this study focused only on the perspective of the clients being served (Flash et al., 2018). Several researchers have noted the possible utility of PrEP referrals during HIV testing (Hammack, Meyer, Krueger, Lightfoot, & Frost, 2018) However, to our knowledge, studies focusing on the role staff who provide HIV testing have in PrEP implementation (i.e. inclusion of PrEP in counseling and/or PrEP referrals) are limited.

Damschroder et al. (2009) synthesized implementation theories and frameworks and identified five overarching domains affecting implementation: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process. Collectively, these domains and their related constructs make up the Consolidated Framework for Implementation Research (CFIR). The CFIR helps researchers and practitioners to understand the implementation process and where key changes could be made to improve PrEP implementation. Understanding the constructs within the CFIR domain Characteristics of Individuals may help to explain how intrapersonal characteristics of the staff performing HIV testing may impact PrEP implementation within HIV testing sites. The CFIR domain Characteristics of Individuals covers
a range of intrapersonal constructs regarding the staff implementing the intervention; among these constructs are PrEP-related knowledge and beliefs, self-efficacy, and personal attributes of the staff performing HIV testing (e.g. prior personal experience with PrEP). Understanding how Characteristics of Individuals affect PrEP implementation during HIV testing could help organizations to plan program and training development. The Inner Setting describes the organizational characteristics that may affect implementation of an intervention (e.g. the culture of an organization or the resources available to those who implement the intervention) (Damschroder, 2016). Thus, the CFIR domain Inner Setting could provide guidance on what organizational attributes are associated with successful PrEP implementation. The Outer Setting describes factors external to the organization that may impact implementation of an intervention (e.g. the needs of the clients the organization serves or the degree to which an organization is networked with other organizations) (Damschroder, 2016). Given that organizations exist in communities, the Outer Setting may provide important context to understanding implementation.

This study examined how the intrapersonal characteristics of HIV testing staff (Characteristics of Individuals), organizational (Inner Setting) and community (Outer Setting) characteristics impact PrEP implementation as performed by staff performing HIV testing. Two research questions were addressed: 1) What characteristics of the individual are associated with PrEP implementation during HIV testing, as guided by the domain of CFIR (i.e. characteristics of the individual)? and 2) What inner and outer setting factors are associated with PrEP implementation during HIV testing, as guided by the domains of CFIR?

**Methods**

**Study Design**

This study utilized a mixed methods concurrent triangulation design (Creswell, 2013) to examine the factors affecting PrEP implementation during HIV testing in Florida. Participants included staff who conduct HIV testing, as they are most aware of the daily activities of PrEP
implementation/non-implementation during the HIV testing process. Eligibility criteria included: 1) working or volunteering at an organization that provides community-based publicly funded HIV testing in the state of Florida; 2) having provided HIV testing/counseling within the past three months and 3) being at least 18 years old. Participants were ineligible if they were unable to complete a computer-based survey without assistance. The guiding framework for the study was the Consolidated Framework for Implementation Research (CFIR).

**Human Protections**

This study was approved by the Institutional Review Board of the University of South Florida (Appendix G). All participants were provided with an electronic informed consent prior to initiating the survey.

**Data Collection**

Quantitative data were collected using an online survey (approximately 15-20 minutes in length) via Qualtrics (Qualtrics, 2017). Contact information for publicly funded HIV testing sites is freely on the internet. The primary investigator of the study contacted each publicly funded testing site via email with a request to share the survey with staff who perform HIV testing and counseling. A log was kept listing all recruitment attempts. Following the Dillman methodology (2011), organizations were contacted up to four times (i.e. a pre-notice, followed by up to 3 additional contacts that include the survey link) (Dillman, 2011).

After completing the online survey, participants had the option to provide their name and contact information; three of the 150 participants received a $50 gift card. Participants were also asked if they were willing to be contacted to complete a semi-structured interview. A subset of participants who agreed to be contacted were considered for the qualitative interview. These participants were purposefully sampled to ensure data from participants with a wide range of experiences in PrEP implementation. Participants who took part in the qualitative interview received a $20 gift card. A total of 22 participants completed the semi-structured interviews.
Measures

Quantitative Measures

Quantitative study measures were related to constructs within the CFIR domains Characteristics of Individuals, Inner Setting, and Outer Setting, as well as PrEP implementation behaviors occurring within HIV testing sites. [A full list of items can be found in Appendix D and rationale for domain and construct inclusion can be found in Appendix C.] The study outcome was PrEP implementation. In this setting, PrEP implementation is conceptualized as the inclusion of PrEP in counseling and/or PrEP referrals. PrEP implementation was determined based on a latent class analysis (Manuscript 1). Briefly, five items were used in a latent class analysis, and a three-class model was determined to be the most appropriate model to describe implementation. The three groups of PrEP implementation were defined as: 1) Universal (42% of the sample; participants who were highly likely to talk about PrEP with their clients and provide physical materials regarding PrEP, regardless of if the client was at a high risk for HIV); 2) Eligibility Dependent (33% of the sample; participants who were likely to discuss PrEP only if they felt their client was at a particularly high risk for HIV; they may also give out physical material, but not consistently); and 3) Limited (25% of the sample; participants who sometimes discuss PrEP with clients, but not systematically; least likely to give clients physical materials regarding PrEP).

Model 1. Three constructs within the CFIR domain Characteristics of Individuals were included in analysis: 1) knowledge and beliefs about the intervention; 2) self-efficacy; and 3) other personal attributes. Knowledge and beliefs about the intervention were measured using two composite variables. Knowledge was measured using an adapted version of the 5-item PrEP knowledge scale (α=.66) developed by Walsh and Petroll (2016), with the addition of an item measuring the frequency in which participants should get tested for side effects related to taking PrEP (Blumenthal et al., 2015). This scale was originally used to measure provider knowledge, and adapted for this study by replacing the word “patient” with the word “client”.

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Additionally, an item measuring knowledge of the antiretroviral medicine used for PrEP was simplified for a nonmedical audience. Beliefs about the intervention were measured using a 10-item scale on personal beliefs related to PrEP (α = .78), originally intended to measure attitudes towards PrEP (Walsh & Petroll, 2016). Self-efficacy was measured as a composite variable derived from a six-item scale (Walsh & Petroll, 2016) that measured how comfortable participants were with a variety of behaviors related to PrEP implementation within HIV testing sites (α = .88). Other personal attributes included key participant characteristics: gender, age, race, HIV status, and prior personal experience with PrEP.

Model 2. Within the CFIR domain Outer Setting, three constructs were included in the analysis: patient needs and resources, cosmopolitanism, and external policies and incentives. Patient needs and resources was measured as a composite score of four items adapted from the Organizational Readiness for Change Assessment (ORCA) (Helfrich et al., 2009). These items are suggested as proxy measures based on the CFIR technical assistance website (Damschroder, 2016). In this setting (i.e., HIV testing sites), patient needs and resources measured the degree to which clients would benefit from increased opportunities for HIV prevention, including PrEP. This construct also measured how the needs of clients are prioritized by the organization in which the participant (i.e., staff performing HIV testing) works. Cosmopolitanism was measured as a composite score of three items. CFIR guidance does not suggest proxy measures for this construct; as such, items were created based on the provided definition of cosmopolitanism, “The degree to which an organization is networked with other external organizations” (Damschroder, 2016). Cosmopolitanism was measured based on attendance at local, statewide, or national meetings that discuss HIV prevention and knowledge of local clinics or organizations to which they could refer clients if the client was interested in PrEP. External policy and incentives was measured as a composite score of three items. CFIR guidance suggests that external policy and incentives is similar to item 8a in the Organizational Change Manager (OCM) (Gustafson et al., 2003), which asks about external pressures to
implement an intervention (Gustafson et al., 2003). As such, three items were developed to assess the influence of external recommendations and guidelines, such as those from the CDC and WHO.

Within the CFIR domain Inner Setting, the constructs *structural characteristics, culture, tension for change, compatibility, relative priority, learning climate, and available resources* were included. *Structural characteristics* describe the structure of an organization. Three items were used in analysis: size of the organization, if the organization has offices in more than one county or state, and if the organization specializes in serving Lesbian, Gay, Bisexual, and/or Transgender (LGBT) populations. *Culture* was measured by a composite score determined by five items adapted from the ORCA (Helfrich et al., 2009), as suggested by CFIR technical assistance (Damschroder, 2016). *Culture* describes organizational norms and values. Tension for change is defined as “the degree to which stakeholders perceive the current situation as intolerable or needing change (Damschroder, 2016);” this was measured using two items adapted from the OCM (Gustafson et al., 2003) as suggested based on CFIR guidance (Damschroder, 2016). *Tension for change* was applied as the degree to which participants felt a change was needed in order to effectively reduce the spread of HIV. *Compatibility* measures how well the intervention (PrEP implementation) fits within an organization (Damschroder, 2016). Compatibility was measured by two items adapted from the ORCA (Helfrich et al., 2009) and OCM (Gustafson et al., 2003). *Relative priority* was measured by one item “Talking about PrEP during HIV testing is less important than talking about other HIV prevention methods.” This construct describes how important PrEP implementation is in relation to the other tasks in which the staff who provide HIV testing take part. *Available resources* was measured by one item describing the availability of physical materials related to PrEP that could be disseminated to clients. The CFIR construct *learning climate* evaluates if an organizational culture allows for mistakes during the learning process and empowers staff to believe they can make a difference
in implementing the intervention (here, that they can make a difference in PrEP implementation) (Damschroder, 2016). Two items, created based on the CFIR definition for learning climate, were used to measure the organizational learning climate. These items were based on the empowerment of staff in believing that they are an integral part of PrEP implementation. Constructs of the process domain – engaging, executing, planning, and reflecting and evaluating - were not included in this study, as staff performing HIV testing may not be best suited to provide feedback on these processes; other programming staff may be more intricately involved in these processes.

**Qualitative Measures**

Qualitative interviews were used to gather additional information about the most salient barriers to, and facilitators of, PrEP implementation within HIV testing sites. These interviews were used to provide a comprehensive and contextual look into the specific constructs most important to how the CFIR domains Characteristics of Individuals, Inner Setting, and Outer Setting domains affect PrEP implementation within HIV testing sites. Interviews were audio recorded and transcribed. [A comprehensive instrument can be found in Appendix F.]

**Sample Size**

A total of 150 participants from 48 unique organizations were used in analysis. For the qualitative sample, saturation was met after 22 interviews and determined when no new themes emerged from the data.

**Data Analysis**

Quantitative data were exported from Qualtrics (Qualtrics, 2017) into SPSS v.24 (SPSS, 2011). Data were cleaned and examined for suspicious or repeat responses (i.e. outliers and missingness were assessed; responses with matching IP addresses were reviewed). Descriptive statistics and bivariate analyses were conducted.

Multiple participants from the same organization completed the survey and, as such,
may be more similar to each other than they would otherwise be by chance alone. To account for clustering (i.e. the groups of participants working within the same organization), generalized linear mixed models (Heck et al., 2013) with multinomial distribution, logit link, and robust variance estimator were used to estimate PrEP implementation as a function of key CFIR variables from the domains Characteristics of Individuals, Inner Setting, and Outer Setting.

To address the first research question (What Characteristics of the Individual are associated with PrEP implementation during HIV testing, as guided by the domain of CFIR (i.e. Characteristics of individuals)?), PrEP implementation was estimated as a function of variables from the CFIR domain Characteristics of Individuals. Predictor variables included PrEP knowledge, PrEP beliefs, PrEP-related self-efficacy, gender, age, race, HIV status, and prior personal experience with PrEP. Key organization characteristics (i.e. if a participant identified as working for an organization that specializes in serving LGBT populations and organizational PrEP policies) were controlled.

To address the second research question (What inner and outer setting factors are associated with PrEP implementation during HIV testing, as guided by the domains of CFIR?) PrEP implementation was estimated as a function of CFIR variables from the domains Inner Setting and Outer Settings. Outer Setting predictors included: patient needs and resources, cosmpolitanism, and external policy and incentives. Inner Setting predictors included: structural characteristics (size of the organization, if the organization has offices in more than one county or state, and if the organization specializes in serving Lesbian, Gay, Bisexual, and/or Transgender populations), culture, tension for change, compatibility, relative priority, learning climate, and available resources.

Qualitative interview transcripts were verified by the primary author to ensure correct transcription. Qualitative data were imported into MaxQDA (Kuckartz, 2007) and analyzed thematically (Guest et al., 2011). An initial codebook was created using the CFIR technical assistance website (Damschroder, 2016) and emerging codes. Two researchers trained in
qualitative data analysis coded the same transcript independently before discussing revisions and edits for the codebook. An additional transcript was coded by both researchers to refine the codebook. Following agreement on the codebook, four transcripts were coded to calculate interrater reliability (IRR). At the first attempt the overall Kappa was K=0.75. The same two coders reviewed these transcripts, discussed interpretation and clarification of codes, and again attempted IRR with four new transcripts. IRR was reached, with an overall K=0.86. The primary author coded the remaining transcripts (n= 12).

**Data Integration and Interpretation**

Data integration was included in the study design, methods, and interpretation. During data collection and analysis, the quantitative data were used to recruit qualitative participants via connecting (Creswell, 2013; Creswell et al., 2011). Moreover, the qualitative and quantitative data were used iteratively to build upon each other for data interpretation via building (Fetters et al., 2013), and the quantitative and qualitative data sets were merged (Creswell et al., 2011; Fetters et al., 2013). A joint display of data was used with all analyses performed in MaxQDA – where the qualitative data was displayed and analyzed in relation to the participants’ quantitative responses (Fetters et al., 2013).

**Results**

**Participant and Organization Characteristics**

A total of 150 participants from 48 organizations (M=3.1 participants per organization [1-17]; SD= 3.5); took part in the survey. Participants ranged in age from 20 to 73 years, with an average age of 41.4 (+/-14.1) years. The majority of participants identified as male (53.7%), heterosexual (48.3%), and White (51.3%). All full list of participant characteristics can be found in Table 3.1.
Participants also described the agencies in which they worked.

About 29% (28.7%) of participants described their organization as small (under 20 staff members), 30% as moderately sized (21-50 staff members), and 41% as large (more than 50 staff members). Half of participants indicated that their organization has offices in multiple counties or states (50.3%). Many (73.3%) stated that their organization specialized in serving lesbian, gay, bisexual, and/or transgender (LGBT) clients.

Participants served clients from a range of geographic areas: 4.7% exclusively rural, 37.3% exclusively urban, and 58% a mix of both rural and urban.

### Table 3.1
**Participant Characteristics (N=150)**

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range)</td>
<td>41.4±14.1 (20-73)</td>
</tr>
<tr>
<td>Gendera</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>80 (53.7)</td>
</tr>
<tr>
<td>Female</td>
<td>65 (43.6)</td>
</tr>
<tr>
<td>Transgender female to male</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Another gender</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Sexual Orientationb</td>
<td></td>
</tr>
<tr>
<td>Heterosexual (Straight)</td>
<td>72 (48.3)</td>
</tr>
<tr>
<td>Homosexual (Gay/Lesbian)</td>
<td>61 (40.9)</td>
</tr>
<tr>
<td>Bisexual</td>
<td>7 (4.7)</td>
</tr>
<tr>
<td>Another Sexual Orientation</td>
<td>5 (3.4)</td>
</tr>
<tr>
<td>Racec</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>77 (51.3)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>35 (23.3)</td>
</tr>
<tr>
<td>Asian</td>
<td>6 (4.0)</td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Native Hawaiian/Pacific Islander</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>50 (33.3)</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>118 (78.7)</td>
</tr>
<tr>
<td>Part time</td>
<td>13 (8.7)</td>
</tr>
<tr>
<td>Volunteer</td>
<td>19 (12.7)</td>
</tr>
<tr>
<td>Prescriber (employed in position that involves prescribing medicine)d</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Ever taken PrEPe</td>
<td>20 (13.4)</td>
</tr>
<tr>
<td>Currently on PrEPf</td>
<td>14 (9.6)</td>
</tr>
<tr>
<td>HIV statuse</td>
<td></td>
</tr>
<tr>
<td>Living with HIV (HIV positive)</td>
<td>29 (19.5)</td>
</tr>
<tr>
<td>Not living with HIV (HIV negative)</td>
<td>120 (80.3)</td>
</tr>
</tbody>
</table>

---

a No participant identified as transgender male to female. One participant selected “prefer not to answer”. One participant skipped the question. N=149
b Two participants indicated “not sure” and two indicated “prefer not to answer”. One participant skipped the question. N=149
c Participants could select all races/ethnicities that applied. Some participants did not select a race, and only selected Hispanic ethnicity
d One participant skipped the question N=149
e One participant selected “prefer not to answer” N=149
f One participant selected “prefer not to answer”. Three participants skipped the question N=146
Table 3.2. Bivariate analyses of factors within the CFIR domain Characteristics of Individuals and PrEP Implementation

<table>
<thead>
<tr>
<th></th>
<th>Eligibility Dependent (Ref: Limited)</th>
<th>Universal (Ref: Limited)</th>
<th>Eligibility Dependent (Ref: Universal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>wald</td>
<td>Sig</td>
<td>Exp(B) [CI]</td>
</tr>
<tr>
<td>Knowledge</td>
<td>.754</td>
<td>.385</td>
<td>1.123 (.864-1.460)</td>
</tr>
<tr>
<td>Age</td>
<td>5.029</td>
<td>.025*</td>
<td>.965 (.936-996)</td>
</tr>
<tr>
<td>Attitudes</td>
<td>.502</td>
<td>.479</td>
<td>1.305 (.625-2.724)</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>1.487</td>
<td>.223</td>
<td>1.439 (.802-2.582)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Racial minority</td>
<td>6.088</td>
<td>.014*</td>
<td>3.077 (1.260-7.513)</td>
</tr>
<tr>
<td>White</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual minority</td>
<td>8.612</td>
<td>.003*</td>
<td>3.939 (1.577-9.842)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever Taken PrEP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with HIV</td>
<td>1.237</td>
<td>.266</td>
<td>.518 (.162-1.651)</td>
</tr>
<tr>
<td>Not living with HIV</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significance p<.05
Table 3.3. Mixed model of factors within the CFIR domain Characteristics of Individuals associated with PrEP Implementation

<table>
<thead>
<tr>
<th>Characteristics of Individuals</th>
<th>Eligibility Dependent (Ref: Universal)</th>
<th>Limited (Ref: Universal)</th>
<th>Limited (Ref: Eligibility Dependent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>Std. error</td>
<td>t</td>
</tr>
<tr>
<td>Intercept</td>
<td>3.89</td>
<td>2.11</td>
<td>1.83</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>-.39</td>
<td>.47</td>
<td>-.83</td>
</tr>
<tr>
<td>Attitudes</td>
<td>-.48</td>
<td>.42</td>
<td>-1.14</td>
</tr>
<tr>
<td>Knowledge</td>
<td>-.17</td>
<td>.16</td>
<td>-1.07</td>
</tr>
<tr>
<td>Age</td>
<td>-.002</td>
<td>.01</td>
<td>-.17</td>
</tr>
<tr>
<td>Gender (Men; Ref=Women)</td>
<td>.05</td>
<td>.54</td>
<td>.09</td>
</tr>
<tr>
<td>Ever Taken PrEP (Yes; Ref=No)</td>
<td>.34</td>
<td>.52</td>
<td>.66</td>
</tr>
<tr>
<td>HIV Status (PLH; Ref=not PLH)</td>
<td>-1.01</td>
<td>.75</td>
<td>-1.35</td>
</tr>
<tr>
<td>Race (Racial minority; Ref=White)</td>
<td>.38</td>
<td>.48</td>
<td>.78</td>
</tr>
<tr>
<td>Sexual Orientation (Sexual minority; Ref=heterosexual)</td>
<td>1.04</td>
<td>.66</td>
<td>1.57</td>
</tr>
</tbody>
</table>

Probability distribution: Multinomial; Link Function: Generalized Logit
Model controlled for organizational policy for PrEP referral & identification as an organization specializing in serving LGBT populations.
CFIR – Consolidated Framework for Implementation Research
Characteristics of HIV Testing Staff Affecting PrEP Implementation

In bivariate analyses (Table 3.2), significant differences existed between the Eligibility Dependent participants and the Limited participants in age, race, sexual orientation, and ever taken PrEP status. Significant differences were found between Universal and Limited participants in knowledge, attitudes, self-efficacy, and sexual orientation. No statistically significant differences were found between the Eligibility Dependent participants and the Universal participants in bivariate analyses.

The intraclass correlation coefficients produced by the unconditional model reflected limited intraclass correlation (Heck et al., 2013), with neither ICC being statistically significant. This means that most of the variation between participants is due to individual characteristics, rather than due to their organizational affiliation. When comparing the Universal group (Ref) and the Limited group, organizational affiliation was responsible for approximately 25% of the variation in responses – with individual characteristics being responsible for the remaining 75%. This value was found to be lower between the Universal group (Ref) and the Eligibility Dependent group – with only approximately 3% of the variation being attributed to organizational affiliation.

In multivariate analyses, only race and sexual orientation remained significant predictors of PrEP implementation group (Table 3.3). Participants who identified as a racial minority were less likely to be in the Limited group (compared to both the Universal or Eligibility Dependent groups) compared to their White counterparts; however, race did not differentiate the odds of group affiliation when comparing the Eligibility Dependent vs. Universal groups. Sexual orientation only played a role in differentiating between the Limited group and the Eligibility Dependent groups – participants who identified as a sexual minority were less likely to be in the Limited group compared to the Eligibility Dependent group; however, sexual orientation did not appear to differentiate between the Limited vs. Universal groups, nor the Eligibility Dependent
vs. *Universal* groups. Self-efficacy, attitudes, knowledge, age, gender, ever having taken PrEP, and HIV status did not impact the odds of being in a specific PrEP implementation group.

The Characteristics of Individuals construct most salient in the data was participant knowledge and beliefs about PrEP and implementing PrEP within HIV testing sites (i.e. the knowledge and beliefs HIV testing staff have regarding PrEP). Regardless of PrEP implementation groups, participants mentioned their personal knowledge and beliefs regarding the side effects of PrEP. Participant concerns related to side effects were mentioned regardless of race and sexual orientation. However, when examining the statements made by people identifying as a sexual minority compared to heterosexual, people identifying as a sexual minority often provided greater detail of PrEP-related side effects, such as one participant who stated:

> But it [PrEP] also has side effects. It's a strong medication, antiretroviral for HIV. These people, they don't have HIV. They're negative. They're taking it as a prevention. They have side effects in the liver, in the kidneys. Also, they said on the pamphlet that in younger people, [PrEP can] diminish the density of the bones (Participant 103).

This detailed explanation can be contrasted to a participant identifying as heterosexual who simply stated “I think it’s great. I know the side effects are bad (Participant 101).”

While quantitively PrEP knowledge was high across participants in all groups of PrEP implementation, there were a few statements in the qualitative findings that reflected some staff performing HIV testing had inadequate, or incorrect, knowledge of PrEP, such as:

> Yeah, and oftentimes, it [PrEP] being a shot, and it staying in your system, we've received concern from clients that ... because they'll be stuck with those side effects for whatever, a month. So that just concerns them, as opposed to where they could just stop taking it. (Participant 102)

Participants identifying as a sexual minority also brought up additional prevention concepts, including undetectable=untransmittable (U=U). U=U is a campaign that promotes the science
behind the statement that once a person living with HIV has an undetectable viral load, he or she can no longer sexually transmit the virus (Rodger et al., 2018; Rodger et al., 2016). For example, one participant stated:

I would say the main one, people, sometimes they just have issues believing the science behind it [U=U], because at the beginning, it was so easy to say ‘Yeah, undetectable equals untransmittible,’ but at the time, people didn’t feel like there was enough research done in that. We’re still getting research everyday saying that yes, this is the thing, if you’re undetectable for six months, and if you were to bareback, you’d have no risk of … spreading the disease (Participant 112).

Only one participant identifying as heterosexual mentioned U=U. Cost (e.g. “Obviously it's [PrEP] 700, 800, even $1000 a month, just for the medication… Then of course any doctors bills, any lab work et cetera that would be included with that (Participant 119)”) and concerns about clients not using condoms (e.g. “I see too many young men running around, saying, ‘Oh, I'm taking PrEP now, I don't have to wear a condom’…what about HPV, syphilis, gonorrhea? (Participant 111)”) were also commonly mentioned among participants. Less prevalent themes included concerns regarding the limited research available regarding PrEP and concerns regarding client adherence. These themes appeared in participants (i.e. staff performing HIV testing) across race, gender, sexual orientation and other demographic characteristics.

Organizational and Extra-Organizational Characteristics Affecting PrEP Implementation [Inner Setting and Outer Setting]

Bivariate analyses (Table 3.4) revealed that, compared to participants in the Limited group, participants in the Universal group were more likely to report the presence of PrEP-related physical resources available at their organization (such as brochures related to PrEP), greater tension for change, greater compatibility, a supportive learning environment, and a culture more supportive of PrEP. Universal participants were also more likely to have knowledge of external policies regarding PrEP than their counterparts in the Limited group. Universal
participants were also more likely than Limited participants to specialize in serving LGBT populations. Compared to Limited participants, Eligibility Dependent participants were more likely to indicate tension for change, compatibility, learning climate, and a more PrEP positive culture. Compared to participants in the Eligibility Dependent group, participants in the Universal group were more likely to have physical resources available at their organization to assist in PrEP implementation.

In multivariate analyses (Table 3.5), fewer Inner Setting and Outer Setting constructs predicted group membership. Compared to the Limited group, participants in the Universal group were more likely to have high scores in relative priority (aOR 1.65 [1.09-2.50]), indicating that participants had the perception that PrEP implementation was a high priority within their organization, even when compared to the many tasks that organizations providing HIV testing perform. No constructs were statistically significant when comparing participants in the Eligibility Dependent group to participants in the Limited group. Compared to participants in the Eligibility Dependent group, participants in the Universal group were more likely to indicate the availability of physical resources to assist in PrEP implementation (aOR 1.973 [1.197-3.253]).
Table 3.4. Bivariate Analyses of inner and outer setting characteristics and PrEP implementation

<table>
<thead>
<tr>
<th></th>
<th>Universal (Ref: Limited)</th>
<th>Eligibility Dependent (Ref: Limited)</th>
<th>Universal (Ref: Eligibility Dependent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>t</td>
<td>Sig</td>
<td>Exp(B) [CI]</td>
</tr>
<tr>
<td>Cosmopolitanism</td>
<td>1.424</td>
<td>.157</td>
<td>1.141 (.875-2.274)</td>
</tr>
<tr>
<td>Resources</td>
<td>2.530</td>
<td>.012</td>
<td>2.127 (1.179-3.834)</td>
</tr>
<tr>
<td>Tension for Change</td>
<td>2.444</td>
<td>.016</td>
<td>1.987 (1.140-3.465)</td>
</tr>
<tr>
<td>Compatibility</td>
<td>3.380</td>
<td>.001</td>
<td>4.840 (1.925-12.171)</td>
</tr>
<tr>
<td>External Policies</td>
<td>2.010</td>
<td>.046</td>
<td>1.762 (1.009-3.076)</td>
</tr>
<tr>
<td>Relative Priority</td>
<td>2.907</td>
<td>.004</td>
<td>1.726 (1.191-2.503)</td>
</tr>
<tr>
<td>Culture</td>
<td>1.942</td>
<td>.054</td>
<td>1.957 (.988-3.874)</td>
</tr>
<tr>
<td>Offices in multiple counties or states (Yes; Ref=No) Organization Size (Ref: Large)</td>
<td>.239</td>
<td>.812</td>
<td>1.148 (0.366-3.601)</td>
</tr>
<tr>
<td>Small</td>
<td>.372</td>
<td>.710</td>
<td>1.262 (.367-4.342)</td>
</tr>
<tr>
<td>Specializes in serving LGBT populations</td>
<td>2.016</td>
<td>.046</td>
<td>2.889 (1.021-8.180)</td>
</tr>
</tbody>
</table>

Bivariate analyses conducted with mixed model and intercept (total of 2 random components)
### Table 3.5. Mixed model of factors within the CFIR domains Inner Setting and Outer Setting associated with PrEP Implementation

<table>
<thead>
<tr>
<th>Domain</th>
<th>Universal (Ref: Limited)</th>
<th>Eligibility Dependent (Ref: Limited)</th>
<th>Universal (Ref: Eligibility Dependent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>Std. error</td>
<td>t</td>
</tr>
<tr>
<td>Intercept</td>
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<td>1.706</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>12.30</td>
<td>3.88</td>
<td>8.15</td>
</tr>
<tr>
<td>Patient Needs</td>
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<td>.506</td>
<td>.498</td>
</tr>
<tr>
<td></td>
<td>-.458</td>
<td>.306</td>
<td>1.49</td>
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<tr>
<td></td>
<td>.268</td>
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<td>.950</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>.498</td>
<td>.2102</td>
<td>2.37</td>
</tr>
</tbody>
</table>

63
Table 3.5. Mixed model of factors within the CFIR domains Inner Setting and Outer Setting associated with PrEP Implementation

<table>
<thead>
<tr>
<th>Culture</th>
<th>Universal (Ref: Limited)</th>
<th>Eligibility Dependent (Ref: Limited)</th>
<th>Universal (Ref: Eligibility Dependent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>Std. error</td>
<td>t</td>
</tr>
<tr>
<td></td>
<td>.632</td>
<td>.4297</td>
<td>1.47</td>
</tr>
<tr>
<td>Offices in multiple counties or states (Yes; Ref=No) Q20</td>
<td>.135</td>
<td>.7646</td>
<td>.176</td>
</tr>
<tr>
<td>Organization Size (Ref: Large, 3) Q21</td>
<td>.445</td>
<td>.6736</td>
<td>.661</td>
</tr>
<tr>
<td>Small 1</td>
<td>1.332</td>
<td>.7801</td>
<td>1.70</td>
</tr>
<tr>
<td>Medium 2</td>
<td>.844</td>
<td>.6706</td>
<td>1.25</td>
</tr>
</tbody>
</table>

Probability distribution: Multinomial; Link Function: Generalized Logit
CFIR – Consolidated Framework for Implementation Research
During the qualitative interviews, participants described the process by which PrEP implementation took place within HIV testing sites. Such PrEP implementation could range from handing clients materials and allowing them to make contact with someone if interested in PrEP, physically connected clients with another organization providing PrEP (often referred to by participants as a “warm handoff”), or referring a client to an internal medical provider. A description of these referral processes and be found in Table 3.6. These referral processes also changed over time, as described by one participant:

It's sort of all falling into place and people are readily able to talk to clients and feel safe about talking to clients about PrEP, because we know that at least the ball is rolling… Our job essentially now is we can educate about PrEP, whereas before I felt like educating people about PrEP was like talking about the tooth fairy (Participant 119).

<table>
<thead>
<tr>
<th>Table 3.6. Types of PrEP Implementation within HIV Testing sites</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sharing materials</strong></td>
</tr>
<tr>
<td>“Yeah, so I’ll list a couple, I’ll write down the other doctors that aren't listed on there as well, and I'll discuss it with them if they're insured, call the office, and make sure that they take their insurance, a lot of people will touch base on location as well, how close it is to their home, so I'll tell them check with the office on whether or not you're covered, and then if they don't have insurance, there's a couple of the clinics that we know on there that will take uninsured patients, and so we'll circle those from so they can reach out to them, and now refer them for the health department as well.” – Participant 121</td>
</tr>
<tr>
<td><strong>Directly connecting clients with a provider “Warm handoff”</strong></td>
</tr>
<tr>
<td>“As far as the way that … and it may be different for different organizations, but my personal understanding of linkage is less like write a referral, give them the number. It's an offer. ‘Yeah, hey listen, like while you're in the room, I can call over and we can see if together we can set up your first-time appointment.’ If they don't have transportation services, then I can provide them a bus pass to get over there and a bus pass to get home as well, so that it's, yeah, less just give them the number, but instead like facilitate that first meeting. I have never attended a first meeting, but that is something that we can do as advocates, as testers, or at least [Organization Name] allows us to link a client by taking them over there if they're nervous.” – Participant 119</td>
</tr>
<tr>
<td><strong>Internal referral</strong></td>
</tr>
<tr>
<td>“Most of them come to us [community organization that provides PrEP internally] anyway at the end of the day. It's easier for us to do that directly; it skips a step, and we make sure people get into care as soon as possible.” – Participant 110</td>
</tr>
</tbody>
</table>
Although it was not explicitly included in the interview guide, leadership emerged as an important factor in the initiation of some PrEP programs (i.e. leadership engagement under the CFIR domain Inner Setting). If a participant described a strong organizational commitment to PrEP implementation, he or she was asked to reflect on why their organization was able to implement PrEP successfully. This is reflected in the quotes below.

It was the leadership. When I was at [Former Organization Name], I know we were talking about doing a PrEP program, but there was only 1 or 2 people who really knew a lot about PrEP. You're going back like 5 or 6 years. We had a nurse on staff, I cannot remember her name and I worked with her for a long time, but she was the one who was getting the idea up off the ground, but then there were other barriers about getting what doctor, what provider, and then some of the doctors that we worked with did not want to take on that. Here at [Current Organization Name] they made a requirement, like, ‘Look, if you’re going to be a part of this organization, if you’re going to be a doctor who supports our programs, this is part of your job.’ So there was more buy in from those particular people. The leadership really stepped up, so I think that really made a difference (Participant 106).

Others discussed leadership being involved in administrative decisions, such as creating memorandums of understanding (MOUs). MOUs provided a clear path for participants to form relationships with other organizations to which they could refer clients.

So the MOUs [memorandum(s) of understanding] in the clinical department are spearheaded by the Clinical Director, so either me or the person that was here before me. Some of these MOUs have been intact for, I mean we renew them every year, but some of them they've been there for five years, six years. So it just depends. But the Clinical Director is the one that creates the MOUs [for PrEP referral] with these partnering agencies (Participant 116).
Some participants described PrEP as a natural extension of services from HIV care to HIV prevention. The *availability of resources* was seen as a facilitator to PrEP Implementation in both multivariate analysis (above) and in qualitative analyses. Available resources consisted of time, written referral policies, physical handouts and brochures related to PrEP, and other physical materials used in HIV prevention (e.g. condoms). The availability of physical materials, especially those containing information about PrEP that could be provided to the client, assisted participants in discussing PrEP. For example, one participant who described how available resources assisted them in linking clients to PrEP:

> Our testing kits, we have PrEP brochures and referral cards and all that, so they [HIV testing staff] would have all that information. A lot of times we do testing at off site locations. We actually have a box that has all sort of brochures and referral information…More and more PrEP is part of that linkage to care for HIV negative individuals. (Participant 104).

The importance of these materials was salient, as another participant stated: “Yeah, we have all the material there. Like a little business card specifically for the PrEP clinic with the number that is directly to someone who works there. Instead of having to call the menu. (Participant 105).”

Lastly, participants focused much of their discussion on utilization of the state-required form that must be completed with each HIV test performed, the DH1628, referred to by participants as “the 1628”. This form was a resource that created a natural transition to talking about PrEP. For example:

> In the 1628, which is the state form that you fill out when you’re doing an HIV test, there is a section on PrEP and nPEP, so we talk, I make sure that I talk to clients both about PrEP, and PEP - post exposure prophylaxes, and how to get it, if they ever need it. Most people have heard about PrEP, they haven’t heard about PEP (Participant 104).
Another participant noted a similar response:

The form that we use [DH1628] asks them if they’ve ever taken PrEP or PEP, so that really is ... people most of the time are like, what’s that? So it’s really a way for us to talk to them about it... A lot of people ask us, what is that? I don't know. So it starts a whole conversation for us to be able to continue and talk to them about it and give them the information about it and some of them ask more details and stuff (Participant 107).

In qualitative analyses, participants discussed how the Outer Setting influenced their PrEP implementation behaviors. The Outer Setting includes factors external to the organization that directly affect implementation within the agency. The most salient themes within the Outer Setting were related to the needs and resources of the clients who HIV testing staff served (i.e. needs and resources of the clients served by the organization; a construct within the CFIR domain Outer Setting). Among the client barriers to PrEP were: client concerns regarding the potential side effects of PrEP; lack of available and knowledgeable providers to prescribe PrEP; inadequate or varied levels of client knowledge regarding PrEP; client concerns regarding the costs associated with PrEP and PrEP use; and community-level HIV and PrEP related stigma experienced by clients. Although the perspective of the clients was not directly captured in this study, the perceived needs and resources of these clients do impact the behaviors of the staff who perform HIV testing. Participants across all implementation groups referenced the needs and resources of the clients they served; however, participants in the Universal group discussed these barriers to the greatest extent.

Participants reported that although client knowledge of PrEP varied (some participants were aware and knowledgeable of PrEP, others were not), generally clients identifying as LGBT knew more about PrEP than their heterosexual counterparts. Participants in all implementation groups indicated that their clients expressed concerns regarding the possible side effects of taking PrEP. Client concerns about the cost of PrEP were cross-cutting and independent of
implementation group; however, participants in the *Universal* and *PrEP Eligibility* groups were more likely to reference the existence of the copay assistance program run by Gilead, the producers of Truvada (the brand name of the medication used as daily PrEP).

Medical staff in the surrounding community acted as both a barrier and facilitator to PrEP implementation within community-based organizations. Some clients told participants (i.e. staff performing HIV testing) that they were unable to access PrEP via their general healthcare providers or that their providers were unaware of, or uncomfortable prescribing, PrEP. However, some participants identified key medical staff within their community to whom they could refer their clients for PrEP referrals. Participants also reflected on the HIV and PrEP-related stigma external to the agency in which they worked, but prevalent to the broader community they served. HIV and PrEP-related stigma was also reported across implementation groups. Other community factors, such as cosmopolitanism, also impacted PrEP implementation within HIV testing sites.

Cosmopolitanism (i.e. how well an organization is networked with other organizations) (Damschroder, 2016) was expressed in several ways. Some participants noted the formal role of partnerships, such as one participant who described how memorandums of understanding (MOUs) were present within her organization and aided in PrEP implementation.

We go to these huge meetings where we all talk about barriers to health and what lacks in the community and stuff like that, and if a doctor's like ‘Hey, these are the services I have, you can always send your clients over. We’re doing this for free. Or we do this and we’re low income cost.’ That's how the MOU [memorandum of understanding] is kind of drawn to place. So, it's honestly knowing people (Participant 116).

Quantitatively, cosmopolitanism was not statistically associated with PrEP implementation. Similar findings were found in qualitative interviews – where participants discussed such networking regardless of implementation group. Some participants described that relationships
were established at planning meetings occurring in various places within the state of Florida and often occurred because both organizations had a relationship with the state-run health department. One participant, when asked to describe if he felt other organizations in his community were familiar with PrEP, highlighted the role the health department has in networking between community-based organizations:

At least from my CBO [community-based organization], which I can speak to with some level of confidence, and then also from going to consortium meetings when other CBOs are in the room, if they’re absorbing what the health department is sending out, the information that the health department is sending out, at the same rate that my CBO is, then all the CBOs should have at least minimum knowledge to link clients to PrEP services (Participant 119).

While cosmopolitanism is important for organizations implementing any program that may require outside referrals, it may be most important for organizations without onsite medical providers. One participant who was located at a community-based organization that did not have medical providers on staff stated:

Yeah, so we don’t have a health provider on site, but we do have a list of providers that we know for sure that provide PrEP in the area. Now the health departments are also rolling it out, so they’re also going to be doing it, and there’s a couple organizations that are the HIV resource centers that are now implementing their own RN's that can prescribe PrEP. So we go through the list, and tell them a couple more, and I’m currently working on a project to determine what other primary care providers provide PrEP because most of the people on the list are either ID [infectious disease] or HIV doctors, or something of that nature. There’s not very many primary care doctors on the list (Participant 121).
Participants also used external networking (i.e. cosmopolitanism) to understand how other organizations worked – specifically, which organizations may be good to form partnerships with and which organizations would not be appropriate for partnerships. Such partnerships were seen as particularly important because participants were hesitant to refer their clients to an unknown entity. One participant, stated the following:

I mean we work with a good amount of agencies and the agencies that we do work with, we kind of know their work ethic 'cause we all literally go to the same meetings, our missions are the same. 'Cause I don't want to send someone to an unknown area and then them just get shut down because I don't know how everyone else is, like if I send them to someplace that I've never heard of or never met, 'cause usually we have a contact at every agency that we call for these reasons. They usually pick up and know too, kind of like a mini counseling session with the client over the phone and kind of be like, 'Hey, okay you can come in at this time.' And they set up the initial appointment (Participant 116).

Here, the participant discussed the importance of not only cosmopolitanism, but developing trust within networking relationships. By trusting the services that another organization provided, the participant was able to refer client without fear of the client having a negative experience.

Discussion

Guided by the CFIR (Damschroder et al., 2009), this study investigated the role of Characteristics of Individuals (i.e. characteristics of the staff performing HIV testing), Inner Setting (i.e. organizational characteristics) and Outer Setting (i.e. characteristics of the community that the organization serves) in PrEP implementation via a mixed methods concurrent triangulation design (Creswell, 2013). Quantitative data were modeled using a generalized linear mixed models to estimate PrEP implementation as a function of key CFIR variables. Qualitative data was collected via in-depth semi-structured interviews.
In the first research question we sought to understand how characteristics of the HIV testing staff affected their PrEP implementation behaviors. Bivariate analyses revealed significant associations between PrEP implementation group and select demographic variables, knowledge, attitudes, and self-efficacy; however, after performing a multinomial generalized linear mixed model, only sexual orientation and race remained statistically significant. These findings are contrary to the expectation that all variables under the CIFR domain Characteristics of Individuals (e.g. knowledge, self-efficacy, beliefs) would be associated with PrEP implementation. Such findings can help in preparing training materials or programs for HIV testing staff.

In the second research question we sought to understand how organizational (i.e. CFIR domain Inner Setting) and extra-organizational (i.e. CFIR domain Outer Setting) characteristics impacted the PrEP implementation behaviors of HIV testing staff. In a multilevel multinomial model, only relative priority and availability of physical resources remained significantly associated with PrEP implementation. Triangulation with the qualitative findings highlighted the importance of physical resources and provided insight into the role of cosmopolitanism and patient needs and resources in PrEP implementation. These findings are important because in order to effectively implement PrEP, knowledge is needed on how best to equip community-based HIV testing sites, and the role that the surrounding community has in such implementation (Smith et al., 2016). Such knowledge could help community-based organizations when planning what is needed to start a PrEP program and how their community may receive such programs.

In this study, knowledge, self-efficacy, attitudes, and demographic characteristics were captured under the domain Characteristics of Individuals. Race and sexual orientation were important variables in predicting association with specific PrEP implementation classes in quantitative analyses; however, in qualitative analyses, the race and sexual orientation of the
person providing the testing were not directly discussed as an important factor in PrEP implementation. It may be possible that those who identify as members of a racial minority and/or sexual minority group are more prone to talking about PrEP than their peers because HIV disproportionately affects these populations (CDC, 2015; FDOH, 2016a). These factors are demographic characteristics that cannot be changed. As such, they may be important to note, but may need to be considered in the larger context of Characteristics of Individuals.

Based on quantitative findings participants had relatively high rates of PrEP knowledge. PrEP knowledge among HIV testing staff has been understudied; however, research of PrEP knowledge among providers has indicated high rates of PrEP knowledge among HIV care providers compared to their counterparts specializing in general medicine (Krakower & Mayer, 2016; Krakower et al., 2015; Mimiaga, White, Krakower, Biello, & Mayer, 2014). These findings may provide some insight into why PrEP knowledge is high among staff specifically working in HIV testing (i.e. the HIV field, much like HIV care providers). Perhaps knowledge may not play a significant role in PrEP implementation during the HIV testing process because those working in HIV testing are naturally more familiar with knowledge related to HIV prevention, regardless of their views on PrEP. Previous research has indicated mixed findings regarding the association between PrEP knowledge and PrEP prescribing practices; some researchers have found that PrEP knowledge is associated with a greater likelihood of prescribing PrEP (Blumenthal et al., 2015), and others have noted that PrEP knowledge alone was unlikely to result in an increase in prescribing practices (Krakower & Mayer, 2016). This same line of reasoning may be true among staff providing HIV testing, as knowledge may not be enough to increase rates of actual referrals. Moreover, qualitative knowledge findings may reflect the need for future research into a more nuanced scale to measure PrEP-related knowledge among non-clinical staff.

PrEP beliefs have also been found to play a role in PrEP prescription among providers and were hypothesized to play a role in PrEP implementation occurring during the HIV testing
process. Among HIV care providers the most important factor triggering screening for PrEP was the patient being in a serodiscordant relationship (Tellalian, Maznavi, Bredeek, & Hardy, 2013), especially those who were MSM in serodiscordant partnerships (Adams & Balderson, 2016; Smith et al., 2015); these eligibility driven specifications were also mentioned among participants of this study, particularly in the Eligibility Dependent group, who targeted their PrEP discussions based upon presumed client eligibility. The concerns related to PrEP mentioned by our participants were also similar to the concerns mentioned among providers, including increased sexual risk behavior or a lack of adherence among patients (Blumenthal et al., 2015; Calabrese et al., 2016; Krakower & Mayer, 2012; Tellalian et al., 2013; White et al., 2012).

The CFIR construct patients’ needs and resources (within the domain, Outer Setting), although not a statistically significant predictor of group membership (i.e. patient needs and resources does not predict if a participant is in the Universal, Eligibility Dependent, or Limited class), was prominent throughout the qualitative interviews. Most staff providing HIV testing are aware of the general facilitators and barriers their clients’ experience, likely resulting in this construct not differentiating participants into a particular implementation group. Many of the client barriers to, and facilitators of, PrEP initiation (i.e. starting a PrEP regiment) mentioned by participants have also been stated as barriers and facilitators in recent provider and client focused research (Koechlin et al., 2017; Pinto et al., 2018; Refugio et al., 2018). Among these barriers are cost (Koechlin et al., 2017; Refugio et al., 2018), stigma (Pinto et al., 2018; Refugio et al., 2018), and side effects (Koechlin et al., 2017). Moreover, the complex role that providers have in community-wide uptake of PrEP has been discussed elsewhere; however, with a focus on provider knowledge, attitudes and willingness to prescribe PrEP (Turner, Roepke, Wardell, & Teitelman, 2018). More research is needed on how patient perceptions of providers’ willingness to prescribe PrEP may impact PrEP implementation and initiation.
Notably, all groups mentioned client concerns regarding the cost of PrEP; however, only participants in the *Universal* and *Eligibility Dependent* groups referenced the co-pay assistance program provided by Gilead, the manufacturer of Truvada. This may reflect a lack of awareness of the co-pay assistance program in the *Limited* group. If participants in the *Limited* group are unaware of co-pay assistance resources, they may be less likely to discuss PrEP with low income clients whom they know could not afford PrEP without financial assistance.

Participants discussed the role of medical providers in PrEP implementation, as medical providers are needed in order for a client to be medically screened for, and to initiate, PrEP. There appeared to be a dichotomy in how participants viewed medical providers. Some participants discussed the barrier of low knowledge of PrEP among general medical providers, a theme prominent in the literature (Krakower & Mayer, 2016; Smith, Mendoza, Stryker, & Rose, 2016). When provider PrEP knowledge was low in a community, clients often became discouraged to seek out PrEP. However, in some instances medical providers advocated for PrEP and provided a trusted source to whom clients could turn. Participants also reiterated a common theme in the literature – that at least some clients may be hesitant to talk to their primary care doctor about PrEP; this hesitation was heightened if the client was a man who has sex with men and not out to their provider about their sexual activity (Arrington-Sanders et al., 2016; Mehta et al., 2011). These findings are important because they reinforce the need of PrEP programs outside of traditional medical settings. They may also suggest a need for provider education – a reoccurring suggestion in the literature (Turner et al., 2018).

Community level stigma also impacted the approach that staff performing HIV testing took when discussing PrEP. Some participants discussed that sex and/or HIV was seen as taboo in their community, so they had to tread lightly when bringing up HIV prevention methods – including PrEP (Nunn et al., 2018; Pinto et al., 2018; Sang, Matthews, Meanley, Eaton, & Stall, 2018). While consideration of such stigma is certainly important, the level of stigma may
vary depending upon the community in which the agency exists. As in many community-based programs, it may be particularly important for staff performing HIV testing to be aware of the culture, norms, and stigma of the community they serve (Nunn et al., 2018; Pinto et al., 2018).

*Cosmopolitanism*, a construct under the CFIR domain Outer Setting which describes the degree to which organizations are networked with each other, was also prominently discussed in the qualitative findings, although not significant in the quantitative findings. Cosmopolitanism may be important across implementation groups and thus may not be a predictor of group membership. When studying PrEP implementation, cosmopolitanism may be particularly important because at least some level of cosmopolitanism is needed in order for staff who perform HIV testing to refer clients to external PrEP resources. Without a sense of which external organizations are providing PrEP, or financial assistance programs, participants may not know to whom to refer clients. Several participants also noted the importance of trusting external organizations prior to any referrals being made. Trust is meaningful in all community partnerships, but may be particularly important in this setting, as participants want the best for their clients' health. It may be important to draw a distinction regarding the strength of these external ties – such as if formal partnerships (e.g. memorandums of understanding, etc.) are in place, or if the participant is only merely aware of the resources provided by other organizations outside of the one in which they work. This distinction in future quantitative and qualitative research may be helpful to understand the types of networks necessary to realize the full potential of PrEP implementation.

*Available resources*, a CFIR construct found under the domain Inner Setting, was significant in quantitative findings and salient in qualitative interviews. Quantitatively, a greater availability of PrEP resources was found among participants in the *Universal* group compared to participants in the *Limited* group. Physical materials describing PrEP may be an important factor for PrEP implementation, after all, if resources are not available they cannot be shared with
clients. In qualitative findings, the importance of a form required by the health department – the DH1628, was particularly salient. Participants commonly spoke about the ease of talking about PrEP because of the format of the DH1628. Participants stated that they were required to fill out the DH1628 for each client they test, and this form has a required question asking clients if they have ever taken antiretroviral medication, providing an easy transition to discuss PrEP. In 2016, prior to the time of this study, specific questions regarding the use of antiretroviral medications for PrEP and/or PEP were added to the DH1628 (FDOH, 2018a), a decision that seems to facilitate an easy transition to talking about PrEP.

These findings also provide insight into how a PrEP referral typically looks within HIV testing. While the availability of materials is certainly important in PrEP implementation (as discussed above), participants also differentiated between simply handing a client materials about organizations providing PrEP vs. helping a client to make the initial appointment. HIV testing guidelines in Florida require that community-based staff providing HIV testing should be able to assist clients with linkage to other related services such as PrEP – going beyond a referral or distribution of materials (FDOH, 2018a). Based on these findings, this requirement may not be met at all community-based HIV testing sites. Follow through of referrals was not studied here, but these varying methods of PrEP referral may play an important role in PrEP initiation and continued use. Additionally, several participants referenced that the ideal PrEP program would be a one-stop-shop, or one in which participants can receive both social and medical services within the same organization. This preference for a one-stop-shop has also been noted elsewhere (Ongwandee et al., 2018). Participants felt that existence of a “one-stop-shop” would facilitate internal referrals – or referrals to medical staff who work within the same organization.

As with any study, limitations exist. CFIR technical assistance suggests that not all constructs and domains of the CFIR need to be included in every study (Damschroder et al.,
2009), nonetheless, constructs or domains that were not the focus of the study may also be important to PrEP implementation within HIV testing sites. Measurement of CFIR constructs was determined based on CFIR guidance (Damschroder, 2016); however, many of these scales have not been previously validated for this use. Despite the scales not being previously validated, all scales had adequate internal consistency. Additionally, some scales were adapted for the population being studied (i.e. staff performing HIV testing). For example, an adapted version of a scale originally intended to measure behavioral skills (Walsh & Petroll, 2016) was used to estimate self-efficacy. It is possible that different scales could be more appropriate for the given population. Lastly, this study only collected data from staff who perform HIV testing; other types of staff members may have different experiences. Future research should investigate other decision makers, such as administrative staff, as well as the clients receiving an HIV test.

Despite these limitations, this study also has many strengths. The study investigated the Characteristics of HIV testing staff, Inner Setting, and Outer Setting components related to PrEP implementation within HIV testing sites – a relatively understudied context. The study design was a mixed methods triangulation design and included concurrent analysis of the quantitative and qualitative data, allowing for integration and contextualization of the findings. Overall, these findings provide a greater understanding of how PrEP is implemented within HIV testing sites and provides evidence for the potential use of such organizations in PrEP implementation. Future research can build upon these findings to provide a more comprehensive understanding of PrEP implementation within HIV testing sites. Additionally, given the possible limited role that knowledge, self-efficacy, and PrEP attitudes may have in differentiating PrEP implementation groups, organizational characteristics may be an important consideration when designing a PrEP program.
SECTION 4: ADDITIONAL ANALYSES AND EMERGENT FINDINGS

This section includes emerging findings from the data, not directly relevant to the research questions presented here, but relevant to the larger context of PrEP implementation within HIV testing sites.

Prevention Methods Discussed During HIV Testing

In the quantitative assessment, participants were asked a series of questions regarding which prevention and testing methods they typically included when counseling for HIV prevention during the testing process. The majority of participants (n=78; 52%) reported using rapid testing (clients received their results on the same day they take the test), 6% (n=9) used non-rapid tests (clients come back at a later date to receive their results, often referred to as the 2 week test), and 42% (n=63) provided HIV testing using a combination of both rapid and non-rapid testing. Participants were also asked what type of test they performed most often and given the options of an 1) antibody test; 2) combination or fourth-generation test, or 3) I’m not sure/don’t know. A total of 70.7% (n=106) of participants indicated that they most often performed an antibody test, while nearly a quarter (n=37; 24.7%) performed combination/fourth generation tests most often. Seven participants (4.7%) indicated that they did not know or could not be sure what type of test they performed most frequently.

Participants also discussed the degree to which they included a number of prevention methods during the HIV counseling process (Table 4.1). Participants most commonly discussed regular testing for HIV and condom use with their clients. PrEP, TasP, and partner testing were often discussed during counseling, but not as consistently as regular testing for HIV and
condom use. Monogamy and post-exposure prophylaxis were included least frequently in the counseling process.

Table 4.1. How often do you discuss the following during HIV testing and counseling?

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular testing for HIV</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>5 (3.3%)</td>
<td>16 (10.7%)</td>
<td>129 (86%)</td>
</tr>
<tr>
<td>Condom use</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>10 (6.8%)</td>
<td>27 (18.2%)</td>
<td>111 (75%)</td>
</tr>
<tr>
<td>Monogamy(^{a})</td>
<td>11 (7.4%)</td>
<td>22 (14.9%)</td>
<td>39 (26.4%)</td>
<td>35 (23.6%)</td>
<td>41 (27.7%)</td>
</tr>
<tr>
<td>Partner testing</td>
<td>1 (.7%)</td>
<td>5 (3.4%)</td>
<td>24 (16.1%)</td>
<td>51 (34.2%)</td>
<td>68 (45.6%)</td>
</tr>
<tr>
<td>PEP</td>
<td>3 (2.0%)</td>
<td>16 (10.7%)</td>
<td>33 (22.0%)</td>
<td>41 (27.3%)</td>
<td>57 (38.0%)</td>
</tr>
<tr>
<td>PrEP</td>
<td>1 (.7%)</td>
<td>6 (4.0%)</td>
<td>20 (13.3%)</td>
<td>44 (29.3%)</td>
<td>79 (52.7%)</td>
</tr>
<tr>
<td>TasP</td>
<td>1 (.7%)</td>
<td>6 (4.0%)</td>
<td>27 (18.0%)</td>
<td>36 (24.0%)</td>
<td>80 (53.3%)</td>
</tr>
</tbody>
</table>

\(^{a}\) Two participants skipped this question

In qualitative findings several themes emerged from the data unrelated to discussing PrEP during the HIV testing process. Although the qualitative interview questions focused on PrEP implementation, participants often discussed the undetectable = untransmittable movement, PEP, Hep-C, and condom use.

**Undetectable Equals Untransmittable (U=U)**

Over a quarter of interview participants (6/22) discussed U=U (Rodger et al., 2018; Rodger et al., 2016). Notably, in quantitative analyses, all of these participants were assigned to either the Universal or Eligibility Dependent groups. Some participants spoke about a low, but slowly increasing awareness of U=U in their communities:

So I'm definitely all about PrEP, but also a lot lately, I've been seeing an increase in treatment as prevention, and people utilizing … undetectable equals transmittable.

There's still people that have their issues about it, but it's becoming a little bit more accepted than what it was… people, sometimes they just have issues believing the science behind it, because at the beginning, it was so easy to say "Yeah, undetectable equals untransmittible," but at the time, people didn't feel like there was enough research done in that. We're still getting research everyday saying that yes, this is the thing, if
you're undetectable for six months, and if you were to bareback, you'd have no risk of contracting HIV or spreading the disease (Participant 112).

Another participant described:

I think it's [U=U] mostly talked about by people in the community or in our circle of people [who] are knowledgeable on HIV, people who currently have HIV, people who work in the field, I think, know more about it and are more open about it. It's kind of like the pay it forward thing. The people who are in the community are the main starters of it, but then they tell other people, and then those people might tell other people and it goes on like that. I think little by little, it'll start growing, kind of like PrEP did. But as of right now, it's not widely known. It's minimally known. (Participant 115).

Several participants compared the knowledge of U=U to knowledge of PrEP within the community.

Kind of the same way whenever PrEP first came out. They were worried about people who were just going to take PrEP and be unsafe in other measures. They were thinking the same way about undetectable, untransmittable ... meaning that people were just going to go out and be completely unsafe. Like this was a method where you didn't have to wear condoms anymore and who cares if you're HIV positive? You know, that sort of thing. So there was this whole thing about it until the CDC actually said a little something about it. And we're starting to work that in now, as far as whenever people come in ... who are in a relationship with an HIV positive person or considering a relationship with an HIV positive person or recently slept with someone who is HIV positive, just trying to get that message out as well. (Participant 105).

As seen in the quotes above, even participants who felt knowledge was increasing regarding U=U noted the lack of general wide-spread awareness of the campaign. More often, participants focused on the lack of awareness of the U=U campaign within their communities without
acknowledging a slow increase in knowledge. Some people simply stated low community
knowledge of U=U. For example, one participant simply stated:

It's the same thing about the term undetectable. Some people, they don't know anything
about that. They're completely ignorant about it. (Participant 103).

Another participant, who was living with HIV, provided more context to the lack of knowledge of
U=U in their community:

There's needs, at least in my area, we need more education. If someone asks me if I'm
positive, I say yes, but I'm undetectable, and they automatically think they can catch it
from me… I feel like everyone knows what HIV is. They say it's manageable and we
compare it to diabetes now, but I think there needs to be more education about what
undetectable means, and how easy is it transmitted, and how fragile the virus actually is
( Participant 110).

This participant later affirmed that the lack of knowledge of U=U also perpetuates HIV related
stigma.

[During the HIV testing/counseling process] I try to get as much [information] as I can in
a small amount of time, just enforce it to retain. You can't get HIV by hugging, kissing.

When I first told people, my family used to bleach everything that I touched. That was a
horrible feeling, so I try to explain to them, it can't get transmitted like that. The virus is
very fragile actually. If you're undetectable, for 3-6 months then you can't pass it on,
they're like "Oh, I didn't know that." (Participant 110).

Another participant discussed the confusion between U=U and a “cure” for HIV:

… then I know the CDC says once an individual has been undetected [undetectable] for
about six months they're non-transferable [untransmittable], meaning they can't give the
HIV to another person. I think I was interested about that so I looked it up. I'm like "Oh,
that is something" because when I used to do testing with youth and young adults they'll
tell me "Oh, well if I get it I can be cured of it" and it's reminding people that once you have HIV, once you take this medication, yes, you can get better. Yes, you can be non-transmittable but you will still have the virus and it's educating people but also a lot of people will tell you there's a cure and it's sort of that misconception (Participant 101).

Some participants stated that the training they had received prior to being certified to tests/counsel for HIV did not include U=U, or stated a need for training to include the prevention method; and, while they personally knew about the related research, they felt HIV prevention training should be updated to include these findings, such as one participant who stated:

Well one thing that they [staff providing training on HIV prevention] did say was that if someone's undetectable …they said yes, always the person can still transmit the disease. You know, the CDC had come out two months prior to that saying that in a study of some 400 couples, some were positive and some were negative, were having unprotected sex, and no one contracted HIV. So they’re still teaching that if you're undetectable can still transmit you know, the virus. So I think that needs to be updated. (Participant 110).

Another participant explained that the lack of training may be a contributor to the lack of discussing U=U during the HIV testing and counseling process.

I think they were worried about not having enough training on it, maybe. And that we were just telling clients without giving them the ... "You have to understand that if you are in care and you adhere to your medication and you’re being good, still take precautions, but being undetectable means that you're untransmittable because XYZ." (Participant 105)

**PEP**

Although post-exposure prophylaxis was one of the least included methods of HIV prevention during the counseling process, the prevention method was mentioned in over half of
the qualitative interviews (13/22). Mentioning PEP most often co-occurred when participants discussed client knowledge and available resources. Some participants simply stated that client PEP knowledge is low, such as “…so, a lot of people don’t know what the pill preventions are, like the prophylaxis that they have for HIV like PEP and PrEP (Participant 116) or “Also, something that is very interesting, that in five years of use [at this time it was approximately 5-6 years since FDA approval of PrEP], almost no one heterosexual know about the use of PrEP or PEP, it’s all in the gay community (Participant 103).” Other participants contrasted the awareness of PrEP and PEP, such as “for the most part, most [clients] are more aware of PrEP than they are of nPEP. I always let them know about that [PEP] as well (Participant 117)” or “most people have heard about PrEP, they haven't heard about PEP (Participant 104).” This finding was highlighted by another participant who described that, despite the number of years PEP has been available in comparison to PrEP, many clients were still unaware of this prevention option:

The same thing with PEP. I tell them that, because that’s an option that you have, and most of the people, they don't even know that they have it. If they have any risky situation, in the first 72 hours, to get access to take the Truvada for 28 days, which is the PEP. That's something that's a tool that you should know that you have… That's something that has been in use for, I don't know, 10, 15 years. I remember when it used only for people working in the medical field, and now it’s available for everybody. I explain all that, and at least they know, if they have sex last night with someone that, today, they come and tell them that they have HIV, they have available PEP, and avoid the infection. (Participant 103)

Some participants felt that this lack of PEP awareness was not only prevalent among clients, but also providers, such as one participant who described PEP knowledge in emergency room departments:
You walk into an emergency room and say, "I was exposed to HIV. I want PEP." They look at you like what? Because the education hasn't been done. The easiest way to get PEP, is to go through a PrEP provider. ...I don't think PEP is utilized enough, I don't think people know enough about it, but it's definitely part of the counseling we do whenever we test (Participant 104).

For some participants, PEP came up naturally during the counseling process. In 2016, the Florida Department of Health began collecting information about PrEP and nPEP on the DH1628, a mandatory form required to be completed with publicly funded HIV tests in Florida (FDOH, 2018a). Several participants discussed how the DH1628 acted as a resource to initiate a discussion about PEP “because one of the questions on the 1628 is about if you've ever taken PrEP or nPEP, which is non-occupational post-exposure prophylaxis (Participant 112)."

Usefulness of the DH1628 was reiterated throughout conversations with many participants:

Well, in the setup of a test, it's super easy, because it's on the same subject. I brought it out. I just question, "Do you know about PrEP? Do you know about PEP?" Oh, no, I don't know what it is. So then I start explaining the whole thing. It's super easy in a testing location. (Participant 103)

Another participant stated:

I don't find it very hard to introduce the subject. In the 1628, which is the state form that you fill out when you're doing an HIV test, there is a section on PrEP and nPEP, so we talk, I make sure that I talk to clients both about PrEP, and PEP - post exposure prophylaxes, and how to get it, if they ever need it. (Participant 104)

HEP-C

The concordance of testing for HIV and hepatitis C emerged in the qualitative interviews. Participants naturally spoke about hepatitis C testing as a resource available at their organizations. This can be seen through the following quotes: “So, we did a lot of HIV testing,
hepatitis C testing, we also provided syphilis, gonorrhea, and chlamydia testing as well to the local community (Participant 116)" or "We serve anybody who walks through the door from whatever county they may come from. Free HIV testing is what we offer, and also Hep C (Participant 117)." Some programs or funding required testing for both HIV and hepatitis C, such as "and it's just a screen [screening] program for HIV and HCV actually, so Hepatitis C as well (Participant 118)." The need for this dual testing within certain populations served was also discussed, most often when referencing concurrent risk due to sexual risk behaviors and injection drug use:

For this particular population [injection drug users], everything is geared towards preventing people from contracting HIV and Hep C, and/or transmitting it to their partners. (Participant 106)

Another participant stated:

Because we have a few clients once in a while from another organization that we have close by that's called [Name of Organization], which is a rehab for people that they use drug and alcohol. That population, actually, is super high on HIV transmitted through needles, and more than HIV, hepatitis. Hepatitis B or C. (Participant 103)

There appeared to be an ease in testing for both HIV and hepatitis concurrently:

Normally when people come into our office to get a test, if they're voluntarily coming in, they want whatever information you give them; and because we have a set amount of time, usually we're doing the rapid test and we're also pushing for people to also go ahead and take that Hep C rapid test, which is a little bit longer than the 15 minutes is going to be for the HIV test. It may be as long as 20-25 minutes, so in that amount of time, the paperwork isn't going to take 25 minutes so it's enough time to bring up different information. (Participant 106)
Reflecting on Alternative Forms of PrEP

In the quantitative survey participants were asked to respond to how they believed their PrEP implementation behaviors would change if alternative forms of PrEP or alternative policies existed. Responses to these questions can be found in Table 4.2.

Table 4.2. Likelihood of talking about PrEP

<table>
<thead>
<tr>
<th>My likelihood of telling clients about PrEP would be about the same</th>
<th>I would be less likely to tell clients about PrEP</th>
<th>I would be more likely to tell clients about PrEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>There is ongoing research about the use of PrEP injections (instead of a daily pill). Which is true of you? If injections were available a</td>
<td>126 (84.6)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>There is ongoing research about the use of intermittent PrEP (instead of a daily pill, a pill that would be used before and after a potentially risky sexual encounter). Which is true of you? If intermittent PrEP was approved a</td>
<td>111 (74.5)</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>If talking about PrEP with clients during HIV testing/counseling was required for funding purposes, how would your likelihood of telling clients about PrEP change? b</td>
<td>103 (69.6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>If talking about PrEP with clients during HIV testing/counseling was mandated by the state, how would your likelihood of telling clients about PrEP change? b</td>
<td>100 (67.6)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

a. One participant did not provide a response
b. Two participants did not provide a response

Alternative forms of PrEP, although not explicitly covered in the interview guide, emerged during the qualitative interviews: This included injectable PrEP which is in clinical trials, but not yet approved for general use (Landovitz, Kofron, & McCauley, 2016).

I learned that there’s injectables. There’s a little implant that they put under the skin that has to be removed and then they could put another one in, but it’s removed every two months or something like that. The injectables that are ...they originally thought it was
gonna be three months, but they found that it's probably gonna be two months because it doesn't stay as long (Participant 115).

Participants also discussed “on-demand” PrEP:

There's also, I think a lot of curiosity and a lot of people asking about PrEP on demand is what they're calling it back in Europe, but it's essentially the idea of getting certified for PrEP, but not really taking it until you're going to expose yourself to risk, right. A lot of the studies have been done in Europe that show as long as you've been taking your medication for seven days or more you're protected. People might get their meds, but not really start taking them...If they're on an insurance company that might cause trouble with their insurance, we have to be careful not to get dropped off the program and stuff like that, but I think people are trying to figure out how to make it work for themselves (Participant 104).

While sometimes discussions of alternative forms of PrEP reflected knowledge of emerging technology, other statements concerned participants:

The most common misconception is that they think it works immediately and they only have to take it right before they go out or something like that (Participant 117)

It's even been found that there are people that get on PrEP and they almost treat it as a Morning After pill (Participant 109).

Another participant described an alternative dosing regimen:

It varies. It really does vary because we have had instances where somebody was like, “Oh, no, I only take two on Friday, one on Saturday, one on Sunday, and two on Monday for my weekend so that I can have sex like that.” It's like, that's not how it works.

(Participant 115)

These findings are important because clients believe they are receiving the protection of PrEP, even when taking a dosing regimen not approved by the FDA. In reality, some methods of
alternative dosing could be clients at greater risk, since their perception of risk would be different than the actual risk they may be experiencing.

Client Barriers and Facilitators to PrEP Access and Use

Within the CFIR domain *Outer Setting* participants were asked to reflect on the facilitators and barriers that their clients had to PrEP access and use. Client needs were a particularly salient topic for HIV testing staff. Key sub-themes reflecting client needs and resources are listed in Appendix B. While these barriers and facilitators to PrEP initiation among clients were prevalent across all PrEP implementation groups (*Universal, Eligibility Dependent*, and *Limited*), they were discussed in greatest detail among participants in the *Universal* group. While it may seem contrary that those promoting PrEP are most aware of the barriers to PrEP implementation, it is likely because the *Universal* participants talk about PrEP with their clients most frequently; as such, *Universal* participants are most aware of the facilitators and barriers to PrEP initiation experienced by their clients.
SECTION 5: CONCLUSIONS AND PUBLIC HEALTH IMPLICATIONS

Overview of Findings

Together, the results of these two manuscripts and the emerging analyses provide insight into the role HIV testing staff have in PrEP implementation. A description of related hypotheses, analyses, and results can be found in Table 5.1.

Manuscript one sought to understand the latent PrEP implementation subgroups within an existing population of HIV testing staff. Latent Class Analysis suggests three subgroups of HIV testing staff taking part in PrEP implementation: 1) *Universal* participants who are advocates for PrEP and speak about PrEP with most clients, regardless of eligibility status; 2) *Eligibility Dependent* participants who talk with clients about PrEP when they believe the client may be eligible; and 3) *Limited* participant who may speak to clients about PrEP, but do so inconsistently.

Manuscript two answered two research questions. The first research question sought to understand the relationship between the CFIR domain Characteristics of Individuals and PrEP implementation within HIV testing sites. Understanding the role of Characteristics of Individuals (i.e. staff performing HIV testing) is important because these staff are the people in closest contact with the clients during the HIV testing process, thus able to directly connect with clients and share information or referrals regarding PrEP. If PrEP-related knowledge, self-efficacy, and/or attitudes were found to be significantly associated with PrEP implementation outcomes, then PrEP implementation trainings could target these areas. The quantitative results from manuscript one suggests no statistically significant findings between PrEP implementation groups and most variables under the CFIR domain Characteristics of Individuals. Two
participant characteristics, sexual orientation and race, were statistically significantly related to PrEP implementation during the HIV testing process. Those in the Limited group were significantly less likely to identify as a sexual minority (e.g. homosexual, bisexual) than as heterosexual. Additionally, compared to participants in the Universal and Limited groups, participants in the Limited group were less likely to identify as a racial minority. Qualitative findings revealed that a more nuanced understanding of PrEP knowledge, beliefs, and self-efficacy may be needed to fully understand how these constructs may affect PrEP implementation by HIV testing staff. Participants also noted their personal beliefs regarding PrEP – including concerns about side effects, cost, and behavior change. These beliefs may impact the way in which HIV testing staff talk about PrEP with their clients.

The second research question furthered the investigation of PrEP implementation in HIV testing sites utilizing the CFIR. Quantitative results from manuscript two suggest that greater access to PrEP-related resources, such as brochures to hand clients (i.e. available resources under the CFIR domain Inner Setting) and relative priority to implement PrEP over the many other things that need to be completed during the HIV testing process (a variable under the CFIR domain Outer Setting) may be positively associated with PrEP implementation. Specifically, participants in the Universal group were more likely than participants in the Eligibility Dependent group to indicate availability of physical resources regarding PrEP to share with clients (e.g. PrEP-related brochures, referral cards, etc.). Compared to the Limited group, participants in the Universal group were more likely to indicate that implementing PrEP was a priority within their organization. Qualitative findings revealed that staff providing HIV testing felt they were aware of patient needs and resources (an Outer Setting construct within the CFIR). This self-reported awareness of patient needs and resources occurred regardless of their implementation group. Such needs and resources reflected facilitators and barriers to PrEP implementation – namely, stigma, the role of medical providers, varied levels of client
knowledge, and client concerns regarding the cost and side effects of PrEP. Although participants in all implementation groups discussed these Outer Setting patient needs and resources, solutions to potential barriers were primarily discussed among participants in the Universal and Eligibility Dependent groups. Perhaps participants within these implementation groups are more dedicated to PrEP implementation, thus more committed to finding a solution for barriers to PrEP initiation for their clients. Cosmopolitanism also emerged in the qualitative findings, reflecting a potential need for specific quantitative measures regarding the role of cosmopolitanism in the referral process in future research. The strength of the ties occurring between organizations may also be an important consideration to explain PrEP implementation within HIV testing sites. For example, knowledge of the services another organization provides may produce different outcomes than having a memorandum of understanding with another organization. These ties between organizations could be quantified in a meaningful way to better understand how cosmopolitanism affects PrEP implementation within HIV testing sites.

**Theoretical Implications**

Collectively, these findings provide an understanding of the role that staff who perform HIV testing have in PrEP implementation, spanning multiple levels of the Socio-ecological Model. Constructs found under the CFIR domains Characteristics of Individuals (i.e. intrapersonal characteristics), Inner Setting (i.e. organizational characteristics) and Outer Setting (i.e. characteristics external to the organization) can help to explain PrEP implementation during HIV testing. Together these findings provide an initial understanding of PrEP implementation within HIV testing sites.
<table>
<thead>
<tr>
<th>Research Question</th>
<th>Hypotheses</th>
<th>Related Analyses</th>
<th>Related Results</th>
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<tbody>
<tr>
<td>Research question 1: What, if any, PrEP implementation subgroups exist among staff providing HIV testing in Florida?</td>
<td>Within the population of HIV testing staff, subpopulations exist based on PrEP Implementation behaviors.</td>
<td>Descriptive Statistics</td>
<td>Latent Class Analysis suggests three subgroups of HIV testing staff taking part in PrEP implementation: 1) Universal participants who are advocates for PrEP and speak about PrEP with most clients, regardless of eligibility status; 2) Eligibility Dependent participants who talk with clients about PrEP when they believe the client may be eligible; and 3) Limited participant who may speak to clients about PrEP, but do so inconsistently.</td>
</tr>
<tr>
<td>Research question 2: What characteristics of the individual are associated with PrEP implementation during HIV testing, as guided by the domain of CFIR (i.e. characteristics of the individual)?</td>
<td>High levels of PrEP knowledge, PrEP-related self-efficacy, prior/current PrEP use, and positive personal PrEP motivations and beliefs will be associated with greater frequency of referrals and/or PrEP discussion (i.e. PrEP implementation), when controlling for key organizational factors. Low levels of PrEP knowledge, PrEP-related self-efficacy, and negative personal PrEP motivations and beliefs will be associated with lower frequency of referrals and/or PrEP discussion (i.e. PrEP implementation) when controlling for key organizational factors.</td>
<td>Generalized linear mixed model [multinomial distribution; logit link]</td>
<td>Generalized linear mixed model results suggest that neither knowledge, self-efficacy, nor PrEP attitudes were associated with assignment to a particular PrEP implementation group; however the participant characteristics sexual orientation and race may be important predictors of PrEP implementation group affiliation. Qualitative findings suggest the important of participant knowledge and beliefs in understanding PrEP implementation.</td>
</tr>
<tr>
<td>Research question 3: What inner and outer setting factors are associated with PrEP implementation during HIV testing, as guided by the domains of CFIR?</td>
<td>A belief that clients need the option for PrEP (patient needs and resources), cosmopolitanism; pro-PrEP internal policy and incentives, structural characteristics, culture, tension for change, compatibility, relative priority; a positive learning climate; and PrEP-related available resources will be positively associated with high levels of PrEP implementation; while a belief that clients do not have a need for the option of PrEP (patient needs and resources); limited cosmopolitanism; anti-PrEP external policy and incentives, structural characteristics, culture, tension for change, compatibility, relative priority; a negative learning climate; and a lack of PrEP-related available resources will be negatively associated with greater frequency of referrals and/or PrEP discussion (i.e. PrEP implementation).</td>
<td>Generalized linear mixed model [multinomial distribution; logit link]</td>
<td>Inner setting constructs relative priority (see generalized linear mixed model results) and available resources (see quantitative and qualitative findings) may be important predictors of successful PrEP implementation. Outer setting constructs patient needs and resources (qualitative findings) and cosmopolitanism (qualitative findings) may be important predictors of successful PrEP implementation.</td>
</tr>
</tbody>
</table>
Alternative theoretical applications may have provided additional explanation of the data. For example, manuscript two examined Characteristics of Individuals, a CFIR domain inclusive of intrapersonal characteristics. Perhaps, then, a dual application of CFIR and an intrapersonal theory could provide additional insight into the intrapersonal facilitators and barriers to PrEP implementation. As discussed earlier, Walsh and Petroll (2016) investigated the role of primary care providers in PrEP implementation via an exploration of the intrapersonal factors that could predict provider discussion and prescription of PrEP. These researchers applied the Information-Motivation-Behavioral Skills model in their investigation. Additional intrapersonal theories that could be applied include the Theory of Planned Behavior and Health Belief Model, as constructs related to these theories have been applied elsewhere in the PrEP implementation literature (Krakower, Oldenburg, et al., 2015).

**Study Strengths and Weaknesses**

There are many strengths in this study. To date, there has been a paucity of research investigating PrEP implementation within HIV testing sites. This study sought to fill this gap in the literature by providing an investigation into the role HIV testing staff have in PrEP implementation. Additionally, this study adds to the limited theory-based research on PrEP implementation in non-medical sites. This study also utilizes a mixed methods design – providing both qualitative and quantitative data related to PrEP implementation. This mixed methods approach allowed for triangulation of the study findings and reliability of the findings. Additionally, this study took place in a state with diverse geographic variability and high rates of both HIV incidence and prevalence, Florida (FDOH, 2016a). Finally, the data in this study are from staff who provide HIV testing at community-based organizations. As such, the participants are nested within organizations. This study utilizes general linear mixed modeling to take the nested nature of the data into account – a step often ignored in the literature.
Weaknesses also exist in this study. This study occurred in Florida, a single state within the United States. Although Florida is a high HIV prevalence state, these findings may not be applicable to other geographic locations, especially those that were early adopters of PrEP. Participants were assured that their responses would not be shared with their employers; however, some participants may have feared organizational repercussions and not been truly honest in all responses – especially if their actions were against the organizational policy of the agency in which they worked. Additionally, even those participants who were not concerned that their employer may see their responses may have been affected by social desirability bias.

Although treating the clustered data appropriately was a strength of the study, this approach could be strengthened by including organizational (level 2) variables, such as the agency-reported number of clients served or internal policies of which the staff who provide HIV testing may be unaware. Inclusion of organizational variables would allow for a deeper investigation into organizational differences – possibly increasing our understanding of PrEP implementation within HIV testing sites. In this dissertation data was only collected from staff who provide HIV testing. Organization, agency, or supervisor data (all possible considerations for level 2 variables in a two-level multilevel model) were not collected in this dissertation for several reasons. There is limited data available on the role that staff who provide HIV testing have in the implementation process. Thus, data collection at one level (i.e. from the staff who provide HIV testing) was an important first step. Future research should explore a diverse range of data sources that could impact PrEP implementation during HIV testing, including, other agency staff, supervisors, and/or clients.

**Implications for Policy, Practice, and Future Research**

**Practice**

This study was driven by the need to understand PrEP implementation occurring within HIV testing sites. By its very nature, PrEP implementation within HIV testing sites is practice
based. The theoretical framework used throughout this study (CFIR) also provides guidance on how the study findings relate to practice-based implementation. Investigating the Characteristics of Individuals can help us to better understand the intrapersonal characteristics needed to implement PrEP. In this study, only participant characteristics (sexual orientation and race) statistically significantly impacted group membership (i.e. if a participant belonged in the Universal, Eligibility Dependent, or Limited group). However, qualitative findings revealed the importance of a more intricate understanding of PrEP knowledge and beliefs. Some participants had PrEP knowledge scores, despite stating an incomplete or inaccurate understanding of PrEP implementation. In practice, hands-on training may be beneficial to further investigate gaps in PrEP implementation knowledge by staff performing HIV testing. Additionally, people identifying as a sexual and/or racial minority were less likely than their counterparts not identifying as sexual or racial minorities to be in the Limited group; people in these demographic groups are also more likely than their peers to be adversely impacted by HIV (CDC, 2015; FDOH, 2016a). Perhaps this is because there is a more urgent need to address HIV within these communities, thus influencing their commitment to PrEP implementation.

In this study, Outer Setting constructs were not statistically associated with PrEP implementation; however, qualitative findings indicted that both patient needs and resources and cosmopolitanism may be important to understanding the role of HIV testing staff in PrEP implementation. In practice, staff providing HIV testing can use these findings to better prepare the ways in which they engage with clients. For example, understanding client concerns regarding PrEP-related side effects can help staff providing HIV testing to research and better understand these concerns so that they have an appropriate, accurate, and culturally relevant response for their clients. The salience of cosmopolitanism may suggest the need for staff who provide HIV testing to attend networking or community-wide meetings. These findings also
highlight the importance of formalizing organizational partnerships with written policies or MOUs.

Several constructs within the CFIR domain Inner Setting were found to be associated with PrEP implementation: relative priority and available resources. Inner Setting characteristics help to explain which organizational characteristics may be enhanced or changed to promote PrEP implementation within HIV testing sites. For example, if an organization is trying to implement a PrEP program, providing physical resources to their clients may be a good place to start. Some participants stated that these resources provided them with confidence, while others simply noted their usefulness for clients.

Policy

These findings may also have implications for the interplay between federal and organizational level policy on PrEP implementation. Some participants within the same organization reported inconsistent knowledge of an organizational policy regarding if, or when, they should talk about PrEP with clients. Organizations can use these findings to more consistently promote internal policies within organizations to ensure all participants have the same level of awareness. While some organizations may implement PrEP related activities due to organizational values and a belief that PrEP is an important component of an HIV prevention framework, others may need external motivation. Government agencies and community-based organizations may be more likely to include PrEP in programming if it is linked to funding. The CDC has linked some programmatic funding to PrEP related activities – making PrEP-related counseling a required deliverable to for some, but not yet all, HIV prevention grants (CDC, 2016a). Other grant announcements encourage PrEP implementation activities, but do not require them as a condition of funding (CDC, 2016b, 2016c). However, availability of, and the terms associated with, such funding may vary based on the economic or political climates.
Past research has shown providers may be more likely to adopt guidelines that are endorsed by professional organizations. For example, in a study of dental health, professional organizations were seen as influential in promoting and disseminating guidelines (Vamos et al., 2015). This has already proven true to some degree for PrEP related guidelines. One study that took place prior to the release of the CDC PrEP guidelines found that, among Massachusetts providers, 96% indicated that formal CDC guidelines would increase their likelihood to prescribe PrEP (White, Mimiaga, Krakower, & Mayer, 2012). It is not unrealistic to believe that endorsements by other professional entities would also encourage consideration of PrEP. Moreover, dissemination of PrEP guidelines (Lachowsky et al., 2016; The White House Office of National AIDS Policy, 2015; U.S. Public Health Service, 2014; World Health Organization, 2012b, 2014, 2015) may also assist with giving medical staff and others the needed information to implement PrEP within organizations.

Another area of policy implication is at the state level. The Florida Department of Health (FDOH) is currently involved in a statewide push for PrEP implementation via state-run health departments. The findings of this dissertation can help the state in implementing PrEP programming within their own health departments and in partnering community organizations. For example, although external policies and incentives were not particularly salient in these findings, the use of the DH1628 was. The requirement to complete the DH1628 is due to the mandatory reporting of HIV to the federal government. Thus, a continued policy enforcing the use of this form would be supported by these findings.

Research

This study also has implications for future research. Based on the findings of this study, a continued investigation into the role that HIV testing sites have in PrEP implementation is needed. Future research could include organizational level data, or a three-level model inclusive of clients receiving HIV testing, staff performing HIV testing and organizations/supervisors.
overseeing these staff. This multi-prong approach would provide more clarity on PrEP implementation within this setting. The presence of significant or emerging CFIR constructs also lends itself to engagement in future research. As discussed in theoretical considerations, application of the intrapersonal data, from the CFIR domain Characteristics of Individuals, to an intrapersonal level theory may be useful. Additionally, the role of weak and strong ties in relation to cosmopolitanism could be further investigated through a social network analysis examining how the strengths and density of such ties contribute to successful PrEP implementation.

Emerging qualitative findings suggest that staff who provide HIV testing may be a useful vehicle to promote other important sexual health/HIV prevention techniques, including: Hepatitis C, the undetectable = untransmittable movement, and PEP. Studies utilizing implementation science could investigate the barriers and facilitators to implementation of these prevention mechanisms in addition to PrEP.

Building on the study limitations, further work in the measurement of PrEP implementation should also be explored. The items used for Latent Class Analysis could be vetted by a broader audience and a variety of items could be applied. Additionally, although the application of the CFIR constructs/variables was based on technical assistance provided on the CFIR website, measurement work is needed to understand the best number and types of items to measure each construct/variable (Damschroder, 2016).

Final Remarks

Despite PrEP being an important component of the HIV prevention toolkit, the prevention method remains underutilized. PrEP implementation is needed via a variety of sites – including those sites that could assist in non-medical implementation aspects of PrEP. HIV testing sites are one such location. This study contributes to the growing body of literature examining the implementation science behind PrEP programming. Findings indicate that key demographic
characteristics, as well as highlighted variables within the Inner and Outer Settings of the CFIR, may be important to consider when implementing PrEP programs within HIV testing sites.
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APPENDIX A: LITERATURE REVIEW

Establishing a Need for PrEP

HIV Rates: Globally, Domestically, and Locally

Human Immunodeficiency Virus (HIV) is an incurable infection that can result in Acquired Immune Deficiency Syndrome (AIDS). The virus is spread through exchange of blood, fluids exchanged during sex, and sometimes breastmilk (CDC, 2015). Although preventable, HIV remains a significant problem globally, in the United States (U.S), and in Florida. According to the World Health Organization (WHO), over 36 million people worldwide were thought to be living with HIV in 2015; including an estimated 1.9 million new diagnoses in that same year (Joint United Nations Programme on HIV/AIDS, 2016). The number of new diagnoses, and the treatment available to individuals who are diagnosed with a positive HIV serostatus, varies widely by region, gender, and a multitude of other factors (Joint United Nations Programme on HIV/AIDS, 2016).

The Centers for Disease Control and Prevention (CDC) estimated that approximately 1.2 million people in the U.S. were living with HIV in 2012 (CDC, 2015). Although the annual number of newly diagnosed HIV cases has declined in the last decade, there were still nearly 45 thousand people newly diagnosed with HIV in 2014 (CDC, 2015). These new diagnoses have disproportionately affected Black (44% of new diagnoses) and Hispanic (23% of new diagnoses) Americans, women (19% of new diagnoses), and gay, bisexual, and other men who have sex with men (MSM; 67% of new diagnoses) (CDC, 2015).

Florida is particularly important for HIV prevention. The state ranked second in the U.S. for the number of new HIV infections in 2014, and third in the nation for the cumulative number of people living with HIV (FDOH, 2016a). As with the nation, Black and Hispanic Floridians, as
well MSM, have higher rates of HIV than other demographic groups in the state, with rates of 47%, 21%, and 77%, respectively (FDOH, 2016a).

**The State of HIV Prevention**

Social, behavioral, and structural HIV prevention has included efforts that address the social determinants of health, community and structural changes, and behavioral interventions. In a large-scale review, Rotheram-Borus and colleagues (2009) found that more than 140 interventions were available, and efficacious, in promoting HIV risk related behavior change; however, the target populations for these interventions, as well as access to the interventions is not universal. Biomedical prevention methods include those focusing on the non-behavioral methods of HIV prevention, such as methods directly affecting the biological transmission of the virus. Emtricitabine/tenofovir DF as pre-exposure prophylaxis (henceforth, PrEP) has been introduced as an innovative way to curb the spread of HIV. This method of HIV prevention includes daily use of antiretroviral medication (ARVs) by HIV-negative individuals who are at high risk of acquiring HIV. The CDC (2016f) describes such high risk individuals as: “people who are HIV-negative and in an ongoing sexual relationship with an HIV-positive partner." PrEP information delivery, referral, or prescriber visit (henceforth referred to as PrEP implementation) is important to implementing these guidelines. PrEP is rooted in a history of other biomedical methods for HIV prevention and care, among them: ARV use to reduce mother to child HIV transmission, ongoing microbicide and vaccine trials, post-exposure prophylaxis (PEP), male circumcision, and treatment as prevention (TasP) (McCormack, Gafos, Desai, & Cohen, 2014; Rotheram-Borus et al., 2009). Some practitioners have also considered condom use, treating sexually transmitted infections (STIs), and HIV testing as biomedical methods of prevention (Rotheram-Borus et al., 2009).

Despite social dialogue suggesting there has been a shift away from socio-behavioral prevention to biomedical HIV prevention, researchers tend to agree that combination prevention
– including biological, structural, and socio-behavioral prevention methods – is the key to furthering the success of HIV prevention (Kippax & Stephenson, 2012; Koblin et al., 2013; McNairy & El-Sadr, 2014; Rotheram-Borus et al., 2009; Underhill, Operario, Skeer, et al., 2010). This is because, even with the evolution of efficacious biomedical preventive methods, there exists a social side of prevention – including promoting initiation and adherence to these methods, partner-based communication, and the need for behavioral counseling or interventions (Rotheram-Borus et al., 2009; Underhill, Operario, Skeer, et al., 2010). Additionally, McNairy and El-Sadr (2014) recommend prevention to be an ongoing process, similar to the HIV care continuum, where the HIV prevention continuum describes the iterative steps needed to reduce the spread of HIV. Krakower and Mayer (2016) take this prevention continuum a step further to propose a “cascade for PrEP” to document available providers, awareness and training of these providers, prescription practices, and peer-based training. Similarly, Kelley et al. (2015) have developed a PrEP cascade for clients, documenting the steps necessary to get the most effective outcomes from PrEP (including actions such as PrEP initiation and adherence).

**Efficacy and Effectiveness of PrEP for HIV Prevention**

*An Introduction to PrEP Trials*

As previously stated, PrEP is the use of ARVs by individuals with a negative HIV serostatus to reduce the likelihood of acquiring HIV (CDC, 2014). Pharmacological efficacy studies have included tenofovir disoproxil fumarate (referred to as TDF) and a combination of tenofovir-emtricitibine (referred to as TDF/FTC); some studies have also compared these two formulations for the use of PrEP (Jiang et al., 2014; Spinner et al., 2016). This study refers to combination TDF/FTC (also known by its brand name Truvada) as PrEP, and its use as a daily, oral medication, as this is the formulation currently approved by the Food and Drug Administration (FDA). Studies on intermittent PrEP use (PrEP used only immediately before and
after HIV exposure) and other drug formulations used as PrEP are ongoing (Spinner et al., 2016), and their implementation will not be directly studied in this study.

PrEP efficacy has varied across studies, with systematic reviews reporting efficacy to be between 44 to 86%; when adjusted for adherence (and thus, concentration of the drug actually in the blood), reported efficacy has been higher, varying between 74 to 92% (Spinner et al., 2016). This has led many governmental agencies to market PrEP as up to 92% effective (CDC, 2016f). As will be noted in the following section, some agencies use the highest possible efficacy when PrEP is taken every day as intended, as indicated in pharmacological studies to be 99% (Anderson et al., 2012).

It is important to note that although studies are often segregated based upon sexual orientation and gender categorization, the drug concentration present varies by the type of tissue (vaginal, anal, etc.), and thus is most relevant to the type of sex in which an individual engages (anal, vaginal, etc.), rather than solely based on the gender or sexual orientation of the person taking PrEP (Buchbinder & Liu, 2015). However, studies addressing how the pharmacological effect of the medication varies between males and females are also warranted.

Through the current dissemination of PrEP (as a daily, oral pill), studies have found that drug concentrations are greatest in the rectal tissue, followed by blood and vaginal/cervical tissue (Anderson et al., 2012). Because studies have found that the drug concentration in anal tissue is higher than within vaginal tissue, it is plausible that PrEP may have a greater protective effect for anal sex when compared to vaginal sex. It is also important to note that some studies have found PrEP to be less efficacious than others. These studies, and the researchers’ rationale for low efficacy, will also be reviewed in the following paragraphs, and have led to important guidelines regarding the level of adherence needed to achieve the maximum effect of HIV risk reduction (Murnane et al., 2013).

The efficacy of PrEP in seminal efficacy trials will be discussed in the sections following.
**Efficacy among Men Who Have Sex with Men and Transgender Women**

One of the best known and most commonly cited PrEP efficacy trials, the iPrEx study, occurred over four continents, enrolling 2499 MSM and transgender women in a randomized control trial (Grant et al., 2010). This study reported that Truvada reduced the incident rate of HIV by 44% in the study sample (Grant et al., 2010). Based on a secondary data analysis, Anderson et. al. (2012) reported the rate of risk reduction varied based upon the number of PrEP doses participants took each week; where, when PrEP was taken twice a week participants were 76% less likely to contract HIV, 96% less likely when four doses were taken per week, and 99% less likely when PrEP was taken all seven days of the week (Anderson et al., 2012). Anderson and colleagues (2012) reported that the rate of efficacy in the iPrex trial would likely have been greater if participant had better rates of adherence.

The iPrEx team hypothesized that PrEP may most benefit particular subpopulations of MSM at the highest risk of HIV infection, and studied the factors most likely to result in HIV infection among the participants in the control group (Buchbinder et al., 2014). These researchers examined the number need to treat (NNT) across the control group, and within specific sub-populations of the control group who may have been at increased risk of HIV infection. When examining the full control sample, the NNT was 62 (meaning that 62 people need to take PrEP daily for a year before someone receives the benefit of an adverted HIV infection) (Buchbinder et al., 2014). The NNT was lower in subpopulations with increased risk of HIV infection, such as those regularly engaging in receptive condomless anal sex (NNT of 36), using cocaine (NNT of 12), or with a current STI diagnosis (NNT of 41) (Buchbinder et al., 2014). Meaning that without PrEP, men and transgender women in these subpopulations would have been at a particularly heightened risk of acquiring HIV. In fact, these researchers suggest that:
the simplest and perhaps most effective strategy for identifying MSM/TGW [men who have sex with men and transgender women] who may benefit most from PrEP would be to ask two questions of men and TGW: In the last three months, have you 1) had sex with men, women, or both; and 2) had anal sex as a bottom without a condom (ncRAI). By offering PrEP to MSM/TGW reporting ncRAI, regardless of partner serostatus, PrEP would be offered to the subgroup of MSM/TGW most likely to benefit from PrEP (Buchbinder et al., 2014, p.6).

The iPrEx study had very few transgender women and, although the risk behaviors being examined in transgender women study participants were the same as those being studied among the MSM participants (condomless anal sex, drug use, etc.), research has shown that transgender women are at an increased risk of HIV acquisition, warranting further studies (Deutsch et al., 2015; Grant et al., 2016). Combining MSM and transgender women in the study has been noted as a limitation by the iPrEx researchers (Grant et al., 2016), but has also allowed the benefits of PrEP to be studied in a population at a particularly high risk for HIV infection. Sub analyses by the iPrEx team revealed that adherence was particularly low among transgender women when compared to MSM (Deutsch et al., 2015). Additionally, staff in both research and practice have questioned how the hormones used by some transgender women may impact the efficacy of PrEP (Anderson, Reirden, & Castillo-Mancilla, 2016). However, initial findings have suggested that these hormones will likely not affect the efficacy of PrEP, and that more research is needed specifically among transgender women (Anderson et al., 2016). Researchers examining PrEP implementation have further investigated the unique barriers and facilitators to PrEP initiation and use among transgender women.

**Efficacy among Heterosexuals and Opposite-sex Partners**

A recent systematic review indicated that several randomized control trials have investigated PrEP efficacy among heterosexual men and women (Jiang et al., 2014). These
studies included sexually active women, heterosexual couples, and serodiscordant couples (Jiang et al., 2014). The efficacy achieved across these studies ranged widely, including rates of 65% (study inclusive of only high-risk women), 62% (study inclusive of heterosexual discordant couples), 73% (study inclusive of heterosexual discordant couples), 6% (study inclusive of women), and 63% (study inclusive of heterosexual men and women).

The Partners PrEP study was a randomized, double-blind, placebo controlled clinical trial of nearly 5000 serodiscordant heterosexual couples throughout Kenya and Uganda, examining the use of FTC/TDF and TDF alone as PrEP (Baeten et al., 2012). This study resulted in such significant efficacy results (reporting an overall 67% protection with TDF; 75% efficacy with FTC/TDF) (Baeten et al., 2012; Donnell et al., 2014), that the placebo arm of the study was discontinued (Donnell et al., 2014). These protective results were found in both the male and female participants taking part in the study.

Subsequent studies of the clinical data from Partners PrEP study further investigated the drug concentrations in the blood of participants. Donnell et al. (2014) examined the treatment arm of the study, comparing the 29 cases in which seroconversion occurred with 196 randomly chosen participants from those who did not seroconvert. Researchers found that the concentration of PrEP in the blood of those who did not convert was consistently high; among those who seroconverted the concentration of PrEP in the blood was only high among 5 of the 29 seroconverters. Thus, among the majority of participants who converted to a positive HIV serostatus, adherence was likely low (Donnell et al., 2014). This study also found that the protective effect of PrEP was higher among participants taking FTC/TDF, compared to TDF alone (Donnell et al., 2014). Subanalyses investigating the protective rate of PrEP for individuals at a particularly high risk of HIV infection (such as having a partner with a high viral load) and by gender have also been reported (Murnane et al., 2013). In high risk women, efficacy ranged
from 69 to 84% (Murnane et al., 2013). In an additional study of over 1,000 heterosexuals in Botswana, PrEP efficacy was 62.2% (Thigpen et al., 2012).

Some studies have reported lower rates of efficacy for PrEP. The FEM PrEP study among African women found PrEP to not be efficacious, either as TDF or FTC/TDF (Marrazzo et al., 2015). This study cites low adherence as a possible reason for the findings; but points to an important need to better understand adherence in PrEP implementation. Kingori (2015) explains that these trials began as a way to further social justice and create better prevention methods for women, particularly African women who were disproportionately affected by, and infected with, HIV (Kingori, 2015). However, women in the intervention arm of this study were just as likely to contract HIV as their counterparts in the control arm. Low adherence is thought to be the culprit in this trial. The reports, however, are conflicting, as biological data indicates low adherence and self-reported data indicated consistent PrEP and birth control use. In addition to the lack of protection from HIV, nine pregnancies occurred in this study, leading researchers to increase their suspicions of low adherence (Kingori, 2015).

**Efficacy among Injection Drug Users**

There is limited clinical data available assessing the efficacy of PrEP among injection drug users. Only one clinical trial (a randomized, double-blind, placebo-controlled trial), the Bangkok Tenofovir Study, has assessed the efficacy of PrEP among injection drug users (Choopanya et al., 2013). This study was conducted in Thailand among 2413 men and women who had injected drugs in the past year (Choopanya et al., 2013). Findings resulted in a nearly 50% reduction in HIV incidence; 17 participants (of 1204 in the study arm) and 33 participants (of 1209 in the control arm) seroconverted during the study. When participants with low (or not present) levels of PrEP were removed from efficacy analyses, the efficacy in the treatment arm increased to 73.5%.
International and Domestic Guidelines for PrEP

PrEP is supported by a wide array of governmental agencies. These agencies are similar in that they support, or provide suggested guidelines, for PrEP implementation. As in all public health implementation, the guidelines are a great start, but only the beginning of creating systematic organizational change (Bhattacharyya et al., 2009).

It is also important to note that PrEP is not the right choice for everyone. These guidelines suggest indications for beginning PrEP, but this is just an option. People should be offered the information and given the choice in making the decision best for them, typically alongside a healthcare provider.

**WHO/Global PrEP Recommendations**

Early guidance from the WHO in 2012 found the clinical trials to be promising, and encouraged demonstration projects for serodiscordant couples, MSM, and transgender women (World Health Organization, 2012b). WHO officially recommended PrEP for MSM in 2014, and expanded this recommendation to all high risk populations in 2015 (World Health Organization, 2015). The WHO recommendations are similar to those elsewhere (to be discussed in the paragraphs following), in that PrEP is recommended only when combined with other prevention methods, such as condom use and behavioral counseling. PrEP has also been included as an important option within the WHO report *Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples: recommendations for a public health approach* (World Health Organization, 2012a).

**U.S. National Guidelines and Recommendations**

In 2011, the CDC published interim guidelines for PrEP use (Smith et al., 2011), followed by comprehensive guidelines recommending the use of PrEP, alongside condom use and other prevention methods, for such individuals at high risk for acquiring HIV.
**Other County-Specific Guidelines**

The availability and recommendation to use Truvada as PrEP varies widely between countries. Currently, PrEP demonstration projects are also ongoing in Australia, Belgium, Botswana, Brazil, Canada, Netherlands, Nigeria, Peru, South Africa, Thailand, France, India, Italy, Kenya, Malawi, Uganda, United Kingdom, United States, Zambia, and Zimbabwe (PrEP Watch, 2016b), but many of these countries do not have regulations or guidelines regarding PrEP use. A review by Elion and Coleman (2016) noted that, as of 2015, PrEP had only been approved by regulatory bodies in the United States; yet, this has not stopped researchers from exploring the potential for PrEP implementation worldwide, or stopped people from beginning the use of PrEP (either post clinical trials or independent of clinical trials). Since Elion and Coleman's review, PrEP has been registered in several countries, including: Australia, Canada, France, Kenya, Peru, and South Africa (PrEP Watch, 2016a). However, outside of the U.S., only Botswana, France, Kenya, Malawi, and South Africa have current national guidance for PrEP implementation (PrEP Watch, 2016a). The cost and availability of PrEP also varies by country; for example, in France and Norway PrEP is provided free of charge (PrEP Watch, 2016a). However, PrEP was only recently approved by the European Medicines Agency for high risk populations, and remains unregistered in many countries, limiting its prescription availability in many European countries (Cairns, McCormack, & Molina, 2016; Spinner et al., 2016).

**PrEP Implementation in the United States and Beyond**

As review by Elion and Coleman (2016) eloquently described:

The first challenge in [PrEP] implementation in the US is to get individuals to recognize the actual risks that their behaviors represent and to engage with providers to address these issues. The second challenge is getting a population of providers to recognize the exact same issues and offer PrEP in a compassionate, nonjudgmental fashion. The third
challenge is identifying the set of providers and locations to scale-up the response in a timely, cost-effective fashion. (p.1).

These challenges are being researched to determine the most effective way to implement PrEP in the U.S., and certainly have implications for PrEP implementation globally. This section will discuss the main issues in PrEP implementation, with a focus on domestic implementation in the U.S. Special considerations for PrEP implementation globally, and within Florida, will also be discussed.

**Demonstration Trials**

Although PrEP is now considered to be part of an HIV prevention regimen for at-risk populations (Liu et al., 2014; Mayer et al., 2013), many individual, structural, and community-level barriers limiting the success of PrEP initiatives still exist. PrEP demonstration projects are ongoing in the U.S. and abroad (AVAC: Global Advocacy for HIV Prevention, 2016). For example, PrEP Watch, an advocacy organization, has logged at least 51 demonstration and implementation projects worldwide (AVAC: Global Advocacy for HIV Prevention, 2016; PrEP Watch, 2016b). According to the WHO (2014),

“The demonstration projects are aimed to serve two purposes: 1) enable countries to learn enough about implementation issues related to PrEP so that the transition between research, including demonstration project research, and the wider expansion and institutionalization that is entailed in scaling up implementation is more feasible; and 2) enable WHO to extract generalizable information for the eventual development of guidelines for PrEP delivery more generally” (para. 2).

Such demonstration projects are ongoing and supported by governmental agencies such as the CDC and the National Institute of Health (NIH) (CDC, 2016c).
**Provider/Stakeholder Awareness, Knowledge, and Opinions on PrEP**

Engaging providers and other stakeholders is critical to PrEP implementation. Although research is still needed, there is a growing literature surrounding stakeholder views of PrEP implementation (Arnold et al., 2012; Brooks et al., 2011; Scholl, 2016; Tellalian, Maznavi, Bredeek, & Hardy, 2013). Common themes have emerged in the literature regarding the views of both medical providers and other stakeholders.

PrEP awareness, knowledge, and prescribing practices have varied across specific types of clinical providers. Several studies have found that, compared to doctors specializing in HIV or infectious diseases, general medical providers were less aware, less informed, and less likely to prescribe PrEP to their clients (Krakower & Mayer, 2016; Krakower et al., 2015; Mimiaga, White, Krakower, Biello, & Mayer, 2014). It has been suggested that, although HIV care providers primarily serve people living with HIV, these providers may be important in disseminating PrEP to people who are at a high risk of HIV infection with a negative serostatus; largely because they are already familiar with the medication, side effects, and speaking openly about HIV with clients. Several studies have reported high levels of PrEP knowledge and awareness among HIV care providers (Blumenthal et al., 2015; Finocchiaro-Kessler et al., 2016; Krakower, Oldenburg, et al., 2015; Tellalian et al., 2013). In 2011, Tellalian et al. (2013) surveyed nearly 200 American HIV care providers regarding PrEP. Knowledge that PrEP was an efficacious intervention was high in this population (90% familiar with efficacy results and CDC recommendations); yet, rates of ever having prescribed PrEP were low (19%) (Tellalian et al., 2013). Another study of HIV care providers found similar results; almost half of the providers had been asked about PrEP from their clients, and nearly 20% had prescribed PrEP (Krakower & Mayer, 2012). However, in a recent mixed methods study of 85 providers across seven U.S. cities, HIV care providers were aware of PrEP; Approximately 20% had prescribed it and over 70% would consider prescribing it (Finocchiaro-Kessler et al., 2016). However, these studies
are limited by convenience samples that may bias the results. Beyond HIV care providers, other provider types have also been studied to assess PrEP awareness and knowledge. A study of over 1000 infectious disease doctors found that while most doctors had heard of PrEP, the majority (91%) had never prescribed it (Karris et al., 2014). Moderate rates of PrEP knowledge were found in a studies of generalist in several U.S. based states (Krakower & Mayer, 2012; Krakower, Oldenburg, et al., 2015; White, Mimiaga, Krakower, & Mayer, 2012). Lower rates of PrEP knowledge have been reported in military-based healthcare providers (Hakre et al., 2016) and family planning providers (38% of providers being able to define PrEP) (Seidman et al., 2016). Additionally, at least one study has found that policy members and program level staff expressed initial willingness to support PrEP implementation (Wheelock et al., 2012).

Acceptance and awareness of PrEP has appeared to increase in providers since the release of the CDC PrEP Guidelines in 2014 (Krakower & Mayer, 2016; Smith, Mendoza, Stryker, & Rose, 2016). However, despite this general increase in knowledge and acceptance, there may be differential understanding in the prescribing practices of PrEP, where prescribers are more comfortable addressing a need for sexual risk reduction, than for injection drug users (another target group for PrEP consideration) (Adams & Balderson, 2016; Krakower & Mayer, 2016). A 2015 study found that providers may differentially provide PrEP to clients within certain risk populations, such as prescribing to those at highest possible risk for HIV – MSM in serodiscordant partnerships (Adams & Balderson, 2016; Smith et al., 2015), or biases in prescription by race (Calabrese et al., 2014). Moreover, there are mixed findings regarding if PrEP awareness and knowledge alone results in prescribing practices; with some researchers finding this PrEP knowledge was associated with a greater likelihood of prescribing PrEP (Blumenthal et al., 2015), and others noting that PrEP knowledge was unlikely to result in an increase in prescribing practices (Krakower & Mayer, 2016). Therefore, it is important to examine other factors that may affect prescribing practices.
Providers have noted several benefits of and facilitators to PrEP implementation. As described above, high knowledge of PrEP has been found in some studies to be associated with a greater likelihood to be willing to prescribe PrEP (Blumenthal et al., 2015; Tripathi, Ogbuanu, Monger, Gibson, & Duffus, 2012). A Massachusetts based study found that providers believed several factors would increase their likelihood of prescribing PrEP: patient request of PrEP, recommendations by professional or government groups, and additional efficacy trials yielding promising results (White et al., 2012). Since the time of this study, the latter two items on this list have become a reality. Another facilitator prompting willingness to prescribe PrEP among providers included a belief that PrEP could empower women (Tripathi et al., 2012). Among HIV care providers the most important factor triggering screening for PrEP was the patient being a serodiscordant relationship; however, these findings may be unique to HIV care providers who regularly serve people living with HIV (Tellalian et al., 2013).

However, providers have also expressed concern regarding PrEP implementation in a standard clinical environment, and uncertainty regarding the most appropriate locations to dispense PrEP (Arnold et al., 2012; Karris et al., 2014). HIV care providers have expressed some concern with PrEP, including: fear of medication resistance, increased sexual risk behaviors, and lack of adherence among patients (Blumenthal et al., 2015; Calabrese et al., 2016; Krakower & Mayer, 2012; Tellalian et al., 2013; White et al., 2012). Additional barriers have included structural barriers, such as the need for training (Bacon et al., 2016; Calabrese et al., 2016; Seidman et al., 2016), logistical concerns (Calabrese et al., 2016; Seidman et al., 2016), and questions about billing and laboratory needs (Calabrese et al., 2016; Seidman et al., 2016). The amount of clinical efficacy data to support PrEP prescription has also been questioned by some providers (Hakre et al., 2016).

A broader concern regarding the lack of sexual health communication between clients and providers may also limit the reach of PrEP interventions (Krakower & Mayer, 2012; Thrun,
However, suggestions for incorporating HIV risk screening into routine health exams have been suggested in the literature (Krakower & Mayer, 2012; Thrun, 2013). Hesitation regarding talking about sexual health may occur in both clients and providers. For example, Mehta et al. (2011) found that, among MSM in New York City, the majority of men stated their primary care provider was not aware that they had sex with men; these findings were replicated in a study in several urban locations throughout the east coast, where over half of young MSM reported that they had never told their provider that they had sex with men (Arrington-Sanders et al., 2016). This is particularly important because some findings have suggested that being out to a provider about sexual orientation is associated with awareness of PrEP (Raifman et al., 2016). Clients not being out to their provider about their sexual orientation may further complicate the implementation of PrEP because providers may not be aware of which HIV-related risk factors for which to screen. One solution to both the lack of provider knowledge about client risk behaviors, and overcoming the discomfort in talking about sex with clients, is the use of tablet based risk assessment; a focus group of MSM suggested this method could assist providers in conducting preliminary risk behavior screenings and may start the conversation about sexual health between patients and providers (Jones et al., 2014).

Client/At-risk Population Views

Recent data suggests that over one million people in the U.S meet the clinical indications for PrEP (Smith et al., 2015). This includes nearly 25% of sexually active MSM, nearly 19% of injection drug users, and nearly 0.5% of heterosexual adults (Smith et al., 2015). Studies have found that candidates for PrEP use are willing to consider using it. In one study of nearly 2,000 people considered possible candidates for PrEP across seven countries, willingness to use PrEP was found to be at least moderately high (Eisingerich et al., 2012). Population specific barriers have also been identified, such as varied programmatic needs for MSM and women (Arnold et al., 2012; Mayer et al., 2013; Underhill, Operario, Mimiaga, et al., 2013).
Specific implementation considerations for priority populations are described in greater detail below. Additional county-level barriers will be discussed in the section *Special Considerations for Global PrEP Implementation.*

**PrEP, MSM, and Transgender Women**

The majority of social-behavioral PrEP research has focused on MSM and transgender women, due to the disparate rates of HIV that occur in these populations. The term MSM is widely used throughout public health research and practice. The term is thought to provide an epidemiological approach to measure sexual behavior, without the complexity added by the introduction of culture and identity (Young & Meyer, 2005). The differentiation between sexual behavior and sexual orientation is thought to be important because a greater number of men are categorized as MSM than identify as homosexual or bisexual alone (Gates, 2011). To further complicate matters, many studies group MSM and transgender women into a single risk category, despite transgender women being at increased risk of HIV infection and identifying as women (Baral et al., 2013; Herbst et al., 2008). Typically, this is because the studies are using risky anal sex or use gender assigned at birth as the inclusion criteria for the study. MSM have also been identified as a priority population for being screened for HIV related risks and possible PrEP prescription (CDC, 2014; FDOH, 2016c; U.S. Public Health Service, 2014; World Health Organization, 2012b, 2014, 2015). This section will discuss several factors important to PrEP implementation among MSM (including TGW); namely, awareness of PrEP, barriers and facilitators to PrEP uptake, and other factors affecting PrEP implementation.

Early PrEP studies proposed hypothetical scenarios depicting a medication that could reduce the likelihood of contracting HIV; during this time PrEP trials were underway and promising results had emerged (Liu et al., 2008; Nodin, Carballo-Dieguez, Ventuneac, Balan, & Remien, 2008). Additional studies asked participants about both PrEP and post-exposure prophylaxis (PEP) concurrently (Liu et al., 2008; Mehta et al., 2011). However, more recently
researchers have identified repeat PEP users to discuss the possibility of PrEP (Jain, Krakower, & Mayer, 2015; Siemieniuk et al., 2015). In 2011, Mehta et al. found limited awareness of PrEP among MSM surveyed in New York City bathhouses; in a sample of over 550 participants, less than 40% had knowledge of PrEP or PEP, the latter of which has been approved for many years. This knowledge and acceptance of PrEP among MSM has increased over time, as noted in a systematic review of 33 studies conducted between 2008 and 2012 (Young and McDaid, 2014). This same systematic review found that acceptability of PrEP ranged from 28 to 80% among MSM (Young & McDaid, 2014). However, despite this acceptability, PrEP initiation remains low (Scholl, 2016), warranting an investigation into facilitators and barriers to PrEP initiation beyond knowledge.

Several facilitators of and barriers to PrEP implementation among MSM have been noted in the literature. Reasons for interest in PrEP among MSM have included desires to protect oneself against HIV, reduce the associated fears with contracting HIV, or to have unprotected sex (Young & McDaid, 2014). Facilitators to going on PrEP have included the availability of free or low-cost medication, as well as access to healthcare and HIV testing (Golub et al., 2013). However, among men who were already engaged in PrEP care, several studies have found that medication costs were not seen as a significant barrier to its initiation or continued use (Chan et al., 2016). Men have also noted concerns with the availability of PrEP (Brooks et al., 2011; Young & McDaid, 2014) and fears regarding potential side effects of the medication (Brooks et al., 2011; Golub et al., 2013; Mantell et al., 2014; Scholl, 2016; Young & McDaid, 2014). Some men and transgender women have also noted concerns regarding drug resistance if they were to acquire HIV after using PrEP and questioned the efficacy of PrEP (Golub et al., 2013). Because concerns may vary between men and transgender women in monogamous relationships compared to those who are not in a monogamous relationship, researchers have noted that specific interventions may be needed based on relationship status,
and that it is important to remember that a “standard” system for implementing PrEP may differ even within groups of MSM (Muessig & Cohen, 2014).

Moreover, specific strategies may be needed to implement PrEP in transgender women. Recent data has suggested that there has been low uptake of PrEP by TGW (Kuhns et al., 2016; Marshall & Mimiaga, 2015). Facilitators for PrEP initiation among these women have included stigma free clinical environments and medical staff who are gender affirming (Grant et al., 2016; Marshall & Mimiaga, 2015; Sevelius, Deutsch, & Grant, 2016). Barriers specific for transgender women have included fear of discrimination and violence (Escudero, Kerr, Operario, et al., 2015; Marshall & Mimiaga, 2015).

Demographic and behavioral factors have also been studied in relation to willingness to try, or acceptability of, PrEP among MSM and transgender women. To date, the studies comparing demographic factors to PrEP acceptability or willingness have yielded mixed results (Young & McDaid, 2014). In an analysis based on 2011 data collected in New York City, interest in taking PrEP varied significantly based upon race and ethnicity; where Latino men expressed the most interest in PrEP (over 70% interested), followed by Black men (just under 70% interested), and lastly White men (less than 40% interested) (Mantell et al., 2014). Golub et al. (2013) also noted possible racial differences in the acceptance of PrEP; however, these findings indicated that men who were Black and Latino rated the concerns and barriers to PrEP use higher than their White counterparts. Although there is no comprehensive database of PrEP users, available data suggests the men most likely to use PrEP are middle and older aged adults who are White (Snowden et al., 2016). This variation in PrEP uptake by race and ethnicity may further exasperate the disparities in HIV rates in minority populations (Galindo et al., 2012; Snowden et al., 2016). Other studies have confirmed that PrEP knowledge may be higher among men living with HIV than in the general population of MSM (Mantell et al., 2014).
This may help implementation because, although men living with HIV cannot use PrEP, they can suggest its use to appropriate partners.

**PrEP and Women**

Because women are at greater biological susceptibility to HIV than men, and are more likely to experience partner resistance to condom use, there has been a push for female centered HIV prevention methods (Chen, Meyer, & Springer, 2011; Kofman & Adashi, 2014; Mastro, Sista, & Abdool-Karim, 2014). PrEP is one such method women can use to reduce the spread of HIV (Kofman & Adashi, 2014; Mastro et al., 2014; Matthews et al., 2010). Despite this need, lower rates of PrEP awareness among women, compared to MSM, have been cited throughout the literature (Auerbach et al., 2015; Garfinkel et al., 2016). In a study of nearly 150 young adult women accessing a family planning clinic in 2014, 60% of women would be willing to take a daily pill to reduce the likelihood of HIV infection, but few were aware of it (Garfinkel et al., 2016). Data has suggested that despite limited knowledge of PrEP, women in the U.S. may find PrEP an acceptable and worthwhile intervention after being informed about the risks and benefits of the intervention (Auerbach et al., 2015; Flash et al., 2014; Rubtsova et al., 2013).

Many of the facilitators of and barriers to PrEP uptake for women are similar to those experienced by MSM. For example, women have noted concerns with costs, side effects, and related stigma from using PrEP (Auerbach et al., 2015; Flash et al., 2014; Geary & Bukusi, 2014). The efficacy of PrEP in women was also questioned among women (Auerbach et al., 2015). Women have also expressed concern with side effects their partner may experience, a barrier not noted in the literature regarding men (Flash et al., 2014).

Demographic characteristics have also been shown to affect PrEP uptake in women. One study found Black women were more likely than their non-Black counterparts to report willingness to take PrEP (Garfinkel et al., 2016). Despite hope that PrEP can be utilized among women experiencing domestic violence, at least one study indicated women who had
experienced domestic violence were *less willing* to take PrEP (Garfinkel et al., 2016). Potential barriers to PrEP among women experiencing intimate partner violence have included the partner questioning the need for the medical visit and/or their partner expressing resistance to PrEP initiation (Braksmajer, Senn, & McMahon, 2016).

*PrEP and Serodiscordant Couples*

PrEP also has implications to provide another method of safe conception for serodiscordant couples, sometimes referred to as PrEP-C (Heffron et al., 2016; Lampe et al., 2011; Mack et al., 2014; Matthews et al., 2010; Matthews et al., 2014; Matthews et al., 2012; Ngure et al., 2016; Whetham et al., 2014). This method has been used in the United Kingdom (UK), resulting in no HIV infections and in seven of ten couples birthing a child (all also with a negative HIV serostatus) (Whetham et al., 2014). Some results have also suggested that PrEP adherence may be higher in serodiscordant couples attempting pregnancy than in general populations of people using PrEP (Matthews et al., 2014); but this adherence may be complicated by the typical ups and downs that occur in relationships (Ware et al., 2015; Ware et al., 2012). Heterosexual serodiscordant couples have also expressed interest in learning more about PrEP (Falcao et al., 2016). Similar to other groups meeting PrEP indications, concerns over cost, efficacy of PrEP, and related side effects were salient among serodiscordant couples (Falcao et al., 2016). Additional studies have found concerns regarding increased stigma brought to the relationship due to PrEP use (Idoko et al., 2015; Mack et al., 2014).

Of course, PrEP may also be useful for serodiscordant couples not trying to get pregnant. A study among women in serodiscordant relationships found that hormone birth control can be safely used with PrEP, affecting neither the efficacy of the birth control or PrEP (Heffron et al., 2014). Men were more likely than women to mention such non-conception based reasons for PrEP use in serodiscordant relationships (Falcao et al., 2016).
PrEP and Injection Drug Users

Compared to other risk groups, limited research has been conducted on PrEP and injection drug users. This dearth of research was noted in a 2014 review of PrEP implementation among injection drug users, citing limited empirical research on the topic beyond the initial efficacy trials (Escudero et al., 2014). Not surprisingly, injection drug users are perhaps the population least aware of PrEP. A Washington, D.C. based study found that out of over 300 participants surveyed in 2012, only 13% had heard of the use of ARVs to prevent HIV (Kuo et al., 2016). Other studies have also produce low rates, averaging about 30% willingness to use PrEP (Escudero, Kerr, Wood, et al., 2015).

Among injection drug users, cost of PrEP was the most frequently cited concern related to PrEP use (Kuo et al., 2016); however, gender specific norms and housing concerns also emerged in the literature (Stockman, Ludwig-Barron, Hoffman, Ulibarri, & Dyer, 2012). Adherence may also be an issue among injection drug users, especially among young men, those who are transient, or those who experience time in jail or prison; preliminary results have indicated that adherence may also differ based on the type of injection drug being used (Martin et al., 2015). Stakeholders have also noted concerns regarding how PrEP may affect the uptake of other harm reduction activities (Escudero et al., 2014; Kuo et al., 2016). Similarly, there has also been some concern that PrEP will become a solely biomedical approach, limiting the conversation about other HIV prevention strategies for injection drug users, such as rehabilitation or needle exchange programs (Escudero et al., 2014; Kuo et al., 2016).

Demographic characteristics may also play a role in PrEP implementation among those who inject drugs. Page et al. (2015) suggest that women who are injection drug users are told about, or screened for, PrEP less often than their male counterparts; they go on to suggest that specific interventions and strategies may be needed to target women who are injection drug users. Des Jarlais et al. (2015) call for a need to address minority groups of people who are
injection drug users, as this population is most at risk for HIV transmission via injection drug use. If we do not address these demographic factors, disparities in HIV infection could increase.

**Other Considerations**

Other considerations important to PrEP implementation do exist. While these topics are critical to the long-term implementation of PrEP, they are beyond the scope of this project (examining the implementation of information delivery and prescription referral within HIV testing sites in Florida), and will only be briefly mentioned here. Such considerations include fear of risk compensation, uncertainty of PrEP adherence, and debates regarding the cost-effectiveness of PrEP. Each of these will be briefly explained below.

In the context of PrEP, risk compensation has been described as a perception of decreased HIV related risk due to using PrEP (Golub, Operario, & Gorbach, 2010). There have been mixed findings in the literature regarding PrEP and risk compensation resulting in riskier sexual behavior. Some studies have reported a possible increase in possible risk compensation while using PrEP (de Wit et al., 2015), while others have found that PrEP use does not affect a persons perceived level of risk (Grov, Whitfield, Rendina, Ventuneac, & Parsons, 2015; Marcus et al., 2013; Sowicz, Teitelman, Coleman, & Brawner, 2014). There is a field of literature studying sexual risk behaviors while a person is on PrEP, and how these behaviors may differ from sexual behaviors prior to PrEP use. Sexual risk compensation is important in the study of PrEP implementation, but not directly related to the factors affecting the facilitators and barriers of PrEP implementation within the context of publicly funded HIV testing sites. Sexual risk compensation is briefly mentioned again below, as it relates to ethical implications of PrEP.

Biomedical researchers have suggested that adherence should play a particularly important role in the PrEP demonstration projects (Anderson et al., 2012). Social-behavioral PrEP research has included studies on adherence (Daughtridge, Conyngham, Ramirez, & Koenig, 2015; Hosek et al., 2013; Marcus et al., 2014; Tangmunkongvorakul et al., 2013;
Underhill, Operario, Skeer, Mimiaga, & Mayer, 2010; Ware et al., 2012). For example, PrEP adherence was found to be high in a group of young men who have sex with men, where, on average, participants who had been on the medication for at least one month were 73% adherent to their daily dose (Daughtridge et al., 2015). A qualitative study of serodiscordant couples found that adherence may be motivated by trying to maintain the serostatus of the negative partner, while also fulfilling the emotional and physical needs of both partners (Ware et al., 2012). Research also suggests that adherence may be greater in those who actively seek out and bring up the possibility of PrEP on their own accord, without prompting from medical staff (Calabrese et al., 2016). Adherence may also be affected by time. Six-month retention in care was low (approximately 50%) across a study of MSM in three urban locations (Chan et al., 2016). Although researchers have noted the importance of adherence, they have also reminded us that this is not a new phenomenon; in fact, adherence is not unique to biomedical programs, but a requirement for any program to be effective (Rotheram-Borus et al., 2009).

The cost-effectiveness of PrEP implementation have also been studied. Cost-effectiveness analyses have found PrEP to be a cost-effective addition to standard HIV prevention activities in some populations (Alistar, Owens, & Brandeau, 2014); although these findings have varied based upon the age of the client and long-term pricing of PrEP (Paltiel et al., 2009). A systematic review of cost-effectiveness analyses found mixed results regarding PrEP use in a U.S. based setting; where some studies found PrEP use to be cost effective, especially when considering how PrEP may limit the horizontal transmission of HIV, while others noted that it is only cost-effective when aimed at those most at particularly high risk of acquiring HIV (Gomez et al., 2013). It has also been suggested that PrEP may be most cost effective in global contexts or within populations where HIV is endemic (Verguet, Stalcup, & Walsh, 2013).
Although PrEP is recommended for high risk populations, it remains unregistered in many countries, limiting its ability for prescription (Cairns et al., 2016). Despite this, researchers have studied PrEP acceptability in numerous global settings, for example: Peru, UK, China, Kenya, Uganda, and India (Young & McDaid, 2014). There are some people within these countries who are able to receive PrEP through research trials, friends, or through off label prescription scripts from their providers (Philpott, 2013). Other countries may not require medication to undergo review at a national regulatory body, limiting prescribing restrictions. There are also online pharmacies catering to those who are unable to get PrEP in their country of residence or unable to obtain the medication otherwise (An et al., 2014).

Target populations for PrEP implementation may vary between countries. For example, the need for PrEP implementation with women may be higher in sub-Saharan Africa compared to the United States, based upon social norms and risks and prominent transmission routes (Celum et al., 2015; Chirenje, Marrazzo, & Parikh, 2010; Matthews et al., 2014). Different cultural aspects may also come into play for a global PrEP perspective. For example, in Western Kenya, fishermen and widows are considered targeted populations for PrEP implementation due to the cultural norms surrounding the trade of sex for fish and widow cleansing (Mack et al., 2014); while in India a target group for PrEP implementation has included truck drivers (Schneider et al., 2010). Concerns regarding staffing to assist with PrEP implementation are also particularly salient in the global community (Mack et al., 2014).

Not surprisingly, just as access to PrEP varies, awareness and willingness to take PrEP also varies globally. Due to the wide variety of countries in which PrEP may be helpful, it is impossible to provide comprehensive rates of awareness and knowledge. However, some themes do exist. Some Western countries, such as Canada, have rates of PrEP knowledge and acceptance similar to those of the U.S. (Karris et al., 2014) For example, limited awareness of PrEP was found in Canada in 2011 (approximately 12% of the sample) (Leonardi, Lee, & Tan,
2011), but these rates were much higher (greater than 50%) in a 2016 study (Kesler et al., 2016). In a multinational study of PrEP acceptability, with respondents from Peru, Ukraine, India, Kenya, Botswana, Uganda, and South Africa, acceptability of PrEP was generally high; over 90% of the sample said they had at least some level of interest in using PrEP (Eisingerich et al., 2012), although knowledge of PrEP prior to the survey was not assessed. Research conducted by Zablotska et al. (2016) found that knowledge and use of PrEP were low in the Asia-Pacific region, with the exception of a few countries. For example, willingness to use PrEP in 2013 among Thai MSM was high, with 80% of one study’s sample reporting willingness (Wheelock et al., 2013). Thailand may be better prepared, in terms of infrastructure and resources, for PrEP implementation (Zablotska et al., 2016). In Latin America, PrEP knowledge varied widely, but implementation was found to be very limited (Ravasi et al., 2016).

The concerns among global PrEP candidates are similar to the concerns documented among PrEP candidates in the U.S. For example, cost (Eisingerich et al., 2012; Galea et al., 2011; Ravasi et al., 2016; Wheelock et al., 2013), efficacy (Galea et al., 2011; Kesler et al., 2016), stigma (Galea et al., 2011; Zablotska et al., 2016), and related side effects (Eisingerich et al., 2012; Galea et al., 2011; Kesler et al., 2016; Wheelock et al., 2013) were noted concerns in many global contexts. The facilitators and barriers to PrEP implementation in Canada are particularly similar to those in the United States (Karris et al., 2014). Globally, some studies have reported a moderate likelihood that clients would share their PrEP medication with family or friends (Eisingerich et al., 2012; Kingori, 2015) or, in some cases, sell the medication (Eisingerich et al., 2012; Wheelock et al., 2013). This is concerning because intermittent PrEP use is currently not medically indicated, and adherence is an important part of the efficacy of PrEP. Concerns over client ability to trust the prescribing staff have also been raised (Galea et al., 2011; Schneider et al., 2010). Internationally, significant barriers may also exist surrounding sexual orientation, legality, and stigma (Taegtmeyer et al., 2013; Zablotska et al., 2016). For
example, in Kenya, providers have noted that although PrEP may be a good intervention for MSM, being publicly out as a man who has sex with men has serious legal ramifications that would likely affect uptake (Taegtmeyer et al., 2013).

**Special Considerations for implementing PrEP in Florida**

Florida is a particularly important climate for PrEP implementation, as it consistently ranks among the top three states for new HIV diagnoses (FDOH, 2016a), thus warranting a need for prevention activities. The State of Florida Integrated HIV Prevention and Care Plan 2017–2021 (FDOH, 2016c) lists the following as one of four key components in the state plan: “Incorporate antiretroviral pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP) as a risk reduction strategy” (p.11). Along with this component are specific PrEP related activities that the state hopes to implement within the next 4-5 years, among them:

to develop resources for community based organizations, create a statewide inventory of PrEP friendly providers, increase and train PrEP navigators, and utilize social marketing in the dissemination of PrEP related information (FDOH, 2016c). There are some challenges to achieving this goal, however, because of Florida’s diverse geography, demographic groups, and political climates.

A handful of PrEP-related studies have been conducted specifically in Florida. Doblecki-Lewis and Jones (2016) conducted focus groups with providers and other administrative staff working in south Florida Federally Qualified Health Centers. These staff supported PrEP implementation, though it was not currently being prescribed at most of their sites (Doblecki-Lewis & Jones, 2016). Although these findings mirrored some of the same facilitators and barriers described in the rest of the United states (in terms of cost, availability, and insurance); some concerns were raised that have not been seen elsewhere in the literature, including concerns related to immigration and related access to healthcare (Doblecki-Lewis & Jones, 2016). Shaeer, Sherman, Shafiq, and Hardigan (2014) surveyed pharmacists in Florida to
assess knowledge, attitudes, and perceptions of PrEP. This study revealed low levels of knowledge among pharmacists in Florida regarding PrEP and PrEP counseling (Shaeer et al., 2014). Pharmacists expressed concerns regarding sexual risk compensation, cost, and an increase in the spread of sexually transmitted infections (Shaeer et al., 2014), similar to those previously reported among primary care providers.

**Major Gaps in the Literature Regarding PrEP Implementation Domestically**

The PrEP literature is relatively new and, in many ways, still emerging. Researchers investigating PrEP have indicated several directions for future research in the field of HIV prevention and PrEP. Researchers investigating the biological efficacy of PrEP have suggested future research on intermittent PrEP, or alternative delivery methods - including gels, rings, and injections (Jay & Gostin, 2012). It has also been suggested that future research should address disparities in PrEP accessibility and uptake (Jay & Gostin, 2012; Sugarman & Mayer, 2013), and an increase in locations where PrEP is implemented (Underhill, Operario, Mimiaga, et al., 2010; Underhill, Operario, Skeer, et al., 2010). There is also a lack of theoretically driven research for PrEP implementation, despite the fact that HIV frameworks and theories for guiding HIV prevention activities are widely available in the literature (Fishbein, 2000). After the success of the efficacy trials, there was a call for the need of implementation research – including the best ways to move the clinical PrEP findings into practice (AVAC: Global Advocacy for HIV Prevention, 2016; Caceres, Mayer, Baggaley, & O'Reilly, 2015; Caceres, O'Reilly, Mayer, & Baggaley, 2015). The proposed research contributes to this literature by answering the call for implementation research via unique provider settings – HIV testing sites.

**Implementing PrEP in HIV Testing Programs**

To best reach the populations in need, researchers have suggested that PrEP information delivery, referral, and prescriber visits should occur in a diverse array of settings, including emergency room departments, primary care doctors, and infectious disease specialist
sites (Smith et al., 2015; Underhill et al., 2014; Underhill, Operario, Mimiaga, et al., 2010; Underhill, Operario, Skeer, Mimiaga, & Mayer, 2010); however, not all of these settings have been explored for PrEP implementation. A notable amount of research has been conducted within sexually transmitted disease clinics, as well as an array of non-generalists sites. A study of Lesbian-Gay-Bisexual-Transgender (LGBT) clinics in Boston suggests that PrEP referral and prescription may be higher in LGBT focused settings than in generalist offices alone (Krakower, Maloney, Grasso, Melbourne, & Mayer, 2016). Smith et. al. (2016) conducted a study of 175 community-based organizations, both clinical and non-clinical in nature, and examined the knowledge and infrastructure for PrEP implementation at these sites. While the organizations were knowledgeable about PrEP, non-clinical CBOs felt ill-equipped for PrEP related activities (Smith et al., 2016). Despite feeling ill-equipped, these agencies were still interested in being involved in PrEP implementation (Smith et. al., 2016).

There is a paucity of research regarding the specific role HIV testing sites in non-clinical settings may have in PrEP implementation. Existing studies have only utilized HIV testing sites for recruitment of people who may be eligible for PrEP (Gallagher et al., 2014; King, et al. 2014), and have not focused on the role staff performing HIV tests have in PrEP implementation. HIV testing sites are an ideal location for PrEP implementation because these sites often provide services free of charge, and not dependent upon health insurance - unlike many other health care services. Additionally, such locations already collect information on sexual risk behavior, and may provide an easy outlet for PrEP implementation. Research with providers has indicated that support staff were important to the successful implementation of PrEP (Calabrese et al., 2016). Staff performing HIV testing could be one group of support staff to bridge the gap between PrEP information delivery and clinical prescription. Furthermore, researchers examining practice viewpoints of PrEP implementation also suggested the possibility of providing PrEP linkages during HIV testing campaigns (Jay & Gostin, 2012; King et al., 2014).
Integration of HIV Testing and Other Related Services

Advocates of PrEP have stated that it is necessary to develop integrated delivery systems to increase the number of people accessing PrEP; akin to the suggestion to meet people where they are (Delany-Moretlwe, Mullick, Eakle, & Rees, 2016). HIV testing has been successfully integrated into other healthcare settings – perhaps most notably immunization programs (Chamla et al., 2015; Wang et al., 2015), antenatal care settings (An et al., 2015; Turan et al., 2015), family planning settings and sexual and reproductive healthcare services (Ngo, Ha, Rule, & Dang, 2013; Schwartz et al., 2015; White et al., 2013), sexually transmitted infection clinics (Balira et al., 2015; Moss, Martin, Klausner, & Brown, 2014; Sweeney et al., 2014), and as part of substance abuse rehabilitation (Guerrero, Aarons, & Palinkas, 2014; Hood, Robertson, & Baird-Thomas, 2015). In addition to specialty clinics, HIV testing has also been conducted as part of primary care services (Myers et al., 2012). Despite concerns about stigma related to HIV testing (Chamla et al., 2015; White et al., 2013), such programs have been successful and considered acceptable (Chamla et al., 2015). In fact, in some settings, such integration has been shown to increase the utilization of both services (HIV testing and the services provided at the site of HIV testing integration) (Chamla et al., 2015; Ngo, Ha, Rule, & Dang, 2013; Turan et al., 2015; Wang et al., 2015). Concerns about integrating HIV testing and other services have included limited resources, such as supplies and staff time (An et al., 2015; Hood et al., 2015; Sweeney et al., 2014). These concerns will likely hold true for integration of PrEP referral and prescription into HIV testing sites; but, in the long run such integration may prove to be successful, just as the programs discussed above have been.

Existing Systems for Training People to Implement PrEP Referral and Prescription

To my knowledge no public PrEP implementation training is available specifically for staff performing HIV testing, although, anecdotally, some organizations may have internal trainings. Additionally, referral systems would likely be based on the geographic area in which
the organization is based. However, numerous trainings are available for clinical providers, government staff, researchers, and others regarding PrEP. These resources can be accessed and used by those implementing PrEP referral and prescription during HIV testing. These resources include assistance with payment, indications for PrEP, and general information about PrEP. They also have resources for both lay workers, providers, and clients available.

Training and informative resources can be found at many locations, including the government and nonprofit entities [for example, the CDC (CDC, 2016d, 2016e), AIDS Education and Training Centers (Herman, 2014), National Network of STD Clinical Prevention Training Centers (National Network of STD Clinical Prevention Training Centers, 2015)], through the manufacturer of Truvada, Gilead (Gilead, 2016), and state-specific agencies [for example, the Florida Department of Health (FDOH, 2016b), or the Minnesota AIDS Project (Minnesota AIDS Project, 2016)]. The U.S. Public Health Service (2014) has a clinical supplement for the PrEP guidelines, with resources that can be used to screen for HIV-related risk, handouts that can be used to discuss PrEP with clients, and many other helpful resources. Although designed for medical providers, these resources could be used and adapted by staff performing HIV testing to provide accurate and complete information to clients.

PrEP navigators, and related training programs, have also been created to assist clients with navigating the procedures and paperwork necessary for PrEP prescription and payment (California Department of Public Health, 2016; Minnesota AIDS Project, 2016). In addition, it is within the Florida state plan to expand PrEP navigators within our state (FDOH, 2016c). To assist with PrEP referral or finding a provider who is PrEP-friendly, Emory has a PrEP locator service (Emory University, 2016). In addition to the information described above, specific resources are offered to medical providers. The University of San Francisco is federally funded to provide clinical consultation about PrEP free of cost via the Internet or phone to anyone in the U.S. (UCSF Clinician Consultation Center, 2016). One limitation is that this resource is meant to
assist with clinical matters and does not assist with navigating the insurance, payment, or existing co-pay assistance programs (UCSF Clinician Consultation Center, 2016). The university also provides free consultation on PEP, HIV care, and prevention of mother to child transmission (UCSF Clinician Consultation Center, 2016).

**Contribution to PrEP Implementation Literature and HIV Prevention**

This study is among the first to investigate the facilitators of and barriers to PrEP implementation specifically occurring during HIV testing. Such findings could support PrEP implementation at other less conventional sites for PrEP implementation, such as drug rehabilitation sites or community-based organizations. This study is also among the first to examine PrEP implementation using a theoretical framework. This study may contribute to findings promoting the availability and uptake of PrEP in Florida and more broadly. It adds a particularly important piece to the literature, because programs implemented based on findings from a theoretical framework are thought to be more likely to produce positive change (Davidoff, Dixon-Woods, Leviton, & Michie, 2015; Glanz & Bishop, 2010).
APPENDIX B: QUALITATIVE THEMES DERIVED FROM CFIR CONSTRUCT PATIENT NEEDS AND RESOURCES

Table B.1. Qualitative themes derived from CFIR construct Patient Needs and Resources: Perceived client barriers and facilitators to PrEP initiation

Client concern regarding the potential side effects of PrEP

“Some people would come in and be concerned, they would have a very high sexual activity throughout the year, but they would be like, ‘No, PrEP gives people symptoms, I don't wanna have to not sleep at night or get nauseous all the time.’ Then we would go and explain, symptoms happen with every drug, but once your body gets used to it, once your body notices the drug then it won’t do that anymore. So, some people wouldn’t even try PrEP because of those fears.”
– Participant 116, Universal implementation group

“People are worried about side effects of taking PrEP”
– Participant 107, Eligibility Dependent implementation group

“I've gotten a couple where I've been asked if there's any side effects of PrEP, and so I would discuss some possible side effects, the reason why the labs are drawn, to measure kidney and liver function is one of the possible side effects, and a couple of the common ones like nausea, vomiting, or uneasiness in the first couple weeks. Kind of going through common symptoms.”
– Participant 121, Eligibility Dependent implementation group

Medical doctors as a barrier to PrEP implementation

“The big thing that I have seen is physicians, especially primary care physicians who don't even know what PrEP is. I don’t think that in all of their continuing education that physicians have to do, or even nurse practitioners or anything of that nature ... I think that having that implemented toward care providers would go a long way. Because I have seen so many people who come in and they'll say, "One, I don't want to bring it up with my doctor." Or they’re not out to their doctor if they happen to be LGBTQ. And then of course, like the older private practice physicians, around here especially, it's just not anything they know about, so they're not going to prescribe it. So that's been our biggest barrier as far as getting people on PrEP, is we have a lot of people who do have primary care physicians, but they don't know about it or they refuse to prescribe it because they don't know about it. Whether we send the material or try to set up a meeting with them or not.”
– Participant 105, Universal implementation group
“I feel like there needs to be more providers that are knowledgeable about PrEP that we don't have. I've had so many clients come and tell me, 'Hey, I went to my primary care doctor and they told me that they couldn't prescribe me PrEP because they didn't know what it was.' Or, they would be like ‘You need to go see Infectious Disease because it's an Infectious Disease.”

-- Participant 116, Universal implementation group

“So roadblocks since PrEP came about was that trying to find a doctor who would write the script and you would think they would want to write the script, but it was like well if you don't have the insurance or you don't have the right insurance or we don't do that. Just roadblocks.”

– Participant 107, Eligibility Dependent implementation group

Medical doctors as a facilitator to PrEP implementation

“I believe the doctor presented PrEP information to us as an organization, and we just started to utilize him, as far as, you know, referrals.”

– Participant 102, Universal implementation group

“One doctor told me when I was getting my certification he said, "If I knew 20 years ago that there was a pill I could take every day and I wouldn't get HIV, I would take that pill without a doubt." Hearing that from somebody who is in practice and who is working with clients who have HIV, was something that really kind of changed my mind in regards to the whole PrEP talk. I'm obligated as somebody who's doing HIV prevention and testing to talk to somebody about this. It's just like if I have heart disease and I should exercise. Or I should take X, Y, and Z.”

– Participant 113, Universal implementation group

“There are some people who, maybe they have a partner or something who recently found out about their HIV status, or something like that, and they'll come to us and they'll be like, "You know, I was trying to research it online," or "My partner's doctors mentioned something where I could maybe get some type of treatment, and then continue to have sex with my partner."

-- Participant 108, Limited implementation group

Varied client knowledge of PrEP

“You would get a lot of people that were like, "Yeah, I heard about it, but what does it do?" So, then you kind of explain it to them and their minds would be blown because they're like, "What, it's a drug that can help prevent HIV?" And I'm like, "Yeah. There are medication out there that does help. It's not 100 percent, I don't want you to get the wrong idea and kind of a sex spree. But it's a preventative method that you can, to give you that extra layer of precaution I guess."

– Participant 116, Universal implementation group

“When they [gay men] come, they ask you questions, but they already know. They did research. They have friends that they're on it. Yes, definitely.”

– Participant 103, Eligibility Dependent implementation group

“That's fine. I would say here in North Florida, we are in [specific region], but in North Florida, it seems like fewer members of the community have awareness of PrEP or what PrEP is as
compared to other locations within the state. For instance, South Florida, when you're talking more about Miami or Ft. Lauderdale, knowledge about PrEP seems to be wider than it is up here. The thoughts about PrEP, a lot of times it's "I don't know what PrEP is."

- Participant 100, Limited implementation group

Client concerns about cost or insurance

“And there’s definitely a split of people who say, ‘I’ve never heard of that’ or of people who say, ‘I know of it, but I don’t know what it is.’ And then we have a large section of people who are, ‘I know about it, but I can’t afford it.’ And that seems to be sort of the split.”

- Participant 105, Universal implementation group

“You know, they think it costs too much. So, I give them their results and then I get up and I go.”

- Participant 110, Universal implementation group

“But on the patient side, I would say education about both PrEP itself and access and financial would be a big thing because that's kind of a big hindrance that I've seen would be hesitation about cost.”

- Participant 121, Eligibility Dependent implementation group

“It's pretty difficult. If someone is uninsured, then our best option is to set up a linkage to a community clinic here. Then from the community clinic, same deal, I can help that person navigate the first-time meeting with their essentially primary care provider now, at that community clinic, to try and see if that primary care provider has resources for the uninsured for PrEP services, but so far I've not had much success as far as finding PrEP for the uninsured. It might become a matter of helping that person apply for any sort of insurance that they can afford. That's another thing that the community clinics can help with.

- Participant 119, Limited implementation group

Copay assistance as a solution to cost concerns

“Then we break down, well there is a Gilead co-pay system. There is different resources available to get PrEP to you at a very reasonable co-pay, if not for free. As soon as we're able to break down that barrier, then clients are a lot more apt to use PrEP.”

- Participant 113, Universal implementation group

“[The next question clients ask] Which is, ‘How am I supposed to afford PrEP?’ And then we have to go through the co-pay assistance program. Which I have the form there, but the doctor or the nurse fills it out for them. And I just walk them through that. And most of the time, the majority of the time, people get PrEP paid for like a year. The only thing you have to come up with, you have two initial visits. You see the doctor and then you'll go back to get your results and see the nurse and you'll pick up your prescription. And then you have to go get it filled. And then you have to have your three other blood tests for the rest of the year. So that's what you have to pay for.”

- Participant 105, Universal implementation group
“Yeah, I guess paying for PrEP is a big thing, because a lot of people don't know about the copay program, or if they're not insured, how to get it that way. The patient finance-assistance program, or not going through the health department, that kind of thing, those are an issue.”
– Participant 121, Eligibility Dependent implementation group

Financial help for PrEP outside of copay assistance

“We usually refer people to programs that we know do a real good job of getting people access to the medications with the least amount of grief, or based upon where they live, if it's like being more convenient for them to see one provider over another. We also have a provider that has been paying people’s insurance premiums in order to provide them with PrEP and then have the insurance pay for PrEP. If we come up on uninsured people, we sometimes will refer them to that provider, because we know that if people are insured, not only are they going to get full affordable care act health insurance, but they'll also get PrEP. They have health insurance, so that means that if they have any other conditions that they're suffering from, they will have health insurance and they'll be able to be seen for those other conditions.”
– Participant 104, Limited implementation group

“But we talk about the sliding fee that goes along with that at the health department and if they really need PrEP then they can go do this. And then there's a couple of little organizations here, and by organization I mean a few people who have banded together who, if a person really needs PrEP, like we think they are super at risk, and they are like “I want PrEP.” Then we can set them up with them and they may be able to provide some financial assistance.”
– Participant 105, Universal implementation group

“We're finding out, of course, as PrEP is becoming more prevalent, insurance companies are covering it. It's my understanding now that the state Florida has mandated to all of their health departments within each county and area that the health departments cover, that they are required. If they cannot offer PrEP within their clinics inside the Health Department, they are required to connect that individual to someone where they can receive PrEP based on their limitations or personal issues that might prevent them from going to just a standard clinic to sign and get PrEP.”
-- Participant 109, Limited implementation group

Community level HIV and PrEP-related stigma

“PrEP is easy to talk about. It's when you say the word HIV that people kind of shudder and pull back and get quiet that I find. When I say PrEP, they know what it's for, and so I don't have to say HIV or AIDS, and then the conversation is much more smooth.”
– Participant 110, Universal implementation group

“But we have a big split here. Like we have a very conservative population, a very religious population, but we also have the biggest [holiday] gathering, which is coming up this weekend, where we'll be at work. And that's on [City Name]. We have a very large split as far as low income Black and African-American hetero males and females. And then we have another group of MSMs [men who have sex with men] of all races and ethnicities. So it's kind of like this trifecta of stigma and discrimination and knowledge that you have to kind of work
around. Where all three groups have very, very different beliefs as it pertains to, especially PrEP. But whenever you start talking about HIV in general."

-- Participant 105, Universal implementation group

“Stigma is still a big thing. I don't know what it looks like to have a world free of stigma, because God knows I've never lived in one of them. As bad as that sounds ... but definitely like the stigma associated with it, because at the beginning of the whole Truvada as PrEP movement, you can actually look it up, there was an individual and I think he was in southern California, maybe LA -ish, but he started campaign called Truvada Whore.”

-- Participant 112, Eligibility Dependent implementation group

“But the areas tend to dictate the amount of stigma that's there and who may be providing the stigma, so to speak. Whether, you know, again it's from a religious perspective or some other perspective. The areas kind of determine that. But going back to the stigma, plays a huge part and it's what I personally say, that's what causes death when you're dealing with HIV. It's not HIV. Because if someone has HIV, you can live a healthy life and not die from it. But if to choose to die from it based on stigma and how stigma affects you, then of course HIV would then rain on that persons' life.”

-- Participant 109, Limited implementation group

Client perception of risks

“So I don't know a lot of women that are getting it because of, again I think that a lot of people still have the mind set of, 'It's a gay disease, so why should I worry about it?’. But I do mention in my classes that African-American women have now been put on the list of recommended recipients for PrEP, because the HIV infection is so high in the African-American community. So I try to emphasize that. That anybody should have access to PrEP, not just because you're gay or bisexual, but anyone in the ... and I give them the behaviors: multiple partners, sharing IV drugs, prostitution, solicitation, you have another STD. Go talk to your doctor, sharing IV needles. So if you fall in any of these categories, you are a strong candidate for PrEP, but anyone should go and talk to their doctor about PrEP.”

-- Participant 111, Universal implementation group

“A lot of times, I've found that the heterosexual women that I've dealt with really don't understand or see themselves as being at any risk until it’s too late. They don't think that they need to be on PrEP. I'm careful with my words because I do know that a lot of these women are certain that they're in a mutually monogamous relationship, that they're at no risk for HIV.”

-- Participant 100, Limited implementation group

“I don't think folks that are a little less aware of these things, sometimes have a skewed perception of risk. You know, 'I don't have to worry about it because I'm in a monogamous relationship', and the numbers don't seem to bear that out.”

-- Participant 104, Limited implementation group
## APPENDIX C: DESCRIPTION OF RATIONALE FOR INCLUSION/EXCLUSION OF CONSOLIDATED FRAMEWORK OF IMPLEMENTATION RESEARCH (CFIR) CONSTRUCTS

### Table C.1. Rationale for Inclusion and Exclusion of Consolidated Framework for Implementation Research (CFIR) Constructs

<table>
<thead>
<tr>
<th>Domain</th>
<th>Construct</th>
<th>Short Description</th>
<th>Rational for Inclusion/Exclusion</th>
<th>OCM and ORCA Past Items Used</th>
<th>Potential Item(s) for Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Characteristics</td>
<td>Intervention Source</td>
<td>Perception of key stakeholders about whether the intervention is externally or internally developed.</td>
<td>Exclude. PrEP is a pharmaceutical medical that must be developed outside of a clinical or social service organization. The way in which PrEP is implemented during HIV testing would naturally vary based upon location.</td>
<td>OCM 8b Project has been influenced strongly by: Successful applications from non-health care organizations; 8c Project has been influenced strongly by: Successful health care applications outside our organization</td>
<td>No items for the construct will be included</td>
</tr>
<tr>
<td>Intervention Characteristics</td>
<td>Evidence Quality &amp; Stakeholders’ perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.</td>
<td></td>
<td>Include. Some skeptics have questioned the efficacy of PrEP. This is also a common barrier to PrEP initiation. This may, or may not, be a barrier for staff to discuss PrEP during HIV testing. It has previously been found in the literature to be a client-level and provider-level barrier to PrEP initiation. Support: Hakre et al., 2016 Golub et al., 2013 Auerbach et al., 2015 Falcao et al., 2016</td>
<td>OCM 9a The change we have in mind: Is supported by concrete evidence from an organization similar to ours ORCA 1a. Based on your assessment of the evidence basis for this statement, please rate the strength of the evidence in your opinion, on a scale of 1 to 5 where 1 is very weak evidence and 5 is very strong evidence; 1b. Now, please rate the strength of the evidence basis for this statement based on how you think respected clinical experts in (your organization) feel about the strength of the evidence, on a 1 to 5 scale similar to the one above; 2a. The (proposed practice changes or guideline</td>
<td>• Based on your assessment of the evidence supporting PrEP, please rate the strength of the evidence in your opinion, on a scale of 1 to 5 where 1 is very weak evidence and 5 is very strong evidence. (adapted from ORCA measure 1a). • How confident are you that there is good research that shows PrEP can reduce HIV transmission? • Now, please rate the strength of the evidence supporting PrEP based on how you think respected clinical experts in your organization feel about the strength of the evidence, on a 1 to 5 scale similar to the one above. (adapted from ORCA measure 1b)</td>
</tr>
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implementation) are (is) supported by randomized control trials (RCTs) or other scientific evidence from the VA.; 2b. The (proposed practice changes or guideline implementation) are (is) supported by randomized control trials (RCTs) or other scientific evidence from other health care systems; 2c. The (proposed practice changes or guideline implementation) should be effective, based on current scientific knowledge; 3a. The (proposed practice changes or guideline implementation) are supported by clinical experience with VA patients; 3b. The (proposed practice changes or guideline implementation) are supported by clinical experience with patients in other health care systems; 4a. The (proposed practice changes or guideline implementation) have been well-accepted by VA patients in a pilot study; 4b. The (proposed practice changes or guideline implementation) are consistent with clinical practices that have been accepted by VA patients.

• PrEP use is supported by research or other scientific evidence. (adapted from ORCA measure 2a)
• Talking to my client about PrEP during HIV testing will result in fewer new cases of HIV in my community.
• Talking to my client about PrEP during HIV testing would result in more people in my community taking PrEP daily for HIV prevention

<table>
<thead>
<tr>
<th>Intervention Characteristics</th>
<th>Relative Advantage</th>
<th>Stakeholders’ perception of the advantage of implementing the intervention versus an alternative solution.</th>
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<tr>
<td></td>
<td></td>
<td>Include. Some disadvantages have been discussed with regard to PrEP implementation (e.g. risk compensation, resource deprivation). These may affect PrEP implementation during HIV testing.</td>
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<td></td>
<td></td>
<td>Support: Philpott, 2013 Sugarman &amp; Mayer, 2013 de Wit et al., 2015</td>
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<td></td>
<td></td>
<td>OCM 6d Staff, in general, are not depressed by the prospect of change; 9c. The change we have in mind: Appears to have many more advantages than disadvantages; 9d. The change we have in mind: Is likely to be supported by staff because they will believe that the advantages outweigh disadvantages</td>
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<tr>
<td></td>
<td></td>
<td>ORCA 4d. The (proposed practice changes or guideline implementation) appear to have</td>
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<td></td>
<td></td>
<td>Talking about or referring people to where they can get a prescription for PrEP has more advantages than disadvantages. – strongly disagree to strongly agree (adapted from OCM and ORCA)</td>
</tr>
<tr>
<td>Intervention Characteristics</td>
<td>Adaptable</td>
<td>More advantages than disadvantages for VA patients.</td>
</tr>
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<td>-----------------------------</td>
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<td>-----------------------------------------------------</td>
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<tr>
<td>The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.</td>
<td>Exclude. PrEP implementation during HIV testing can already be changed to meet local needs. PrEP as a medication cannot be adapted given its current FDA approval.</td>
<td>OCM 11a The likely change can be adapted to fit current situation; 11b The likely change can be adapted and retain effectiveness; 11c The adaptation will be ethically easy to make; 11d The adaptation will be politically easy to make.</td>
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<thead>
<tr>
<th>Intervention Characteristics</th>
<th>Trialability</th>
<th>No items for the construct will be included.</th>
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<tbody>
<tr>
<td>The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.</td>
<td>Exclude. While important, this cannot be assessed by staff performing HIV testing.</td>
<td>None</td>
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<tr>
<th>Intervention Characteristics</th>
<th>Complexity</th>
<th>No items for the construct will be included.</th>
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<tbody>
<tr>
<td>Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.</td>
<td>Include. The literature has suggested that training may be needed to implement PrEP. This may also be true among staff performing HIV testing.</td>
<td>None</td>
</tr>
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- Referring a client to a place they could talk to a provider about a PrEP prescription would be complicated.
- Talking to clients about PrEP during HIV testing would be too complicated.

<table>
<thead>
<tr>
<th>Intervention Characteristics</th>
<th>Design Quality &amp; Packaging</th>
<th>No items for the construct will be included.</th>
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<tbody>
<tr>
<td>Perceived excellence in how the intervention is bundled, presented, and assembled.</td>
<td>None</td>
<td>None</td>
</tr>
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Grov, Whitfield, Rendina, Ventuneac, & Parsons, 2015
Marcus et al., 2013
Sowicz, Teitelman, Coleman, & Brawner, 2014
158
### Intervention Characteristics

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<th>Cost</th>
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<tbody>
<tr>
<td>Cost of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.</td>
</tr>
</tbody>
</table>

Exclude. Cost, and the cost effectiveness, of PrEP implementation have been investigated in the literature. These concerns may be relevant to PrEP implementation at HIV testing sites. However, while important, this cannot be accurately assessed by staff performing HIV testing.

Support:
- Elion & Coleman, 2016
- Alistar, Owens, & Brandeau, 2014
- Gomez et al., 2013

### Outer Setting

<table>
<thead>
<tr>
<th>COSMOPOLITANISM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The degree to which an organization is networked with other external organizations.</strong></td>
</tr>
</tbody>
</table>

Include. There may be some pressures to learn about PrEP from other organizations. Cosmopolitanism may also increase an organization’s ability to refer clients to a provider who can prescribe PrEP.

Support:
- FLDOH, 2016a
- Smith et al., 2015
- Young and McDaid, 2014

None

- Senior leadership in your organization seek ways to improve patient education and increase patient participation in treatment.
- Senior leadership values asking clients what they think about how our services could be improved?
- The clients I serve would benefit from access to PrEP
- The clients I serve would appreciate the opportunity to learn about new ways to protect themselves from HIV
- I go to local, statewide or national meetings that discuss HIV prevention.
- If a client asked me about places they could go to get a PrEP prescription, I would know clinics or organizations to suggest to them.

### Outer Setting

<table>
<thead>
<tr>
<th>PEER PRESSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mimetic or competitive pressure to implement an</strong></td>
</tr>
</tbody>
</table>

Exclude. Competitive pressure may encourage organizations to include PrEP in HIV prevention.

None

- Other organizations in my community talk about (or refer people to organizations that provide) PrEP during HIV testing.
intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge. A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaborative, and public or benchmark reporting. Discussions. This can be noted through funding announcements that include PrEP. However, this may not be accurately assessed by staff performing HIV testing.

Sources: CDC, 2016a, 2016b, 2016c

OCM 8a Project has been influenced strongly by: Pressures from outside the organization

- Implementing PrEP (via education, interventions, or prescriptions) would make my organization more competitive for funding opportunities.

Outer Setting External Policy & Incentives

A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaborative, and public or benchmark reporting.

Research has shown providers may be more likely to adopt guidelines that are endorsed by professional organizations.

Sources: Vamos et al., 2015 White et al., 2012

OCM 8a Project has been influenced strongly by: Pressures from outside the organization

- How much have national PrEP guidelines (such as those from the CDC) impacted your view on PrEP implementation during HIV testing?
- How much have guidelines within your organization impacted your view on PrEP implementation during HIV testing?
- How much have international guidelines (such as those from the WHO) impacted your view on PrEP implementation during HIV testing?
- The organization I work for has formal guidelines (guidelines that are written or provided in training) in place about how, when, and if I should talk about PrEP when performing HIV testing, counseling, or testing. (Yes, this is true of the organization I work for; No, this is not true of the organization I work for)
- Do these guidelines state that you SHOULD talk about PrEP or that you SHOULD talk about PrEP during testing/counseling?

Inner Setting Structural Characteristics

The social architecture, age, maturity, and size of the organization may affect

ORCA 7b. Senior leadership/Clinical management in (your organization) clearly

- How would you describe the size of the organization you work for? Small, medium, or large?
| Inner Setting | Networks & Communications | The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization. | Define areas of responsibility and authority for clinical managers and staff. | OCM 3b Linkages and Communication: Senior Leadership: Mechanisms have been developed to keep leaders informed and involved 4b Linkages and Communication: Operating Unit Managers: Mechanisms have been defined to keep key managers informed and involved ORCA 5b. Senior leadership/clinical management in (your organization) solicit opinions of clinical staff regarding decisions about patient care. 7a. Senior leadership/Clinical management in (your organization) provide effective management for continuous improvement of patient care. 7c. Senior leadership/Clinical management in (your organization) promote team building to solve clinical care problems. 7d. Senior leadership/Clinical management in (your organization) promote communication among clinical services and units. 16a. Communication will be maintained through regular project meetings with the project champion and team members 16b. Communication will be maintained through involvement of quality management staff in project planning and implementation. |
| Inner Setting | Culture | Norms, values, and basic assumptions of an organization. | Organizational culture often affects implementation. This may define areas of responsibility and authority for clinical managers and staff. | • My organization has offices in multiple counties or states? • There are people in my organization I can talk to if I have a question about PrEP • Senior leadership in my organization reward |
given
organization.

be the case in implementing PrEP during HIV testing.

outside to fit our organization's way of doing things.

5a. Senior leadership/clinical management in (your organization) reward clinical innovation and creativity to improve patient care; 6a. Staff members in (your organization) have a sense of personal responsibility for improving patient care and outcomes; 6b. Staff members in (your organization) cooperate to maintain and improve effectiveness of patient care; 6c. Staff members in (your organization) are willing to innovate and/or experiment to improve clinical procedures; 6d. Staff members in (your organization) are open to change.

8a. Senior Leadership/clinical management in (your organization) provide staff with information on VA performance measures and guidelines; 8b. Senior Leadership/clinical management in (your organization) establish clear goals for patient care processes and outcomes; 8c. Senior Leadership/clinical management in (your organization) provide staff members with feedback/data on effects of clinical decisions; 8d. Senior Leadership/clinical management in (your organization) hold staff members accountable for achieving results; 11a. Senior leadership/clinical management will propose a project that is appropriate and feasible; 11b. innovation and creativity to improve client care.

• Staff members in my organization have a sense of personal responsibility for improving the health outcomes of the people we serve.

• Staff members in my organization cooperate to maintain and improve effectiveness of patient care.

• Staff members in my organization are open to change.

• Senior Leadership in my organization provide staff with information about PrEP.

• Senior Leadership in my organization provide staff members with feedback from clients who receive HIV testing.

• PrEP doesn't fit in with my organization's values.
<table>
<thead>
<tr>
<th>Inner Setting</th>
<th>Implementation Climate</th>
<th>The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.</th>
<th>Exclude. Although the idea of implementation climate is important, this will be assessed by PrEP related policy (either formal or informal). PrEP related implementation climate is also not persistent in the existing PrEP literature.</th>
<th>No items for the construct will be included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner Setting</td>
<td>Tension for Change</td>
<td>The degree to which stakeholders perceive the current situation as intolerable or needing change.</td>
<td>Include. Many Florida communities have high rates of HIV. This may contribute to the tension for change, and in turn affect PrEP implementation.</td>
<td>OCM 5a Informal opinion leaders really dislike current process; 6b Informal opinion leaders believe change is essential; 6c Staff, in general, are very upset with the current process</td>
</tr>
<tr>
<td>Inner Setting</td>
<td>Compatibility</td>
<td>The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with</td>
<td>OCM 5a Linkages and Communication: Operating Unit Staff: The project, if successful will meet staff needs. ORCA 3c. The (proposed practice changes or guideline implementation) conform to the opinions of clinical experts in this setting.</td>
<td>• Staff at my organization believe that new prevention methods are needed to stop the spread of HIV</td>
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<tr>
<td>Inner Setting</td>
<td>Relative Priority</td>
<td></td>
<td>Organizational Incentives &amp; Reward</td>
<td></td>
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<tr>
<td>---------------</td>
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<tr>
<td></td>
<td>Individuals’ own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.</td>
<td>Include. Organizations are often overworked and the relative priority of this task may be relevant.</td>
<td>Individuals’ shared perception of the importance of the implementation within the organization.</td>
<td>ORCA 13d. Senior leadership/clinical management/staff opinion leaders set a high priority on the success of the intervention.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.</td>
<td>OCM 14a The following items are likely to be set up to make the new solution work: Staff incentives</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exclude. There is no current evidence in the PrEP implementation literature to support the inclusion of this construct.</td>
<td>ORCA 18a. The following are available to make the selected plan work: staff incentives.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exclude. This cannot be accurately assessed by staff providing HIV testing.</td>
<td></td>
</tr>
<tr>
<td>Inner Setting</td>
<td>Learning Climate</td>
<td>A climate in which: a) leaders express their own fallibility and need for team members’ assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.</td>
<td>Include.</td>
<td>None</td>
</tr>
<tr>
<td>Inner Setting</td>
<td>Readiness for Implementation</td>
<td>Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.</td>
<td>Exclude</td>
<td>No items for the construct will be included</td>
</tr>
<tr>
<td>Inner Setting</td>
<td>Leadership Engagement</td>
<td>Commitment, involvement, and accountability of leaders and managers with the implementation.</td>
<td>Include. Because staff providing HIV testing are often employees, the views of leadership may impact their decisions to talk about PrEP.</td>
<td>OCM 1c Project launch: You and the Senior Leadership team: Indicated that not changing is unacceptable and set a firm deadline; 1d Project launch: You and the Senior Leadership team: Designated a champion/s to make the project succeed; 3c Linkages and Communication: Senior Leadership: Leaders have endorsed the project in visible ways; 4c Linkages and Communication: Senior Leadership: Leaders have endorsed the project in visible ways.</td>
</tr>
<tr>
<td>Inner Setting</td>
<td>Available Resources</td>
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<td>---------------</td>
<td>---------------------</td>
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<tr>
<td></td>
<td>The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.</td>
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<tr>
<td></td>
<td>Include. Research has suggested that availability of resources affects PrEP implementation.</td>
<td></td>
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</tbody>
</table>

**Communication: Operating Unit Managers:** Those operating unit managers openly endorse the project; 14b The following items are likely to be set up to make the new solution work:

- Leadership roles
  - ORCA 13b. Senior leadership/clinical management/staff opinion leaders will be informed and involved in the intervention; 13c. Senior leadership/clinical management/staff opinion leaders agree on adequate resources to accomplish the intervention

**OCM 3d Linkages and Communication: Senior Leadership:** Leaders have committed to spend their time & resources to remove obstacles when they arise; 4d Linkages and Communication: Operating Unit Managers: The operating unit managers have committed to spend their time & resources to remove obstacles when they arise in the project; 10a Enough money is available to support: The customer needs assessment

- 10b Enough money is available to support: Solution exploration (to identify key features of solutions); 10c Enough money is available to support: Solution development
- 10d Enough money is available to support: Implementation and Testing

- 14d The following items are likely to be set up to make the new solution work: Equipment and materials

- My organization gives out free condoms to clients who want them
- I have physical information (such as pamphlets or flyers) about HIV prevention that I give clients during HIV testing/counseling
- I have physical information (such as pamphlets or flyers) about PrEP that I give clients during HIV testing/counseling
- My organization has physical information (such as pamphlets or flyers) about PrEP available for clients to pick up if they are interested
- My organization has physical information (such as pamphlets or flyers) about HIV prevention available for clients to pick up if they are interested
- There is enough time during the HIV testing/counseling process to discuss PrEP
- My organization provides training to learn about updates in HIV prevention
<table>
<thead>
<tr>
<th>Inner Setting</th>
<th>Access to Knowledge &amp; Information</th>
<th>Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Include. Without access to knowledge and information about PrEP, PrEP implementation would be difficult.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>See Available Resources above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristics of Individuals</th>
<th>Knowledge &amp; Beliefs about the Intervention</th>
<th>Individuals’ attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Include. Personal attitudes, etc. toward PrEP may affect if a staff member discusses PrEP with clients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Items on knowledge, attitudes, and behavior scales in quantitative assessment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristics of Individuals</th>
<th>Self-efficacy</th>
<th>Individual belief in their own capabilities to execute courses of action to achieve implementation goals.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Include. A person must be confident in discussing PrEP or referring people to an outside organization to learn more about PrEP.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OCM 13d The changes in staff jobs are likely to be: Changes that staff believe are confident they can do well</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Items on knowledge, attitudes, and behavior scales in quantitative assessment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristics of Individuals</th>
<th>Individual Stage of Change</th>
<th>Characterization of the phase an individual is in, as</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Exclude. Exclude. Not yet included in the literature.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No items for the construct will be included</td>
</tr>
</tbody>
</table>

ORCA 14c. The implementation team members have release time or can accomplish intervention tasks within their regular work load; 14d. The implementation team members have staff support and other resources required for the project; 18b. The following are available to make the selected plan work: equipment and materials.

13b The changes in staff jobs are likely to be: Clearly spelled out in writing
13c The changes in staff jobs are likely to be: Supported by good training and training materials
14c The following items are likely to be set up to make the new solution work: Organization structure and documented procedures

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he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.

May be used for future work.

Characteristics of Individuals  | Individual Identification with Organization  | A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.

Exclude. Not yet included in the literature. May be used for future work.

None

No items for the construct will be included

Characteristics of Individuals  | Other Personal Attributes  | A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

Include. Personal attributes, such as prior PrEP use and personal values may affect PrEP implementation.

OCM 1a Project launch: You and the Senior Leadership team: Carefully selected the project; 1b Project launch: You and the Senior Leadership team: Provided a very clear aim for the project 7d Problem Exploration: Reviewed data proving the problem's severity 12a The plan for implementing the change will likely: Be detailed; 12b The plan for implementing the change will likely: Be simple; having no unnecessary or overly complex steps 12c The plan for implementing the change will likely: Have clear and realistic time schedule 12d The plan for

Items on knowledge, attitudes, and behavior scales and demographics

No items for the construct will be included

Process  | Planning  | The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.

Exclude. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.
implementing the change will likely be understood by those affected. 13a. The changes in staff jobs are likely to be: Few in number.

ORCA 15a. The implementation plan for this intervention identifies specific roles and responsibilities. 15b. The implementation plan for this intervention clearly describes tasks and timelines. 15c. The implementation plan for this intervention includes appropriate provider/patient education. 15d. The implementation plan for this intervention acknowledges staff input and opinions. 18f. The following are available to make the selected plan work: evaluation protocol. 19a. Plans for evaluation and improvement of this intervention include periodic outcome measurement. 19b. Plans for evaluation and improvement of this intervention include staff participation/satisfaction survey. 19c. Plans for evaluation and improvement of this intervention include patient satisfaction survey. 19d. Plans for evaluation and improvement of this intervention include dissemination plan for performance measures. 19e. Plans for evaluation and improvement of this intervention include review of results by clinical leadership.

Process Engaging Attracting and involving appropriate individuals in the implementation

Exclude. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.

OCM 7c. Problem Exploration: Personally experienced the problem - Someone has assessed my ability to talk about PrEP during HIV testing.
<table>
<thead>
<tr>
<th>Process</th>
<th>Opinion Leaders</th>
<th>Excluded. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.</th>
<th>OCM 5b Linkages and Communication: Operating Unit Staff: Mechanisms have been developed to inform and involve staff opinion leaders; 5c Linkages and Communication: Operating Unit Staff: Staff opinion leaders openly endorse the project 5d Linkages and Communication: Operating Unit Staff: Informal leaders have committed to spend time &amp; resources to support the project ORCA 14a. The implementation team members share responsibility for the success of this project; 14b. The implementation team members have clearly defined roles and responsibilities. 18e. The following are available to make the selected plan work: intervention team.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process</td>
<td>Formally Appointed Internal Implementation Leaders</td>
<td>Excluded. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.</td>
<td>No items for the construct will be included</td>
</tr>
<tr>
<td>Process</td>
<td>Champions</td>
<td>Excluded. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.</td>
<td>OCM 2a Project champion: Is very committed to making this project successful 2b Project champion: Has substantial power to make things happen 2c Project champion: No items for the construct will be included</td>
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<tr>
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</tbody>
</table>
an implementation, overcoming indifference or resistance that the intervention may provoke in an organization.

Has substantial prestige in the organization

2d Project champion: Shows respect for the involved staff

ORCA 12a. The project clinical champion accepts responsibility for the success of this project. 12b. The project clinical champion has the authority to carry out the implementation. 12c. The project clinical champion is considered a clinical opinion leader. 12d. The project clinical champion works well with the intervention team and providers. 18d. The following are available to make the selected plan work: provider buy-in.

7b Problem Exploration: Involved many staff to understand the problem
7a Problem Exploration: Involved many customers to understand the problem that will be attacked

No items for the construct will be included

<table>
<thead>
<tr>
<th>Process</th>
<th>External Change Agents</th>
<th>Excluding. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.</th>
<th>7b Problem Exploration: Involved many staff to understand the problem. 7a Problem Exploration: Involved many customers to understand the problem that will be attacked.</th>
<th>No items for the construct will be included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process</td>
<td>Executing</td>
<td>Excluding. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.</td>
<td>15d Small pilot tests of the improvement are set up to: Use results to make continued improvements.</td>
<td>No items for the construct will be included</td>
</tr>
<tr>
<td>Process</td>
<td>Reflecting &amp; Evaluating</td>
<td>Excluding. Constructs related to the Process domain cannot be accurately measured via staff performing HIV testing.</td>
<td>OCM 15a Small pilot tests of the improvement are set up to: Collect honest reactions from customers; 15b Small pilot tests of the improvement are set up to: Collect honest reactions from staff; 15c Small pilot tests of the improvement are set up to: Publicly display performance measures over time.</td>
<td>No items for the construct will be included</td>
</tr>
</tbody>
</table>
about progress and experience.

**ORCA**

16c. Communication will be maintained through regular feedback to clinical management on progress of project activities and resource needs; 16d. Communication will be maintained through regular feedback to clinicians on effects of practice changes on patient care/outcomes; 17a. Progress of the project will be measured by collecting feedback from patients regarding proposed/implemented changes; 17b. Progress of the project will be measured by collecting feedback from staff regarding proposed/implemented changes. 17c. Progress of the project will be measured by developing and distributing regular performance measures to clinical staff; 17d. Progress of the project will be measured by providing a forum for presentation/discussion of results and implications for continued improvements.
APPENDIX D: QUANTITATIVE INSTRUMENT

Eligibility

<table>
<thead>
<tr>
<th>Items</th>
<th>Question Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Which of the following statements is true of you? Please select all that apply.</td>
<td>N/A</td>
</tr>
<tr>
<td>a. Part of my job (or all of my job) is to provide HIV testing/counseling with clients</td>
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<tr>
<td>b. I volunteer with an organization and provide HIV testing and/or counseling to clients</td>
<td></td>
</tr>
<tr>
<td>c. I work at an organization that provides HIV testing, but I do not test for HIV or take part in the testing/counseling process</td>
<td></td>
</tr>
<tr>
<td>d. My work is not related to HIV prevention</td>
<td></td>
</tr>
<tr>
<td>2. When was the last time you tested/counseled someone for HIV?</td>
<td>N/A</td>
</tr>
<tr>
<td>a. Within the past 3 months</td>
<td></td>
</tr>
<tr>
<td>b. Not within the last 3 months, but within the past 6 months</td>
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</tr>
<tr>
<td>c. Between 6 months to a year ago</td>
<td></td>
</tr>
<tr>
<td>d. More than a year ago</td>
<td></td>
</tr>
<tr>
<td>3. How old are you?</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Organization/Work Characteristics

First, I have a few questions about where you are working. I am only asking the next two questions to make sure the same person does not answer the survey twice.

<table>
<thead>
<tr>
<th>Items</th>
<th>Question Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of the organization you work for? All of your information will be kept private and your answers will not be shared with anyone at your work place.</td>
<td>N/A</td>
</tr>
<tr>
<td>What are your initials?</td>
<td>N/A</td>
</tr>
<tr>
<td>1. Who do you primarily serve?</td>
<td>N/A</td>
</tr>
<tr>
<td>a. Rural clients</td>
<td></td>
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<tr>
<td>b. Urban clients</td>
<td></td>
</tr>
<tr>
<td>c. A mix of both rural and urban clients</td>
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</tr>
<tr>
<td>2. What type of organization do you work for?</td>
<td>N/A</td>
</tr>
<tr>
<td>a. Community based organization</td>
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<tr>
<td>b. AIDS service organization</td>
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<tr>
<td>c. Clinic</td>
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<tr>
<td>d. Government agency</td>
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<tr>
<td>e. Other (describe)</td>
<td></td>
</tr>
</tbody>
</table>
### HIV Testing and Prevention Discussions

1. How often do you discuss the following during HIV testing? [Source: N/A]

<table>
<thead>
<tr>
<th>Topic</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV transmission methods and relative risk</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Regular testing for HIV</td>
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<tr>
<td>Condom use</td>
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<tr>
<td>Monogamy</td>
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<tr>
<td>Abstinence (or waiting to have sex)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partner testing</td>
<td></td>
<td></td>
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<tr>
<td>PEP</td>
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<tr>
<td>PrEP</td>
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<tr>
<td>Treatment as Prevention</td>
<td></td>
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</tr>
</tbody>
</table>

### Organizational PrEP Implementation Outcomes  [Source: N/A]

1. The organization I work for has formal guidelines (guidelines that are written or provided in training) about how, when, or if I should talk about PrEP when performing HIV testing or counseling.
   a. Yes, this is true of the organization I work for;
   b. No, this is not true of the organization I work for

   **Leadership Engagement (strongly disagree to strongly agree)**
   - My organization requires that I talk to clients about PrEP
   - My organization prohibits counselors from talking about PrEP

   **Also listed under Available Resources & Access to Knowledge & Information (strongly disagree to strongly agree)**
   2. At my organization there is physical information (such as pamphlets or flyers) about PrEP available for clients to pick up if they are interested
   3. At my organization there is a formal referral system set up if someone is interested in starting PrEP
   4. My organization has medical professionals (doctors, nurse practitioners, etc.) on site who could prescribe PrEP if a client was eligible and interested
**Individual PrEP Implementation Outcomes**  [Source: N/A]

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Yes; No)</strong></td>
<td></td>
</tr>
<tr>
<td>1. I talk to clients about PrEP when I think they might be eligible</td>
<td></td>
</tr>
<tr>
<td>2. I talk to clients about PrEP every time I test for HIV</td>
<td></td>
</tr>
<tr>
<td><strong>Also items under Available Resources &amp; Access to Knowledge &amp; Information (only asked once)</strong></td>
<td></td>
</tr>
<tr>
<td>3. I give physical information (such as pamphlets or flyers) about PrEP to clients during HIV testing/counseling</td>
<td></td>
</tr>
</tbody>
</table>
**PrEP Implementation CFIR Questions**

Note: Adapted from ORCA and OCM measures and CFIR definitions (Damschroder, 2016)

**Intervention Characteristics**

<table>
<thead>
<tr>
<th>Construct</th>
<th>Item(s)</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Evidence Strength &amp; Quality</strong></td>
<td>• There is good research that shows PrEP can reduce HIV transmission.</td>
<td>• On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• Talking to my client about PrEP during HIV testing would result in fewer new cases of HIV in my community.</td>
<td>• Higher the score, greater belief in evidence strength and quality</td>
</tr>
<tr>
<td></td>
<td>• Talking to my client about PrEP during HIV testing would result in more people in my community taking PrEP daily for HIV prevention</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• More research is needed to determine if PrEP can reduce the risk of HIV transmission. (reverse coded)</td>
<td></td>
</tr>
<tr>
<td><strong>Relative Advantage</strong></td>
<td>• Talking about PrEP during HIV testing/counseling has more advantages than disadvantages.</td>
<td>• On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• Referring people to where they can get a prescription for PrEP during the HIV testing/counseling has more advantages than disadvantages.</td>
<td>• Higher the score, greater belief in relative advantage</td>
</tr>
<tr>
<td><strong>Complexity</strong></td>
<td>• Referring a client to a place where they could talk to a provider about PrEP would be too complicated. (reverse coded)</td>
<td>• On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• Talking to clients about PrEP during HIV testing would be too complicated. (reverse coded)</td>
<td>• Higher the score, greater belief in complexity</td>
</tr>
</tbody>
</table>

**Outer Setting**

<table>
<thead>
<tr>
<th>Construct</th>
<th>Item(s)</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Needs &amp; Resources</strong></td>
<td>• Leadership at my organization seeks ways to improve client education about HIV.</td>
<td>• On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• Leadership at my organization values asking clients what they think about how our services could be improved.</td>
<td>• Higher the score, greater belief in patient needs and resources</td>
</tr>
<tr>
<td></td>
<td>• The clients I serve would benefit from access to PrEP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The clients I serve would appreciate the opportunity to learn about new ways to protect themselves from HIV</td>
<td></td>
</tr>
<tr>
<td><strong>Cosmopolitanism</strong></td>
<td>• I go to local, statewide or national meetings that discuss HIV prevention.</td>
<td>• On a scale from strongly disagree to strongly agree</td>
</tr>
</tbody>
</table>
• I go to local, statewide or national meetings that discuss PrEP.
• If a client asked me about places they could go to get a PrEP prescription, I would know clinics or organizations to suggest.

Higher the score, greater cosmopolitanism

External Policy & Incentives
• National PrEP guidelines (such as those from the CDC) have impacted my view on PrEP implementation during HIV testing
• Internal organization guidelines have impacted my view on PrEP implementation during HIV testing
• International guidelines (such as those from the WHO) have impacted my view on PrEP implementation during HIV testing

On a scale from strongly disagree to strongly agree
Higher the score, greater pro-PrEP External Policy & Incentives

Inner Setting

<table>
<thead>
<tr>
<th>Construct</th>
<th>Item(s)</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural</td>
<td>• How would you describe the size of the organization you work for?</td>
<td>Individual items</td>
</tr>
<tr>
<td>Characteristics</td>
<td>Small, medium, or large?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Does your organization have offices in multiple counties or states?</td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td>• Leadership in my organization rewards innovation and creativity.</td>
<td>On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• Staff members in my organization have a sense of personal responsibility for improving the health outcomes of the people we serve.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Staff members in my organization are open to change.</td>
<td>Higher the score, greater pro-PrEP culture</td>
</tr>
<tr>
<td></td>
<td>• PrEP doesn’t fit in with my organization’s values.</td>
<td></td>
</tr>
<tr>
<td>Tension for Change</td>
<td>• Staff at my organization believe that new prevention methods are needed to stop the spread of HIV</td>
<td>On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• I believe that new prevention methods are needed to stop the spread of HIV</td>
<td>Higher the score, greater tension for change</td>
</tr>
<tr>
<td>Compatibility</td>
<td>• People in my organization think PrEP could help to decrease the spread of HIV</td>
<td>On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td>• I think PrEP could help to decrease the spread of HIV</td>
<td>Higher the score, greater compatibility</td>
</tr>
<tr>
<td>Relative Priority</td>
<td>• Talking about PrEP during HIV testing is less important than talking about other HIV prevention methods. R</td>
<td>On a scale from strongly disagree to strongly agree</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Higher the score, greater degree of relative priority</td>
</tr>
</tbody>
</table>
### Learning Climate

- I can decide what I should talk to clients about when I am testing/counseling for HIV.
- I have an important role in HIV prevention.
- I have an important role in educating clients about PrEP.

- On a scale from strongly disagree to strongly agree
- Higher the score, greater pro-PrEP learning climate

### Available Resources & Access to Knowledge & Information

- My organization gives out free condoms to clients who want them.
- I give clients physical information (such as pamphlets or flyers) about HIV prevention during HIV testing/counseling.
- There is physical information (such as pamphlets or flyers) about HIV prevention at my organization available for clients to pick up if they are interested.
- There is enough time during the HIV testing/counseling process to discuss PrEP.
- My organization has a referral system set up if someone tests positive for HIV.

- On a scale from strongly disagree to strongly agree
- Higher the score, greater PrEP-related available resources & access to knowledge and information

### Characteristics of Individuals

Skip patterns will be inserted for staff based on if they do, or do not, prescribe.

<table>
<thead>
<tr>
<th>Construct</th>
<th>Item(s)</th>
<th>Scoring</th>
</tr>
</thead>
</table>
| **Knowledge & Beliefs about the Intervention** | **Participant PrEP knowledge** [Walsh & Petroll, 2016]  
1. According to current guidance, is HIV antibody testing suggested prior to initiating PrEP in a patient who is not experiencing any symptoms?  
a. Yes  
b. No  
c. I don’t know  
Original question listed below. Will consider removing the question.  
2. How many antiretroviral medications are in the regimen that is FDA-approved for PrEP?  
a. 1  
b. 2  
c. 3  
d. 4  
e. Not sure/Don’t know | • Scored as correct or incorrect |
Original item listed below. Will consider taking the other options out, and only keep in the combined option, Truvada.

4. Which antiretroviral medication(s) are FDA-approved for PrEP? (choose all that apply)
   - a. Zidovudine, also known as AZT or Retrovir
   - b. Lamivudine, also known as 3TC or Epivir
   - c. Abacavir, also known as Ziagen
   - d. Tenofovir, also known as Viread
   - e. Emtricitabine, also known as FTC or Emtriva
   - f. Lopinavir, also known as Kaletra
   - g. Efavirenz, also known as Sustiva
   - h. Emtricitabine + tenofovir, also known as Truvada
   - i. Emtricitabine + tenofovir + efavirenz, also known as Atripla
   - j. Not sure/don't know

5. What is the FDA-approved dosing frequency for the antiretrovirals used for PrEP?
   - a. Once weekly
   - b. Immediately prior to sexual activity
   - c. Once daily
   - d. Immediately following sexual activity
   - e. Twice daily
   - f. Three times per day
   - g. Not sure/don't know

6. Which of the following is a relative contraindication to prescribing PrEP?
   - a. Reduced creatinine clearance (<50 mL/min)
   - b. Squamous cell carcinoma of the skin
   - c. Previous myocardial infarction
   - d. Hypertension
   - e. Obesity
   - f. None of the above
   - g. Not sure/don't know

7. How often should individuals be tested for HIV while taking PrEP?
   - a. Weekly
   - b. Every 2-3 months

| 179 |
| c. Every 6 months  
| d. Annually  
| e. Monthly  
| f. Not sure/don’t know  
| g. Other: _______________________

8. In the U.S., what is the approximate retail cost of the antiretrovirals used for PrEP (without insurance coverage)?
   a. $50/month  
   b. $2,400/month  
   c. $200/month  
   d. $1,200/month  
   e. Not sure/don’t know

Participant PrEP knowledge [Blumenthal et al., 2015]
1. How often should patients on PrEP be followed for medication side effects and lab toxicities after initial assessment? (PrEPMonitor)
   a. Every month  
   b. Every 3 months  
   c. Every 6 months  
   d. Yearly  
   e. Not necessary to monitor after the first year

PrEP attitudes (Walsh & Petroll, 2016; 1=completely disagree, 5=completely agree)
1. PrEP can be a cost-effective HIV prevention intervention if used with an appropriate population of patients.
2. PrEP is too costly to warrant its use. (R)
3. Individuals who are at risk for HIV should be encouraged to use condoms rather than to take PrEP. (R)
4. Individuals who take PrEP are likely to increase their sexual risk behaviors and negate the benefits of PrEP. (R)
5. Individuals who take PrEP are likely to have increased rates of sexually transmitted infections. (R)
6. Money should not be spent on HIV prevention for men who have sex with men. (R)
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>7.</td>
<td>There is insufficient evidence at this time for me to consider PrEP an appropriate preventive treatment option. (R)</td>
</tr>
<tr>
<td>8.</td>
<td>Widespread use of PrEP will likely significantly increase rates of antiretroviral resistance. (R)</td>
</tr>
<tr>
<td>9.</td>
<td>Individuals who are prescribed PrEP are not likely to adhere to their medication. (R)</td>
</tr>
<tr>
<td><strong>Self-efficacy</strong></td>
<td>Self-efficacy (Described by Walsh &amp; Petroll, 2016 as Behavioral skills): Comfort prescribing PrEP, (1=completely uncomfortable, 5=completely comfortable)</td>
</tr>
<tr>
<td>1.</td>
<td>Determining whether a patient’s sexual risk behaviors warrant the use of PrEP.</td>
</tr>
<tr>
<td>2.</td>
<td>Determining whether a patient’s IV drug use behaviors warrant the use of PrEP.</td>
</tr>
<tr>
<td>4.</td>
<td>Discussing whether PrEP is a good option for a patient.</td>
</tr>
<tr>
<td>5.</td>
<td>Discussing the potential side effects of the antiretroviral medications used for PrEP (emtricitabine and tenofovir, together called Truvada) with a patient.</td>
</tr>
<tr>
<td>6.</td>
<td>Prescribing PrEP to a patient for whom PrEP was appropriate and no contraindications were apparent.</td>
</tr>
<tr>
<td>7.</td>
<td>Determining whether a patient has a contraindication to using PrEP.</td>
</tr>
<tr>
<td>8.</td>
<td>Following patients on PrEP to monitor for side effects.</td>
</tr>
<tr>
<td>9.</td>
<td>Following patients on PrEP to test them for HIV.</td>
</tr>
<tr>
<td><strong>Other Personal Attributes</strong></td>
<td>Please answer the questions below. If you do not feel comfortable answering a question you can skip the question and move on to the next one.</td>
</tr>
<tr>
<td>1.</td>
<td>What is the highest level of education you have achieved?</td>
</tr>
<tr>
<td>a.</td>
<td>Some high school</td>
</tr>
<tr>
<td>b.</td>
<td>High school/GED</td>
</tr>
<tr>
<td>c.</td>
<td>Associates degree</td>
</tr>
<tr>
<td>d.</td>
<td>Some college</td>
</tr>
<tr>
<td>e.</td>
<td>Bachelor’s degree</td>
</tr>
<tr>
<td>f.</td>
<td>Master’s degree</td>
</tr>
<tr>
<td>g.</td>
<td>Professional degree (J.D., M.D. etc.)</td>
</tr>
</tbody>
</table>

- On a scale from completely uncomfortable to completely comfortable
- Higher the score, greater self-efficacy
<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>h. Doctoral degree (Ph.D.)</td>
<td></td>
</tr>
<tr>
<td>2. How would you describe yourself?</td>
<td></td>
</tr>
<tr>
<td>a. Male</td>
<td></td>
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<tr>
<td>b. Female</td>
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</tr>
<tr>
<td>c. Transgender male to female</td>
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<tr>
<td>d. Transgender female to male</td>
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<tr>
<td>e. Another gender</td>
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<tr>
<td>3. Have you ever had sex with a man?</td>
<td></td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
<tr>
<td>4. Have you ever had sex with a woman?</td>
<td></td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
<tr>
<td>5. How would you describe your sexual orientation?</td>
<td></td>
</tr>
<tr>
<td>a. Heterosexual (straight)</td>
<td></td>
</tr>
<tr>
<td>b. Homosexual (gay/lesbian)</td>
<td></td>
</tr>
<tr>
<td>c. Bisexual</td>
<td></td>
</tr>
<tr>
<td>d. Another sexual orientation</td>
<td></td>
</tr>
<tr>
<td>6. Have you ever taken PrEP?</td>
<td></td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
<tr>
<td>7. Are you currently on PrEP?</td>
<td></td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
<tr>
<td>8. Have you ever taken PEP?</td>
<td></td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
<tr>
<td>9. What is your HIV status?</td>
<td></td>
</tr>
<tr>
<td>a. I am living with HIV</td>
<td></td>
</tr>
<tr>
<td>b. I am not living with HIV</td>
<td></td>
</tr>
<tr>
<td>c. I am not sure of my HIV status</td>
<td></td>
</tr>
<tr>
<td>10. (If yes to living with HIV). Are you currently in treatment?</td>
<td></td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
</tbody>
</table>
**Introduction to Contact Information**

<table>
<thead>
<tr>
<th>Items</th>
<th>Question Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Would you like to be entered into a raffle to receive one of three $50 gift cards?</td>
<td>Adapted from Dr. Marhefka Survey</td>
</tr>
<tr>
<td>2. For the second part of my study, I plan to follow up with about 20 people to do an interview via phone or video-conferencing. I will offer a $20 gift card to everyone who completes the interview. This will help me to complete my dissertation research and it will contribute to the literature on HIV prevention. Would you be willing to let me contact you?</td>
<td>Adapted from Dr. Marhefka Survey</td>
</tr>
<tr>
<td>a. Yes</td>
<td></td>
</tr>
<tr>
<td>b. No</td>
<td></td>
</tr>
</tbody>
</table>

**Gift Card Raffle**

If you would like to be entered into the gift card raffle, please provide your contact information below. If you are selected for the gift card I will contact you using the information you provide.

<table>
<thead>
<tr>
<th>Items</th>
<th>Question Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name: ___________</td>
<td>Adapted from Dr. Marhefka Survey</td>
</tr>
<tr>
<td>Email: _______________</td>
<td></td>
</tr>
<tr>
<td>Phone number: ___________</td>
<td></td>
</tr>
<tr>
<td>Preferred gift card: (List of options provided)</td>
<td></td>
</tr>
</tbody>
</table>

**Future Contact**

<table>
<thead>
<tr>
<th>Items</th>
<th>Question Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. If yes, please provide the following:</td>
<td>N/A</td>
</tr>
<tr>
<td>First name: ___________</td>
<td></td>
</tr>
<tr>
<td>Email: _______________</td>
<td></td>
</tr>
<tr>
<td>Phone number: ___________</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX E: FINAL SCALE DECISIONS

Table E.1. Rationale for Scale Use and/or Development

<table>
<thead>
<tr>
<th>Scale</th>
<th>Scale Cronbach’s Alpha</th>
<th>Items in survey</th>
<th>Items in analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Scale Statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>Variance</td>
<td>Std. Deviation</td>
</tr>
<tr>
<td></td>
<td>4.1733</td>
<td>2.359</td>
<td>1.53591</td>
</tr>
<tr>
<td></td>
<td>Reliability Statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cronbach’s Alpha</td>
<td>N of Items</td>
<td></td>
</tr>
<tr>
<td></td>
<td>.658</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. According to current guidance, is HIV antibody testing suggested prior to initiating PrEP in a patient who is not experiencing any symptoms?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Which antiretroviral medication(s) are FDA-approved for PrEP? (choose all that apply)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. How often is the FDA-approved dosing for PrEP?</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>4. Which of the following might make a doctor question prescribing PrEP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. How often should individuals be tested for HIV while taking PrEP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. How often should patients be followed for medication side effects after starting PrEP?</td>
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</tr>
<tr>
<td><strong>Attitudes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Scale Statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>Variance</td>
<td>Std. Deviation</td>
</tr>
<tr>
<td></td>
<td>37.9510</td>
<td>33.261</td>
<td>5.76726</td>
</tr>
<tr>
<td></td>
<td>Reliability Statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cronbach’s Alpha</td>
<td>N of Items</td>
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</tr>
<tr>
<td></td>
<td>.772</td>
<td>.779</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>1. PrEP can be a cost-effective HIV prevention intervention if used with an appropriate population of patients. (Q31_1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. PrEP is too costly to warrant its use. (R) (Q31_2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Individuals who are at risk for HIV should be encouraged to use condoms rather than to take PrEP. (R) (Q31_3)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>4. Individuals who take PrEP are likely to increase their sexual risk behaviors and negate the benefits of PrEP. (R) (Q31_4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>All items kept in analysis</td>
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<tr>
<td>*</td>
<td>Missingness counted as incorrect</td>
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184
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5. Money should not be spent on HIV prevention for men who have sex with men. (R) Q31_5
6. There is insufficient evidence at this time for me to consider PrEP an appropriate preventive treatment option. (R) Q31_6
7. Widespread use of PrEP will likely significantly increase rates of antiretroviral resistance. (R) Q31_7
8. Individuals who are prescribed PrEP are not likely to adhere to their medication. (R) Q31_8
9. Individuals who take PrEP are likely to have increased rates of sexually transmitted infections. R Q31_9
10. There are resources available to help people to pay for PrEP if they cannot afford it on their own. Q31_10

### Self-efficacy

<table>
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<tr>
<th>Case Processing Summary</th>
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a. Listwise deletion based on all variables in the procedure.

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<tr>
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<td></td>
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<tr>
<td>Cronbach’s Alpha Based on Standardized Items</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>N of Items</td>
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1. Determining whether a patient’s sexual risk behaviors warrant the use of PrEP. Q32_1
2. Determining whether a patient’s IV drug use behaviors warrant the use of PrEP. Q32_2
3. Discussing the efficacy of PrEP with a patient. Q32_3
4. Discussing whether PrEP is a good option for a patient. Q32_4
5. Discussing the potential side effects of the antiretroviral medications used for PrEP (emtricitabine and tenofovir, together called Truvada) with a patient. Q32_5
6. Following patients on PrEP to test them for HIV. Q32_9

- All items kept in analysis
- Average value used for missingness
| Culture | With all items: |  |  |  |  |
| --- | --- |  |  |  |  |
| Reliability Statistics | Cronbach's Alpha | Based on Standardized Items | N of Items |  |  |
| Cronbach's Alpha | .628 | .647 | 4 |  |  |
| With item Q19_4_Recode removed |  |  |  |  |  |
| Reliability Statistics | Cronbach's Alpha | Based on Standardized Items | N of Items |  |  |
| Cronbach's Alpha | .747 | .761 | 3 |  |  |
| • Leadership in my organization rewards innovation and creativity. Q19_1 |  |  |  |  |  |
| • Staff members in my organization have a sense of personal responsibility for improving the health outcomes of the people we serve. Q19_2 |  |  |  |  |  |
| • Staff members in my organization are open to change. Q19_3 |  |  |  |  |  |
| • PrEP doesn’t fit in with my organization’s values. R Q19_4 |  |  |  |  |  |
| REMOVED – by removing this item negatively coded so this may have affected the scaling. This was also the only item that specifically mentioned PrEP. |  |  |  |  |  |

| Compatibility |  |  |  |  |  |
| Reliability Statistics | Cronbach's Alpha | Based on Standardized Items | N of Items |  |  |
| Cronbach's Alpha | .649 | .656 | 2 |  |  |
| • People in my organization think PrEP could help to decrease the spread of HIV Q19_7 |  |  |  |  |  |
| • I think PrEP could help to decrease the spread of HIV Q39_8 |  |  |  |  |  |

| Relative Priority | N/A single item |  |  |  |  |
| • Talking about PrEP during HIV testing is less important than talking about other HIV prevention methods. R Q39_9 |  |  |  |  |  |
| • Single item |  |  |  |  |  |
| • No missingness |  |  |  |  |  |

<p>| Learning Climate | Cronbachs alpha without removing item: |  |  |  |  |
| Reliability Statistics | Cronbach's Alpha | Based on Standardized Items | N of Items |  |  |
| Cronbach's Alpha | .564 | .638 | 3 |  |  |
| With item removed: |  |  |  |  |  |
| Reliability Statistics | Cronbach's Alpha | Based on Standardized Items | N of Items |  |  |
| Cronbach's Alpha | .564 | .638 | 3 |  |  |
| • I can decide what I should talk to clients about when I am testing/counseling for HIV. Q39_10 |  |  |  |  |  |
| • I have an important role in HIV prevention Q39_11 |  |  |  |  |  |
| • I have an important role in educating clients about PrEP Q39_12 |  |  |  |  |  |
| • I can decide what I should talk to clients about when I am testing/counseling for HIV. Q39_10 |  |  |  |  |  |
| REMOVED – by removing this item Cronbachs alpha changed from .564 to .743 |  |  |  |  |  |
| • No missingness |  |  |  |  |  |</p>
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<th>Based on Standardized Items</th>
<th>N of Items</th>
<th>Notes</th>
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<tbody>
<tr>
<td><strong>Patient Needs</strong></td>
<td><strong>Leadership at my organization seeks ways to improve client education about HIV. Q44_1</strong></td>
<td><strong>Leadership at my organization values asking clients what they think about how our services could be improved. Q44_2</strong></td>
<td>The clients I serve would benefit from access to PrEP Q44_3</td>
<td>The clients I serve would appreciate the opportunity to learn about new ways to protect themselves from HIV Q44_13</td>
<td>1 item missing for 44_13, replaced with mean</td>
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<tr>
<td></td>
<td><strong>Leadership at my organization seeks ways to improve client education about HIV. Q44_1</strong></td>
<td><strong>Leadership at my organization values asking clients what they think about how our services could be improved. Q44_2</strong></td>
<td>The clients I serve would benefit from access to PrEP Q44_3</td>
<td>The clients I serve would appreciate the opportunity to learn about new ways to protect themselves from HIV Q44_13</td>
<td>1 item missing for 44_13, replaced with mean</td>
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<tr>
<td><strong>Cosmopolitanism</strong></td>
<td><strong>I go to local, statewide or national meetings that discuss HIV prevention. Q49_5</strong></td>
<td><strong>I go to local, statewide or national meetings that discuss PrEP. Q49_6</strong></td>
<td>If a client asked me about places they could go to get a PrEP prescription, I would know clinics or organizations to suggest. Q49_7</td>
<td></td>
<td>Q49_5 missing 1, Q49_6 missing 2; Q49_7 missing 1</td>
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<tr>
<td><strong>External policy and incentives</strong></td>
<td><strong>National PrEP guidelines (such as those from the CDC) have impacted my view on PrEP implementation during HIV testing Q44_10</strong></td>
<td><strong>Internal organization guidelines have impacted my view on PrEP implementation during HIV testing Q44_11</strong></td>
<td><strong>International guidelines (such as those from the WHO) have impacted my view on PrEP implementation during HIV testing Q44_12</strong></td>
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<td>Q44_12 missing 3 participants, used mean to replace</td>
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<td>Items in survey</td>
<td>Items in analysis</td>
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<tr>
<td><strong>Complexity</strong></td>
<td>Cronbach's Alpha Based on Standardized Items N of Items</td>
<td>• Referring a client to a place where they could talk to a provider about PrEP would be too complicated. (reverse coded) Q17_7 New: Q17_7_Recode • Talking to clients about PrEP during HIV testing would be too complicated. (reverse coded) Q17_8 New: Q17_8_Recode</td>
<td>• No missingness</td>
<td></td>
<td></td>
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<tr>
<td><strong>Evidence</strong></td>
<td>Cronbach's Alpha Based on Standardized Items N of Items</td>
<td>• There is good research that shows PrEP can reduce HIV transmission. Q17_1 • Talking to my client about PrEP during HIV testing would result in fewer new cases of HIV in my community. Q17_2 • Talking to my client about PrEP during HIV testing would result in more people in my community taking PrEP daily for HIV prevention Q17_3 More research is needed to determine if PrEP can reduce the risk of HIV transmission. (reverse coded) Q17_4 New variable Q17_4_Recode</td>
<td>• 4 missing, replaced with mean</td>
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<tr>
<td><strong>Relative advantage</strong></td>
<td>Cronbach's Alpha Based on Standardized Items N of Items</td>
<td>• Talking about PrEP during HIV testing/counseling has more advantages than disadvantages. Q17_5 • Referring people to where they can get a prescription for PrEP during the HIV testing/counseling has more advantages than disadvantages. Q17_6</td>
<td>• No missingness</td>
<td></td>
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</tr>
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</table>
APPENDIX F: QUALITATIVE INSTRUMENT

A completed interview guide with all possible constructs is listed below.

Core questions to be included with all participants:

- Tell me about the area your organization is in – is it a high prevalence area, low prevalence?
- Describe the type of clients you normally see – high income, low income, men, women, LGBT populations? What type of people do you generally serve?
- What types of HIV prevention methods do people in your community prefer?
- Tell me about what your community thinks of PrEP? What about other organizations outside of the one you work for?
- Are you aware of any policies surrounding PrEP – in the government, etc.?
- Has administration, or anyone in your org, ever said what they think about PrEP?
- Does your organization have any trainings, etc. about HIV testing? What about PrEP?
- Have any clients ever talked to you about using PrEP?
- What do you personally think about PrEP? Is it a worthwhile prevention option, or not so great?
- Is PrEP better or worse than other prevention methods?
- What do you, personally, know about PrEP? What makes it easy for you to talk about PrEP during HIV testing?
- What makes it hard? How confident are you in your knowledge to navigate the system – and help a client to navigate the system to end up talking to someone about a PrEP referral?
- What makes it difficult or easy for your clients to get access to PrEP?

Additional questions to include, as needed and appropriate:

OUTPUT FROM CFIR TECHNICAL ASSISTANCE WEBSITE (Damschroder, 2016)

Welcome to the Interview Guide Tool

- **Choose Interview Questions:** Choose this option to select domains, constructs, questions for your customized interview guide.
- **Get Guide:** Choose this option after you’ve selected all the questions you want. Then follow the instructions for copying your guide to a word processor.
- **Start Over:** Your question choices are cumulative. You can choose some questions, get a guide, then choose more questions. The ensuing guide will contain ALL the questions you’ve chosen during the session - unless you click “Start Over”.
- **Main Site:** Choose this option to return to the main CFIR site.
**Intervention Characteristics**

**Evidence Strength & Quality**  What kind of information or evidence are you aware of that shows whether or not the intervention will work in your setting?

- What evidence have you heard about from your own research? Practice guidelines? Published literature? Co-workers? Other settings?
- How does this knowledge affect your perception of the intervention?

2. In a healthcare setting, influential stakeholders may include influential and well-respected clinicians, where as in an education setting, this may include influential and well-respected teachers or educators.

   What do influential stakeholders think of the intervention?
   - What do administrative or other leaders think of the intervention?

**Relative Advantage**  Is there another intervention that people would rather implement?  Can you describe that intervention?  Why would people prefer the alternative?

**Design Quality & Packaging**

1. What supports, such as online resources, marketing materials, or a toolkit, are available to help you implement and use the intervention?
   - How do you access these materials?

2. How will available materials affect implementation in your setting?

**Cost**

1. What costs will be incurred to implement the intervention?

**Outer Setting**

- Tell me about the area your organization is in – is it a high prevalence area, low prevalence?
- Describe the type of clients you normally see – high income, low income, men, women, LGBT populations? What type of people do you generally serve?
- What types of HIV prevention methods do people in your community prefer?
- Has anyone ever talked to you about using PrEP?
- What do you personally think about PrEP?  Is it a worthwhile prevention option, or not so great?
- Is PrEP better or worse than other prevention methods?
- Has administration, or anyone in your org, ever said what they think about PrEP?
- Does your organization have any trainings, etc. about HIV testing?  What about PrEP?
- Tell me about what your community thinks of PrEP?  What about other organizations outside of the one you work for?
- Are you aware of any policies surrounding PrEP – in the government, etc.?
**Patient Needs & Resources**

1. To what extent is staff aware of the needs and preferences of the individuals being served by your organization?
   - How "in touch" are staff and leadership with the individuals served by your organization?
2. To what extent were the needs and preferences of the individuals served by your organization considered when deciding to implement the intervention?
   - Can you describe specific examples?
   - Will the intervention be altered to meet their needs and preferences?
3. How well do you think the intervention will meet the needs of the individuals served by your organization?
   - In what ways will the intervention meet their needs? E.g. improved access to services? Reduced wait times? Help with self-management? Reduced travel time and expense?
4. How do you think the individuals served by your organization will respond to the intervention?
5. What barriers will the individuals served by your organization face to participating in the intervention?
6. Have you elicited information from participants regarding their experiences with the intervention?
   - What are their perceptions of the intervention?
   - Can you describe what kind of specific information you have heard?
7. Have you heard stories about the experiences of participants with the intervention?
   - Can you describe a specific story?

**Cosmopolitanism**

1. To what extent do you network with colleagues or people in similar professions/positions outside your setting?
   - What are the venues?
2. What kind of information exchange do you have with others outside your setting, either related to the intervention, or more generally about your profession?
   - What professional networking do you engage in? Listservs? Local or national conferences? Trainings?

**Peer Pressure**

1. Can you tell me what you know about any other organizations that have implemented the intervention or other similar programs?
   - How has this information influenced the decision to implement the intervention?
2. To what extent are other organizations implementing the intervention?
   - How does this affect support for implementing the intervention in your setting?
3. To what extent would implementing the intervention provide an advantage for your organization compared to other organizations in your area?
   - Is there a competitive advantage?
   - Is there something about the intervention that would bring more individuals into your organization, instead of another one in your area?
**External Policies & Incentives**

1. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention?  
   ○ How will the intervention affect your organization’s ability to meet these measures, policies, regulations, or guidelines?
2. What kind of financial or other incentives influenced the decision to implement the intervention?  
   ○ How will the intervention affect your organization’s ability to receive these incentives?  
   ○ How will the new intervention affect payment or revenue for your organization?

**Inner Setting**

**Structural Characteristics** How big is your organization? Do you have any policies in place about whether or not staff can talk about PrEP during HIV testing?

1. How will the infrastructure of your organization (social architecture, age, maturity, size, or physical layout) affect the implementation of the intervention?  
   ○ How will the infrastructure facilitate/hinder implementation of the intervention?  
   ○ How will you work around structural challenges?
2. What kinds of infrastructure changes will be needed to accommodate the intervention?  
   ○ Changes in scope of practice? Changes in formal policies? Changes in information systems or electronic records systems? Other?  
   ○ What kind of approvals will be needed? Who will need to be involved?  
   ○ Can you describe the process that will be needed to make these changes?

**Networks & Communications** How do you typically find out about new information, such as new initiatives, accomplishments, issues, new staff, staff departures? When you need to get something done or to solve a problem, who are your “go-to” people?

**Implementation Climate** How do people in your organization feel about PrEP? What about talking about PrEP during HIV testing?

1. This question is likely to uncover topics to explore more within other sub-constructs, but be attentive to other themes that may not be included in your assessment.
   
   What is the general level of receptivity in your organization to implementing the intervention?  
   ○ Why?

**Compatibility** How well does the intervention fit with your values and norms and the values and norms within the organization? Can you describe how the intervention will be integrated into current processes? How will it interact or conflict with current programs or processes?
Leadership Engagement

1. What level of involvement has leadership at your organization had so far with the intervention?
   o Do they know about the intention to implement the intervention?
   o Who are these leaders? How do attitudes of different leaders vary?
   o What kind of support have they given you? Can you provide specific examples?
2. What kind of support or actions can you expect from leaders in your organization to help make implementation successful?
   o Who are these leaders? How do attitudes of different leaders vary?
   o Do they know about the intention to implement the intervention?
   o What kind of support can you expect going forward? Can you provide specific examples?
   o What types of barriers might they create?

Access to Knowledge & Information

1. What kind of training is planned for you? For colleagues?
   o Do you feel the training will prepare you to carry out the roles and responsibilities expected of you? Can you explain?
   o What are the positive aspects of planned training?
   o What is missing?
   o What kind of continued training is planned?
2. What kinds of information and materials about the intervention have already been made available to you? What types of things would you need?
   o Copies of materials?
   o Personal contact?
   o Internal information sharing; e.g., staff meetings?
   o Has it been timely? Relevant? Sufficient?
3. Who do you ask if you have questions about the intervention or its implementation?
   o How available are these individuals?

Characteristics of Individuals

- What do you, personally, know about PrEP? What makes it easy for you to talk about PrEP during HIV testing?
- What makes it hard? How confident are you in your knowledge to navigate the system – and help a client to navigate the system to end up talking to someone about a PrEP referral?

Knowledge & Beliefs about the Intervention

1. What do you know about the intervention or its implementation?
2. Do you think the intervention will be effective in your setting?
   o Why or why not?
3. At what stage of implementation is the intervention at in your organization?
   o How do you think the program is going?
   o Why do you say that?
Self-efficacy

1. How confident are you that you will be able to successfully implement the intervention?
   o What gives you that level of confidence (or lack of confidence)?
2. How confident are you that you will be able to use the intervention?
   o What gives you that level of confidence (or lack of confidence)?
3. How confident do you think your colleagues feel about implementing the intervention?
   o What gives them that level of confidence (or lack of confidence)?
4. How confident do you think your colleagues feel about using the intervention?
   o What gives them that level of confidence (or lack of confidence)?
February 13, 2018

DeAnne Turner
Community and Family Health
Tampa, FL 33612

RE: Expedited Approval for Initial Review
IRB#: Pro00030102
Title: Views of Staff Performing HIV Testing and Counseling

Study Approval Period: 2/13/2018 to 2/13/2019

Dear Ms. Turner:

On 2/13/2018, the Institutional Review Board (IRB) reviewed and APPROVED the above application and all documents contained within, including those outlined below.

Approved Item(s):
Protocol Document(s):
Study Protocol V1

Consent/Assent Document(s)*:
Online Survey & Interview V1 2.9.18.docx
Verbal Survey & Interview V1 2.9.18.docx

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent documents are valid until
the consent document is amended and approved. The Online and Verbal consents are not stamped forms.

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110. The research proposed in this study is categorized under the following expedited review category:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117(c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (Online and Verbal consents).

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

[Signature]

John A. Schinka, Ph.D.
John Schinka, Ph.D.,
Chairperson USF Institutional
Review Board