

**An Implementation Science Study About Sexual History Screening and Dissemination of PrEP  
within a Multi-site Federally Qualified Health Center**

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Kelly West Gagnon, PhD

University of Pittsburgh, 2022

Sexual history screening (SHS) is an evidence-based guideline recommended to identify patients' risk of adverse sexual health outcomes, including sexually transmitted infections (STIs), which is not routinely or consistently implemented in healthcare settings. Lack of SHS prevents clinical providers from systematically identifying patients at risk of STIs who may benefit from harm reduction methods, such as pre-exposure prophylaxis (PrEP). This dissertation analyzed patient data from the electronic health record and staff survey and interview data from a multi-site Federally Qualified Health Center (FQHC) in Connecticut. In the first analysis, younger patients and patients whose primary language was not English were significantly less likely to have SHS documented in their medical charts (AOR= 0.99, 95% CI: 0.99, 0.99 and AOR= 0.91, 95% CI: 0.85, 0.97), while patients who were gay, lesbian, and/or homosexual and cisgender women were significantly more likely (AOR= 1.23, 95% CI: 1.04, 1.45 and AOR= 1.01, 95% CI: 1.04, 1.16). PCPs who were cisgender women were more likely to have patients with documented SHS (AOR= 1.80, 95% CI: 1.00, 3.21). The second analysis found SHS documented in the medical chart was associated with a higher proportion of PrEP prescription duration (IRR = 1.44, 95% CI: 1.17, 1.77). There was no significant effect for referral to the PrEP Navigator or having both SHS documented in the medical chart and a referral to the PrEP Navigator. Lastly, the third study found that barriers to implementation of SHS and PrEP services were: external reimbursement and payment policies,

time, insurance and finances, and variation by site. In contrast, facilitators were organizational culture, PrEP support staff, and the patient-provider relationship. In addition to facilitators and barriers, influential factors reflected the influence of the structure of SHS and PrEP services and providers' knowledge of and attitudes. Our findings indicate identify factors associated with the ability to implement SHS and PrEP services with adult FQHC patients. These results provide preliminary evidence of factors that are necessary to address to improve the implementation of SHS and PrEP services among adult patients in a large FQHC setting.

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## Preface

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## **1.0 Introduction**

### **1.1 Sexually Transmitted Infections and Human Immunodeficiency Virus (STIs/HIV)**

#### **1.1.1 STI and HIV Rates in the United States**

Among industrialized countries, the United States (US) has the highest rates of sexually transmitted infection (STIs) (Tanne, 2018). This acknowledgement was made in 2018 by the Executive Director of the National Coalition of STI Directors after rates of syphilis, gonorrhea, and chlamydia rose every year during the preceding five years (Tanne, 2018). Public health officials requested federal declaration of STIs as a public health crisis to address these increasing rates of infection (Tanne, 2018). Historically, the US has experienced temporal trends in STIs with periods of rise, decline, and stability (Aral, Fenton, & Holmes, 2007). These variations differ between bacterial (gonorrhea, chlamydia, and syphilis) and viral [herpes, human papillomavirus (HPV), hepatitis B, and human immunodeficiency virus (HIV)] STIs. Recent differentials in bacterial and viral STI rates began after a steady increase of all STIs throughout the 1960s with a divergence in viral and bacterial STI rates in the 1970s (Aral et al., 2007). Specifically, viral STIs continued to increase, particularly with the HIV epidemic in the 1980s, while bacterial STIs were stable or declined. Beginning in the 2000s, bacterial STIs patterns reversed and began to rise in the US (Aral et al., 2007). The resulting rates of infection have a critical impact not only on the health of Americans but also on the US economy. The estimated preventable financial impact of the 20 million STI cases reported annually in the US is almost 16 billion dollars (Owusu-Eduesei

Jr et al., 2013). Eighty-one percent of this cost is attributable to HIV (Owusu-Edusei Jr et al., 2013).

The most recent reports from the Centers for Disease Control and Prevention (CDC) in 2019 showed an increase in the three most commonly reported STIs, syphilis, gonorrhea, and chlamydia (Centers for Disease Control and Prevention, 2019c). The CDC reported that between 2015 and 2019 there was a 74% increase in syphilis cases totaling 129,813, a 56% percent increase in gonorrhea cases totaling 616,392, and a 19% percent increase in chlamydia cases totaling 1.8 million (Centers for Disease Control and Prevention, 2021d). By the end of 2019, 1,189,700 people in the US were living with HIV (Centers for Disease Control and Prevention, 2021a). Although the rate of new HIV diagnosis has decreased by 9% between 2015 and 2019, of the 39,801 people who received a new HIV diagnosis in 2019, 65% were men who had sex with men (MSM) (Centers for Disease Control and Prevention, 2021a). The most commonly affected subpopulation of those with new HIV diagnoses in 2019 was African American MSM (Centers for Disease Control and Prevention, 2021a).

### **1.1.2 Current STI Rates in Connecticut**

Although Connecticut (CT) has some of the lowest STI rates in the country, STI rates within the State are at an all-time high (Centers for Disease Control and Prevention, 2017c). Between 2015 and 2019, CT experienced a 16% increase in reported chlamydia cases (13,126 to 15,290) a 111% increase in reported gonorrhea cases (2,088 to 4,418), and a 128% increase in reported primary and secondary syphilis cases (92 to 210) (Centers for Disease Control and Prevention, 2021d). In CT between 2015 and 2019, the prevalence of HIV increased slightly (1.4%) (Connecticut Department of Health, 2020). New HIV diagnoses were relatively consistent



during this period, between 257 and 280 annually, with a marked decrease (14%) between 2018 and 2019 from 257 to 220 (Connecticut Department of Health, 2020). Geographically, STI cases in CT are concentrated in Hartford, Bridgeport, and New Haven, urban areas with the lowest per capita income across the state (CT Mirror, 2018; United States Census Bureau, 2019). Current efforts from the Connecticut State Department of Public Health to address the increasing rates of STIs include: disease surveillance, case and outbreak investigation, screening, preventive therapy, outreach, diagnosis, case management, and education (Connecticut State Department of Public Health, 2020).

### **1.1.3 Negative Outcomes of Untreated STIs/HIV**

There are myriad of adverse health outcomes that arise from exposure to and delayed treatment of STIs and HIV. Individuals with female sexual organs who contract an STI are at risk of pelvic inflammatory disease (PID), cervical cancer, and developing fertility issues (Centers for Disease Control and Prevention, 2020b; Eng & Butler, 1997b). Additionally, fetuses and newborn children of pregnant individuals who remain untreated are at risk of infant death and other perinatal health problems. Adverse health outcomes specific to individuals with male sexual organs are less common and severe than those for individuals with female sexual organs. Potential adverse health outcomes due to untreated and long-term exposure to STIs among this population include increased severity of prostate cancer, epididymitis, and reactive arthritis (Eng & Butler, 1997b).

Individuals, regardless of sexual organs, who contract HIV and do not receive anti-retroviral therapy are at risk of developing acquired immunodeficiency syndrome (AIDS) (Centers for Disease Control and Prevention, 2018). Untreated HIV attacks the immune system and can destroy critical cells (CD4, more commonly referred to as T cells) that help the body fight off

infections and disease (Centers for Disease Control and Prevention, 2018). AIDS is the third and most severe stage of HIV infection (Centers for Disease Control and Prevention, 2018). The damage to the immune system during this phase of HIV infection leaves the body prone to opportunistic illnesses and increases the severity of typically mild illnesses because of the weakened immune system (Centers for Disease Control and Prevention, 2018). Prior to the discovery of HIV/AIDS in the early 1980s, PID and syphilis accounted for the majority of deaths due to STIs (Grimes, 1986). Since the AIDS epidemic in the 1980s, more than 675,000 people in the US have died from AIDS-related deaths (Center for Disease Control and Prevention, 2016). Currently about 1.1 million US residents are living with HIV with an estimated 14% unaware of their infection (Centers for Disease Control and Prevention, 2020a). Those who are unaware that they are infected with HIV are at the highest risk of developing AIDS. An estimated 13,000 people US residents die each year from an AIDS-related cause (Center for Disease Control and Prevention, 2016). While the rate of new HIV cases diagnoses per year is decreasing, HIV infection disparately affects subpopulations of US residents. Specifically, MSM accounted for 69% of all new HIV diagnoses in 2018 (Centers for Disease Control and Prevention, 2020a). In 2018, Black and African American and Hispanic MSM had the highest proportion of new HIV diagnoses, with 9,499 and 7,543 cases respectively compared to 6,432 cases among white MSM (Centers for Disease Control and Prevention, 2020a). Among women in 2018, Black and African American women (3,768 cases) with heterosexual contact have higher rates of new HIV cases compared to Hispanic and Latina (1,109 cases) and White women (999 cases) (Centers for Disease Control and Prevention, 2020a).

#### **1.1.4 Social Ecological Burden of STI/HIV Risk**

The CDC uses a four-level social ecological model (SEM) to explore factors related to adverse health outcomes (Centers for Disease Control Prevention, 2015). These levels include: individual, relationship, community, and societal factors (Centers for Disease Control Prevention, 2015). Exploration of factors at each of these levels for subpopulations of US residents at the highest risk for STIs/HIV provides key social and contextual information about factors influencing the burden of STIs/HIV. The prevalence and burden of STIs/HIV is most predominant among racial and ethnic minorities and sexual and gender minorities.

##### **1.1.4.1 Racial and Ethnic Minorities**

Rates of STIs/HIV are higher among Black and Hispanic people when compared to their White counterparts (Center for Disease Control and Prevention, 2014; Centers for Disease Control and Prevention, 2020c). These disparities are due to systemic and societal barriers to STI/HIV knowledge, screening, and care. Black and Hispanic US residents experience higher poverty rates, lower educational attainment, and lower rates of insurance coverage (Berk & Schur, 2001; Centers for Disease Control and Prevention, 2020c; Frieden, 2013; Harling, Subramanian, Bärnighausen, & Kawachi, 2013; Perez-Escamilla, 2010; Semega, Fontenot, & Kollar, 2017). In 2016, compared to White Americans who experienced a poverty rate of 8.8% (17.3 million), the poverty rates of Black and Hispanic Americans were more than double at 22.0% (9.2 million) and 19.4% (11.1 million) respectively (Centers for Disease Control and Prevention, 2020c; Semega et al., 2017). Higher poverty and lower insurance cover rates directly impact their ability to access routine and STI-specific care (Eng & Butler, 1997a; Hogben & Leichter, 2008; Sharpe et al., 2012).

In addition to limited access to care, Black and Hispanic people experience stigma and discrimination in health care settings, decreasing their trust in their health care organizations and providers (Berk & Schur, 2001; Centers for Disease Control and Prevention, 2020c; Frieden, 2013; Harling et al., 2013; Perez-Escamilla, 2010; Semega et al., 2017). Negative interpersonal experiences between racial and ethnic minorities and health care professionals, whether from direct discrimination, cultural miscommunication, or language barrier, result in delay and avoidance of health care and lack of communication about STI/HIV risk and STI/HIV testing (Berk & Schur, 2001; Centers for Disease Control and Prevention, 2020c, 2020c; Frieden, 2013; Harling et al., 2013; Perez-Escamilla, 2010; Semega et al., 2017; Smedley, Stith, & Nelson, 2003).

In addition to systemic and interpersonal barriers to STI/HIV preventive testing and care, when compared to White individuals, Black and Hispanic individuals have lower levels of sexual literacy and more negative attitudes towards contraceptive and barrier usage due to poor sexual health education and/or lack of clinical guidance (Guzzo & Hayford, 2012). Compounding these issues, Black and Hispanic men have higher rates of maintaining more than one concurrent sexual partner, a known risk for STIs/HIV (Dariosis, Sifakis, Pleck, Astone, & Sonenstein, 2011). These factors derive from and are exacerbated by the disproportionate amount of racial and ethnic minorities living in low-income areas with less access to medical resources and high-quality education (Berk & Schur, 2001; Centers for Disease Control and Prevention, 2020c; Frieden, 2013; Harling et al., 2013; Perez-Escamilla, 2010; Semega et al., 2017).

#### **1.1.4.2 Sexual and Gender Minorities**

Sexual and gender minorities experience higher rates of STIs and HIV compared to their cisgender (a person whose gender identity corresponds with their sex assigned at birth) heterosexual peers (Center for Disease Control and Prevention, 2014; Centers for Disease Control

and Prevention, 2017b; Ward, Dahlhamer, Galinsky, & Joestl, 2014; Wood, Salas-Humara, & Dowshen, 2016). Among sexual and gender minorities, MSM and transgender women have the highest rate of new infections (Center for Disease Control and Prevention, 2014). Like racial and ethnic minorities, higher rates of STIs and HIV in these populations are due to systemic and cultural barriers to sexual health knowledge, screening, and care.

A major systematic barrier to seeking and engaging in clinical care for sexual and gender minorities is lack of health insurance coverage. Recent studies found that sexual minorities are twice as likely to be unemployed and uninsured compared to their heterosexual peers (Charlton et al., 2018; Diamant, Wold, Spritzer, & Gelberg, 2000; Lunn et al., 2017). In one of these studies, these populations were more likely to report poorer health and a lower quality of life (Charlton et al., 2018). Not only are sexual and gender minorities less likely to be insured, they are more likely to report being unable to afford health related needs, such as paying for medical care visits and medicine (Gates, 2014). Due to higher rates of poverty and community discrimination, sexual and gender minorities, particularly youth, engage in survival sex work, which puts them at an increased risk for STIs/HIV (Dank et al., 2015; Marshall, Shannon, Kerr, Zhang, & Wood, 2010).

When choosing to engage in health care, LGBT face the fear of discrimination from medical providers (Preston et al., 2004). Research has shown that LGBT people encounter discrimination in medical environments based on their sexual orientation or gender identity (Mirza & Rooney, 2018). While rates of discrimination and stigmatization of these populations in health care settings have decreased over time, studies show about 10%-15% of patients experience a denial of service, unequal treatment, or verbal harassment (Macapagal, Bhatia, & Greene, 2016; Mirza & Rooney, 2018). Reported discrimination increases among transgender patients, patients of color, and patients in rural communities (Macapagal et al., 2016; Mirza & Rooney, 2018;

Whitehead, Shaver, & Stephenson, 2016). Among sexual and gender minorities who do seek care, routine and needed screenings do not always take place. Research has shown that lesbians and women who have sex with women are less likely to report undergoing routine Papanicolaou tests (screening to detect precancerous and cancerous cells in the cervix) and receiving a pelvic exam (Marrazzo, 2004). Providers also report discomfort asking sexual and gender minorities about their sexual health and practices (Macapagal et al., 2016; Mirza & Rooney, 2018; Whitehead et al., 2016).

Few sexual and gender minorities in the US report receiving comprehensive sexual health education that includes information specific to STI/HIV prevention for their specific sexual behaviors and practices (Kosciw, Greytak, Palmer, & Boesen, 2017). A 2015 study found that only 12% of participants learned about same sex relationships in their sexual education courses (Jones, 2015). Similar to racial and ethnic minorities, sexual and gender minorities in the US have earlier sexual debut and higher rates of concurrent sexual partners (Everett, Schnarrs, Rosario, Garofalo, & Mustanski, 2014). These risk behaviors are most common among young gay and bisexual men and MSM (Everett et al., 2014).

## **1.2 Sexual History Screening to Address STIs/HIV**

To identify and treat risk and exposure to STIs/HIV, the CDC recommends the following process: 1) conducting a sexual history and physical examination, 2) discussing prevention methods (e.g., discussing barrier use), 3) testing at-risk patients for asymptomatic STIs, and 4) offering services to the patients' sexual partner (Barrow, Ahmed, Bolan, & Workowski, 2020). Patients who present with symptoms of STIs should be physically evaluated, receive laboratory

testing to confirm diagnosis, have identified STIs treated, and be referred to STI specialists for complex STI-related conditions, if necessary (Barrow et al., 2020).

The first step of this process, sexual history screening (SHS), is an evidence-based practice recommended by the US Preventive Task Force and the CDC to assess risk of STIs and HIV (Barrow et al., 2020; Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). In addition to screening for risk of STIs and HIV, SHS helps clinical providers identify risk of sexual abuse, drug use during sex, and poor sexual function (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). SHS is recommended at each patient's intake, during annual preventive care visits, and if STI symptoms are present (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). SHS can be practiced in any medical specialty (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). The implications of inconsistent or incomplete SHS are that clinical providers are unaware of their patients' risk of STIs, HIV, sexual abuse, drug use during sex, sexual function, or pregnancy planning (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Plotkin et al., 1993; U.S. Preventative Task Force, 1997). Without this information clinical providers may not initiate conversations about harm reduction methods, referrals to specialists or relevant resources, and screening of at-risk patients for STIs/HIV (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Plotkin et al., 1993; U.S. Preventative Task Force, 1997). Substantial evidence exists to demonstrate that SHS achieves the desired outcome of decreasing STI rates through patient-specific strategies, such as site-specific STI testing based on risk-behaviors, identification of patients who meet recommendations for pre-exposure prophylaxis (PrEP) to prevent HIV, and discussion of harm and risk-reduction strategies (barrier usage) (Fisher et al., 2006; Gardner et al.,

2008; Golub, Gamarel, & Lelutiu-Weinberger, 2017; O'Connor et al., 2014; Politi, Clark, Rogers, McGarry, & Sciamanna, 2008; Rose et al., 2010).

The CDC lists five sections to a comprehensive SHS: partners, practices, protection from STIs, past history of STIs, and prevention of pregnancy (Center for Disease Control and Prevention). The CDC also provides supplemental recommendations for conducting SHS with transgender patients (Centers for Disease Control and Prevention, 2019d). The summary of recommendations specific to transgender patients include: ask a patient about their pronouns and how they would like to be addressed, avoid assuming a patient's sexual orientation or gender identity, avoid assuming any specific sexual practice or activity, and do not assume that a patient is at high risk for an adverse health outcome based on their gender identity alone (Centers for Disease Control and Prevention, 2019d). Further, these recommendations state the provider should regularly reinforce that a sexual history is for their patients' medical care and well-being and should be reflective of where their patient is in the process of transitioning in terms of hormone usage and gender-affirming surgeries (Centers for Disease Control and Prevention, 2019d).

Recommendations for SHS questions and process differ across expert entities, both federal and private non-profit. In a review of guidance from the National LGBT Health Education Center, the American Association of Family Physicians, the National Coalition for Sexual Health, and a published standard operating procedure for SHS published in the Journal of Sexual Medicine, there was a high-level of consistency in SHS recommendations and guidance. The majority of outlined guidance employs the CDC recommended five Ps (partners, practices, protection from STIs, past history of STIs, and prevention of pregnancy (Altraum Institute, 2016; Center for Disease Control and Prevention; Center., 2013). Among those that do not directly state recommendation of the five Ps, they recommend very similar questions and/or domains that overlap in terms of topic coverage



(Althof, Rosen, Perelman, & Rubio-Aurioles, 2013; Nusbaum & Hamilton, 2002; Savoy, O'Gurek, & Brown-James, 2020). There is notable recognition across the recommendations around importance of asking patients about their sexual orientation and gender identity and how these factors play into sexual health (Althof et al., 2013; Altraum Institute, 2016; Center for Disease Control and Prevention; Center., 2013; Nusbaum & Hamilton, 2002; Savoy et al., 2020). Additionally, all SHS guidance documents included behavioral counseling and follow-up screening based on patient's behaviors (Althof et al., 2013; Altraum Institute, 2016; Center for Disease Control and Prevention; Center., 2013; Nusbaum & Hamilton, 2002; Savoy et al., 2020). Given the agreement across guidance documents, the five Ps (or questions similar to those in the CDC's five Ps) and patient-specific screening and behavior counseling appear to be the core components of SHS. Based on the outlined guidance documents, recommended follow-up to sexual history screening questions include: STI and HIV screening, administering relevant vaccinations, conducting brief behavioral counseling about risk reduction methods, and preventive prescriptions, such as PrEP (Althof et al., 2013; Altraum Institute, 2016; Barrow et al., 2020; Center for Disease Control and Prevention; Center., 2013; Nusbaum & Hamilton, 2002; Savoy et al., 2020).

PrEP is a once daily pill to prevent the contraction of HIV. Historically, the CDC has recommended discussing PrEP with MSM who report unprotected anal sex, patients who report limited or no condom use with a partner of unknown or HIV-positive status, men who have sex with men and women, and injection drug users who share equipment or engage in risky sexual behaviors (Altraum Institute, 2016). In 2021, the CDC updated this guidance to recommend discussing PrEP with all sexually active adult and adolescent patients and people who use injection drugs (Centers for Disease Control and Prevention, 2021c). PrEP can reduce the risk of HIV

through sexual practices among these and other populations by 99% if taken as directed (Centers for Disease Control and Prevention, 2019a). Among injection drug users, PrEP can reduce HIV infection by 74% when taken as directed (Centers for Disease Control and Prevention, 2019a). People taking PrEP to prevent HIV transmission are advised to continue barrier usage as PrEP alone does not protect against other STIs (Centers for Disease Control and Prevention, 2019a). To start PrEP, a patient must be screened for HIV with follow up screening every three months (Centers for Disease Control and Prevention, 2019a). PrEP reaches maximum protection from HIV for receptive anal sex and receptive vaginal sex and injection drug use after seven and 21 days, respectively (Centers for Disease Control and Prevention, 2019a).

For patients with infrequent risk of HIV, the International AIDS Society USA recommends prescribing PrEP using “2-1-1” (also referred to as on-demand) dosing in which two pills are taken a maximum of 24 hours prior to sex and a pill 24 and 48 hours after (Centers for Disease Control and Prevention, 2021c). Conversely, for people consistently at risk of contracting HIV, the CDC recently outlined the indication and protocol for prescription of cabotegravir (CAB), a bimonthly injection to prevent the contraction of HIV (Centers for Disease Control and Prevention, 2021c). Approved in December 2021, CAB injections are initiated after testing a patient for HIV and, in addition to bimonthly injections, bacterial STI screenings should routinely take place based on the patients’ individual risk factors (Centers for Disease Control and Prevention, 2021c).

To assist patients in need of PrEP through the health care system and to remove barriers to care and adherence, some patients may be referred to a PrEP Navigator (Pinto, Berringer, Melendez, & Mmeje, 2018). A PrEP Navigator is a service offered by some health care organizations to guide patients through the process of getting and adhering to PrEP (Mugavero, Amico, Horn, & Thompson, 2013). PrEP Navigators are non-clinical staff, and in some cases

patient-peers, who are trained to help patients overcome structural barriers (Pinto et al., 2018). The duties and role of the PrEP Navigator differ by organization; however, common tasks include determining insurance coverage, discussing the PrEP process, working with the patient on realistic expectations, assisting patient with scheduling follow-up visits and visit adherence (Doblecki-Lewis et al., 2019; Pinto et al., 2018; University of California San Francisco, N.D.). Studies exploring the use of PrEP Navigators have found that this service has high acceptability among high-risk populations (young racial and ethnic MSM, transgender women) and patients who met with or who were enrolled in PrEP Navigator programs reported feeling supported, and a reduction in worry about structural barriers (issues with making an appointment, getting to an appointment, finding a provider that speaks their language) (Bradford, Coleman, & Cunningham, 2007; Pagkas-Bather et al., 2020). Furthermore, research shows that engagement with a PrEP Navigator reduced delays in PrEP initiation, increased the number of visits attended and utilization of HIV primary medical care, and was associated with consistent PrEP adherence at 90-day follow up (Bradford et al., 2007; Pagkas-Bather et al., 2020; Reback, Clark, Rünger, & Fehrenbacher, 2019; Spinelli et al., 2018). Although research is limited, PrEP Navigators may have an impact on patients' long term sexual health through increasing the proportion of patients with an undetectable viral load one year after initiating PrEP Navigator services (Bradford et al., 2007).

### **1.2.1 Federally Qualified Health Centers as a Setting for SHS to Access for Risk of STIs/HIV**

To date, research has predominantly explored SHS behaviors and practices among primary care providers (PCPs), general practitioners, and obstetricians in the US and Australia (Burd, Nevadunsky, & Bachmann, 2006; Ginige, Chen, & Fairley, 2006; Gongidi, Sierakowski, Bowen,

Jacobs, & Fernandez, 2010; Hayes, Blondeau, & Bing-You, 2015; Khan, Plummer, Hussain, & Minichiello, 2008; Lewis & Freeman, 1987; Temple-Smith, Hammond, Pyett, & Presswell, 1996; Torkko, Gershman, Crane, Hamman, & Barón, 2000; Wimberly, Hogben, Moore-Ruffin, Moore, & Fry-Johnson, 2006). Research has not yet explored the SHS behaviors of PCPs at Federally Qualified Health Centers (FQHCs), also commonly referred to as Community Health Centers (CHCs). FQHCs are funded by the Health Resources and Services Administration (HRSA) to provide primary care services in underserved areas and to at-risk and vulnerable populations (Health Resources and Services Administration, 2019a; Proser, 2005). FQHC patients are more likely to be racial, ethnic minorities, have less education, have Medicaid or no insurance, and/or live in a rural area compare to patients at private primary care clinics (Forrest & Whelan, 2000; O'malley & Mandelblatt, 2003). Additionally, studies have shown that PCPs at FQHCs have different treatment and counseling behaviors compared to PCPs at private primary care clinics (Goldman, Chu, Tran, Romano, & Stafford, 2012; O'malley & Mandelblatt, 2003; Rothkopf, Brookler, Wadhwa, & Sajovetz, 2011). The documented differences between FQHC and private primary care patients and providers indicate a need for research specific to FQHC PCPs' provision of care to patients.

In 2017, CT was home to 16 FQHCs with 282 delivery sites (National Association of Community Health Centers, 2017). In this year, FQHCs in CT served 123,737 pediatric patients, 13,943 homeless patients, and 2,937 veterans (National Association of Community Health Centers, 2017). The utilization of FQHCs in CT is on the rise, with a 30% increase in patients served between 2010 and 2017 (National Association of Community Health Centers, 2017). In 2017, 62% and 90% of patients at CT FQHCs live at or below 100% poverty and 200% poverty respectively (National Association of Community Health Centers, 2017). Furthermore, in this year, seventy-

six percent of CT FQHC patients are racial and/or ethnic minorities (National Association of Community Health Centers, 2017). Among CT FQHC patients in 2017, 61% had Medicaid, 8% had Medicare, and 17% were uninsured (National Association of Community Health Centers, 2017). These patients accessed a wide variety of services from these health care organizations, including treatment for chronic conditions, behavioral health, preventive services, and dental services. The combined total number of visits across these services in 2017 was 2,030,316 (National Association of Community Health Centers, 2017). In addition to caring for at risk populations in CT, these health care organizations are also major economic drivers. For every federal dollar invested in FQHCs in CT generates \$6.98 in economic activity within the State, totaling to \$796.9 million dollars in economic activity (National Association of Community Health Centers, 2017).

This study utilized data from a multi-site FQHC in CT that provides care to more than 145,000 patients each year. Locations and services (including medical, behavioral health, and dental services) offered by this organization are available throughout most of CT, predominantly serving five of CT's eight counties: Fairfield, Hartford, Middlesex, New Haven, and New London. This healthcare organization is focused on providing and improving care to at-risk patient populations, including patients with substance use disorders, homeless patients, and lesbian, gay, bisexual, and transgender patients.

### **1.2.2 Implementation of Sexual History Screening in Clinical Practical**

Although the benefits of conducting SHS during clinical visits are well-known, a complete sexual history is not consistently taken by clinical providers during preventive care visits (Lewis & Freeman, 1987; Ribeiro et al., 2014; Torkko et al., 2000; Wimberly et al., 2006). From a survey

of 416 physicians in Atlanta, GA conducted between 2003 and 2004, less than half (34%) reported asking about the number of sexual partners during preventive care visits (Wimberly et al., 2006). Although recommended by the CDC, even fewer physicians reported asking additional questions as part of a sexual health history, with only 12% reporting that they ask about sexual practices of the patient's partner, and 11% asking about sexual abuse (National LGBT Health Education Center, 2015). Conversely, higher proportions of physicians (75.5%) reported asking sexual history questions if it was relevant to the patient's chief complaint (National LGBT Health Education Center, 2015). The findings from this study reflect those of similar studies that surveyed the SHS practices of physicians with self-reported administration of SHS consistently around or below 50% (Lewis & Freeman, 1987; Ribeiro et al., 2014; Torkko et al., 2000; Wimberly et al., 2006). Limited research to date on SHS has explored the myriad of factors influencing the implementation of this evidence-based practice in clinical settings.

As SHS is an evidence-based practice, an implementation theoretical framework is most appropriate way to explore known factors that influence the implementation of SHS in clinical settings. The Consolidated Framework for Implementation Research (CFIR) is a theoretical framework created to assess the facilitators and barriers to implementation of an evidence-based practice or intervention (CFIRguide.org, 2018). CFIR contains five major domains: the intervention, inner and outer setting, the individuals involved in implementation, and the process of implementation (CFIRguide.org, 2018). Data collected using the CFIR theoretical framework are coded to constructs within the five major domains and then analyzed to indicate the role of the construct as a facilitator or barrier (CFIRguide.org, 2018). To contextualize what is currently known about the implementation of SHS during clinical visits, an overview of findings will be presented within the relevant CFIR.

### **1.2.2.1 Intervention Characteristics**

This domain pertains to features of the evidence-based intervention that impact its implementation. Within this domain, there are eight constructs: intervention source, evidence strength and quality, relative advantage, adaptability, trialability, complexity, design quality and packaging, and cost (CFIRguide.org, 2018).

While there is limited research on clinicians' or other health care staffs' perception of SHS as an evidence-based intervention, this evidence-based guideline may benefit from its strength of evidence and source. As SHS is medical guideline recommended by the US Preventive Task Force and the CDC, among many other medical and public health organizations (Althof et al., 2013; Altraum Institute, 2016; Center for Disease Control and Prevention; Center., 2013; Nusbaum & Hamilton, 2002; Savoy et al., 2020; U.S. Preventative Task Force, 1997). Furthermore, there is evidence that SHS achieves the intended outcomes of STI/HIV testing, reduction in patient risk behaviors, and preventive prescriptions (Fisher et al., 2006; Gardner et al., 2008; Golub et al., 2017; O'Connor et al., 2014; Peters et al., 2011; Politi et al., 2008; Rose et al., 2010).

In terms of intervention source, 25% of 50 clinicians in one study reported low accessibility to guidelines as a barrier to implementing SHS (Ribeiro et al., 2014). This may be true for many providers given the volume of guidance and recommendations for SHS. The number of organizations who release SHS recommendations and the size of the documents may be overwhelming or that providers are unsure how to adapt SHS to be feasible during visit time.

### **1.2.2.2 Outer Setting**

This domain involves features of the environmental and external context that influence implementation. Within this domain, there are four constructs: patient needs and resources, cosmopolitanism, peer pressure, and external policies and incentives (CFIRguide.org, 2018).

A major external influence on SHS during clinical visits is the culture of the community in which a health care organization is situated. In one study, medical students reported cultural and religious differences between themselves and patients as a barrier to discussing sexual history (Ariffin et al., 2015). This may be true on a broader scale for health centers situated in religious communities. Clinicians in these areas may find it difficult to implement SHS with their patients because of the content of SHS. Religious doctrine often includes beliefs, views, and practices related to sex and talking about sex (Cochran & Beeghley, 1991; Dillon & Savage, 2006; Ellison, Wolfinger, & Ramos-Wada, 2013; Flores, Eyre, & Millstein, 1998; Haidt & Hersh, 2001; Hordern & Street, 2007; Meier, 2003; Minturn, Grosse, & Haider, 1969; Shell, 2007). Patients whose religious views are conservative towards sex or who see sex as a taboo subject of discussion may be resistant to conversations with healthcare providers about their sexual history (Cochran & Beeghley, 1991; Dillon & Savage, 2006; Ellison et al., 2013; Flores et al., 1998; Haidt & Hersh, 2001; Hordern & Street, 2007; Meier, 2003; Minturn et al., 1969; Shell, 2007).

In terms of external policies and incentives, FQHCs are not required to report SHS data as part of HRSA's Uniform Data System (UDS) reporting requirements (Health Resources and Services Administration, 2019b). FQHCs prioritize data collection to meet UDS reporting requirements, which include sexual orientation and gender identity data (Health Resources and Services Administration, 2019b). This may decrease the relative priority of SHS within the health center in favor of UDS mandated data. Additionally, the fee-for-service model (a common payment model in primary care) limits the visit time allocated to each patient and rewards speed and patient turnover rather than comprehensiveness during visits (Berenson & Rich, 2010).



### **1.2.2.3 Inner Setting**

This domain is inclusive of internal features within an organization that may affect implementation. This is the largest domain, with a total of 12 constructs: structural characteristics, networks and communications, culture, implementation climate, tension for change, compatibility, relative priority, organizational incentives and rewards, goals and feedback, learning climate, readiness for implementation, leadership engagement, available resources, and access to knowledge and information (CFIRguide.org, 2018).

As this domain addresses the context of a specific health care organization, there is limited research or results on the internal system-level factors impacting SHS. Potential factors that can be drawn from research to date include the limited time allocated to preventive care visits. As previously stated, the fee-for-service model often results in short patient visits (Berenson & Rich, 2010). Allocated visit time can be impacted by patients' timely arrival to the appointment, the providers' workloads, and emergent medical needs during the visit, which limits the time that can be spent conducting a SHS (Barbee, Dhanireddy, Tat, & Marrazzo, 2015; Haley, Maheux, Rivard, & Gervais, 1999; Temple-Smith et al., 1996).

### **1.2.2.4 Characteristics of Individuals**

This domain encompasses attributes about those who implement the intervention that may influence implementation. There are five constructs in this domain: knowledge and beliefs about the intervention, self-efficacy, individual stage of change, individual identification with organization, and other personal attributes (CFIRguide.org, 2018).

Providers have reported education, training, and comfort discussing sex as major factors determining their SHS practices. Variations in education from different credentialing programs (i.e. family physicians compared to internists, nurse practitioners), limited or insufficient training,

and discomfort discussing sex are associated with less frequent SHS of patients (Carter Jr, Hart-Cooper, Butler, Workowski, & Hoover, 2014; Torkko et al., 2000; Wimberly et al., 2006) (Carter Jr et al., 2014; Wimberly et al., 2006) (Barbee et al., 2015; Burd et al., 2006; Carter Jr et al., 2014; Haley et al., 1999; Khan et al., 2008; Torkko et al., 2000). Patients want to address sexual health with their medical providers; however, they want their provider to initiate the conversation (Metz & Seifert, 1990). Barriers to initiating this conversation with patients include: the providers' fear of offending their patients, difficulty asking sexual health questions of patients of the opposite sex or who are sexual and/or gender minorities, assuming that certain patients are not at risk (particularly for older adults), language barriers between patients and providers, and presence of a health care companion at the visit (Carrasquillo, Orav, Brennan, & Burstin, 1999; Gray, Hilder, & Donaldson, 2011; Kanter et al., 2009; Lee, Batal, Maselli, & Kutner, 2002) (Wolff & Roter, 2011) (Hayes et al., 2015; Khan et al., 2008; Temple-Smith et al., 1996).

#### **1.2.2.5 Process**

This domain addresses strategies or tactics as part of the process of implementation that may affect the outcome. There are eight constructs in this domain: planning, engaging, opinion leaders, formally appointed internal implementation leaders, champions, external change agents, executing, and reflecting and evaluating (CFIRguide.org, 2018).

Research to date has explored various methods for implementing SHS during clinical visits. Specifically, previous studies have explored patient self-administered SHS and computer-guided SHS for providers (Koch et al., 2008; Martyn & Martin, 2003; Martyn, Reifsnider, & Murray, 2006; Pappas et al., 2017). Among adolescents, a series of studies explored the use of an events history calendar to map sexual initiation and behaviors (Martyn & Martin, 2003; Martyn et al., 2006). Adolescents in these studies completed an events history calendar and then reviewed it with

a medical professional (Martyn & Martin, 2003; Martyn et al., 2006). Medical professionals who reviewed the event histories reported this process helped clarify what patients reported and provided more information than was typically gathered during SHS (Martyn & Martin, 2003; Martyn et al., 2006). These findings were similar to another study among HIV-positive MSM, which showed a self-completed sexual history questionnaire was associated with a more detailed record of sexual behavior (Koch et al., 2008). Another implementation process explored in previous research is computer-assisted history taking systems (CAHTS) (Pappas et al., 2017). A systematic review of literature on CAHTs suggested that it saves clinician time, improves delivery of care, and is particularly helpful when eliciting sensitive information, like sexual history (Pappas et al., 2017).

### **1.3 Conclusion**

Although studies demonstrate inconsistent implementation of SHS, few studies have explored facilitators and barriers to widespread uptake in clinical settings (Lewis & Freeman, 1987; Ribeiro et al., 2014; Torkko et al., 2000; Wimberly et al., 2006). Specifically, research has not yet investigated if sociodemographic factors are associated with SHS. There is preliminary research to suggest that these factors may impact implementation of SHS. Specifically, patients' age, gender, cultural background, and sexual and/or gender minority (SGM) identity (Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). Additionally, this research indicates that providers' gender, degree, and years of practice are associated with SHS behaviors (Gongidi et al., 2010; Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). Exploration of these factors is critical, as

stigma may be the driving force in these provider-patient interactions. Stigma and discrimination are particularly salient for populations at the highest risk of STIs/HIV and other adverse sexual health outcomes, like racial and ethnic and sexual and gender minorities (Center for Disease Control and Prevention; Centers for Disease Control and Prevention, 2017a, 2017b).

Research has also not yet thoroughly investigated whether SHS is associated with dissemination of PrEP services, specifically referrals to PrEP Navigators, who are trained to provide care coordination to patients prescribed PrEP (Doblecki-Lewis et al., 2019; Pinto et al., 2018; University of California San Francisco, N.D.). This is a missed opportunity, as providing PrEP in FQHC settings presents a viable method of impacting STI and HIV rates in vulnerable populations. Lastly, there is a dearth of research on system-level facilitators and barriers to implementation of SHS. Previous research has explored influential factors utilizing survey methods at the individual level, but has not yet taken a system-level perspective to understanding these factors (Barbee et al., 2015; Burd et al., 2006; Carter Jr et al., 2014; Haley et al., 1999; Khan et al., 2008; Torkko et al., 2000).

## 2.0 Current Dissertation Research

This dissertation addresses current gaps in the understanding of the implementation of SHS and dissemination of PrEP in FQHCs. Data analyses were conducted using secondary data from the electronic health record (EHR) and primary data from surveys and interviews with key stakeholders at a multi-site FQHC in Connecticut. This study collected data on adult patients who had a medical visit between June 2018 and December 2019, adult patients with a PrEP prescription between January 2016 and December 2019, and from primary care providers (PCPs), clinical leadership, medical assistants, and a PrEP Navigator. Patient data was extracted from the EHR by the FQHC and provided to the researcher. Data from PCPs, clinical leadership, medical assistants, and a PrEP Navigator were collected via survey and qualitative interview by the researcher.

The first analysis investigates whether the sociodemographics of patients and PCPs are associated with patients having sexual history documented in their medical charts. Building upon the first analysis, the second analysis explores the relationship between having sexual history documented in the medical chart and having a referral to the organization's PrEP Navigator with PrEP prescription duration during the study period. Lastly, the third analysis examines facilitators, barriers, and other influential factors on the implementation of SHS and PrEP services from the perspectives of PCPs, medical assistants, clinical leadership, and a PrEP Navigator.

In addition to addressing the dearth of research on the implementation of sexual history screening and dissemination of PrEP in FQHC settings, this dissertation has two primary strengths. To date, most research on SHS practices was assessed using self-report data from physicians and other clinical providers. Not only does this study utilize real-world EHR data to accurately identify whether a sexual history was conducted and documented but has a large sample size of 53,246

patients. Additionally, this dissertation utilized a mixed methods approach to provide a holistic understanding of influential factors to implementation of SHS and dissemination of PrEP. Through the combined analyses, this dissertation proposes realistic next steps for research and training and program development.

## **2.1 Study 1: Specific Aims and Hypotheses**

**Aim 1.** Examined how the sociodemographics of patients and PCPs are associated with having sexual history documented in the medical chart of adult FQHC patients between June 2018 and December 2019.

Hypothesis 1.1: Patients whose providers were younger would be more likely to have sexual history documented in their medical charts.

Hypothesis 1.2: Patients whose providers were cisgender women would be more likely to have sexual history documented in their medical charts.

Hypothesis 1.3: Patients who identified as a sexual and/or gender minority would be less likely to have sexual history documented in their medical charts.

Hypothesis 1.4: Patients who were older would be less likely to have sexual history documented in their medical charts.

## **2.2 Study 2: Specific Aims and Hypotheses**

**Aim 2.** Tested (1) the independent effects of having sexual history documented in the medical chart and a referral to the PrEP Navigator on PrEP prescription duration and (2) whether referral to the PrEP Navigator moderates the relationship between having sexual history documented in the medical chart and PrEP prescription duration for adult FQHC patients with a PrEP prescription between January 2016 and December 2019.

Hypothesis 2.1: Patients who have sexual history documented in the medical chart will have higher PrEP prescription duration.

Hypothesis 2.2: Patients who had a referral to the PrEP Navigator will have higher PrEP prescription duration.

Hypothesis 2.3: The combined effect of having sexual history documented in the medical chart and a referral to the PrEP Navigator will be associated with higher PrEP prescription duration than independently or not having sexual history documented in the medical chart or a referral to the PrEP Navigator.

## **2.3 Study 3: Specific Aims and Hypotheses**

**Aim 3.** Investigated the facilitators, barriers, influential factors, and opportunities to the implementation of SHS and PrEP services from the perspectives of PCPs, medical assistants, clinical leadership, and a PrEP Navigator. Guided by CFIR, qualitative interviews were conducted to understand the facilitators and barriers to SHS and PrEP services.

### **3.0 Relationship Between Adult Medical Patients' and Providers' Sociodemographics and Having Sexual History Documented in The Medical Chart at a Multi-site Federally Qualified Health Center in Connecticut**

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#### **3.1 Introduction**

During 2018, one in five people in the United States (US) had an active sexually transmitted infection (STI) (Centers for Disease Control and Prevention, 2021e). The most recent surveillance data from the Centers for Disease Control and Prevention (CDC) found that chlamydia, gonorrhea, and syphilis infection rates have continued to rise since 2015, with increases of 19%, 56%, and 74%, respectively (Centers for Disease Control and Prevention, 2021b). During this timeframe, rates of new human immunodeficiency virus (HIV) diagnoses have decreased; however, a majority of new infections were among men who have sex with men (MSM) (65%) (Centers for Disease Control & Prevention, 2019e). Furthermore, rates of new HIV diagnosis remain highest for Black and African American and Hispanic/Latino MSM, particularly young MSM (Centers for Disease Control & Prevention, 2019e). This disparate burden of disease is also observed across other STIs, with Non-Hispanic Black and African American adults accounting for 30.6% of all chlamydia, gonorrhea, and syphilis cases in 2019 (Centers for Disease Control and Prevention, 2021b).



Although Connecticut has some of the lowest STI rates in the country, these rates are at an all-time high (Centers for Disease Control and Prevention, 2017c). Between 2015 and 2019, CT experienced a 16% increase in reported chlamydia cases, a 111% increase in reported gonorrhea cases, and a 128% increase in reported primary and secondary syphilis cases (Centers for Disease Control and Prevention, 2021d). In CT between 2015 and 2019, the prevalence of HIV increased slightly (1.4%) (Connecticut Department of Health, 2020). New HIV diagnoses were relatively consistent during this period, between 257 and 280 annually (Connecticut Department of Health, 2020). Geographically, STI cases in CT are concentrated in Hartford, Bridgeport, and New Haven, urban areas with the lowest per capita income across the state (CT Mirror, 2018; United States Census Bureau, 2019). In the most recent report on income inequality in 2016, CT was ranked second in the country (Kolmar, 2018). This report demonstrated that the distribution of wealth in CT is skewed to a smaller number of residents in proportion to the population of the state, second only to New York State (Kolmar, 2018). Social conditions like poverty and income inequality contribute significantly to higher rates of STIs among racial and ethnic minorities due to decreased access to health services and lower education levels (Cunningham & Cornelius, 1995; Gonzalez, Hendriksen, Collins, Durán, & Safren, 2009; Hogben & Leichter, 2008).

Given the myriad of adverse health outcomes that arise from exposure to and delayed treatment of STIs and HIV, national efforts have been made to address this critical public health issue. The Office of Disease Prevention and Health Promotion developed an objective specific to STIs in the US under HealthyPeople2030. The HealthyPeople2030 goal is to: “reduce sexually transmitted infections and their complications and improve access to quality STI care” (HealthyPeople2030, 2021).

Sexual history screening (SHS) is an evidence-based, medical guideline to identify risk of STIs/HIV and adverse sexual health outcomes (Barrow et al., 2020; Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). While SHS can be as brief as three questions, this process helps providers understand their patients' sexual practices, behaviors, and risk factors (Barrow et al., 2020; Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). A patient may report having frequent unprotected sexual intercourse and would benefit from education about barrier use and/or medication, such as birth control or pre-exposure prophylaxis (PrEP) to prevent HIV infection. Although SHS is a recommended practice, it is not routinely implemented, with provider-reported utilization rates below 50% (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Ribeiro et al., 2014; Torkko et al., 2000; U.S. Preventative Task Force, 1997; Wimberly et al., 2006). Patient characteristics may influence providers' SHS behaviors, including patients' age, gender, cultural background (e.g., race, ethnicity, religion), and sexual and/or gender minority identity (Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). Providers report the most discomfort and avoidance conducting SHS with sexual and gender minority patients and older patients (65-years-old and older) (Burd et al., 2006; Hayes et al., 2015; Khan et al., 2008; Lewis & Freeman, 1987; Temple-Smith et al., 1996). Additionally, this research indicates that providers' gender, degree, and years of practice are associated with SHS behaviors (Gongidi et al., 2010; Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). Specifically, prior research demonstrates female providers and those who recently graduated from their clinical training were more likely to report conducting SHS with their patients (Gongidi et al., 2010; Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006).

To date, research has predominantly explored SHS behaviors and practices among PCPs, general practitioners, and obstetricians in the US and Australia (Burd et al., 2006; Ginige et al., 2006; Gongidi et al., 2010; Hayes et al., 2015; Khan et al., 2008; Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). Research has not yet explored the SHS behaviors of primary care providers (PCPs) at Federally Qualified Health Centers (FQHCs), which are funded to provide primary care services in underserved areas and to at-risk and vulnerable populations (Health Resources and Services Administration, 2019a; Proser, 2005). FQHC patients are more likely to be racial and ethnic minorities, have less education, have Medicaid or no insurance, and/or live in a rural area compared to patients at private primary care clinics (Forrest & Whelan, 2000; O'malley & Mandelblatt, 2003). Additionally, there is some evidence that PCPs at FQHCs may have different treatment and counseling behaviors compared to PCPs at private primary care clinics (Goldman et al., 2012; O'malley & Mandelblatt, 2003; Rothkopf et al., 2011). Although studies have shown that FQHC providers have lower rates of counseling about diet and exercise, PCP at FQHCs have shown equal or greater adherence to 18 guidelines in four areas: pharmacologic management of common chronic diseases, prevention counseling for smoking cessation, appropriate use of screening tests for blood pressure, electrocardiogram, and urinalysis, and appropriate prescriptions for older patients (Goldman et al., 2012; O'malley & Mandelblatt, 2003). This may account for lower emergency department visits, inpatient hospitalizations, and preventive hospital readmissions for FQHC patients when compared to private clinic patients (Rothkopf et al., 2011).

The aim of this study was to answer the research questions: what sociodemographics of patients and PCPs are associated with sexual history documentation among adult medical patients in a multi-site FQHC setting? Based on existing literature, the hypotheses for this study were: (1)

patients whose providers were younger would be more likely to have sexual history documented in their medical charts; (2) patients whose providers were cisgender women would be more likely to have sexual history documented in their medical charts; (3) patients who identified as a sexual and/or gender minority would be less likely to have sexual history documented in their medical charts and (4) patients who were older would be less likely to have sexual history documented in their medical charts. The results of this study will address gaps in the literature pertaining to the relationship between SHS and sociodemographic factors of FQHC patients and providers and lay a critical foundation for future research and programming efforts to increase SHS practices in routine clinical care.

## **3.2 Methods**

### **3.2.1 Study Description**

#### **3.2.1.1 Study Site**

This study utilized data from a multi-site FQHC in CT that provides care to more than 145,000 patients each year. Locations and services (including medical, behavioral health, and dental services) offered by this organization are available throughout most of CT, predominantly serving five of CT's eight counties: Fairfield, Hartford, Middlesex, New Haven, and New London. This healthcare organization is focused on providing and improving care to at-risk patient populations, including specialized services for patients with substance use disorders, homeless patients, and lesbian, gay, bisexual, and transgender patients.

### **3.2.1.2 Eligibility**

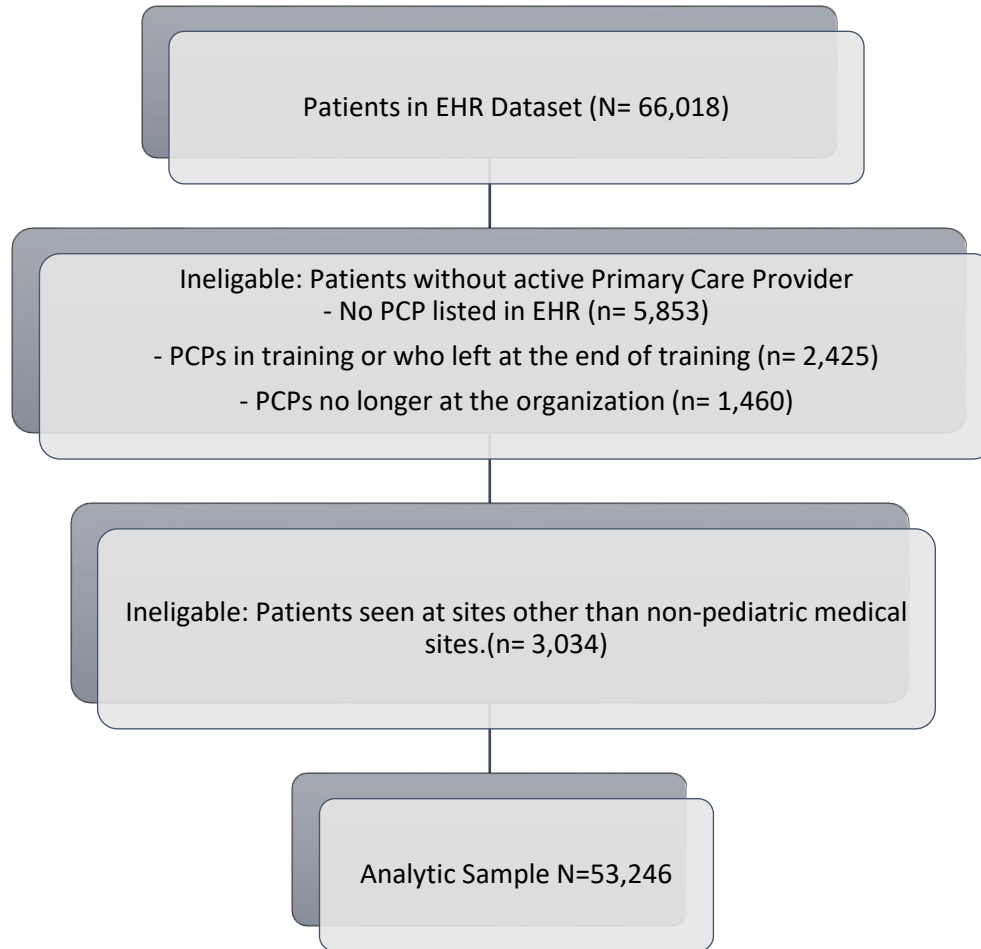
The sample population for this paper was: adult patients (18-years-old or older at the first visit that occurred during the study period) who had a medical visit between June 2018 and December 2019 and whose PCP was listed in the electronic health record (EHR) and still employed at the time of the study. Figure 1 outlines the exclusion process for patients based on eligibility. Most of the ineligible patients did not have a provider listed (n= 5,853). Patients who had providers who were residents at the time of the study (meaning they were in training during the study period) or who left the organization at the conclusion of training (n= 2,425) and patients whose providers were not listed in the EHR or who were no longer with the organization at the time of the study were also eliminated (n= 1,460). As policies and services vary by site, sites that did not serve adult patients or only served a specified group of adult patients were excluded (pediatric, school-based health, mobile dental, homeless services, or sites with no medical practice, n= 3,211). Patients were not included in the sample if they were seen for non-medical visits (e.g., behavioral health, dental, quick care). The sample was limited to patients seen in the 18 months prior to December 2019, as to avoid confounding the analysis with differences in clinical practice that occurred as a result of the COVID-19 pandemic that began in March of 2020. The analytic sample for this study was 53,246.

### **3.2.1.3 Recruitment**

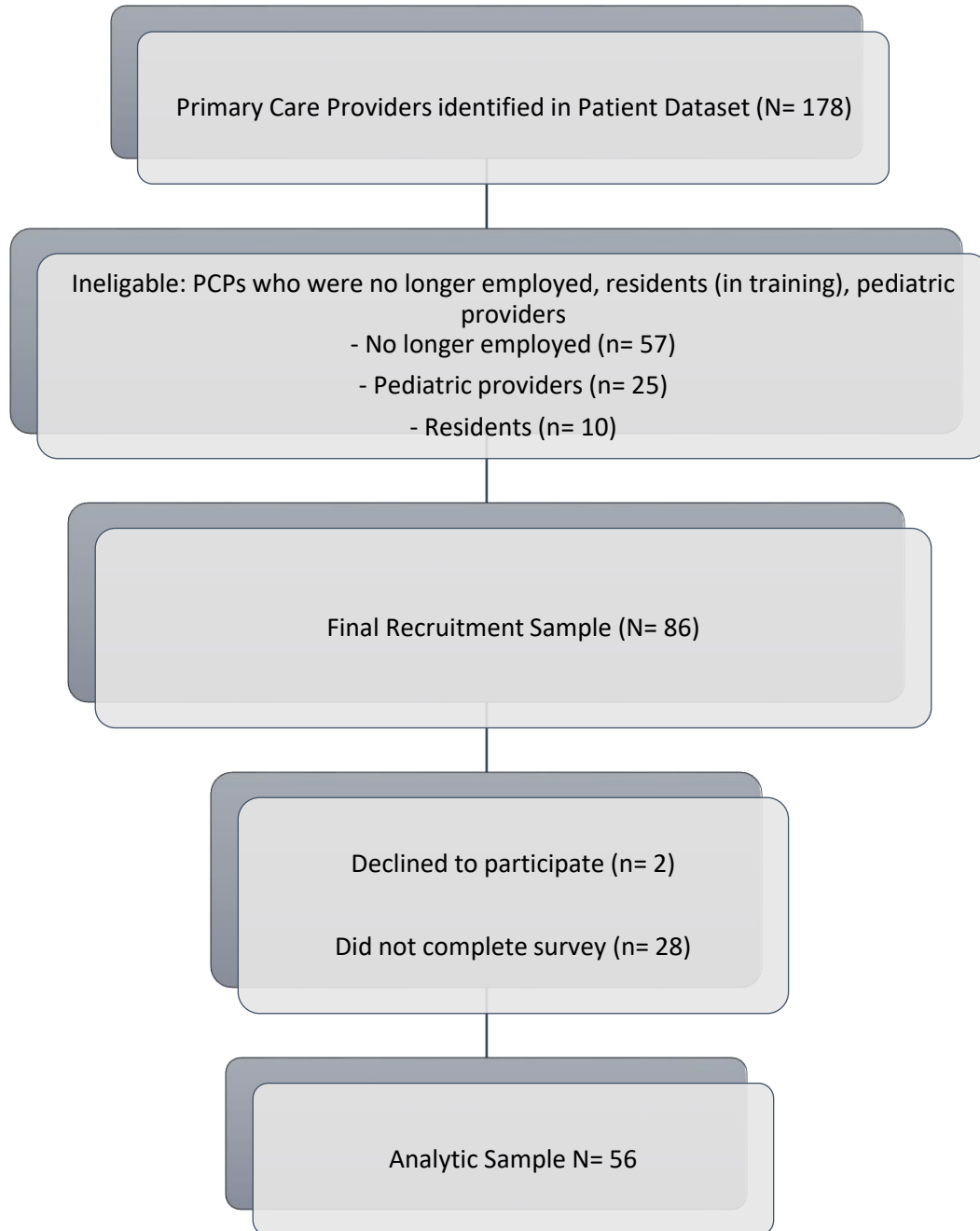
This study received approval from the Institution Review Board at the health center. Data were collected through a purposive sampling of the EHR and a provider census survey. A data request was made to the FQHC's EHR management department to extract patient- and provider-level data from the EHR for adult patients with a medical visit between June 2018 and December 2019. The EHR data request included: patients' age, sexual orientation, gender identity, race,

ethnicity, primary care site, primary language, insurance status, whether sexual history was documented in the chart, PCP, PCPs' medical credentials, and the number of patients on the PCPs' patient panel. Additionally, this process identified PCPs eligible for inclusion in the census survey. Figure 2 outlines the exclusion process for PCPs based on eligibility and recruitment.

To gather PCPs' sociodemographics, a brief survey was created in Qualtrics and disseminated via the health care organization's e-mail system. PCPs were asked to report their age, sexual orientation, gender identity, race, ethnicity, years of employment at the health center, years since graduating from their clinical degree program, postgraduate specialty (if applicable), and years since completing postgraduate training (if applicable). PCPs were compensated \$10 for their participation in the Qualtrics survey. Of 86 eligible providers, 56 completed the survey for a response rate of 65.12%.



**Figure 1. Patient Eligibility CONSORT Diagram**



**Figure 2. Provider Eligibility and Recruitment CONSORT Diagram**



## **3.2.2 Measures**

### **3.2.2.1 Outcome Variable**

To determine whether sexual history was documented in the medical chart of eligible patients, patients' responses to each sexual history question were extracted from the EHR for all eligible patients, regardless of whether there was a response documented. In cases where nothing was documented, it was considered "no sexual history documented". The SHS tool in this EHR reflects the CDC recommended questions (Center for Disease Control and Prevention; Centers for Disease Control and Prevention, 2019b). In this EHR system, there are three primary SHS questions: 1) Have you been sexually active in the last 12 months? 2) With men, women, or both? 3) Did you use protection during your last sexual encounter? A possible fourth question was: how often do you use protection during your sexual encounters? Since the fourth question was intended as a follow-up to question #3, having sexual history documented was considered having a response to any of the first three questions regardless of how many questions were completed.

### **3.2.2.2 Primary Predictors**

#### Patient Age

Patients' age was calculated by the EHR at the time of data extraction (December 2020) based on the birth date entered into the system.

#### Patients' Race/Ethnicity

Race and ethnicity were extracted for each patient. Upon intake at the health center, patients self-report their race as one of the following: 'White', 'Hispanic', 'Black or African American', 'Asian', 'Native Hawaiian or Other Pacific Islander', 'American Indian or Alaska Native', 'Multi-racial', or 'other'. Patients could decline to respond, or this information may be withheld by the

State in cases where they were under the ward of the State. A limited number of patients self-reported their race as ‘Native Hawaiian or Other Pacific Islander’ (n= 37), ‘American Indian or Alaska Native’ (n= 130), ‘Multi-racial’ (n= 17), or their race was undetermined but not declined (n=341). Some patients did identify their race as ‘Other’ (n= 420). For the purposes of this study, these races were categorized as ‘Other’ (n= 945).

At intake, patients also self-reported their ethnicity as either ‘Hispanic’ or ‘Non-Hispanic’. As with race, patients were able to decline to respond or their responses were prohibited by the State. To determine race/ethnicity, patients were considered ‘White Non-Hispanic’ if their race was ‘White’ and their ethnicity was ‘Non-Hispanic’; ‘Hispanic’ if their race and/or ethnicity was ‘Hispanic’; ‘Black or African American Non-Hispanic’ if their race was ‘Black or African American’ and their ethnicity was ‘Non-Hispanic’; ‘Asian Non-Hispanic’ if their race was ‘Asian’ and their ethnicity was ‘Non-Hispanic’; and ‘Other Non-Hispanic’ if their race was ‘Other’ and their ethnicity was ‘Non-Hispanic’.

#### Patients’ Sexual Orientation

Patients’ sexual orientation information was self-reported as part of new patient registration and pre-visit intake for existing patients. This process has been in place since April 2016 and is part of the routine screening process for all patients. Response options to “what is your sexual orientation?” were: ‘straight or heterosexual’, ‘gay, lesbian, or homosexual’, ‘bisexual’, ‘something else’, ‘don’t know’, and ‘other’. Open text fields were available to document patient-provided responses for ‘something else’ or ‘other’ sexual orientation. ‘Something else’, ‘don’t know’ and ‘other’ were collapsed into ‘other’ for the purposes of this study.

#### Patients’ Gender

Gender identity information was captured through self-reported response as part of the same process to collect sexual orientation data. To determine gender identity, patients were asked “what is your gender identity?”. Response options were: ‘male’, ‘female’, ‘transgender male/transman’, ‘transgender female /transwoman’, ‘genderqueer (neither exclusively male nor female)’, ‘questioning’, ‘additional gender category/other’, and ‘do not know’. Open text fields were available to document patient-provided responses for ‘additional gender category/other’ gender identity. For data analysis purposes, a patient was considered cisgender if either their sex assigned at birth (which is self-reported as part of the same screening process as sexual orientation and gender identity) was ‘male’ and their gender identity was ‘man’ or their sex assigned at birth was ‘female’ and their gender identity was ‘woman’. A patient was considered transgender if they self-identified as ‘transgender’, or their gender identity was discordant with their sex assigned at birth. Patients whose gender identity was discordant with their sex assigned at birth were considered transgender men if their sex assigned at birth was ‘female’ and gender identity was ‘man’ or “transgender man”; and were considered transgender women if their sex assigned at birth was ‘male’ and gender identity was ‘woman’ or “transgender woman”. All other gender categories (i.e., ‘genderqueer’, ‘questioning’, ‘additional gender category/other’, and ‘do not know’) were dropped as there were an insufficient number of patients with these identities to maintain in the analyses (n= 89, 0.002%).

#### Patients’ Primary Language

Upon paper or electronic registration at the health center, patients have the option to provide their primary language as part of their medical record. Patients may indicate any language as their primary language. For the purposes of this study, any language other than ‘English’ was considered ‘Other’.

### Patient's Insurance Status

To capture patients' insurance status, the insurance type was extracted from the EHR, categorized as 'Private', 'Medicaid', 'Medicare', 'Uninsured', and 'Other Public'. Included within uninsured are patients that qualify for sliding-fee-scale. Patients' insurance is considered 'Other Public' when it is an Affordable Care Act Insurance.

### Number of Patients on Primary Care Providers Panels

The EHR maintains a list of all active patients and their assigned PCP. To capture the size of each PCPs' patient panel, the total number of active patients (patients are considered active if they had a medical visit in the previous 18 months), regardless of inclusivity in this study, was extracted from the EHR.

### Primary Care Providers' Age

Eligible PCPs provided their age in response to the question: 'What is your age?'

### Primary Care Providers' Race/Ethnicity

PCPs self-reported their race and ethnicity in the Qualtrics survey. In response to 'What is your race?', providers could select from the following: 'White/Caucasian', 'Black or African American', 'Asian or Pacific Islander', 'Native American or American Indian', or use free text space to input another race. In response to 'What is your ethnicity?', providers selected from 'Hispanic' and 'Non-Hispanic'. PCP's race/ethnicity was determined using the same method as the patients' race/ethnicity.

### Primary Care Providers' Sexual Orientation

PCPs responded to the question: 'what is your sexual orientation' by selecting from the following multiple-choice options: 'Heterosexual or Straight', 'Lesbian', 'Gay', 'Bisexual',

‘Queer’, or ‘Another sexual orientation’. If they selected ‘Another sexual orientation’, they were provided a space to enter free text.

#### Primary Care Providers’ Gender

In alignment with published guidance from the Williams Institute, PCPs responded to two sex and gender identity questions: ‘What sex were you assigned at birth, on your original birth certificate?’ (options: ‘Male’ or ‘Female’) and ‘What is your current gender identity?’ (Williams Institute, 2014). For gender identity, PCPs could select from any of the following: ‘Male’, ‘Female’, ‘Trans male/ trans man’, ‘Trans female/ trans woman’, ‘Genderqueer/ gender non-conforming’, or ‘Different identity (please state)’. As no PCPs identified as a gender other than their sex assigned at birth, and thus were all cisgender men and women, gender identity alone was used for this study.

#### Primary Care Providers’ Years of Employment

PCPs reported the number of years they were employed at their current healthcare organization by answer the question: ‘How many years have you been employed by [the healthcare organization] as a primary care provider?’.

#### Primary Care Providers’ Medical Credentials and Years Since Graduating from Medical Credentialing Program

As part of the survey, PCPs provided the name of their medical credential by responding to: ‘Which of the following is your medical credential?’. They could select from: ‘Medical Doctor (MD)’, ‘Advanced Practice Registered Nurse (APRN)’, ‘Physician Assistant (PA)’, or ‘Doctor of Osteopathic Medicine (DO)’. After reporting their medical credentials, PCPs were asked: “How many years has it been since you graduated from your medical credentialing program?”. Respondents could only enter numerical values.

### Primary Care Providers' Medical Training, Specialty, and Years Since Completion of Post Graduate Training

After responding to the medical credentialing questions, PCPs indicated whether they completed medical training by selecting 'Yes' or 'No' to the question: "Did you complete training after your medical credentialing program (i.e. post-graduate residency)?" For those that did, they were asked to provide the specialty and number of years since that training in the subsequent questions: 'What was your medical training (i.e., post-graduate residency) specialty?' and 'How many years has it been since your medical training (i.e. post-graduate residency)?'. Medical specialties could be reported using an open text field while years since training required a numerical response.

#### **3.2.2.3 Covariates**

##### Patients' Primary Medical Site

To account for variation by geographic location and site-specific policies and procedures, patients' primary site was extracted from the EHR. Their primary site was determined by where they established care. Patients may transfer sites, which would be documented in the EHR.

#### **3.2.3 Analytic Procedure**

All analyses were conducted in StataSE 16.1 (StataCorp LLC, College Station, Texas) using the following procedures. Descriptive and frequency statistics were conducted for patient- and provider-level variables. To assess for statistical patterns, bivariate analyses were conducted for all patient-level independent variables on whether sexual history was documented in the medical chart. Specifically, chi-squares were conducted for categorical variables and t-test for

patients' age. We ensured there was no multicollinearity among the predictor variables on the outcome variable. The Variance Inflation Factors (VIFs) for each of our predictor variables was 2.17 or below, indicating multicollinearity was not present.

To answer the research question, the following model building process took place using multilevel mixed-effects logistic regressions and a multilevel crossed random effects logistic regression (otherwise known as cross-classified models). A multilevel crossed random effects logistic regression was necessary as their hierarchical structure was not nested directly (patients within PCPs within sites). Patients could move across PCPs and medical sites, which required a crossed random effects model to appropriately account for the clustering of patients within PCPs and within medical sites. As seen in Table 3, Model 1 is the null model, demonstrating the intercept when no predictor variables are present. Model 2 introduces the level one (patients' sociodemographic) variables. Model 3 adds the level two variables (PCPs' sociodemographics) while clustering by PCP. Lastly, Model 4 contains all predictor variables while clustering by PCP and medical site. Statistical significance was determined when  $p < 0.05$ .

### **3.3 Results**

#### **3.3.1 Sample Characteristics**

The final analytic sample was 53,246 adult patients with a medical visit between June 2018 and December 2019 at one of the FQHC's non-pediatric medical sites. A majority of patients were Hispanic (n= 25,371, 52.79%), Heterosexual (n= 47,243, 95.23%), and cisgender women and men (29,059, 58.09% and 20,517, 41.02%, respectively) (Table 1). English was the most common

primary language (37,455, 70.34%) and more than half of the patients had Medicaid insurance (15,761, 59.06%) (Table 1). Less than half of the study population had any sexual history documented in their medical charts (n= 22,581, 42.41%). Having any or no sexual history documented in the medical chart differed significantly by age, race/ethnicity, sexual orientation, gender, primary language, and site (Table 1). In the chi-square analysis, insurance status did not differ significantly by sexual history documentation (Table 1).

The mean age of patients with sexual history documented in their medical charts was one and a half years less than those without sexual history (Table 1). Black Non-Hispanic patients had a higher prevalence of having sexual history documented in their medical charts (43.96%) than all other race/ethnicity groups, with Asian Non-Hispanic patients with the lowest prevalence (39.97%) (Table 1). More than half of gay, lesbian, and homosexual patients had sexual history documented in their chart (50.14%) in contrast to less than 50% of patients identifying as heterosexual, bisexual, or other (Table 1). Cisgender women had the highest prevalence of any sexual history documentation (45.55%) compared to 41.12% of cisgender men, 42.27% of transgender women, and 44.05% of transgender men (Table 1). A slightly higher percentage of patients whose primary language was English had sexual history documented in their chart (42.86% compared to 41.34% of other primary language patients) (Table 1). There was a wide variation in the proportion of any versus no sexual history documented in patients' charts across medical sites from 26.38% of patients at site 12 to 70.62% at site 9 (Table 1).

Among eligible PCPs who responded to the survey (n= 56), the average age was 43-years-old, average years of employment was 7, average years since medical credential completion was 12, and years since post graduate training was 15 (Table 2). A majority of providers were White Non-Hispanic (69.64%), Heterosexual (94.74%), cisgender women (68.42%), and Advanced



Practice Registered Nurses (APRN) (62.50%) (Table 2) Across PCPs in the study, regardless of whether they responded to the survey, the average number of patients on panel was 1,308. No PCPs reported their medical training specialty; thus, this variable could not be used as part of analysis.

Table 3 displays the results of the model building process to answer the primary research question of this study. After adding the patient sociodemographics to the model, patients who were younger (OR= 0.99, 95% CI: 0.99,0.99), Black Non-Hispanic (OR= 1.12, 95% CI: 1.05,120), Hispanic (OR= 1.06, 95% CI: 1.00, 1.11), Gay, lesbian, homosexual (OR= 1.25, 95% CI: 1.10, 1.42), cisgender women (OR= 1.15, 95% CI: 1.12, 1.19), and who had Medicare (OR= 1.11, 95% CI: 1.03, 1.20) had higher odds of having any sexual history documented in their medical charts when clustering by PCP (Table 3).

In Model 3 (Table 3), after adding PCP sociodemographics, odds of having any sexual history documented in the medical chart remained significantly higher for younger patients (OR= 0.99, 95% CI: 0.99, 0.99), gay, lesbian, or homosexual (OR= 1.24, 95% CI: 1.04, 1.47), and cisgender women (OR= 1.10, 95% CI: 1.04, 1.16) (Table 3). Patients whose primary language was not English had a significantly lower odds of having any sexual history documented in their medical chart when clustering by PCP (OR= 0.91, 95% CI: 0.86, 1.05) (Table 3). In this model, patients whose providers who identified as cisgender women had higher odds of having sexual history documented in their charts compared to patients whose providers identified as cisgender men (OR= 1.93, 95% CI: 1.01, 3.72) (Table 3). Additionally, patients whose PCPs had more patients on their panel were less likely to have sexual history in their medical charts (OR= 0.99, 95% CI 0.99, 0.99) (Table 3).

In the final, Model 4, when accounting for both clustering by PCP and medical site, younger patients (OR= 0.99, 95% CI: 0.99, 0.99); gay, lesbian, and homosexual patients (OR= 1.23, 95% CI: 1.04, 1.47); patients who were cisgender women (OR= 1.10, 95% CI: 1.04, 1.16); and patients whose providers were cisgender women (OR= 1.80, 95% CI: 1.00, 3.21) had significantly higher odds of having any sexual history documented in their medical chart (Table 3). Conversely, patients whose providers have more patients on their panel (OR= 0.99, 95% CI: 0.99,0.99) and patients whose primary language is not English had significantly lower odds of having any sexual history documented in their medical chart, when accounting for clustering by PCP and medical site (OR= 0.91, 95% CI: 0.85, 0.97) (Table 3).

### **3.4 Discussion**

This study is the first, to our knowledge, to investigate the relationship between adult patients' and their PCPs' sociodemographics and documentation of any sexual history in the medical chart. The results of this study demonstrate that there are key sociodemographics that are significantly related to higher odds of having sexual history documented in the medical chart when accounting for clustering by PCP and medical site. In addition to adding to the field of literature on the relationship between patients' and providers' sociodemographics and SHS, these findings indicate the need for further investigation into the interplay between social and contextual factors and the implementation of sexual history screening as part of routine clinical care.

The first hypothesis of this study was that patients with younger PCPs would be more likely to have any sexual history documented in their charts. Findings did not support the first hypothesis. However, there was a significant effect to support the second hypothesis that patients whose PCPs

identified as cisgender women were more likely to have any sexual history documented in their medical charts. Specifically, patients whose PCPs were cisgender women were 1.8 times more likely to have any sexual history documented in their charts. This finding aligns with previous research that found that providers who were women reported implementing SHS more often than men (Gongidi et al., 2010; Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). Given that the effect size was so large in this study and is supported by most of the existing research exploring SHS implementation behaviors of PCPs, there appears to be a consistent relationship between providers who are women and the integration of sexual history screening during routine care.

The third hypothesis of this study was that patients who identified as sexual and/or gender minorities would be less likely to have sexual history documented in their medical charts. Our findings were not congruent with this hypothesis. Interestingly, we found an increased odds of having any sexual history documented in the medical chart for patients who identified as gay, lesbian, and homosexual. Although few studies have explored SHS using patient-level data, previous research demonstrated that providers felt uncomfortable conducting sexual history with sexual minority patients (Burd et al., 2006; Hayes et al., 2015; Khan et al., 2008; Lewis & Freeman, 1987; Temple-Smith et al., 1996). The fourth and final hypothesis was that patients who were older would be less likely to have sexual history documented in their charts. Our results supported this hypothesis, as odds of having any sexual history documented in the medical chart decreased with patients' age.

Our findings demonstrating a higher likelihood of having sexual history documented in the medical chart for gay, lesbian, and homosexual patients may be related to the emphasis on affirming care for sexual and gender minority patients at the health center. This FQHC aims to

provide affirming, competent care to oppressed populations, such as sexual and gender minorities. Trainings are routinely conducted throughout the organization to assist other providers in understanding best practices to providing care for these populations. Lastly, provider practices regarding SHS may have been impacted by another study that took place between 2016 and 2017, which was focused on the implementation of sexual orientation and gender identity questions and involved organization-wide training and education on health disparities among sexual and gender minorities (Furness et al., 2020).

While this study does not evaluate the health center or any training pertaining to sexual and gender minority health in particular, our results suggest that knowledge of these health disparities and an emphasis on the importance of affirming care for these populations may make a critical difference in the provision of care provided to these patients on a routine basis. Consistent SHS should identify specific physical concerns as they pertain to sexual health, which may be pronounced for racial, ethnic, sexual, and gender minority populations. PCPs may hold biases that impact their decision to integrate SHS during visits. Specifically, they may ask sexual history questions more often for their sexual minority patients than their heterosexual patients out of belief that these patients are engaging in high-risk sexual behaviors and that prevention of STIs and HIV are what is most important to the patient based on their identity alone. Previous research demonstrated this phenomenon, in a qualitative study of nurse practitioners, they reported one of their primary foci with these patients was sexual health, specifically the prevention of STIs for gay, bisexual, and other MSM (Manzer, O'Sullivan, & Doucet, 2018). Given that the burden of STIs/HIV and perception of behavior differ across SGMs, we investigated whether gender moderated the relationship between sexual orientation and having sexual history documented in the medical chart. This analysis was not significant, indicating that there were no differences in

likelihood of having sexual history documented in the medical chart based on patients combined sexual orientation and gender identity.

An additional important result of this study was the significant variation by medical site. The proportion of patients with sexual history in their medical charts ranged from 26.38% to 70.62% across 13 sites. Although we did not measure any system-level factors that could account for this discrepancy in sexual history documentation behavior, it is a valuable finding that indicates that the system and/or environment of a medical site is an influential factor. Medical sites may have different sexual history documentation rates for a variety of reasons, including the difference in policies and procedures or the size of the site and how much support is available. Additionally, the patient population varies by site and patients at some locations may be more likely to refuse to respond to sexual history questions.

This study is not without limitations. Although EHR data is a realistic representation of what information is available during clinical visits, it is not without its own flaws. It is possible that PCPs conduct SHS with their patients more frequently than is documented in the patients' medical records. Additionally, there is potentially misreported information from false clicks or typos in the EHR. While these errors are possible, the provision of care is often dependent on patient's documented medical history. Even if SHS was conducted at a higher rate, from the perspective of another clinical provider working with the patient, if it is not documented it is not usable information as part of patient care. A second limitation of this study is that not all eligible PCPs responded to the survey. Although a majority did respond, the 30% that did not may be even less likely to regularly conduct sexual history screenings. Conversely, these PCPs may be most concerned with patient care and routine screenings and therefore prioritize care and documentation

over participation in a research study. Without their sociodemographics, it is not possible to estimate how their inclusion would have influenced the results.

The results of this novel study indicate a significant relationship between patient and PCP sociodemographics and the documentation of sexual history in the medical chart. These findings create a critical base for future research exploring these relationships to understand the true drivers behind sexual history screening behavior. Specifically, future research should explore whether patient-provider identity and demographic concordance is associated with increased sexual history screening, whether there is a difference between sexual history screening behavior and documentation, and whether stigma plays a role in the process of deciding whether to implement sexual history screening.

**Table 1. Sociodemographic Characteristics of Adult Patients with a medical visit between June 2018 and December 2019 at a Multisite Federally Qualified Health Center in Connecticut (N= 53,246)**

	Total <sup>a</sup>		Sexual History Documentation <sup>b</sup>				P-value
			Any		None		
	N= 53,246		n= 22,581		n= 30,665		
	n/ Mean	%/ SD	n/ Mean	%/ SD	n/ Mean	%/ SD	
<b>Patient Sociodemographics</b>							
Age	43.13	(15.66)	42.27	(15.55)	43.77	(15.71)	*
Race/Ethnicity							***
White Non-Hispanic	14,580	(30.34)	5,930	(40.67)	8,650	(59.33)	
Hispanic	25,371	(52.79)	10,790	(42.53)	14,581	(57.47)	
Black Non-Hispanic	5,607	(11.67)	2,465	(43.96)	3,142	(56.04)	
Asian Non-Hispanic	1,556	(3.24)	622	(39.97)	934	(60.03)	
Other Non-Hispanic	945	(1.97)	404	(42.75)	541	(57.25)	
Sexual Orientation							***
Heterosexual	47,243	(95.23)	20,722	(43.86)	26,521	(56.14)	
Gay, Lesbian, Homosexual	1,107	(2.23)	555	(50.14)	552	(49.86)	
Bisexual	1,029	(2.07)	506	(49.17)	523	(50.83)	
Other	230	(0.46)	110	(47.83)	120	(52.17)	
Gender							***
Cisgender Woman	29,059	(58.09)	13,236	(45.55)	15,823	(54.45)	
Cisgender Man	20,517	(41.02)	8,641	(42.12)	11,876	(57.88)	
Transgender Woman	227	(0.45)	100	(42.27)	127	(57.73)	
Transgender Man	220	(0.44)	93	(44.05)	127	(55.95)	
Primary Language							**
English	37,455	(70.34)	16,053	(42.86)	21,402	(57.14)	
Other	15,761	(29.66)	6,528	(41.34)	9,263	(58.66)	
Insurance Status							
Uninsured	6,692	(12.59)	2,809	(41.98)	3,883	(58.02)	
Medicare	4,929	(9.27)	2,129	(43.19)	2,800	(56.81)	
Medicaid	31,389	(59.06)	13,355	(42.55)	18,034	(57.45)	
Private Insurance	8,865	(16.68)	3,733	(42.11)	5,132	(57.89)	
Other Public Insurance	1,277	(2.40)	513	(42.55)	764	(57.45)	
Sites							***
Site 1	9,241	(17.36)	2,837	(30.70)	6,404	(69.30)	
Site 2	8,578	(16.11)	2,571	(29.97)	6,007	(70.03)	
Site 3	7,446	(13.98)	4,679	(62.84)	2,767	(37.16)	
Site 4	7,288	(13.69)	2,511	(34.45)	4,777	(65.55)	
Site 5	3,937	(7.39)	1,681	(42.70)	2,256	(57.30)	
Site 6	2,939	(5.52)	1,049	(35.69)	1,890	(64.31)	
Site 7	2,596	(4.88)	1,347	(51.89)	1,249	(48.11)	
Site 8	2,282	(4.29)	1,207	(52.89)	1,075	(47.11)	
Site 9	2,146	(4.03)	1,558	(72.60)	588	(27.40)	
Site 10	2,065	(3.88)	1,510	(72.12)	555	(26.88)	
Site 11	1,971	(3.70)	609	(30.90)	1,362	(69.10)	
Site 12	1,602	(3.01)	421	(26.28)	1,181	(73.72)	
Site 13	1,155	(2.17)	601	(51.89)	554	(48.11)	

\* p<0.05, \*\* p < 0.01, \*\*\* p< 0.001

<sup>a</sup>Percentages are by row to show the distribution of patients by sociodemographic variable

<sup>b</sup>Percentages are by column to show the distribution of patients sociodemographics by having any or no sexual history documented

**Table 2. Sociodemographic Characteristics of Primary Care Providers of Adult Patients who had a medical visit between June 2018 and December 2019 at a Multisite Federally Qualified Health Center in Connecticut (N= 56)**

		<b>Total</b>	
		N= 56	
		n/ Mean	%/ SD
<b>Provider Sociodemographics</b>			
Age		43.48	(12.12)
Race/Ethnicity			
	White Non-Hispanic	39	(69.64)
	Black Non-Hispanic	4	(7.14)
	Hispanic	4	(7.14)
	Other Non-Hispanic	9	(16.07)
Sexual Orientation			
	Heterosexual	54	(94.74)
	Gay	1	(1.75)
	Pansexual	1	(1.75)
Gender Identity			
	Female	39	(68.42)
	Male	17	(29.82)
Years of Employment		7.06	(8.40)
Clinical Credentials			
	Medical Doctor	16	(28.57)
	Doctor of Osteopathic Medicine	2	(3.57)
	Advanced Practice Registered Nurse	35	(62.50)
	Physician Assistant	3	(5.36)
Years since Credentialing Degree Completion		12.33	(11.54)
Patient Panel Size		1308.16	(751.40)
Years since post graduate training		10.39	(12.69)
	Years since any additional training	15.43	(16.90)
Department			
	General Clinical	52	(92.86)
	Center for Key Populations	4	(7.14)



**Table 3. Association Between Patient and Provider Sociodemographic Factors and Sexual History Screening at a Multisite Federally Qualified Health Center in Connecticut between June 2018 and December 2019 (N= 53,246)**

	Model 1: Null Model <sup>a</sup>			Model 2: Patient Sociodemographics <sup>b</sup>			Model 3: Provider Sociodemographics <sup>c</sup>			Model 4: Cross Classified <sup>d</sup>		
	OR	(95% CI)	P	OR	(95% CI)	P	OR	(95% CI)	P	OR	(95% CI)	P
<b>Patient Sociodemographics</b>												
Intercept	0.77	(0.63, 0.94)	<0.001	1.16	(0.91, 1.47)	0.229	1.30	(0.30, 5.67)	0.727	0.52	(0.33, 0.82)	
Age				0.99	(0.99, 0.99)	<0.001	0.99	(0.99, 0.99)	<0.001	0.99	(0.99, 0.99)	<0.001
Race/Ethnicity												
White Non-Hispanic				1.00	(referent)		1.00	(referent)		1.00	(referent)	
Black Non-Hispanic				1.01	(0.94, 1.08)	0.793	1.00	(0.92, 1.09)	0.949	1.01	(0.92, 1.01)	0.874
Hispanic				1.04	(0.98, 1.10)	0.157	1.02	(0.95, 1.09)	0.575	1.02	(0.95, 1.01)	0.523
Asian Non-Hispanic				0.94	(0.84, 1.06)	0.357	0.87	(0.76, 1.00)	0.067	0.88	(0.76, 1.01)	0.071
Other Non-Hispanic				1.04	(0.90, 1.21)	0.564	1.04	(0.87, 1.24)	0.643	1.05	(0.57, 1.33)	0.516
Sexual Orientation												
Heterosexual				1	(referent)		1.00	-	-	1	(referent)	
Gay, Lesbian, Homosexual				1.25	(1.08, 1.44)	0.002	1.24	(1.04, 1.47)	0.017	1.23	(1.04, 1.47)	0.018
Bisexual				1.1	(0.95, 1.28)	0.183	1.12	(0.94, 1.34)	0.215	1.12	(0.937, 1.34)	0.215
Other				0.85	(0.61, 1.19)	0.350	0.87	(0.57, 1.33)	0.527	0.87	(0.57, 1.33)	0.516
Gender												
Cisgender Man				1.00	(referent)		1.00	(referent)		1.00	(referent)	
Cisgender Woman				1.13	(1.08, 1.17)	<0.001	1.10	(1.04, 1.16)	0.000	1.10	(1.04, 1.16)	0.000
Transgender Man				1.02	(0.74, 1.40)	0.919	1.08	(0.72, 1.61)	0.722	1.07	(0.72, 1.60)	0.735
Transgender Woman				1.04	(0.75, 1.43)	0.819	1.25	(0.85, 1.82)	0.254	1.26	(0.86, 1.84)	0.229
Primary Language												
English				1.00	(referent)		1.00	(referent)		1.00	(referent)	
Other				0.90	(0.95, 0.95)	<0.001	0.91	(0.85, 0.97)	0.005	0.91	(0.85, 0.97)	0.006

Insurance Status									
Private Insurance	1.00	(referent)		1.00	(referent)		1.00	(referent)	
Uninsured	0.89	(0.82, 0.97)	<b>0.007</b>	0.95	(0.86, 1.05)	0.316	0.95	(0.86, 1.05)	0.329
Medicare	1.07	(0.98, 1.16)	0.140	1.07	(0.97, 1.19)	0.179	1.07	(0.97, 1.19)	0.170
Medicaid	0.97	(0.92, 1.03)	0.395	1.00	(0.93, 1.08)	0.919	1	(0.93, 1.08)	0.913
Other Public	0.87	(0.75, 1.01)	0.061	0.90	(0.76, 1.07)	0.226	0.9	(0.75, 1.07)	0.219
<b>Provider Sociodemographics</b>									
Age				1.01	(0.98, 1.03)	0.519	1.01	(0.98, 1.04)	0.595
Race/Ethnicity									
White Non-Hispanic				1.00	(referent)		1.00	(referent)	
Black Non-Hispanic				0.74	(0.29, 1.88)	0.521	0.86	(0.37, 1.99)	0.720
Hispanic				1.17	(0.43, 3.23)	0.767	1.30	(0.51, 3.29)	0.578
Other Non-Hispanic				0.72	(0.32, 1.59)	0.414	0.92	(0.41, 1.67)	0.592
Sexual Orientation									
Heterosexual				1.00	(referent)		1.00	(referent)	
Gay				0.45	(0.01, 16.08)	0.663	1.26	(0.07, 23.25)	0.877
Gender Identity									
Cisgender Man				1.00	(referent)		1.00	(referent)	
Cisgender Woman				1.93	(1.01, 3.72)	<b>0.048</b>	1.80	(1.00, 3.21)	<b>0.048</b>
Years of Employment				0.98	(0.94, 1.02)	0.315	0.98	(0.95, 1.02)	0.373
Clinical Credentials									
Advanced Practice				1.00	(referent)		1.00	(referent)	
Registered Nurse									
Medical Doctor				1.21	(0.55, 2.66)	0.634	0.99	(0.49, 2.01)	0.989
Physician Assistant				0.94	(0.16, 5.51)	0.944	1.07	(0.22, 5.22)	0.933
Doctor of Osteopathic Medicine				1.45	(0.34, 6.16)	0.618	1.15	(0.31, 4.21)	0.833
Patient Panel Size				0.99	(0.99, 0.99)	<b>0.011</b>	0.99	(0.99, 0.99)	<b>0.024</b>

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Note:            **Boldface**            indicates            statistical            significance            (p < .05)

<sup>a</sup>Model was estimated using multilevel mixed-effects logistic regression while clustering by primary care provider

<sup>b</sup>Model 2 was estimated using multilevel mixed-effects logistic regression, with the 2nd model adjusting for patients' age, race/ethnicity, sexual orientation, gender, primary language, and insurance status while clustering by primary care provider

<sup>c</sup>Model 3 was estimated using multilevel mixed-effects logistic regression, with the 2nd model adjusting for patients' age, race/ethnicity, sexual orientation, gender, primary language, insurance status, and patients' primary care providers' age, race/ethnicity, sexual orientation, gender identity, years of employment, and clinical credentials while clustering by primary care provider

<sup>d</sup>Model 4 was estimated using multilevel crossed random effects logistic regression, with the 2nd model adjusting for patients' age, race/ethnicity, sexual orientation, gender, primary language, insurance status, and patients' primary care providers' age, race/ethnicity, sexual orientation, gender identity, years of employment, and clinical credentials while clustering by primary care provider and medical site

## **4.0 Relationship Between Sexual History Documented in Medical Chart and Referral to PrEP Navigator on Provision of PrEP at a Multisite Federally Qualified Health Center Between January 2016 and December 2019**

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### **4.1 Introduction**

An estimated 1.1 million people in the US are living with human immunodeficiency virus (HIV) (HIV.gov, 2020). Although the overall rate of new HIV diagnoses has decreased in recent years, HIV continues to disparately affect certain subpopulations (Centers for Disease Control and Prevention, 2020a). Of the new HIV diagnosis in 2019, 65% were men who had sex with men (MSM) (Centers for Disease Control and Prevention, 2021a). A majority of MSM diagnosed with HIV in 2019 were Hispanic and African American gay and bisexual men (Centers for Disease Control and Prevention, 2021a). Among women, African American women with heterosexual contact constitute the largest portion of new HIV infections (Centers for Disease Control and Prevention, 2021a) .

Sexual history screening (SHS) is an evidence-based practice recommended by the United States (US) Preventive Task Force and the Centers for Disease Control and Prevention that encourages clinical providers to assess risk of sexually transmitted infections (STIs) and HIV (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). In addition to

screening for risk of STIs and HIV, SHS helps clinical providers identify risk of sexual abuse, drug use during sex, and poor sexual function (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). SHS is recommended at each patient's intake, during annual preventive care visits, and if STI symptoms are present (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). SHS can be practiced in any medical specialty when medically relevant (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). The implications of inconsistent or incomplete SHS are that clinical providers are unaware of their patients' risk of STIs, HIV, sexual abuse, drug use during sex, sexual function, or pregnancy planning (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Plotkin et al., 1993; U.S. Preventative Task Force, 1997). Without this information clinical providers may not initiate conversations about prevention, harm reduction methods, referrals to specialists or relevant resources, and STIs/HIV prevention and testing (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Plotkin et al., 1993; U.S. Preventative Task Force, 1997).

An intended follow-up strategy of SHS is to implement harm reduction and STI/HIV prevention strategies (Barrow et al., 2020). For patients who are identified to be at risk of contracting HIV and who meet prescribing guidelines, pre-exposure prophylaxis (PrEP) is recommended (Altraum Institute, 2016). The CDC recommends discussing PrEP with all sexually active adolescent and adults and injection drug users (Centers for Disease Control and Prevention, 2021c). To start PrEP, a patient must be screened for HIV with a follow up screening every three months (Centers for Disease Control and Prevention, 2019a). For patients who are HIV-negative and qualify for a prescription, PrEP is a pill that is taken once daily (Centers for Disease Control and Prevention, 2019a). PrEP can reduce the risk of HIV through sexual practices among these and other populations by 99% if taken as directed (Centers for Disease Control and Prevention, 2019a). Among injection drug users, PrEP can reduce HIV infection by 74% when taken as

directed (Centers for Disease Control and Prevention, 2019a). People taking PrEP to prevent HIV transmission are advised to continue barrier usage as PrEP alone does not protect against other STIs (Centers for Disease Control and Prevention, 2019a). PrEP reaches maximum protection from HIV for receptive anal sex and receptive vaginal sex and injection drug use after seven and 21 days respectively (Centers for Disease Control and Prevention, 2019a).

To assist patients in need of PrEP in accessing care through the health care system, remove barriers to care, and improve adherence, some patients may be referred to a PrEP Navigator (Pinto et al., 2018). A PrEP Navigator is a service offered by some health care organizations to guide patients, particularly at-risk patients, through the process of accessing and adhering to PrEP (Mugavero et al., 2013). PrEP Navigators are non-clinical staff, and in some cases patient-peers, who are trained to help patients overcome structural barriers (Pinto et al., 2018). The duties and role of the PrEP Navigator differ by organization; however, common tasks include determining and assisting with insurance and financial coverage, discussing the PrEP process, working with the patient on realistic expectations, assisting patient with scheduling follow-up visits and visit adherence (Doblecki-Lewis et al., 2019; Pinto et al., 2018; University of California San Francisco, N.D.). Studies exploring the use of PrEP Navigators have found that this service has high acceptability among populations at high risk for HIV (e.g., young racial and ethnic MSM, transgender women) (Bradford et al., 2007; Pagkas-Bather et al., 2020). Patients who met with or who were enrolled in PrEP Navigator programs reported feeling supported as well as reductions in worry about structural barriers including issues with making appointments, getting to appointments, and finding providers that speak their language) (Bradford et al., 2007; Pagkas-Bather et al., 2020). Furthermore, research shows that engagement with a PrEP Navigator reduced delays in PrEP initiation, increased number of visits and utilization of HIV primary medical care, and was associated with consistent PrEP adherence at 90-day follow up (Bradford et al., 2007;

Pagkas-Bather et al., 2020; Reback et al., 2019; Spinelli et al., 2018). Although research is limited, PrEP Navigators may have an impact on patient's long term sexual health, specifically with increasing the proportion of patients with an undetectable viral load one year after initiating PrEP Navigator services (Bradford et al., 2007).

Despite extant literature demonstrating the role of PrEP navigators in improving PrEP outcomes, Research to date has not yet explored the relationship between SHS, referral to PrEP Navigators, and prescription of PrEP. This cross-sectional study utilized retrospective EHR data to address this dearth of research by investigating the association between having sexual history documented in the medical chart and referral to the PrEP Navigator and PrEP prescription duration at a multisite Federally Qualified Health Center (FQHC). The objective of this study was to investigate whether adult patients on PrEP had higher rates of PrEP prescription duration if they had both documented SHS and a referral to the PrEP Navigator. The two hypotheses for this study were: (1) having sexual history documented in the medical chart and having a referral to the PrEP Navigator will independently be associated with higher proportion of PrEP prescription duration for adult PrEP patients; and (2) the combined effect of having sexual history documented in the chart and a referral to the PrEP Navigator will be associated with a higher rate of PrEP prescription duration than either of these factors alone or not present at all.

## **4.2 Methods**

### **4.2.1 Study Description**

#### **4.2.1.1 Study Site**

This study utilized data from a multi-site FQHC in CT that provides care to more than 145,000 patients each year. Locations and services (including medical, behavioral health, and dental services) offered by this organization are available throughout most of CT, predominantly serving five of CT's eight counties: Fairfield, Hartford, Middlesex, New Haven, and New London. This healthcare organization focuses on providing and improving care to at-risk patient populations, including patients with substance use disorders, homeless patients, and lesbian, gay, bisexual, and transgender patients.

#### **4.2.1.2 Eligibility**

For patients to be included in this study, eligibility criteria were as follows: 1) having documentation of a prescription to prevent HIV infection, i.e. PrEP (Truvada or Descovy) in the medical chart, 2) 18-years-old or older at the start of the study period January 2019. Patients were excluded if they were prescribed Truvada or Descovy for post-exposure prophylaxis (PEP) or to treat HIV infection, if they were employees at the health center (to align with the organization's privacy policies), or if their PrEP prescription was never sent to the pharmacy, and thus they were never able to acquire the prescription. The timeframe of this study is consistent with the initiation and duration of the role of the PrEP Navigator at the organization. Patients who started or were maintaining a PrEP prescription between January 2016 and December 2019 theoretically had the opportunity to receive a referral to the PrEP Navigator based on their needs. The end period of this



study was December 2019, as to avoid confounding the analysis with differences in clinical practice that occurred as a result of the COVID-19 pandemic that began in March of 2020. After removing ineligible patients from the dataset (n=7), the analytic sample for this study was 214.

#### **4.2.1.3 Data Collection**

This study was approved as exempt from full board review on the basis of secondary data by from the Institution Review Board at the health center. Data were collected through a retrospective extraction from the EHR. A data request was made to the FQHC's EHR management department to extract patient-level data from the EHR for adult patients with a PrEP prescription between January 2016 and December 2019. Data that were collected via the EHR included patients': age, sexual orientation, gender identity, race, ethnicity, primary care site, primary language, insurance status, whether sexual history was documented in the chart, primary care provider (PCP), and PCPs' medical credentials. To collect accurate data on the PrEP Navigator and PrEP prescription details, a chart review of patients' encounters with clinical providers (telephone, virtual, or in-person), list of the patients' prescriptions, and the electronic prescription logs (documentation of prescriptions sent to pharmacies and their status) was conducted by the researcher. Additionally, during chart review the researcher collected the following data: the origin of the PrEP prescription (how the patient was initially identified for PrEP), whether the patient received a referral to the PrEP Navigator, whether they had an intake with the PrEP Navigator, the number of interactions they had with the PrEP Navigator, details on the patients' PrEP prescriptions (the number of prescriptions, the date of each prescription, and the number of refills and pills in each prescription), whether they stopped their PrEP prescription and why, and the date of their last office visit.

## 4.2.2 Measures

### 4.2.2.1 Outcome Variable

#### PrEP Prescription Duration

Since it was not possible to measure PrEP prescription adherence via patients' medical records, the best proxy was a proportion of how many PrEP pills a patient was prescribed (mean: 735, range: 28- 2,018) to the number of eligible days (mean: 443, range: 28 – 1,594). This proportion represents the extent to which patients could theoretically be adherent based on having a PrEP pill available on each day of the study. Two variables were used in the statistical models to determine PrEP prescription duration: 1) the total number of pills across PrEP prescriptions and 2) the number of eligible days. Eligible days was the chosen denominator in lieu of eligible months because PrEP prescriptions varied in duration, quantity of pills, and refills and did not consistently align with a month-long time frame. To calculate this proportion, the number of PrEP pills was the outcome variable and the number of eligible days was the exposure variable. Each of these variables was measured as follows:

Number of PrEP Pills: For each patient, the researcher documented each PrEP prescription, including the date, number of refills, and number of pills in the prescription (mean: 47, range: 3-180). The number of pills in each prescription was necessary as this varied between 3-180 pills. Prescriptions were included if they were successfully transmitted to the pharmacy through the EHR or were written on paper and given to the patient. Both prescription types were considered eligible as this study is focused on PCPs' prescribing behaviors. It was not possible to determine whether patients filled their prescriptions in either case (electronic or written prescription). PrEP prescriptions were considered duplicates if the same prescription occurred more than once in the same two-week span, in which case only the last prescription was maintained in the dataset. Lastly,

if the prescription was terminated, the researcher documented the date and rationale for termination if present in the chart. After collecting data on each non-duplicative PrEP prescription, the number of refills, and the number of pills in the prescription, the researcher calculated the total number of pills each patient had during the study period. This calculation was completed by multiplying the number of pills by the number of refills (including the original prescription) for each prescription. The number of pills in each prescription were then added together for each patient to arrive at the total number of pills across the patients' PrEP prescriptions during the study period.

Number of eligible days: To calculate the number of days eligible to have a PrEP pill, the researcher computed the number of days between the date of each patients' first prescription to either the date the patient stopped their PrEP prescription or to the date of their most recent office visit. For patients who did not terminate their prescription, 182 days (six months) were added to account for pill coverage from their last prescription and time for necessary follow-up.

#### **4.2.2.2 Primary Predictors**

##### Sexual History Documented in Medical Chart

To determine whether sexual history was ever documented in the medical charts of eligible patients, patients' responses to each sexual history question were extracted from the EHR, regardless of whether there was a response documented. In this EHR system, there were three primary SHS questions: 1) Have you been sexually active in the last 12 months? 2) With men, women, or both?, 3) Did you use protection during your last sexual encounter?. A possible fourth question was: how often do you use protection during your sexual encounters? Since the fourth question was intended as a follow-up to question #3, having sexual history documented was considered having a response to any of the first three questions. In cases where nothing was

documented, thus no response to any SHS questions, it was considered as “no sexual history documented”.

#### Referral to PrEP Navigator

Referral to the PrEP Navigator was based on communications between the PCP and the PrEP Navigator in the EHR. The organization’s protocol for referring patients to the PrEP Navigator was to send a ‘telephone encounter’, which is an in-EHR communication method similar to e-mail, to the PrEP Navigator asking them to reach out to the patient. The researcher reviewed all eligible patients’ telephone encounters to identify whether the PCP ever referred the patient to the PrEP Navigator. Any telephone encounter with a subject pertaining to PrEP or referral or directly requesting the help of the PrEP Navigator was opened and reviewed by the researcher. Patients were coded in the dataset as having received a referral if a relevant telephone encounter was present. If not, they were coded as not having received a referral to the PrEP Navigator.

#### **4.2.2.3 Covariates**

##### Patient Age

Patients’ ages were calculated by the EHR based on the birth date entered into the system. Age was calculated based on the date of the first visit each patient had during the study period, representing the age they were upon entering the study.

##### Patients’ Race/Ethnicity

Race and ethnicity were extracted for each patient. Upon intake at the health center, patients self-reported their race as one of the following: ‘White’, ‘Hispanic’, ‘Black or African American’, ‘Asian’, ‘Native Hawaiian or Other Pacific Islander’, ‘American Indian or Alaska Native’, ‘Multi-racial’, or ‘other’. Patients could have declined to respond or this information may be withheld by the State in cases where they were under the ward of the State. A limited number of patients self-

reported their race as, ‘Native Hawaiian or Other Pacific Islander’, ‘American Indian or Alaska Native’, ‘Multi-racial’, or their race was undetermined but not declined. For the purposes of this study, these races were categorized as ‘Other’ (n= 17). Patients’ self-report their ethnicity as either ‘Hispanic’ or ‘Non-Hispanic’. As with race, patients were able to decline to respond or their responses were prohibited by the State. To determine race/ethnicity, patients were considered ‘White Non-Hispanic’ if their race was ‘White’ and their ethnicity was ‘Non-Hispanic’; ‘Hispanic’ if their race and/or ethnicity was ‘Hispanic’; ‘Black or African American Non-Hispanic’ if their race was ‘Black or African American’ and their ethnicity was ‘Non-Hispanic’; ‘Asian Non-Hispanic’ if their race was ‘Asian’ and their ethnicity was ‘Non-Hispanic’; and ‘Other Non-Hispanic’ if their race was ‘Other’ and their ethnicity was ‘Non-Hispanic’.

#### Patients’ Sexual Orientation

Patients’ sexual orientation information was captured through self-reported response during registration to “what is your sexual orientation?” Response options were: ‘straight or heterosexual’, ‘gay, lesbian, or homosexual’ [GLH], ‘bisexual’, ‘something else’, ‘don’t know’, and ‘other’. Open text fields were available to document patient-provided responses for ‘something else’ or ‘other’ sexual orientation. ‘Something else’, ‘don’t know’ and ‘other’ were collapsed into ‘other’ for the purposes of this study as there were an insufficient number of patients in these categories (n=2, 0.009%).

#### Patients’ Gender

Gender identity information was captured through self-reported response during registration to “what is your gender identity?” Response options were: ‘male’, ‘female’, ‘transgender male/ transman’, ‘transgender female /transwoman’, ‘genderqueer (neither exclusively male nor female)’, ‘questioning’, ‘additional gender category/other’, and ‘do not know’. Open text fields were available to document patient-provided responses for ‘additional

gender category/other' gender identity. For data analysis purposes, a patient was considered cisgender if either their sex assigned at birth was 'male' and their gender identity was 'man' or their sex assigned at birth was 'female' and their gender identity was 'woman'. A patient was considered transgender if they self-identified as 'transgender', or their gender identity was discordant with their sex assigned at birth. Patients whose gender identity was discordant with their sex assigned at birth were considered transgender men if their sex assigned at birth was 'female' and gender identity was 'man' or "transgender man", and were considered transgender women if their sex assigned at birth was 'male' and gender identity was 'woman' or "transgender woman". All other gender categories (i.e. 'genderqueer', 'questioning', 'additional gender category/other', and 'do not know') were dropped as there were an insufficient number of patients with these identities to maintain in the analyses (n=1, 0.005%).

#### Patients' Primary Language

Upon paper or electronic registration, patients provided their primary language as part of their medical record. The default primary language is 'English' but patients may write in any language. For the purposes of this study, any language other than 'English' was considered 'Other'.

#### Patient's Insurance Status

To capture patients' insurance status, the insurance type was extracted from the EHR: 'Private', 'Medicaid', 'Medicare', 'Uninsured', and 'Other Public'. Included within uninsured are patients that qualify for sliding-fee-scale. Patients' insurance is considered 'Other Public' when it is an Affordable Care Act Insurance.

#### Primary Care Providers' Medical Credentials

The medical credentials of each patients' PCPs were extracted from the EHR. The medical credentials of PCPs at this organization were: 'Medical Doctor (MD)', 'Advanced Practice

Registered Nurse (APRN)', 'Physician Assistant (PA)', or 'Doctor of Osteopathic Medicine (DO)'.

### **4.2.3 Analytic Procedure**

All analyses were conducted in StataSE 16.1 (StataCorp LLC, College Station, Texas) using the following procedures. Descriptive statistics were conducted for patients' socio-demographic variables. Additionally, we examined how sociodemographic characteristics were bivariate related to having sexual history screening documented in the medical chart and having a referral to the PrEP Navigator.

As these data contain patients who receive care from PCPs at medical sites throughout Connecticut, we used multi-level modeling to test our hypotheses. To determine how many levels of clustering (patients within PCPs or patients within PCPs within medical sites) were appropriate for our analyses, we conducted a likelihood-ratio test on the null model comparing the two-level model to the three-level model. The likelihood-ratio test failed to reject the null hypothesis that the three-level model was a better fit than the more parsimonious model, thus the two-level model was determined to be the best final model for these data.

The outcome variable (Number of PrEP Pills) for this study was a count variable. We examined whether poisson or negative binomial models fit the data using a likelihood-ratio test (LRT). The LRT was significant at  $p = <0.001$  indicating the negative binomial models were the best fit for these data. After determining that the mixed-effects negative binomial regression model was most appropriate model for these analyses, the following model building process took place. In these models, the dependent variable was total number of pills and the exposure variable was number of eligible days, thus creating a proportion of number of pills to number of eligible days.

As seen in Table 6, Model 1 is the predictor model, demonstrating the intercept when only predictor variables are present and accounting for clustering by PCP. Model 2 introduces the covariates. Model 3 adds the interaction effect between Sexual History Documented in the Medical Chart and referral to the PrEP Navigator while clustering by PCP. Statistical significance was determined when  $p < 0.05$ .

## **4.3 Results**

### **4.3.1 Samples Characteristics**

214 patients met final inclusion criteria for this study. The mean age of patients in the sample was 32-years-old (Table 4). A majority of patients were Hispanic (n=74, 40%) and White Non-Hispanic (n=68, 36.8%) (Table 4). More than half of the patients identified as gay, lesbian, or homosexual (n=107, 58.8%), had Medicaid insurance (n=133, 62.7%), were cisgender men (n=149, 79.7%), and spoke English as their primary language (n= 179, 88.2%) (Table 4). A majority (n= 73, 47.40%) of patients in the sample initiated their PrEP prescription because they requested it compared to being identified by their PCP (n=25, 16.23%) or the PrEP Navigator (n=17, 11.04%) (Table 4). Of the 214 patients, 66 (30.8%) had sexual history documented in their medical chart, 38 received a referral to the PrEP Navigator, and 102 had an intake with the PrEP Navigator (Table 5). There were a higher number of intakes with the PrEP Navigator because the PrEP Navigator often identified patients without receiving a referral from a PCP. A higher proportion of patients who had sexual history documented in their medical chart, received a referral to the PrEP Navigator, and had an intake with the PrEP Navigator were Hispanic (n=25, 11.68%,



n=13, 6.07%, and n=33, 15.42%, respectively) and Non-Hispanic White (n=22, 10.28%, n= 8, 3.74%, and 37, 17.29% respectively) (Table 5). Similarly, a larger proportion of patients who had Medicaid insurance, identified as gay, lesbian, or homosexual, cisgender men, and whose primary language was English had sexual history documented in their charts, a referral to the PrEP Navigator, and an intake with the PrEP Navigator (Table 5).

Table 6 presents the findings from the model building process. In the first model (predictor variables), only having sexual history documented in the medical chart was associated with a 1.32 times higher rate of PrEP prescription duration during the study period (IRR= 1.32, 95% CI: 1.10, 1.56) (Table 6) while account for clustering by PCP. There was no significant effect for patients who had a referral to the PrEP Navigator in the predictor-only model. Model 2 introduced covariates including intake with the PrEP Navigator, patients' sociodemographics, and their PCPs' medical credentials, as well as accounting for clustering by PCP (Table 6). In this model, patients who had sexual history documented in the chart had a 1.35 times higher rate of PrEP prescription duration when clustering by PCP and holding all other variables constant (IRR= 1.35, 95% CI: 1.11,1.63) (Table 6). In the final model, the interaction between having sexual history documented in the medical chart and a referral to the PrEP Navigator was introduced (Table 6). This interaction was not significant, indicating that having both sexual history documented in the medical chart and a referral to the PrEP Navigator was not significantly associated with better PrEP prescription duration.

Although not part of our research question or hypotheses, there were interesting findings among the covariates. Specifically, when all other variables were held constant and clustered by PCP, older patients with sexual history documented in their chart had slightly higher rate of PrEP prescription duration (IRR= 1.01, 95% CI: 1.00, 1.02) (Table 6). Conversely, compared to White Non-Hispanic patients, Black Non-Hispanic and Hispanic patients had significantly lower rates of

PrEP prescription duration (IRR= 0.72, 95% CI: 0.55, 0.94 and IRR= 0.71, 95% CI: 0.56, 0.90, respectively). The rate of PrEP prescription duration was even lower for patients with Other Public Insurance (IRR= 0.45, 95% CI: 0.25, 0.79) compared to patients with Private insurance, when all other variables were held constant and accounting for clustering by PCP (Table 6).

#### **4.4 Discussion**

This study is the first to test the relationship between having sexual history documented in the medical chart and referrals to the PrEP Navigator for adult patients on PrEP at a FQHC. This study found that having sexual history documented in the medical chart was associated with a higher rate of PrEP prescription duration during the study period. There was not a significant effect for patients who had a referral to the PrEP Navigator or the interaction between having sexual history documented in the medical chart and a referral to the PrEP Navigator. This study adds to the dearth of research on the role of the PrEP Navigator and sexual history on PrEP adherence among adult patients.

The first hypothesis of this study was that having sexual history documented in the medical chart and a referral to the PrEP Navigator would independently be associated with higher rates of PrEP prescription duration during the study period. The results of this study demonstrated that patients with any sexual history in their medical charts had significantly higher rates of PrEP prescription duration compared to patients without sexual history in their medical chart. This may indicate the importance of sexual history in the identification of patients who are at risk of contracting HIV and would benefit from PrEP. The importance of this relationship is in alignment with the standards of practice set forth by the CDC to use SHS to identify patients with sexual

behaviors and practices that put them at risk of contracting HIV (Centers for Disease Control and Prevention, 2019b; Chandra et al., 2016). Alternatively, this finding may be indicative of the role of SHS during PrEP follow-up appointments. Since any sexual history was included in this study, it is possible that SHS was completed during follow-up visits and aided in PrEP prescription.

The independent relationship between referrals to the PrEP Navigator and PrEP prescription duration was not significant. Previous research evaluating the role of the PrEP Navigator Studies have found that this service has highly acceptability among populations at high risk for HIV (young racial and ethnic MSM, transgender women) (Bradford et al., 2007; Pagkas-Bather et al., 2020). These studies found that patients reported supported and less worry about barriers to PrEP (Bradford et al., 2007; Pagkas-Bather et al., 2020). Furthermore, previous research found that engagement with a PrEP Navigator reduced delays in PrEP initiation, increased number of visits and utilization of HIV primary medical care, and associated with consistent PrEP adherence at 90-day follow up (Bradford et al., 2007; Pagkas-Bather et al., 2020; Reback et al., 2019; Spinelli et al., 2018). In this study, the lack of significant findings for patients who received a referral to the PrEP Navigator may have been due to the FQHC's patients' social and contextual barriers to utilizing the referral or ability to follow-up with the PrEP Navigator and the PCP to maintain their PrEP prescription.

The second hypothesis of this study was that the combined effects of having sexual history documented in the medical chart and referrals to the PrEP Navigator would be associated with a higher rate of PrEP prescription duration during the study period. There was no significant effect for the interaction between these variables in the statistical model. Given that there was no significant, independent effect for referrals to the PrEP Navigator on PrEP prescription duration, this was not a surprising finding. While it was not within the scope of this study to determine why there was not a significant effect, we posit that this may have occurred for a few reasons. Primarily,

the number of patients who received a referral was relatively low, with only 17% of the sample having a documented referral in their medical chart. Additionally, patients that received a referral to the PrEP Navigator may be working with a PCP with lower self-efficacy to prescribe and manage patients on PrEP.

We recognize that there are limitations to this study. Primarily, it was not possible to measure PrEP adherence for this study as data were restricted to what was available in the EHR. While the number of PrEP pills prescribed during the study period is a good preliminary indicator of PCPs' prescribing behaviors, there was no way to assess the degree to which patients adhered to their prescription regimens once receiving the pills. We also were not able to control for whether SHS took place prior to PrEP initiation or as part of PrEP follow-up. Since SHS should take place at PrEP follow-up appointments, when and during why type of visit might explain why we found a significant relationship between SHS and PrEP prescription duration. While our statistical models controlled for variation across providers, we did not control for the impact of providers' adherence to clinical guidance for PrEP prescribing and follow-up on PrEP prescription duration. Additionally, the sample size for this study was small, with only 214 adult patients with a PrEP prescription during the study period. The small sample size limits our ability to fully evaluate the relationship between having sexual history documented in the medical chart and referral to the PrEP Navigator on PrEP prescription duration during the study period. Secondly, this study was limited to data that was available in patients' medical charts; thus, we were unable to control for potentially important factors at the patient, PCP, and PrEP Navigator levels. Specifically, we were not able to control for patients' level of risk of contracting HIV and their knowledge and comfort with the daily PrEP pill and follow-up protocols. Among PCPs, we were not able to measure and control for self-efficacy and comfort identifying and prescribing patients PrEP and their knowledge of and comfort working with the PrEP Navigator. It is possible that many of the PCPs

in the study were unaware of the PrEP Navigator, which could have impacted the number of referrals to a larger extent than patients' need for the PrEP Navigator's services. Additionally, we did not have access to data on the specific services provided by the PrEP Navigator to patients to assist with patients receiving PrEP Pills.

There were also strengths to this study. The use of EHR data represents the true documentation and prescription behaviors of PCPs to patients on PrEP. This may present an opportunity for missing data; however, the provision of care is often dependent on patient's documented medical history. As this study sought to understand PCPs' prescription, documentation, and referral behaviors, these data represent the information that was present for continuity of care across visits with the PCP and for the PrEP Navigator when providing assistance to patients. Additionally, as the focus was on PCPs' behaviors, it was critical to be able to control for the nesting of patients within providers. This was an important strength of our study since we could not control for PCPs' self-efficacy or knowledge, we were able to control for between-groups differences for patients by their PCP. Accounting for clustering by PCP allowed for us to demonstrate the effect of our predictors on PrEP prescription duration while controlling for differences between PCPs and their patients.

This study is the first to investigate the relationship between having sexual history documented in the medical chart, referrals to a PrEP Navigator, and the combined effect of these factors on PrEP prescription duration. Our findings provide evidence for the importance of conducting and documenting sexual history to improve PrEP prescriptions for patients on PrEP. Whether being used to identify patients' risk or to communicate the ongoing importance of PrEP in the patients' care plan, having sexual history documented in the chart was associated with significantly higher rates of PrEP prescription duration during the study period. The results of this study provide strong evidence for further investigation into the relationship between sexual history

screening and PrEP prescription duration. Specifically, investigation into the role sexual history plays into provision of care for PrEP patients and how to increase the rate of having sexual history documented for PrEP patients. While this study did not find significant effects for having a referral to the PrEP Navigator, we propose that given the limitations of this study additional efforts are needed to understand the impact of this role on patients' PrEP initiation and adherence. Specifically, an investigation into the types of support frequently provided by the PrEP Navigator, patients' receptivity to these services, and PCPs' knowledge and attitudes towards the PrEP Navigator.

**Table 4. Sociodemographics of Adult Patients with a PrEP Prescription between January 2016 and December 2019 at a Multi-site Federally Qualified Health Center in Connecticut (N= 214)**

		<b>Total</b>	
		<i>N= 214</i>	
		n/ Mean	%/ SD
<b>Patient Sociodemographics</b>			
Age		32.99	(11.7)
Race/Ethnicity			
	White Non-Hispanic	68	(36.8)
	Black Non-Hispanic	32	(17.3)
	Hispanic	74	(40.0)
	Other Non-Hispanic	11	(6.0)
Sexual Orientation			
	Heterosexual	52	(28.6)
	Gay, Lesbian, Homosexual	107	(58.8)
	Bisexual	20	(11.0)
	Other	3	(1.7)
Gender			
	Cisgender Woman	24	(12.8)
	Cisgender Man	149	(79.7)
	Transgender Woman	13	(7.0)
	Transgender Man	1	(0.5)
Primary Language			
	English	179	(88.2)
	Other	24	(11.8)
Insurance Status			
	Uninsured	12	(5.7)
	Medicare	5	(2.4)
	Medicaid	133	(62.7)
	Private Insurance	53	(25.0)
	Other Public	9	(4.3)
How Patient was Identified for PrEP			
	Patient requested PrEP	73	(47.40)
	Unclear	60	(28.04)
	Provider identified need for PrEP	25	(16.23)
	PrEP Navigator identified Patient	17	(11.04)
	Patient presented with a sexual health concern	11	(7.14)
	Patient was referred from elsewhere for PrEP	9	(5.84)
	Patient was identified at an outreach event	6	(3.90)
	Another provider identified Patients' need for PrEP	5	(3.25)
	Patient was on PrEP elsewhere	4	(2.60)
	Patient stayed on PrEP after PEP	4	(2.60)

**Table 5. Prevalence of Sexual History Documented in Chart, Referral to PrEP Navigator, Intake with PrEP Navigator Among Adult Patients with a PrEP Prescription between January 2016 and December 2019 at a Multi-site Federally Qualified Health Center in Connecticut**

	Sexual History Documented in Chart		Referral to PrEP Navigator		Intake with PrEP Navigator	
	<i>n</i> = 66		<i>n</i> = 38		<i>n</i> = 102	
	n/ Mean	%/ SD	n/ Mean	%/ SD	n/ Mean	%/ SD
<b>Patient Sociodemographics</b>						
Age	32.74	(11.75)	31.84	(10.78)	33.38	(11.51)
Race/Ethnicity						
White Non-Hispanic	22	(10.28)	8	(3.74)	37	(17.29)
Black Non-Hispanic	11	(5.14)	9	(4.21)	16	(7.48)
Hispanic	25	(11.68)	13	(6.07)	33	(15.42)
Other Non-Hispanic	3	(1.40)	3	(1.40)	7	(3.27)
Sexual Orientation						
Heterosexual	17	(7.94)	6	(2.80)	17	(7.94)
Gay, Lesbian, Homosexual	39	(18.22)	20	(9.35)	51	(23.83)
Bisexual	5	(2.34)	4	(1.87)	8	(3.74)
Other	1	(0.47)	1	(0.47)	2	(0.93)
Gender						
Cisgender Woman	8	(3.74)	3	(1.40)	9	(4.21)
Cisgender Man	53	(24.77)	24	(11.21)	68	(31.78)
Transwoman	2	(0.93)	4	(1.87)	5	(2.34)
Transman	0	(0.00)	0	(0.00)	0	(0.00)
Primary Language						
English	54	(25.23)	33	(15.42)	80	(37.38)
Other	10	(4.67)	4	(1.87)	13	(6.07)
Insurance Status						
Uninsured	5	(2.34)	3	(1.40)	12	(5.61)
Medicare	2	(0.93)	1	(0.47)	1	(0.47)
Medicaid	37	(17.29)	25	(11.68)	51	(23.83)
Private Insurance	20	(9.35)	8	(3.74)	32	(14.95)
Other Public Insurance	2	(0.93)	1	(0.47)	4	(1.87)



**Table 6. Association Between Sexual History Documented in Chart, Referral to PrEP Navigator, and the Moderation of Sexual History Documented in Chart and Referral to PrEP Navigator on PrEP prescription duration for Adult Patients with a PrEP Prescription Between**

	Model 1: Predictor Model <sup>a</sup>			Model 2: Covariates <sup>b</sup>			Model 3: Interaction SHxReferral to PN <sup>3</sup>		
	<i>IRR</i>	<i>95% CI</i>	<i>P-value</i>	<i>IRR</i>	<i>95% CI</i>	<i>P-value</i>	<i>IRR</i>	<i>95% CI</i>	<i>P-value</i>
Intercept	0.75	(0.67, 0.84)	> <b>0.001</b>	0.66	(0.38, 1.17)	0.153	0.64	(0.36, 1.12)	0.118
Sexual History Documented in Chart	1.32	(1.10, 1.56)	<b>0.002</b>	1.35	(1.11, 1.63)	<b>0.002</b>	1.44	(0.17, 1.77)	<b>0.001</b>
Referral to PrEP Navigator	0.89	(0.73, 1.11)	0.310	0.87	(0.67, 1.11)	0.257	0.98	(0.73, 1.31)	0.871
Sexual History Documented in Chart X Referral to PrEP Navigator							0.65	(0.37, 1.13)	0.125
<b>Patient Sociodemographics</b>									
Age				1.01	(1.00, 1.02)	<b>0.041</b>	1.01	(0.99, 1.13)	0.067
Race/Ethnicity									
White Non-Hispanic				1.00	(referent)		1.00		
Black Non-Hispanic				0.72	(0.55, 0.94)	<b>0.015</b>	0.71	(0.55, 0.93)	<b>0.012</b>
Hispanic				0.72	(0.56, 0.90)	<b>0.005</b>	0.72	(0.57, 0.91)	<b>0.006</b>
Other Non-Hispanic				0.69	(0.45, 1.07)	0.097	0.68	(0.44, 1.05)	0.085
Sexual Orientation									
Heterosexual				1.00	(referent)		1.00	(referent)	
Gay, Lesbian, Homosexual				1.11	(0.85, 1.45)	0.443	1.09	(0.84, 1.42)	0.503
Bisexual				0.98	(0.67, 1.43)	0.919	0.99	(0.68, 1.42)	0.962
Other				0.73	(0.37, 1.42)	0.353	0.74	(0.38, 1.43)	0.365
Gender									
Cisgender Man				1.00	(referent)		1.00	(referent)	
Cisgender Woman				0.78	(0.57, 1.07)	0.122	0.77	(0.56, 1.05)	0.102
Transgender Man				-	-	-	-	-	-
Transgender Woman				0.9	(0.62, 1.29)	0.559	0.85	(0.59, 1.23)	0.382
Primary Language									

	English	1.00	(referent)	1.00	(referent)	
	Other	1.13	(0.85, 1.51)	0.400	1.17	0.294
<b>Insurance Status</b>						
	Private Insurance	1.00	(referent)	1.00	(referent)	
	Medicare	0.77	(0.41, 1.41)	0.397	0.89	0.709
	Medicaid	0.95	(0.75, 1.21)	0.682	0.97	0.782
	Uninsured	1.22	(0.72, 2.07)	0.457	1.19	0.526
	Other Public	0.45	(0.25, 0.80)	<b>0.007</b>	0.46	<b>0.008</b>
<b>Primary Care Provider</b>						
<b>Clinical Credentials</b>						
	Advanced Practice Registered Nurse	1.00	(referent)	1.00	(referent)	
	Medical Doctor	0.87	(0.69, 1.08)	0.213	0.86	0.194
	Doctor of Osteopathic Medicine	0.87	(0.60, 1.26)	0.467	0.87	0.452
	Physician Assistant	0.79	(0.50, 1.25)	0.311	0.8	0.329

IRR= Incidence Rate Ratio, 95% CI=95% Confidence Interval.

Note: Boldface indicates statistical significance (p < .05)  
<sup>a</sup>Model was estimated using negative binomial regression and clustering by primary care provider  
<sup>b</sup>Model 2 was estimated using multilevel mixed-effects negative binomial regression, with the 2nd model adjusting for patients' age, race/ethnicity, sexual orientation, gender, primary language, insurance status, and their primary care providers' clinical credentials and clustering by primary care provider  
<sup>c</sup>Model 3 was estimated using multilevel mixed-effects negative binomial regression, with the 2nd model adjusting for patients' age, race/ethnicity, sexual orientation, gender, primary language, insurance status, and their primary care providers' clinical credentials and clustering by primary care provider

## **5.0 Facilitators, Barriers, Influential Factors, and Opportunities to the Implementation of Sexual History Screening and Dissemination of PrEP**

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### **5.1 Introduction**

Sexual history screening (SHS) is a practice recommended by the Centers for Disease Control and Prevention (CDC) to identify patients at risk of contracting a sexually transmitted infection (STI), including human immunodeficiency virus (HIV), and other adverse sexual health outcomes (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). A basic sexual history consists of three questions: 1) have you been sexually active in the past year, 2) are your sex partners men, women, or both, and 3) do you and your partner(s) use any protection against STIs (Center for Disease Control and Prevention). A comprehensive sexual history includes more extensive questions pertaining to partners, sexual practices, STI prevention, history of STIs, and prevention of pregnancy (Center for Disease Control and Prevention) (Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997) SHS provides clinicians with the information necessary to initiate conversations about harm reduction methods, referrals to specialists or relevant resources, and screening of at-risk patients for STIs/HIV (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Plotkin et al., 1993; U.S. Preventative Task Force, 1997).

Although the benefits of taking sexual histories are known, clinical providers report inconsistently conducting SHS with their patients, with self-reported implementation rates of 50% or less (Center for Disease Control and Prevention; Lewis & Freeman, 1987; Ribeiro et al., 2014; Torkko et al., 2000; U.S. Preventative Task Force, 1997; Wimberly et al., 2006). Documented systematic barriers to SHS include little training among clinical providers and limited time during medical visits (Temple-Smith et al., 1996; Torkko et al., 2000). In addition to systematic barriers, providers report discomfort discussing sex, fear of offending their patients, and difficulty asking sexual health questions of patients of the opposite sex or who are sexual and/or gender minorities (Barbee et al., 2015; Burd et al., 2006; Carter Jr et al., 2014; Haley et al., 1999; Hayes et al., 2015; Khan et al., 2008; Temple-Smith et al., 1996; Torkko et al., 2000). Even though providers report systemic and personal barriers to initiating SHS conversations, research shows patients rely on and want their providers to initiate discussions about sexual health and functioning (Metz & Seifert, 1990).

In primary care settings, SHS is recommended at intake, during annual preventive care visits, and when STI symptoms are present (Center for Disease Control and Prevention). As an intended outcome of SHS is to identify patients with sexual practices that put them at risk of STIs and HIV, primary care providers (PCPs) should consider SHS as means to identify patients who are appropriate for provision of pre-exposure prophylaxis (PrEP) and PrEP services (Barrow et al., 2020; Center for Disease Control and Prevention; U.S. Preventative Task Force, 1997). PrEP is a once daily oral medication to prevent contraction of human immunodeficiency virus (HIV) (Centers for Disease Control and Prevention, 2019a). The CDC previously recommended discussing PrEP with the following patient groups: MSM who report unprotected anal sex, patients who report limited or no condom use with a partner of unknown or HIV-positive status, men who have sex with men and women, and injection drug users who share equipment or engage in risky

sexual behaviors (Altraum Institute, 2016). In 2021, the guidance changed to discussing PrEP with all sexually adolescents and adults and people who use injection drugs (Centers for Disease Control and Prevention, 2021c). PrEP can reduce the risk of HIV through sexual practices among these and other populations by 99% if taken as directed (Centers for Disease Control and Prevention, 2019a).

An intended outcome of SHS is to identify HIV-negative patients at risk of contracting HIV, of particular importance among highest risk populations (racial/ethnic minorities and young MSM) (Center for Disease Control and Prevention; Centers for Disease Control and Prevention, 2017a, 2017b). Although PrEP is critical to the prevention of HIV infection, Black and Hispanic MSM have limited awareness, uptake, and adherence to PrEP (Chan et al., 2016; Delaney et al., 2016; Hoots et al., 2016; Mayer, Biello, Novak, Krakower, & Mimiaga, 2017; H. Scott et al., 2017; H. M. Scott et al., 2018). Previous research has investigated the impact of SHS on comprehension of PrEP among young people of color (Golub et al., 2017). This study recruited 157 young people of color who were randomized to types of messaging about PrEP, which varied by modality (video versus health educator), message (risk versus health) and level of specificity (verbatim versus gist) (Golub et al., 2017). In addition to being randomized to messaging about PrEP, participants were randomized to whether they completed a sexual history before or after receiving the messaging (Golub et al., 2017). After both the PrEP messaging and sexual history, participants completed a self-administered survey on the extent to which they understood the PrEP message (Golub et al., 2017). This study found that completion of sexual history before delivery of PrEP messaging compared to after delivery of messaging resulted in 2.2 (the whole sample) and 3.5 (video message PrEP delivery group) times higher odds of correctly completing the PrEP comprehension questions (Golub et al., 2017). This finding indicates the critical role sexual history plays in clinical practice and as part of PrEP education (Golub et al., 2017).

To assist with educating patients about PrEP and navigating the health care system and to remove barriers to care and adherence, some patients may be referred to a PrEP Navigator (Pinto et al., 2018). A PrEP Navigator is a service offered by some health care organizations to guide patients, particularly at-risk patients, through the process of getting and adhering to PrEP (Mugavero et al., 2013). PrEP Navigators are non-clinical staff, and in some cases patient-peers, who are trained to help patients overcome structural and individual barriers (Pinto et al., 2018). The duties and role of the PrEP Navigator differ by organization; however, common tasks include determining insurance coverage, discussing the PrEP process, working with the patient on realistic expectations, assisting patient with scheduling follow-up visits and visit adherence (Doblecki-Lewis et al., 2019; Pinto et al., 2018; University of California San Francisco, N.D.).

While research has explored how SHS impacts PrEP comprehension among young people of color, there is a notable lack of research on facilitators and barriers to implementing SHS followed by PrEP and PrEP services. Guided by the Consolidated Framework for Implementation Research (CFIR), this study aimed to understand the facilitators, barriers, and influential factors to the implementation of SHS and PrEP services, specifically the PrEP Navigator, through semi-structured interviews with PCPs, medical assistants, clinical leadership, and PrEP Navigators (CFIRguide.org, 2018; Golub et al., 2017).

## **5.2 Methods**

### **5.2.1 Study Description**

This study employed inductive reasoning and an interpretivist approach to the thematic analysis of semi-structured interviews with key stakeholders at a multi-site federally qualified health center in Connecticut. CFIR was utilized as the underlying framework for the development of the interview guide, codebook, and data analysis. This study was approved by the Institutional Review Board (IRB) at the health care organization.

#### **5.2.1.1 Consolidated Framework for Implementation Research**

The Consolidated Framework for Implementation Research (CFIR) is a theoretical framework created to assess the facilitators and barriers to implementation of an evidence-based practice or intervention (CFIRguide.org, 2018). CFIR contains five major domains: intervention characteristics, inner setting, outer setting, characteristics of individuals involved in implementation, and the process of implementation (CFIRguide.org, 2018). Within each domain are constructs (CFIRguide.org, 2018). Data collected using the CFIR theoretical framework are coded to constructs within the five major domains and then analyzed for relative ratings to indicate the role of the construct as a facilitator or barrier (CFIRguide.org, 2018). Studies using both quantitative and qualitative data have used CFIR to assess health system readiness for implementation, adaptations to an evidence-based program or practice, and evaluation of implementation of an evidence-based program or practice (Breimaier, Heckemann, Halfens, & Lohrmann, 2015; Cole, Esplin, & Baldwin, 2015; Damschroder & Lowery, 2013; Keith, Crosson, O'Malley, Crompton, & Taylor, 2017; Smith, Damschroder, Lewis, & Weiner, 2015).

### **5.2.1.2 Eligibility**

The sample populations for this study were active, non-pediatric PCPs, medical assistants, (MAs) clinical leadership, and previous and current PrEP Navigators employed at the organization at the time of the study. The organization's electronic health record (EHR) was used to identify PCPs. An employee database was utilized to identify medical assistants. Clinical leadership included the Chief Medical Officer (CMO), Chief Nursing Officer (CNO), and Medical Director for the Center for Key Populations, who is responsible for designing processes to implement SHS and PrEP services and train providers. The Medical Director of the Center for Key Populations provided the names of the two employees who held the position of PrEP Navigator historically and currently.

### **5.2.1.3 Interview Guide**

The semi-structured interview guide was designed based on the implementation of SHS and PrEP services with consideration of the 5 domains of CFIR. Specifically, questions pertained to how participants conducted SHS, what they thought made the process easier or harder, their perceptions of patients' reactions, the organization's supportiveness, how they identified and maintained patients on PrEP, and what support services they were aware of when prescribing their patients PrEP. A draft of the interview guide was reviewed by experts in implementation science, qualitative methods, and clinical practice in infectious disease. The initial interview guide was developed for PCPs, as they were the first group of participants recruited. Minor modifications were made for participants with other roles at the organization. As medical assistants did not have experience with PrEP patients, they were asked about their relationships with the PCPs and how that relationship impacts pre-visit screening, including SHS. Clinical leaders were asked about how decisions were made at the leadership level and what the organization's policies were



pertaining to SHS and PrEP. Although knowledgeable of SHS, PrEP Navigators were not responsible for implementing SHS; thus, the interview guide was re-focused to inquire about their experiences with PrEP patients, training providers, and working with PrEP patients' care teams.

After each interview, the researcher began the analytic process, reflecting on responses to the questions and modifying the guide to improve the framing of questions in subsequent interviews. Specifically, the first few participants did not have experience with PrEP patients. A question was added at the start of the PrEP section to inquire about how many PrEP patients are currently on their panel. For respondents that said none, the subsequent questions were modified to inquire about what they would do and their thoughts about PrEP and PrEP services. Additionally, participants struggled to understand a question pertaining to the culture of the organization. To aid these participants, a follow-up prompt was added specifying that the question pertained to the environment and operations of the organization.

#### **5.2.1.4 Recruitment**

Initially, this study only sought to interview PCPs and clinical leaders; however, after speaking to PCPs it became apparent that medical assistants were often responsible for conducting SHS. It also became evident that the perspectives of the PrEP Navigators would be of critical importance to understanding the complete process. For these reasons, medical assistants and PrEP Navigators were recruited. Although recruitment took place virtually, eligible staff from all 13 non-pediatric clinical sites were invited to participate.

In total, 150 staff members were deemed eligible and recruited for this study. This included 77 PCPs, 68 MAs, 3 clinical leaders, and 2 PrEP Navigators. To recruit patients, a weekly e-mail was distributed informing participants of their eligibility for study. After a few interviews, subsequent participants were purposively invited to participate based on identified gaps in

experience with PrEP patients, having worked with the PrEP Navigator, and type of clinical credential [i.e., medical doctor (MD), advanced practice registered nurse (APRN), doctor of osteopathic medicine (DO), and physician assistant (PA)].

Participants chose whether the interview took place via Zoom (Zoom Video Communications, San Jose, CA) or over the phone. The consent form was reviewed and completed prior to the start of the interview. At the conclusion of each interview, participants were compensated for their time with a \$20 Gift Card.

A total of 22 participants were consented and interviewed. Recruitment was terminated after 22 interviews as thematic saturation had been achieved. Thematic saturation was decided through interviewer notes and ongoing review of data during the interview process. Twenty-two participants is a sufficient sample size for this study, as recommended sample sizes for studies employing semi-structured interviews are between 20 and 30 (Creswell, 1998).

### **5.2.2 Analytic Procedure**

The interview recordings were downloaded onto a password protected laptop. The audio files from the interviews were sent to TranscribeMe! (TranscribeMe, Inc., Oakland, CA) to be transcribed. Transcripts and audio files were then imported into NVivo 12 (QSR International, Melbourne, Australia). Transcripts were reviewed and compared to audio files to ensure the quality and accuracy of the transcript. Audio files were included in the NVivo analysis file for instances requiring clarity. All files were de-identified prior to the start of data analysis.

Thematic analysis, using CFIR as an guide, was conducted by a three-person research team in alignment with methods described by Braun & Clark (2006) (Braun & Clarke, 2006; Clarke & Braun, 2015). After familiarizing themselves with the data, two researchers reviewed all transcripts

and documented preliminary codes to develop an initial understanding of the data. From preliminary codes, the researchers independently generated a list of codes, compared these lists, and resolved any inconsistencies. After a resolved list of codes was developed, the primary researcher reviewed the data, codes, and CFIR constructs to organize codes within CFIR domains. For each code, the primary researcher developed definitions that were reviewed by two researchers for clarity. These codes and definitions were tested by all three researchers and final modifications were made before the codebook was fully drafted.

The codebook was then tested independently by two researchers on five transcripts. Prior research has substantiated parallel coding of between 10-25% of data to achieve inter-coder reliability (ICR) (O'Connor & Joffe, 2020). The coding of five transcripts (representing 20% of the data) yielded a Kappa score of 0.66, which indicated good inter-coder reliability (Landis & Koch, 1977). The two researchers then resolved any disagreements in code assignment and made the final modifications to the codebook. The remaining transcripts were divided between the two researchers and coded using the final codebook. After this process was complete, researchers read through the coded data to draw connections between codes and patterns across codes to develop key themes and subthemes. Key themes were facilitators, barriers, influential factors, and opportunities. Subthemes were categorized as facilitators if the sub theme was explicitly noted by participants as something that aided or improved their ability to implement SHS and PrEP services. Conversely, subthemes were categorized as barriers if the subtheme was explicitly noted by participants as something that prevented or negatively affected their ability to implement SHS and PrEP services. Not all subthemes were explicitly noted as facilitators or barriers by participants but were critical factors in the decision and process of implementation, the research team categorized these subthemes to influential factors. Subthemes were categorized as opportunities if

the participants presented a request or idea for change in the future to improve implementation of SHS and PrEP services.

## **5.3 Results**

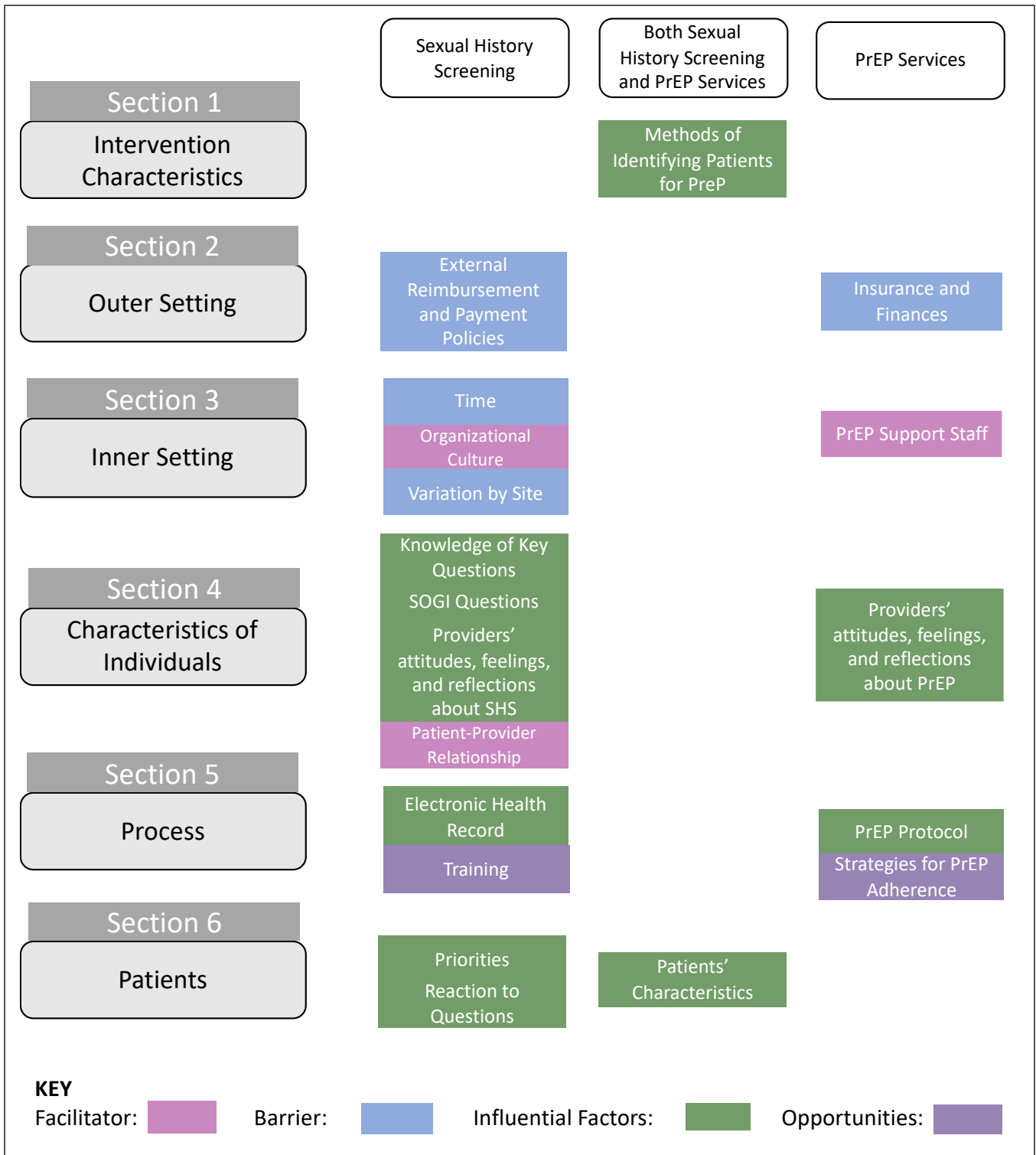
### **5.3.1 Sample Characteristics**

A total of 22 participants were interviewed for this study. Most participants were PCPs (n=16), of which 11 were APRNs, 2 were MDs, 2 were DOs, and 1 was a PA. While not all PCPs could recall experiences with PrEP patients, 3 PCPs stated they had experience with more than 3 PrEP patients. In addition to the 16 PCPS, 3 MAs, 2 clinical leaders, and 1 PrEP Navigator were also interviewed. Across all participants, 15 identified as women and 7 as men. Of the 22 participants, 2 identified as gay while the rest identified as straight. Twelve participants reported their race as White, 2 as Black or African American, 2 as Asian or Pacific Islander, 1 as Native American, 1 as Mixed Race, and 1 as Another Race. Three participants identified both their race and ethnicity as Hispanic. In addition to these three participants, one additional participant reported Hispanic ethnicity (their reported race was Native American).

### **5.3.2 Summary of Themes**

There were four major themes that arose from this study: 1) facilitators, 2) barriers, 3) influential factors, and 4) opportunities. A majority of subthemes (11, 55%) were categorized as influential factor to the implementation of SHS and PrEP services. In addition to 11 influential factors, 4 barriers, 3 facilitators, and 2 opportunities were identified. Influential factors, barriers,

facilitators, and the opportunity for SHS and PrEP services occurred across the 5 CFIR domains. In addition to the presence of themes within the CFIR domains, 5 influential factors pertained to patient-level factors. Identified themes are presented below within their respective CFIR domain (Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, Process) and the identified Patient domain. A visualization of the results of this study can be found in Figure 3.



**Figure 3. Facilitators, Barriers, Influential Factors, and Opportunities for Sexual History Screening and PrEP Services within Consolidated Framework for Implementation Research Domains**

### 5.3.2.1 Intervention Characteristics

This domain pertains to attributes of the intervention (SHS) that serve as barriers, facilitators, or factors influential to implementation from the perspectives of stakeholders (CFIRguide.org, 2018). Participants in this study discussed how they assessed patients to determine whether they would benefit from PrEP. Providers who utilized SHS as part of this process described how the time needed to establish trust and work through the questions was a barrier to prioritization and implementation of SHS.

#### Influential Factor: Methods of Identifying Patients for PrEP

Participants were asked to describe their experiences assessing their patients for indications and the need for PrEP. Participants that cited the use of SHS to screen for risk of HIV exposure stated they had more experience with PrEP patients or specialty training in caring for at-risk populations, such as sexual and gender minorities and patients who used injection drugs.

*[I identify patients by] going through sexual history, I mean, that's sort of your main foray into seeing if they're appropriate for PrEP, right? Like, are you sexually active? And if the answer is yes, then there's a pretty decent chance that they're an appropriate person for PrEP. So then just asking further questions. Are they in a monogamous relationship? Do they know their HIV status or their partner's HIV status? Asking about number of partners or if they've had positive STIs before. So usually, I try to dig into that a little bit. And then I just ask them if they've heard about PrEP. And then usually, I would say that the majority of the patients who I have asked about if they're interested in PrEP were aware of it. - APRN*

One of the intervention characteristics that limits its utility in identifying patients' appropriateness for PrEP is the time required to conduct SHS during patient visits. Participants explained that the sensitive nature of SHS questions necessitated a process of introducing the topic and working through the questions while educating the patient. This process was time-consuming and could uncover issues that would require additional time that was not available. As noted as

part of patient's reactions to questions, if sexual health is not part of the patient's health complaint, SHS was distracting and burdensome on time.

*So, imagine trying to tease out sexual history [during a visit]. There's no reason why you should prioritize it that high when they have so many other things crushing them. - APRN*

While SHS was mentioned as a tool to identify risk of contracting HIV, most providers did not describe using SHS or another screening process. Instead of using SHS to assess for indications of PrEP, participants stated their patients had self-identified by requesting PrEP or had been screened and referred to them by another staff member at the organization. This was pronounced for providers (n= 3) who stated they specialized in PrEP and HIV care.

*Yeah. Yeah. They come in and they say, "I want to do PrEP." [So?], "Okay. Yeah." So, it's not something I specifically screen for. I do have a sense of which patients might be better candidates for it, but, honestly, it's something they bring up to me, and I say, "Okay. Sure." So. - APRN*

Self-identified patients were often discussed in tandem with descriptions of patients who received a referral to the provider from other patients, clinical providers, or the PrEP Navigator. Participants described having appointments scheduled with the chief complaint listed as 'PrEP' or 'PrEP intake' for both patients referred and requesting PrEP. In both cases, the patient arrived with some knowledge about and desire to start PrEP. A few providers, who stated they did not know much about PrEP, said that this was a facilitator for them as the patient education piece had already taken place and, in some cases, the patient had enough knowledge to inform the provider what was needed.

*Usually, they come in self-identified saying, "Oh, I am a PrEP patient. Here's what you need to do, doc," which I appreciate because it's so rare, I'm not even really that familiar with the protocol, or I don't remember the protocol. So, I know at least one of my PrEP patients is really, really good about that. "Here's what you got to do. This what we got to do." "Okay, yeah, okay. We did it." - MD*



Self-identification as a primary means of connecting patients with PrEP services and prescribing PrEP was a barrier for patients with low health literacy, who relied on their provider to guide the medical visit. The PrEP Navigator described a case where, even after identification, the provider did not bring up PrEP during the visit and ultimately the patient did not receive a PrEP prescription.

*I had an MA report to me that this African American woman went into the office and the MA offered an HIV test. [S]he wanted [the] HIV test, and then the MA basically asked, have you heard of PrEP? And [the patient] said they never heard of PrEP before. [T]hen the MA kind of explained what PrEP was and everything, and then the provider saw the patient, didn't mention anything about PrEP. [S]o when the MA was explaining about PrEP, the patient was like, "Why didn't my provider ask me about that? I would have definitely taken that because my partner is not faithful to me, and I'm constantly worried that he's going to give me something." And so, this patient specifically ended up leaving the office without the provider even talking to them about PrEP, which is huge. The MA can do [PrEP education]. But if the patient is not someone who advocates for themselves, if a patient is somebody who just won't bring it up to the provider because they feel like providers know best and the provider should be bringing this up to me, that's a huge barrier, too. – **PrEP Navigator***

Internal referrals from other PCPs to PCPs who were known for prescribing PrEP were frequently described by the PrEP-experienced providers and the PrEP Navigator.

*I think that a lot of times, because I'm in more of a specialty role, they kind of come to me. It may be my patients' partners who schedule visits with me, it might be that a primary care provider or one of the women's health specialists identifies someone that they think is high need but have less experience themselves prescribing the PrEP, so they'll refer the patient to me. I think it's also word of mouth. People know that I do it, so. – **APRN***

Although SHS is a recommended process for detecting risk of HIV exposure, most PCPs who could recall their experiences with PrEP patients described relying on patients to self-identify or be screened and referred to them by another staff member at the organization. From their perspective, this method was advantageous because patients were already educated on the medication and process for initiation and adherence. Additionally, PCPs would describe knowing

their patients well enough to be aware of their risks, without conducting SHS. These methods, although not recommended by the CDC, reflected PCPs' desire to maximize time during visits and streamline care by addressing the primary complaint of the visit and using existing knowledge of the patient in lieu of implementing the SHS process (Center for Disease Control and Prevention).

### **5.3.2.2 Outer Setting**

Although CFIR does not list a formal definition for the outer setting, generally this domain encompasses mechanisms and attributes of the external environment that influence an organization's ability and success implementing SHS and PrEP services (CFIRguide.org, 2018). In this study, participants noted how external policies, particularly insurance companies and payment models, negatively influenced their ability to implement SHS and care for their patients on PrEP.

#### **Barrier: External Reimbursement and Payment Policies**

While there are no external policies (e.g., federal and state health care policy, health insurance, etc.) requiring SHS, participants did note how external policies influenced internal policies to create barriers to implementing SHS. Participants explained how limited time during visits was a result of the organization's response to external policies. Specifically, determined by insurance payment models, the organization had to set short appointment times, limiting the overall time available for within appointments to complete tasks.

Additionally, multiple participants noted that the required volume of patients seen per day by the organization played a major role in the limitation of time. Participants noted that this was driven by insurance payment models that pay per visit. To ensure income to finance operations through these payment models, providers are scheduled for a high volume of visits. Patient volume also stemmed from the organization's dedication to increase access to care through availability of

appointments timeslots. Participants expressed how the prioritization of access through more, often concurrent, appointments could result in limited ability to provide comprehensive care. Both the volume of patients and time allocated to each appointment played a detrimental role in integrating and implementing SHS during patients' visits.

*But I think also the push, you can either call it numbers or you can call it access, [f]or us to see lots of patients so we can finance [the organization] [and] making sure that everyone has access to care. And in that way, we open up the schedules for people to come in. But that makes it difficult to do sexual health, honestly, if you're pushing to see patients, and you have very complex patients, patients with low health literacy, who are Spanish speaking, who the digital divide is enormous and you're trying to deal with sort of more things like do they have their insulin, how do we keep them out of the hospital? And then to think of doing the sexual health on top of that in a 15-minute visit, just-- it's just not realistic. - APRN*

#### Barrier: Insurance and Finances

Participants stated that the cost of PrEP was a barrier to initiating or re-initiating patients (for patients who stopped and considered re-starting) on PrEP. Providers described how patients often did not have insurance and could not afford to pay for their prescriptions. Participants did name financial support programs, such as the PrEP manufacturer's discount program and the 340B program that reduces the cost of drugs from participating manufacturers for eligible health care organizations; however, they mentioned having to include time to educate the patient on and connect them to these programs for the patient to be able to afford the medication. Understanding and applying for these programs increased the time between identification of risk and need for PrEP and the patient receiving the medication.

*And then I just ask [the patient] if they've heard about PrEP. And then usually, I would say that the majority of the patients who I have asked about if they're interested in PrEP were aware of it. Some were not, but most were. But they didn't really think to seek it out, mostly because of the not untrue aspect of it being expensive, because it is expensive, and Gilead makes PrEP very, very expensive. But there are ways to get around that in terms of manufacturer discounts that they get for patients who have private insurance, depending on what it is and for how long and how much it's covered, or patients who are on Medicaid that don't know*

*that they can actually receive it for free in the state of Connecticut or elsewhere. -  
APRN*

Barriers to patients' protection from HIV through PrEP did not stop once patients started PrEP. Participants frequently described challenges to patients' adherence to consistent use of the medication and required follow-up procedures. Similar to barriers to initiation, providers described how changes in insurance plans and coverage meant that patients frequently had to stop the medication. Interruption of PrEP due to loss of financial coverage also occurred for patients enrolled in the discount programs as patients needed to renew it. This was often difficult for patients to remember and navigate, given how many other concerns they had in their lives.

*[The patients] kind of go in and out. I had one guy who was on it for a year, and then he lost insurance, so he was off it for a few months, then he got insurance and he's back on. And so, yeah, they move in and out of PrEP a lot of times. - APRN*

External entities and policies had significant influence on the finances of the organization and patients that prevented participants from successfully and consistently integrating SHS and initiating their patients on PrEP. Payment models from insurance companies and the organization's need to finance operations through many patient visits limited time during medical visits overall and specifically for integrating SHS. Similarly, lack of and inconsistent insurance coverage among patients made PrEP unaffordable. While participants were aware of discount programs, enrolling patients in these programs required ongoing time and effort since enrollment was not indefinite.

### **5.3.2.3 Inner Setting**

This CFIR domain contains constructs that describe how components of the organization in which SHS takes place interact with the implementation of SHS. Participants had a positive view of the impact of organization's culture on implementing SHS and the availability of staff to support prescribing patients PrEP. In contrast, participants described that structural characteristics,

such as the organization's configuration of appointments and the geographic location of medical sites, were barriers to implementing SHS during medical visits.

#### Facilitator: Organizational Culture

When asked how they thought organizational culture impacted implementation of SHS, participants commonly stated that the culture was open and liberal. When discussing the open culture, providers described how the organization was welcoming to everyone and attracted clinicians who wanted to improve patients' lives. From their perspective, this environment had a positive impact on the prioritization and implementation of SHS.

*[P]eople want to work at [this health care organization] because they want to help people genuinely. And I think that it attracts nonjudgmental people who really want to support our patients. So, I think the culture is really encouraging of - I mean, getting the sexual history, yes- but also like helping the patients be healthier and live better lives using that information. - **APRN***

When participants discussed the innovative culture, they described the organization as willing to trying new things and working to integrate new evidence-based care practices. An on-site medical director explained there were re-occurring quality improvement meetings where medical directors and clinical leadership discussed trialing new processes.

*At an organizational level, we have these outside medical director meetings every Thursday and is also the kind of quality improvement. If somebody wants to implement or try something new, it's discussed with the [on-site medical directors], and say, "Hey, should we do a little two-week [Plan, Do, Study, Act] trial kind of thing [for SHS]?" [The organization] has always tried to innovate and try different ideas. So, I think, at an organizational level, they're probably doing as much as they can. - **DO***

The organization's open and liberal culture and focus on innovation were viewed as facilitators to implementing SHS during medical visits from the perspective of participants. Participants shared that the open and liberal culture encouraged and fostered an environment to utilize recommended practices, such as SHS, to improve patient outcomes. The importance of the

open and liberal culture was pronounced for SHS since sex is often viewed as a taboo topic and populations, such as sexual and gender minorities, fear they will be discriminated against if they share their sexual preferences and practices. In addition to the positive impact of the open liberal culture, participants described how the interest and commitment of organization to improve patient care through innovative methods prioritized trialing new methods to integrate SHS as a routine component of medical visits.

Facilitator: PrEP Support Staff

Participants frequently referenced PrEP/HIV specialist staff as available and supportive of education and assistance for prescribing PrEP to their patients. They expressed they could easily reach out to these staff members if they had questions or needed help understanding the standards to initiate and maintain their patients on PrEP. Participants described this group of staff as enthusiastic and helpful.

*I know the people from the [PrEP/HIV specialist] group pretty well, too. So, I know they're so nice. They would do anything to help me get started on [learning how to prescribe] PrEP, even like their nurse. I feel like there's a lot of support. - APRN*

Most of the providers did not know the organization had a PrEP Navigator. Some had heard of the position when it was first introduced but had never worked with them. Providers who knew of the PrEP Navigator and had worked with them thought the position was helpful in caring for their PrEP patients. Participants described that the PrEP Navigator provided support by educating them about PrEP, reaching out and follow-up with PrEP patients, reminding providers that patients were due for follow-up, and helping patients overcome financial hurdles to a PrEP prescription.

*One of my early patients that was on PrEP, I had asked around to a couple of my colleagues, "Hey, any ideas for this?" And they were, "Oh, we have a PrEP navigator. Just reach out to her." Okay. And so that was good because the first time that I did it, I was kind of able to reach out to her, and she sent me emails with policies about how we start it and what we're looking for. So that was kind of nice to have. - APRN*

Although few of the participants knew of and worked with the PrEP Navigator, the existence of specialized PrEP/HIV clinical staff was a facilitator and helped participants feel more comfortable should they felt uncertain treating a patient with PrEP.

#### Barrier: Time

Participants most frequently noted lack of time as a barrier to implementing SHS, specifically having limited or no time to integrate SHS during the medical visit. Providers explained that most adult patient visits are scheduled in 20-minute blocks. These 20 minutes include pre-visit tasks, including completing screeners with the MA, and direct time with the PCP. The participants described that it is not uncommon for patients to not come for their visits. To account for this, the organization would book multiple patients in the same appointment time; however, this could result in providers having to manage co-occurring visits because both patients attended their appointments.

*They're scheduled for 20 minutes, but they put an overbook [scheduling multiple patients at the same time] every hour because the rationale is, "Well, there's so many no shows, so." But that backfires when everybody shows up. - APRN*

In addition to appointments being overbooked, participants also described how patients being late further limited the amount of time they had during visits. Providers acknowledged that patients' reasons for being late were typically outside of their control, given that they face barriers to care (e.g., transportation and childcare). However, the combined effect of late and overbooked patients was detrimental on time during visits. Participants stated that both the MA and PCP typically had between 5-10 minutes each with the patients. Deviation from the allotted appointment slots to afford more time with a patient had a domino-effect with subsequent patient visits.

*So, you technically get 20 minutes, but they inevitably get in 10 to 15 minutes late, so but then you have five minutes-- I tend to take 20 to 40, which really screws me up and everyone suffers. - APRN*

The organization's configuration of appointments was viewed by participants as a major barrier to implementing SHS with patients during medical visits. The individual and combined effects of limited time during each visit and co-occurrence of visits were structural barriers within the organization to integrating and prioritizing SHS with their patients.

Barrier: Variation by Site

Participants described how the organization's medical sites are distributed throughout the state, with the largest sites centrally located towards the middle of the state. They explained that the larger, more centrally located sites were not only busier but also had more co-located resources. In addition to housing the organization's leadership offices, these sites also had PrEP/HIV specialists and staff who were involved in the development of internal SHS protocols. Although participants described appreciating the environment in the smaller medical sites, they expressed that the distance from leadership and resources at the larger medical sites made them feel isolated. Staff from small sites conveyed relying on other on-site staff to support gaps in clinical knowledge.

*I feel like, being in [a smaller medical site], I am so far away from sort of the center of things that sometimes I'm kind of on my own out here, even though the culture still supports [SHS and PrEP]. But we do have [PrEP specialist] out here [at the smaller medical site], if I ever have questions, she's a great resource to reach out to. - APRN*

For participants at smaller clinical sites that are situated farther from the core locations of the organization, geographic distance and distribution of assets were barriers to being aware of and utilizing resources for SHS and PrEP. These participants felt the staff and resources at the larger, central sites were inaccessible and relied on staff within their own medical sites to address their



needs, acknowledging that these resources were not as strong or plentiful as those at the central medical sites.

#### **5.3.2.4 Characteristics of Individuals**

This domain includes attributes of people implementing the intervention, in this case SHS or PrEP services. Attributes include knowledge and beliefs about the intervention and self-efficacy (perceived ability to implement the intervention) (CFIRguide.org, 2018). Participants viewed familiarity with patients as a facilitator to integrating SHS and talking about sex. Additionally, participants in this study shared what they believed to be the key questions to a sexual history, including confusing it with asking patients about their sexual orientation and gender identity. Comfort with SHS and/or PrEP was frequently described across themes, particularly when discussing their perception of SHS and PrEP services.

##### Facilitator: Provider-Patient Relationship

Participants frequently described that their relationships with patients were influential to their comfort and ability to implement SHS. Participants noted that SHS was much easier to implement with patients with whom they are familiar. If they had worked with the patient for a long time and had asked them SHS questions before, they felt more comfortable revisiting the questions. Conversely, providers mentioned that new patients or caring for another providers' patient was typically a barrier to implementing SHS because of the lack of familiarity.

*Easier if we've had the conversation before. So that's always makes it easier. Harder if I'm not familiar with a patient; if the patient is new to myself, if I've only seen them a few times. – Clinical Leadership*

##### Influential Factor: Knowledge of Key Questions

When asked what they considered to be the key questions to a sexual history, some participants did not list any of the CDC recommended questions. Providers frequently discussed

offering STI screening as the only question for SHS. Among providers who did cite CDC recommended questions, multiple reported only using one or two questions. Alternatively, a few providers stated they did not ask any SHS questions at all even if they knew what the recommended questions were. While the participants themselves did not report these factors as barriers to implementing SHS, lack of knowledge on what the questions are and acknowledgement that they do not implement them is certainly a barrier to the SHS process.

*I generally don't ask that many [SHS questions]. I ask people if they want an STI screen. And I usually just kind of leave it at that. - DO*

Although included in guidance for conducting a comprehensive SHS, sexual functioning and gratification questions were not frequently listed as part of SHS questions; however, participants noted that the topic of sexual function typically arose among male patients with concerns about low testosterone and erectile dysfunction (Center for Disease Control and Prevention). Only three participants mentioned women's sexual function and gratification. The providers who did mention it described how patients who were older, cisgender women were unlikely to bring it up because they perceived these patients as believing that low libido was an acceptable, expected part of aging.

*I would say the patient population that kind of is more reticent to talk about the importance or downplays it and I try to encourage them to be like, "It's okay to care about this," and want to talk about it are post-menopausal cis women. They're sometimes like, "Oh, I don't have any interest in sex anymore. I've just kind of accepted that that's how my body is now." I think that's a cultural norm. I try to validate that that's an important part [of life]. I think it's important for everyone. - APRN*

In addition to limited knowledge of key SHS questions and admitted infrequency of use, participants also tended to include or limit key SHS questions to asking their patients about their sexual orientation and gender identity (SOGI).

### Influential Factor: SOGI Questions

In addition to SHS, collection of patients' SOGI data was part of the organization's routine screening process. When talking about SHS, many providers would refer to these questions as part of the larger process of talking to their patients about sex. After differentiating SOGI questions from SHS, participants described how SOGI questions often acted as a productive preface to the SHS questions.

*When the SOGI [questions] came around and we had to ask all those [...] It just kind of made me have to kind of reflect on how I need to kind of approach these things. Investigating as to, "how should I handle these situations? It's like, "Okay, you're marking you're bisexual and just like, 'Okay, what does that mean to you?'" So, I'll do it sometimes. I'll be like, "Okay, tell me a little bit more about this." I go, "I see you marked bisexual." I go, "How long? How many partners?" [T]hat just kind of opens up those things. [T]hose are things I might not necessarily have asked when I would have said, "Sex with men, women, or both?" before. So now it's a little bit a bigger question. – **APRN***

### Influential Factor: Providers' attitudes, feelings, and reflections on SHS

Participants' attitudes towards SHS varied greatly, from those who actively did not implement it to those that were proponents of routine comprehensive SHS.

*Sexually health [depends] on the provider. I'm sure there's some providers who are very, very on top of it, who bring it up, who are conscious of it, and feel it's part of their scope of practice. And then, there is probably the mass of providers who just prefer not to go there, or go there when it's brought up, or it's part of another clinical issue. And I'd probably put myself in [the second] category, honestly. - **APRN***

Regardless of participants' attitudes towards SHS, their comfort asking the questions was consistently mentioned, indicating that comfort was an important underlying issue. Some participants described being comfortable asking the questions and being 'open' and 'welcoming' to patients' responses, which they thought had a positive influence on implementing SHS.

*I'm an open kind of person. So, for me to ask anybody a question, I don't find a problem with it, especially in regard to [SHS]. I mean, we're all human. I mean, for the most part, we are having sex. So, it's pretty easy for me to ask about it. - **MA***

Conversely, some providers described being uncomfortable bringing up sex with their patients. They were also uncomfortable asking follow-up questions when concerns were identified. Participants were cognizant of how this discomfort impacted the implementation of SHS, and further training was often proposed to enhance comfort for providers.

*My comfort on how to conduct a proper [SHS is affected] because sometimes, I don't know for some reason, there is still a little bit of me that feels weird about asking about sex. But I feel like that that's one of the things that I'm aware of that I need to work towards kind of changing that some time and my own perspective on sex. - APRN*

Providers also acknowledged that they held biases about their patients which often interfered with the prioritization of SHS. These included a bias based on the patient's age, meaning that if the patient were older the provider assumed they were not having sex. Participants also mentioned patients' gender and culture as factors that made them uncomfortable bringing up SHS.

*I have a patient who is like 85 who I'd been seeing for a while who lives with her son. And this actually wasn't through a screening, it just came up in conversation. She started talking about her boyfriend and missing him because she had just moved. And I had no idea she had a boyfriend. I just assumed because she lives alone with her-- it's just her and her son, that she didn't have a sex life, and she did, that I didn't know about. So, I think that that was kind of eye-opening of I just-- it wasn't high on my list of things I was thinking about with her, but it was an important part of her emotional health that I hadn't really addressed in visits. - APRN*

Most participants were vocal in their desire to not have biases impact their SHS behaviors. Similar to suggesting more training to increase comfort, providers also recommended trainings to learn how to mitigate their own biases when implementing SHS.

*It goes all the way to religion and everything, for me, my barrier. To me, I'm a Christian, I want to have my patient healthy [and receiving] preventive medicine [with] no problem. [I]t's not discrimination, it's very hard to talk about. [A]s a Christian you may have-- I mean, for me, I'm okay to bring up subject- but some providers may have hard time [knowing] how to [put aside] your own religion and*

*just be free to talk about [SHS]. So, it'd be helpful to have training [on] how to talk to the patient about this issue, how to bring it up, and separately for people who [are] Christian doctors, how to talk. That would be helpful. – DO*

#### Influential Factor: Providers' attitudes, feelings, and reflections on PrEP

When asked directly how comfortable a participating PCP was with prescribing and maintaining a patient on PrEP, all stated that they were comfortable. Interestingly, their reported comfort was distinct and sometimes contrary to their reported knowledge. Some participants expressed that they did not have much knowledge of the protocol for PrEP; however, they felt comfortable enough given that there are resources and internal support systems to help them.

*Pretty comfortable. Yeah, I would definitely [bring up PrEP with a patient]. Again, I try every morning to huddle and look over and see who I am seeing on the day and what the problem is and then kind of looking at-- so, again, I would have to kind of just go refresh myself with the PrEP protocol, but no, I would feel comfortable bringing that up if I thought they were appropriate, yeah. - MD*

Participants understood the importance of PrEP to prevent HIV, particularly for their high-risk patients. Providers' attitudes toward PrEP were positive, whether or not they had much experience with it. However, in contrast to talking about themselves, often when participants spoke about other PCPs, they described a general lack of knowledge and comfort around prescribing PrEP.

*PrEP only works if primary care providers do it. Because if it's only HIV specialists doing it, you can't reach enough people. But I think still there's this hesitancy a little bit among providers who-- it's quite easy to do, actually, but I think some people just haven't learned it. [...] So, I think comfort level among providers. I mean, people are busy and they're like, "Oh, this is another thing to do." So, I think sometimes that can be a challenge. - APRN*

This was supported by statements from clinical leadership and the PrEP Navigator. These participants expressed that in their experience there was a larger number of PCPs who were uncomfortable, which was a barrier to increasing access to PrEP for patients who needed it. The

PrEP Navigator, who was responsible for connecting patients with a PCP to prescribe and manage the patients' medication, explained that they would attempt to refer a patient to a PCP at their local medical site and often the provider would decline to accept the patient for a PrEP prescription.

*One of the biggest challenges for me was the provider buy in. I struggled a lot with that because a lot of providers were like, "I'm not comfortable prescribing PrEP."  
- APRN*

A member of clinical leadership elaborated on how they perceived PCPs' comfort with PrEP and how experience was important for gaining comfort. That initial experience requires additional effort from the providers to seek internal support or research PrEP on top of their existing workload.

*I think, unfortunately, [providers] have the knowledge of what PrEP is, but then when it comes down to them actually writing the prescription, if they themselves are going to write it, there are some that feel very, very uncomfortable. Then there are others that are going to look it up and spend 20 minutes on UpToDate or something to figure it out or they'll just send a message to [PrEP-experienced staff] and say, "Tell me, what do I do? I have this patient. I want to do this, but how do I do it?" So, the good news is, is that I think people have the comfort, but maybe it's their first prescription or they've only done a couple. So, I think until-- it's sort of like, until you've done it the first time or the first couple of times, you don't feel quite as comfortable. – PrEP Navigator*

### **5.3.2.5 Process**

Within CFIR, the process domain recognizes the role and components of approaches to implementation of SHS and PrEP services (CFIRguide.org, 2018). The focus of this domain is not on the intervention itself, but rather on process paths to implementation and sequential steps to the uptake of the intervention across the organization (CFIRguide.org, 2018). In this study, participants noted the role of the EHR on the implementation of SHS. Clinical leadership described the existence of a protocol for identifying and working with PrEP patients to provide guidance and structure to the process. Additionally, participants desired training to improve and facilitate implementation of SHS. Lastly, participants described successful strategies, such as setting alerts

for follow-up appointments and asking the pharmacy to create blister packs for pills, to assist patients on PrEP with adherence.

#### Influential Factor: Electronic Health Record

When explaining how providers are prompted to implement SHS in cases where it is not initiated by the patient, participants described the dashboard, a tool that was integrated in the EHR to house a list of routine screening and health measures that patients should receive. The dashboard is used by the MAs to conduct required screening prior to the patients' time with the PCP. The PCP can then use the patients' responses to the screeners to inform the visit.

*[The] dashboard is a tool that is used [by] our medical assistants [to] go in to see what we might do for that patient. [It includes a] depression screening, [I]f it's a kid's physical, it's like the pediatric screening, domestic violence screening, asking about that. I think there's also the one about drugs and alcohol for diabetics or hypertensives. Whether or not you're up to date on your path for your colonoscopy or your mammogram. So those are the things that are on there that usually then the MA has to address all of those items, ideally, in the visit when they bring the patient back. And then, based on what they ask, then the provider has to look and then address those ones that need addressing. - APRN*

The dashboard will also alert providers when screenings are due. Quality measures, which are mandated reporting measures, are also housed on the dashboard. Providers' completion of dashboard quality measures is monitored by quality improvement staff and clinical leadership as part of their clinical productivity. SHS is not included on the dashboard and is not a mandated quality measure. In addition to being housed elsewhere in the EHR, priority of mandated screening often decreased the importance of SHS as part of routine screening processes.

*The [EHR-integrated SHS screener] was introduced, but the [screener] was shared as an optional tool, it is not required. And I think that's what's hard, right? [I]f you do something as an option, a primary care provider who's already hard pressed, who already has 10 other [required screeners] being collected by their MA, is going to be less likely in a 20-minute visit to then say, "Let's do another tool." So, I think that's the problem, right? Is people want to do the right thing, but we are building it into a system that isn't really designed to be able to deal with everything at once. – Clinical Leadership*

Participants stated that adding SHS to the dashboard could potentially mitigate this issue.

*Participant: I don't think we have the right tool or the right system, like I said, in place, to ask more questions more often.*

*P: I think I would probably make it be a dashboard item. I know that a lot of times those tend to be those measures that we have to meet for the state, or whatever, for accreditation. I get it. But I just don't think that this is up there at all for them to ask. - APRN*

While this may help promote SHS through performance monitoring, participants did express that the number of pre-visit screenings collected in the EHR, regardless of whether they are mandated, were difficult to cover during appointments. The introduction of more mandated processes means there is more burden on providers to integrate the new processes into a visit, further dividing the limited time available to both complete required screenings and address patients' needs.

#### Influential Factor: PrEP Protocol

Clinical leadership, including PrEP/HIV specialist staff, and the PrEP Navigator described the creation of a protocol for providers on how to identify and care for patients on PrEP. This protocol included instructions for all key staff, from the front desk to the PCP. The intention of the protocol was to be a resource for clinical staff to use to understand the organization's process for PrEP patients. In addition to the protocol, informational resources on PrEP, including prescription information and follow-up guidance, was gathered and made available to clinical staff through the organization's intranet.

*We created a PrEP [protocol] which had instructions on what nurses should do, what MAs should do, what the [front desk] staff should do, what the providers should do. So, if it was a nurse and she needed to look through the [protocol] to see what's my next steps, what's the process, because we created process maps and everything for every single one of them, they would be able to look at that and say, "Okay, this is the protocol, this is what we have to do." – PrEP Navigator*



When the PCPs were asked about what types of support were available to help with PrEP, none of them mentioned the PrEP protocol or internally compiled resources. Providers recognized that the organization probably wanted them to be prescribing PrEP to patients but could not think of any specific rules or guidance to do so. Clinical leadership described how the various options and pathways within their PrEP process may be the underlying reason for lack of knowledge and initiative to learn and prescribe PrEP.

*Our protocol really is that we have trained the entire organization in what PrEP is, so there is no one way to get PrEP, which I think is both good and bad. Right? Because I think sometimes if everybody can do it, then certain [PCPs] might just say, "Not my problem. Somebody else will do it." – **Clinical Leadership***

#### Opportunity: Training

Most providers reported received brief training on how to conduct a SHS during their clinical training or as part of routine in-house training as a clinical employee of the organization. In-house training was described as receiving information on SHS via e-mail from clinical leadership, attending a Grand Round session discussing SHS, and/or participating in an ongoing provider training program implemented by the organization focused on HIV and Hepatitis C. A few participants described seeking additional formal training through residencies or external training opportunities, such as conferences. It was also common for participants to state they never received any training on conducting SHS.

In addition to anti-bias training, participants stated they would like training on language to use when implementing SHS. Providers expressed that having practice using SHS language during training would improve their comfort. Additionally, providers wanted training on how to make the patient feel comfortable or to mitigate patients' negative reactions to questions.

*I think it would be being more aware of the patient reactions and being able to assess their thought or feeling towards a specific thing and knowing-- basically,*

*going into the room and feeling comfortable. If a patient does get agitated with me asking the question, being able to calm them down and then explain to them why are we asking these questions, and what does this do for them and the provider? – MA*

#### Opportunity: Strategies for PrEP Adherence

When asked about how they measure adherence for patients on PrEP, most participants stated that they asked the patient if they were taking their medication as directed. When asked what strategies for adherence participants had successfully implemented with their patients, providers listed: setting up alerts in the EHR to contact the patient and schedule a follow-up visit and planning a daily routine for taking the pill with the patient. Providers suggested patients ask the pharmacy to make blister packs or get a pill sorter for patients' PrEP pills to help patients know when they have not taken their pill yet for the day.

*Just a routine, I guess. Taking it at the same time of the day every day during the same kind of activity. So, if that's getting ready for bed, if that's getting up in the morning, before you brush your teeth, or however that works for people, it's kind of taking it at the same time of day every day. I did have one patient who would set an alarm on his phone. - APRN*

#### **5.3.2.6 Patients**

Patient-level factors are not encompassed by the existing CFIR domains and constructs. During interviews, participants frequently discussed reactions, priorities, and attributes of patients as influential factors on the implementation of SHS and PrEP services. Based on these results, this study defined this domain as attitudes, behaviors, needs, and characteristics of patients that influence the integration and uptake of SHS and PrEP services during medical visits, as perceived by providers participating in this study.

#### Influential Factor: Patient Priorities

Patients' priorities during visits were influential on whether providers conduct a SHS. Their priorities could act as a facilitator or barrier, depending on the priority they brought to the visit.

Patients who presented with a complaint related to sexual health, such as an STI exposure or issue with sexual function, were easiest to integrate SHS into the visit. For patients presenting with other concerns, it was much more difficult to screen patients for sexual health concerns, even if they are due for their annual SHS or they have never received it before.

*By the way, they're [for SHS]. But today, it seems like they're falling apart because of all these other things. [I]t's really easy for primary care providers to say, "You know what? We just don't have time for that today." And I think because it is something that is seen as sort of health promotion, it does tend to take the back burner. Right? Because patients have other things that aren't just in that sort of primary prevention category, but are in secondary and tertiary prevention. [T]hey're already sick, they're already dealing with these chronic illnesses. So those tend to bubble to the top. And then, a lot of the other things just don't always make it to the top ever. – **Clinical Leadership***

Given that patient priorities played such a major role in whether SHS was implemented during visits, providers were asked how often patients presented with a sexual health complaint. Most providers said it was not often.

*Rarely. Rarely. It's usually, "My arm hurts. My leg hurts. My head hurts. I'm dizzy. My back hurts." It's not usually [a sexual health] thing. - **APRN***

Participants shared that the most common sexual health complaints were: STI exposure and sexual function (e.g., erectile dysfunction). For patients who did not present with a sexual health complaint, ideally SHS would take place during a well-visit; however, participants observed that patients are not likely to schedule and attend preventive care appointments. This occurred because of everything they have going on in their life and it was often difficult enough for them to attend complaint-specific appointments.

*A lot of times they only come in if they have a complaint. So, to come in for health maintenance is just-- I think it's just low on their priority list. A lot of our patients just have a lot of challenges. And even getting to appointments is challenging for our patients. – **APRN***

Influential Factor: Patients' reactions to questions

Participants reported that patients were generally receptive and responsive when asked sexual history questions. They shared that patients expected to be asked uncomfortable questions as part of the medical visit. Providers reported patients' ability to converse about sex, their recognition that talking about sex is important, and their understanding that it is a required, routine part of a medical visit facilitated the SHS process. Additionally, patients responded well to SHS when it pertained to their chief complaint for the visit, such as having an STI exposure or a concern about sexual function. Providers reported that this elevated the importance of these questions, in contrast to answering SHS questions when it is not part of the patients' primary complaint.

While most participants stated they did not have many patients decline to answer all SHS questions, it did occur from time to time. Participants were not always sure why patients did not want to respond to questions. They surmised that patients did not understand the questions or were uncomfortable answering the questions.

*When people have awareness about sex, and they have awareness about their sexuality, as well as their practices, and they're willing to be open, it makes it so much easier. Whereas, when people are mentally or psychologically-- or there are other blocks, it just makes it way trickier to be like, "Okay. Well, let me figure out how to phrase this four or five different ways for you to understand what I'm saying." That just makes it so much trickier. Or if they don't even want to talk about it, also trickier. And sometimes you just have to leave it because they're like, "No, this is not relevant." So, often, it just gets left off if it's not directly relevant unless it's a preventive wellness or a first-time-getting-to-meet-you kind of thing. - APRN*

Other instances in which participants reported patients' reaction to questions as a barrier varied. Providers often cited age, relationship status, and culture as being common attributes of patients who they perceived to be offended or who refused to answer SHS questions. Generally, participants reported older patients, patients who were perceived by their providers to be in monogamous relationships, and those whose culture held more stringent beliefs around sex as being more likely to have a negative response to SHS questions. Additionally, sexual orientation

was noted as influential on how patients reacted to the questions. Participants reported that patients who identified as sexual minorities displayed more comfort answering the questions compared to straight patients.

*A lot of my patients, probably more than any other provider at CHC, I take care of a lot of gender and sexual-- patients who identify as gender and sexual minorities. And I think that there's a higher comfort level because sexual health is kind of seen as a normal part of their health for those patient populations. Whereas I think often cisgender and heterosexual patients are a little bit more taken aback when they get asked. Especially older patients. – APRN*

#### Influential Factor: Patients' Characteristics

Given the patient population served, it was not unsurprising that participants often mentioned how patients faced challenges and barriers in their lives that prevented them from engaging fully in care. In alignment with published statistics on FQHC patients, participants stated that patients were low income and struggled with health literacy and navigating the healthcare system (National Association of Community Health Centers, 2017). Providers described how patients' primary life concerns were not related to their physical health. Participants' patients were often focused on earning enough income to provide food for their families and maintain housing. Many of the providers' patients lacked health insurance and could not afford to seek care for anything not causing them immediate, detrimental harm. Participants elucidated that these factors were often barriers and challenges to implementing SHS as part of patient care. In addition to visits being focused on an urgent physical complaints in lieu of routine screening, providers also aimed to address the social determinants of health preventing patients from benefitting fully from primary care services during appointments.

*If there was a visit for hypertension and cholesterol, you[re] really also trying to deal with housing issues and income issues. [These issues are] causing someone not to purchase their medications. Or the medication went up in price, but they didn't know to call the [us] to ask them if there was some option to send them something cheaper or somewhere else. [T]he level of involvement is a little bit more [than a private practice] because we have someone whose [struggle to] access*

*care, who need to connect [with] someone to reapply for Medicaid, or if they don't have insurance, but they needed access to certain services. There's just that extra level of connecting patients to care and services that are needed that, at least, in [my private clinic] experience [it] wasn't really an issue. And then you don't get as many patients who are coming in just to ask for scopolamine patch for antinausea while going on a cruise. - APRN*

Participants also described how these factors were influential on patients' PrEP adherence. Specifically, participants reported that patients were often lost to follow-up and their PrEP prescription lapsed. This occurred because of challenges to scheduling and attending medical appointments to complete the necessary bloodwork. Lack of follow-up was often due to barriers to care, such as housing instability.

*Well, I'm thinking of one of the other patients, he also had depression, and also housing instability [and] insurance [coverage issues]. [H]e had all these things that were kind of keeping him from following up with me. So, he'd kind of drop off the radar for a month or two, and then-- or even three or four, and then come back into care. - APRN*

In addition to the influence of social determinants of health on implementation of SHS and PrEP services, participants often stated that there were specific characteristics of patients that played a factor in how easy it was for them to implement SHS. Patients' gender, age, relationship status, culture, and if they were sexual and gender minorities were frequently mentioned characteristics when discussing comfort, ability, and the decision to ask SHS questions. Providers explained how patients' comfort with SHS and discussing sexual health was often influenced by discordance between the patient's and providers' genders. Participants believed patients thought their provider either would not understand because they did not have the same lived experiences or because discussing sex with a provider of another sex was awkward.

*I'm a woman and the other person is a guy and then I have to ask a different sexual history, yeah, some young men they're a little embarrassed. And some of my older patient are in 50s, when they want to talk about sexual history, they will ask for a*

*male provider even though I'm their primary care physician. So that would be the hard part. But otherwise, that's patient preference, so that's fine. - DO*

Additionally, patients' ages were frequently noted as a determining factor on whether or not SHS was important during a visit. Participants believed that unless an older patient brought up a sexual health issue, it was not a potential concern for the patients' overall health. Providers assumed that older people were not having sex or that sexual function was no longer relevant to the patient. Some participants also noted that they felt awkward asking older patients about their sex lives, out of fear they would offend them. At their age, participants believed it was the responsibility of the patient to voice concerns or changes in their sex life.

*If I'm going to be honest, if it's an older patient-- when I say older, let's see, like over 50, and if it's someone I know, pretty stable, straightforward, I really know the person, I'm not going to engage in sexual history with that person unless something comes up or that patient brings it up because you do have some of those patients who are celibate for periods of time. We're talking about having a new partner, then out of the blue, they come in to see me for routine blood pressure follow-up. "Oh, by the way, I have a new partner," and then I'll broach that subject about testing and contraception. That type of thing. If it's a younger patient, I deliberately will broach the sex history. - MD*

This was especially true for adult and senior patients who were in long-term, monogamous relationships. Providers stated that their familiarity with the patient and their partner (whether the partner was a patient or not) gave them the impression that risk of STI infection was not a pressing concern.

*It's sometimes harder to remember to do it in patients who have long-term partners that I know of. It's not ideal to assume that they're monogamous and have no other relationships, but it sometimes kind of falls off the radar if you take care of like a couple who have been together for 10 years. - APRN*

In combination with age and relationship status, culture was frequently mentioned as a patient characteristic that acted as a barrier for providers when deciding to initiate a SHS.

Participants stated that they hesitated to conduct SHS with patients who immigrated from other countries during their adulthood, particularly countries where the provider perceived or knew sex to culturally be a taboo topic of discussion. Typically, patients' culture was listed with age and relationship status when participants described struggling to talk about sexual history. Providers described knowing or operating under the assumption that these cultures held stringent standards on sex and monogamy that would preclude patients from being at risk of STIs within a marriage.

*Certainly, culture comes into it. I would be very reluctant to ask certain women about sex because I know they're having sex with their husbands and they're not going out. Most Pakistani women, Indian women in their 40s, 50s, 60s, they're-- so I think culture. Now, younger ones, I would, but certainly somebody who immigrated as an adult and is living still a fairly traditional life, it's less likely. -  
**APRN***

Interestingly, age and culture were also mentioned in tandem with patients having another person, typically a family member, with them during the medical visit. Participants described how the presence of another person made the conversation more uncomfortable and introduced social desirability bias to the patients' responses. If the patient had an STI exposure or sexual health concern, they may not tell their provider because someone whose opinion they care about was in the visit, listening to their responses.

*I would say a lot of the, I want to say Pakistani, the Muslim faith women that only come in, they will not come into the room without their spouse in there, that can make it difficult. -  
**APRN***

This was particularly pronounced for adolescent patients. While the questions asked during the interviews for this study were focused on adult patients, participants often brought up adolescent patients when describing characteristics of patients that influenced SHS. Participants recognized the importance of SHS for this population and would report asking these questions of adolescent patients on a routine basis, in contrast to their reported lower frequency with adult



patients. Providers often described that adolescent patients were uncomfortable with the questions; however, the questions were developmentally important and prioritized during medical visits. Compounding the underlying discomfort, adolescents were usually accompanied by their parents or caregivers, which was a frequently cited barrier to implementing SHS with this patient population.

*They may have come in with the parents. I mean, I'm not going to ask them about sexual history in front of the parents, but even with the parents outside, sometimes I think they're a little bit hesitant because what I find is they're concerned that it may get back to the parents. - MD*

In addition to focusing on SHS with adolescents, providers also frequently stated they would prioritize SHS screening for patients who reported having sex with the same sex or who were sexual and/or gender minorities. This aligns with CDC guidance to ensure patients disproportionately impacted by HIV, such as men who have sex with men, are routinely screened to identify risk of STIs and HIV. Although not a consensus of participants, two providers recognized this targeted screening may be burdensome and unintentionally discriminatory.

*If they come in and it's fairly obvious they've made it known in their chart [that] they identify as transgender [sic] or a man who has sex with men, they might feel uncomfortable because their provider might ask them about sex at every visit. And that's not fair either. Right? I don't come in just because I'm a man who has sex with men. I might have diabetes; I might have hypertension. So, I think it's sort of like that. There's sort of the two extremes, and then there's a lot in the middle. –  
**Clinical Leadership***

## 5.4 Discussion

Guided by CFIR, this study is the first to our knowledge to investigate facilitators, barriers, and influential factors to the implementation of SHS and PrEP services in an FQHC setting. Our findings provide an understanding of these factors at all levels of CFIR from the perspective of

PCPs, clinical leadership, medical assistants, and a PrEP Navigator. This study addresses the dearth of qualitative literature on the implementation of SHS and PrEP and PrEP services across the health care system, from characteristics of individuals to external influences in the outer setting.

While patients' needs and resources are acknowledged within the Outer domain of CFIR, this construct is limited to whether or not an organization knows and prioritizes patients' needs and what barriers and facilitators are to the knowledge and prioritization of patients' needs (CFIRguide.org, 2018). The patient-level factors in this study were not applicable to this construct and it was evident that these factors were critical to the implementation of SHS and PrEP services from the perspective of participants. For this reason, an additional domain was added to house patient-level themes and recognize their influence on implementation.

Our study found that SHS is not often utilized as part of the process to identify patients at risk of HIV who should be offered PrEP. The limited utilization of SHS to assess for indications of PrEP and to identify patients who would benefit from a referral to the PrEP Navigator may stem from lack of knowledge of the key SHS questions, lack of awareness of the PrEP Navigator, and that most eligible patients were seemingly referred to HIV and PrEP specialists for a prescription. Although participants could describe each step of the process, often listing HIV and PrEP specialist staff in lieu of the PrEP Navigator for support, the connection between the steps and resources was not expressed and is indicative of a need for further education and training. While there was a weak link between SHS and PrEP services from the perspective of our participants, there were common facilitators, barriers, and influential factors between the implementation of SHS and PrEP.

When implementing or deciding whether to implement SHS, providers described patients' reactions to questions, their relationship with patients, and the culture of the organization as facilitators. We found that participants frequently did not receive negative reactions from patients

when implementing SHS and that asking patients' SOGI prior to SHS facilitated the SHS process. This finding aligns with previous research that found patients' believe SHS is an appropriate and acceptable part of medical visits (Ende, Rockwell, & Glasgow, 1984). Familiarity with their patients also improved their reported likelihood of choosing to implement SHS during a visit. Lastly, providers viewed the organization as a positive environment that promoted implementing SHS.

Conversely, participants universally felt that time was the biggest barrier to SHS during visits. Compounding issues of time, patients' priorities often, and appropriately, took priority over SHS during these short visits. In addition to urgent physical needs, patients also faced social obstacles to arriving to medical visits and maintaining their health. Similar to previous research, our study found that patients' medical complaints were an influential factor on how time was used during medical visits. If their primary medical complaint is relevant to SHS, providers are more likely to report implementing SHS (National LGBT Health Education Center, 2015). Time is a very consistently documented barrier to implementing SHS in previous literature, qualitative and quantitative studies (Temple-Smith et al., 1996; Torkko et al., 2000).

While not explicitly barriers from the perspective of participants, there was a lack of knowledge among providers on what the key SHS question were and discomfort talking about sex. Providers also implemented SHS more or less frequently depending on who the patient was and how important the provider perceived SHS to be based on the patient's characteristics. This indicated that there were underlying assumptions about which patients would be comfortable talking to them about sex, were having sex, and were at risk of STIs. Specifically, the patient characteristics providers described as influencing their decision to implement were: 1) older patients, 2) patients with different cultural backgrounds, 3) adolescents, 4) patients who were a different gender, and 4) sexual and gender minority patients. These results are supported by

previous literature indicating that social factors, such as age, sexuality, gender, and cultural differences are influential factors in the providers' decision to implement SHS (Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006).

Pertaining to identification of PrEP patients, patients' knowledge of PrEP prior to an initial medical visit was a facilitator for providers. In our study, providers reported that patients either knew about PrEP on their own or were educated and referred by other staff members. Patient's reported self-identification for PrEP in our study aligns with previous literature that most PrEP patients initiate PrEP at their own request (Chu, Cotler, & Yingling, 2020). It was notable that few of the providers reported using SHS as a tool to identify candidates for PrEP. Given participants did not report consistently conduct SHS screening, there are potentially patients who are not being identified for PrEP but are at risk of contracting HIV. Reliance on the patient to request PrEP was a noted barrier to PrEP initiation from the perspective of the PrEP Navigator.

In addition to patients' knowledge and self-identification for PrEP, providers viewed internal support and resources for PrEP as facilitators to working with PrEP patients. PrEP/HIV specialist staff was viewed as a positive and responsive resource to learn about PrEP. While not many of the providers had heard of the PrEP Navigator, those who had worked with them had positive experiences working together to navigate patients' barriers to PrEP initiation and adherence. These findings, while limited, add to the existing literature on the acceptability and effectiveness of PrEP Navigators (Bradford et al., 2007; Pagkas-Bather et al., 2020; Reback et al., 2019; Spinelli et al., 2018).

Although the providers who participated in the study stated they felt comfortable prescribing PrEP, clinical leadership and the PrEP Navigator described that a larger proportion of PCPs did not feel comfortable. Providers who were uncomfortable would decline to accept a patient who needed PrEP, making it difficult to connect patients to easily accessible providers. In

agreement with the clinical leadership's assessment that providers needed training and experience to gain comfort prescribing PrEP, Researchers Krakower and Mayer have proposed a Hypothetical Provider Cascade for PrEP (Krakower & Mayer, 2016). This construct outlines the steps that providers must work through and achieve to successfully prescribe PrEP: 1) awareness, 2) willingness to prescribe, 3) trained to prescribe, 4) experience prescribing (Krakower & Mayer, 2016).

Participants reported that the cost and follow-up requirements for PrEP were major barriers to initiating and maintaining their patients on their prescription. Patients required education on and assistance with getting their PrEP prescriptions covered through discount programs. These barriers align with previous research on the cost of PrEP for patients, who are often concerned it is not covered or that they cannot consistently pay for the medication (Felsher et al., 2018; Goparaju et al., 2017; Pinto et al., 2018).

This study was not without limitations. Although the sample size was sufficient based on published guidance and saturation, the convenience sampling strategy may have resulted in a selection bias. While not all participants reported consistently implementing SHS or PrEP, this group of providers may have more knowledge and/or favorable attitudes towards SHS and PrEP. Additionally, participants may have wanted to provide socially desirable answers to questions that they perceived to evaluate their knowledge, skills, or productivity. This study also did not recruit or interview organizational leadership, administrative and operations staff, or patients. These additional participant groups may have reported alternative facilitators, barriers, and influential factors not mentioned by the participants in this study. Lastly, although qualitative research does not aim to be generalizable, it should be noted that these factors may differ by geographic region, patient population, and type of clinical organization.

### Reflexivity

Notes from the interviews provide key context to some of our findings. Primarily, the interviewer noted that participants appeared to be reflecting on their experiences with SHS and PrEP for the first time during the interview. For the most part, these were not salient topics that they thought about often. Participants provided short, simple answers or required time to think through their experiences and processes. This was pronounced for MAs, whose job responsibilities are dictated by the EHR. They tended to have a mechanical view of SHS and were often not able to recall things that made it easier or harder to do. When asked about their perspectives of the organization, participants tended to report favorably. The interviewer noted that participants mostly used keywords that are used by leadership to describe the organization. It is possible that their reported view of the organization originated from how the organization is advertised instead of how participants actually perceive and experience it. Lastly, there were consistent differences in perception between clinical leadership and the PrEP Navigator and the PCPs. Established policies, expectations, and experiences at the leadership level did not translate to the lived experiences of PCPs. The disconnect between these groups is notable and would be necessary to address when designing an intervention.

This study is the first to investigate facilitators, barriers, and influential factors to the implementation of SHS and PrEP and PrEP services at an FQHC. Guided by CFIR, this novel study combined the perspectives of PCPs, MAs, clinical leadership, and the PrEP Navigator to understand what factors within the CFIR domains acted to prevent or promote the integration of SHS into medical visits and prescription of PrEP. In addition to building upon documented facilitators and barriers, we explained the relationship between these factors and how they interplay with the larger healthcare organization. Our results provide a map of facilitators, barriers, and influential factors within this healthcare organization that can be used to intervene and promote the uptake of SHS and PrEP and PrEP services. Although our results are not generalizable, they

can be used as evidence to support the need for similar studies evaluating the implementation of SHS and PrEP elsewhere. In addition to addressing the limitations of our study, future research should explore how factors vary across health systems. Future research is also needed to design and investigate the effectiveness of interventions to address barriers and augment facilitators. This is particularly important given the recent changes to PrEP guidance and the approval of injectable PrEP, which inevitably will have a major impact on dissemination of PrEP to oppressed populations as it offers an alternative to the once daily pill. Lastly, the consistent notation of patient-level factors as influential on SHS and PrEP services from the perspective of participants is indicative of the need for the patients' perspectives and the integration of patient-level factors into implementation science frameworks.

## 6.0 Conclusion

### 6.1 Summary of Main Findings

These studies contribute novel information on the implementation of sexual history screening (SHS) and pre-exposure prophylaxis (PrEP) services as part of primary care. Specifically, findings from these studies identify factors that influenced documentation of SHS in adult patients' medical charts and the relationship between SHS and PrEP services.

The first study investigated sociodemographic variables of patients and primary care providers (PCPs) that were associated with having SHS documented in adult patients' medical charts. When accounting for clustering by PCPs and medical sites, patients who identified as gay, lesbian, or homosexual (AOR= 1.23, 95% CI: 1.04, 1.47) had significantly higher odds of having SHS in their medical chart. The higher odds for these patients in this study are remarkable, given previous research indicating that providers felt more discomfort and higher rates of avoidance conducting SHS with sexual and gender minority (SGM) patients. This finding may be explained by findings from the third study in which participants stated they prioritized SHS for SGM patients because they believed these patients had more knowledge about sexual health, more frequently had sexual health concerns, and were at high-risk of HIV and STIs. While the importance of SHS for SGM patients is noted by the Centers for Disease Control and Prevention (CDC), higher rates of SHS and other targeted screening for these populations may stem from biases, including the belief all SGM patients engage in high-risk sexual behaviors. In addition to SGM patients, cisgender women (AOR= 1.1, 95% CI: 1.04, 1.16) had significantly higher odds of having SHS in their medical charts. Although not explored within these studies, this finding may be associated



with the rate of routine gynecological care sought by cisgender women in this organization, since SHS may be highly relevant to the patients' primary complaint during these visits.

In alignment with previous research on SHS, patients whose PCPs were cisgender women had significantly higher odds of having SHS documented in their medical chart (AOR= 1.80, 95% CI: 1.00, 3.21) (Gongidi et al., 2010; Lewis & Freeman, 1987; Temple-Smith et al., 1996; Torkko et al., 2000; Wimberly et al., 2006). There is currently limited research on why PCPs who are women complete SHS at higher rates; however, investigation into the relationship between PCP gender and routine screenings found that providers who were women reported spending more time with patients, held more favorable attitudes towards prevention, and felt comfortable conducting breast and cervical cancer screenings and SHS (Lurie, Margolis, McGovern, Mink, & Slater, 1997). Another finding among PCPs was that as the number of patients assigned to a provider increased, the odds of having sexual history documented in the patients' medical chart decreased (AOR= 0.99, 95% CI: 0.99, 0.99). In the third study, providers described limited or lack of time as one of the biggest barriers to implementing SHS during visits. They also noted that appointment slots could be overbooked further limiting time with each patient, which would occur more often for providers who are responsible for more patients.

The second study examined factors associated with PrEP prescription duration, specifically the independent and combined effects of (a) having sexual history documented in the medical chart and (b) having referral to a PrEP Navigator. Accounting for clustering by PCP, this study found a significant relationship between having sexual history documented in the medical chart and PrEP prescription duration (AOR= 1.35, 95% CI: 1.11, 1.63). This means that patients with SHS documented in their medical charts had higher proportions of prescribed pills to days in the study. While it was not possible to measure whether patients filled these prescriptions, this result suggests that patients had better opportunities for adherence since they had more access to PrEP than

patients with lower PrEP prescription duration. There was no independent effect for having a referral to the PrEP Navigator nor was there an interaction effect for having a referral to the PrEP Navigator and sexual history documented in the medical chart. The low number of referrals in this study may be explained by the fact that participants in the third study were mostly unaware that a PrEP Navigator was available for them and their patients.

The final study sought to understand facilitators, barriers, and influential factors on the implementation of SHS and PrEP services from the perspective of PCPs, clinical leadership, medical assistants (MA)s, and a PrEP Navigator. The results of this study included salient implementation factors within each domain of CFIR and at the patient-level. Barriers to SHS and PrEP services fell in the Outer and Inner Settings and included external reimbursement and payment policies, insurance and finances, time, and variation by medical site. These findings suggest that participants viewed external and internal systems as obstacles to implementing SHS and PrEP services with their patients. Facilitators were identified in the Inner Setting and Characteristics of Individuals. Specifically, organizational culture, PrEP support staff, and patient-provider relationships assisted or improved participants' perceived ability to integrate SHS and PrEP services during medical visits with their patients.

In contrast to facilitators and barriers, which were explicitly described as such by participants, influential factors were distributed across the CFIR domains of Intervention Characteristics, Characteristics of Individuals, and Process and the additional domain of Patients. The most concerning finding among influential factors was the limited use of SHS as a tool to identify patients at risk of contracting HIV and who would benefit from a PrEP prescription. Additionally, most PCPs did not report using SHS questions recommended by the CDC and often confused SHS with asking patients about their sexual orientation and gender identity. Similarly, some PCPs stated they were not knowledgeable about how to prescribe and maintain a patient on

PrEP. Additionally, issues related to comfort among PCPs were frequently mentioned, including providers' discomfort talking about sex and an observed discomfort of prescribing PrEP among other PCPs at the organization. Findings suggest that for the most part, from the participants' perspectives, patients were comfortable answering SHS and rarely refused to answer, although this did occur from time to time. PCPs noted that sometimes patients refused to complete SHS because it was not related to their medical complaints. Medical complaints also superseded the implementation SHS during visits, PCPs focused on medical complaints and did not have time to conduct SHS. Lastly, there were specific characteristics of patients that PCPs noted as playing a role in their comfort or ability to implement SHS during visits and maintain their patients on PrEP. These patient characteristics included age, relationship status, culture, gender, and SGM statuses.

## **6.2 Future Research Implications**

The findings from these studies present an urgent need to further understand the relationship between system, provider, and patient-level factors influencing PCPs' self-efficacy, comfort, and ability to implement SHS and PrEP services in a federally qualified health center (FQHC) setting. Our findings indicate insufficient utilization of SHS and PrEP services among adult patients and identify factors associated with the ability to implement SHS and PrEP services. These results provide preliminary evidence of factors that are necessary to address to improve the implementation of SHS and PrEP services among adult patients in a large FQHC setting.

While this research uncovered novel influential factors to the implementation of SHS and PrEP services in a large FQHC, these analyses are not causal nor do they provide a complete understanding of the relationship between identified factors and implementation. In addition to

addressing the limitations of each study, we propose that future research investigate why certain sociodemographics of patients and providers are associated with higher odds of having sexual history documented in the medical chart. As indicated in the interviews, providers recognized how identities, age, and culture influence their comfort and decision to implement SHS during visits. Based on existing literature, stigma and biases may underly the discomfort to initiate and complete SHS with these patients (Hall et al., 2015; Pleuhs, Quinn, Walsh, Petroll, & John, 2020). In addition to stigma and biases, providers may lack sufficient population-specific knowledge about sexual preferences and practices. The concordance of identities, age, and culture of patients and providers may also play a pivotal role in comfort and knowledge and should be explored in future research. These investigations may uncover explanations to differing likelihood of receiving SHS for adult patients based on sociodemographics, like identity, age, and culture. By understanding the nuances of these relationships, efforts to improve the implementation of SHS can address providers' comfort, knowledge, and biases to eliminated them as barriers to implementation.

Furthermore, future research should further explore the relationship between SHS and PrEP, as our results revealed that SHS was associated with better PrEP prescription duration. In addition to examining whether this relationship is still present in a larger sample of PrEP patients, future work should investigate whether having sexual history documented in the medical chart is associated with patients' PrEP adherence. The lack of effect for referral to a PrEP Navigator also warrants further examination. There were few referrals and a limited awareness of the PrEP Navigator. We recommend that future efforts include provider education and training on the existence and utilization of the PrEP Navigator. This research would also benefit from exploring patients' attitudes towards and belief that the PrEP Navigator is helpful to support adherence.

The results of our qualitative study provide a basis for the development of programs and interventions to overcome barriers to SHS and PrEP services by leveraging modifiable influential

factors, such as provider knowledge and the electronic health record, and facilitators, such as PrEP support staff. These efforts should include the patient perspective, as the patients' role in the implementation process was clearly highlighted by participants in our study. This study also yielded information about structural implementation opportunities, such as training on how to successfully conduct SHS. Future research and efforts to improve the implementation of SHS and PrEP services based on the results of our studies should utilize established implementation frameworks and strategies to guide design and evaluation. Based on the critical role patients' play in these processes, we recommend frameworks that include their perspective and characteristics, such as the Practical, Robust, Implementation and Sustainability Model (Feldstein & Glasgow, 2008).

Finally, investigations should take place in other clinical settings to identify influential factors to the implementation of SHS and PrEP services across health systems. With more substantial knowledge of facilitators, barriers, and influential factors, the field of research on the implementation of SHS and PrEP services can address systemic issues from policy to population health to address disparities in STIs, HIV, and other adverse sexual health conditions.

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